Supplementary Material*

Levine DM, Ouchi K, Blanchfield B, et al. Hospital-level care at home for acutely ill adults. A randomized controlled trial. Ann Intern Med. 17 December 2019. [Epub ahead of print]. doi:10.7326/M19-0600

Trial Protocol and Amendments

* This supplementary material was provided by the authors to give readers further details on their article. The material was reviewed but not copyedited.

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**

Sponsor Name: **Vital Connect, Inc.**

PI Name: **Schnipper, Jeffrey** Protocol #: **2016P001337** Type: **Amendment 7**

Date Received: **January 11, 2017**

Signatures

PI Name: Schnipper, Jeffrey, L, MD,MPH
Authenticated: March 22, 2017

Sponsor Funding: Brigham and Women's Hospital - Internal Funds

Select the source of funding that will be used to support the proposed research:

- ○ Government / Foundation / Other Non-Profit
- ○ Corporate
- ⊙ Institutional Award
- ○ Department Funds
- ○ None

Enter Peoplesoft fund # (if known):

InfoEd proposal number (read-only field):

2016A053507

Enter Principal Investigator name (if different):

Schnipper, Jeffrey L MD,MPH

Medicare Coverage Analysis Requirement

Does the protocol for this study involve any items or services that will be billed to Medicare/private insurance, including study-specific procedures or those considered usual and customary care ("standard of care") outside the trial context?

○ Yes ⊙ No

NOTE: If you are unsure how to answer this question, please contact Sarah Bednar at Partners

Clinical Trials Office at 617-954-9364, or for NWH investigators, please contact Jayita Sen at 617-243-6517 for more information.

Is this the primary source of funding?

- ⦿ Yes
- ○ No
- ○ Not applicable

Will the funding cover all subject study-related drugs, devices, procedures, tests, and visits?

- ○ Yes
- ⦿ No
- ○ Not applicable (no subject study-related costs)

Explain what subject study-related costs are not covered by the study funds and how they will be covered.

Participants in the intervention group will be billed an ambulatory home visit for each day of service. This will help offset the cost of the intervention. The study funds will cover the remainder.

Sponsor Funding: BRIGHAM AND WOMEN'S HOSPITAL [Internal]

Select the source of funding that will be used to support the proposed research:

- ○ Government / Foundation / Other Non-Profit
- ○ Corporate
- ⦿ Institutional Award
- ○ Department Funds
- ○ None

Enter Peoplesoft fund # (if known):

116208

InfoEd proposal number (read-only field):

Enter Principal Investigator name (if different):

Medicare Coverage Analysis Requirement

Does the protocol for this study involve any items or services that will be billed to Medicare/private insurance, including study-specific procedures or those considered usual and customary care ("standard of care") outside the trial context?

○ Yes ⊙ No

NOTE: If you are unsure how to answer this question, please contact Sarah Bednar at Partners Clinical Trials Office at 617-954-9364, or for NWH investigators, please contact Jayita Sen at 617-243-6517 for more information.

Is this the primary source of funding?

○ Yes ⊙ No ○ Not applicable

Sponsor Funding: Department Funds

Select the source of funding that will be used to support the proposed research:

○ Government / Foundation / Other Non-Profit

○ Corporate

○ Institutional Award

⊙ Department Funds

○ None

Enter department name:

Medicine

Enter Peoplesoft fund # (if known):

017898

Is there a research fund, gift or sundry account supporting this study?

○ Yes ⊙ No

Is this the primary source of funding?

○ Yes ⊙ No ○ Not applicable

Sponsor Funding: Vital Connect, Inc. [Industry]

Select the source of funding that will be used to support the proposed research:

- ○ Government / Foundation / Other Non-Profit
- ⊙ Corporate
- ○ Institutional Award
- ○ Department Funds
- ○ None

Select the type of corporate funding:

- ○ Corporate sponsored clinical research
- ⊙ Funding for investigator-initiated clinical research

NOTE: When the corporate sponsor designs the study, the corporate sponsor's protocol must be submitted to PHRC for review. Before the research can begin, PHRC must approve the sponsor's protocol and Partners Clinical Research Office must execute the Agreement with the sponsor.

Enter contact name at sponsor:

Justin Heindel

Enter telephone number of contact:

(408)963-4600

Sponsor protocol # (if known):

InfoEd proposal number (read-only field):

Enter Principal Investigator name (if different):

Medicare Coverage Analysis Requirement

Does the protocol for this study involve any items or services that will be billed to Medicare/private insurance, including study-specific procedures or those considered usual and customary care ("standard of care") outside the trial context?

- ○ Yes
- ⊙ No

NOTE: If you are unsure how to answer this question, please contact Sarah Bednar at Partners Clinical Trials Office at 617-954-9364, or for NWH investigators, please contact Jayita Sen at 617-243-6517 for more information.

Is this the primary source of funding?

○ Yes ⊙ No ○ Not applicable

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ⊙ No

Study Staff Amendment

Are you adding or removing study staff? REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB.

○ Yes ⊙ No

Central IRB Performance Sites

Is this a NeuroNEXT or STRIDE network protocol?

Note: The Partners IRB is the Central IRB for the NeuroNEXT and Stride networks.

○ Yes ⊙ No

Sponsor Amendment

Is there a sponsor amendment number?

○ Yes ⊙ No

Continuing Review

Indicate if this amendment is part of a continuing review submission.

○ Yes ⊙ No

Sponsor / Funding

Is a Sponsor / Funding source being added?

⊙ Yes ○ No

☑ Check to add a Sponsor / Funding source

Note: For protocols submitted originally in Insight, you will be able to add/edit the sponsor form with your original answers after clicking the save button and opening the sponsor/funding form from the Forms page. If the protocol was submitted prior to the eIRB implementation, you will be presented with a blank form to complete.

Protocol Title

Is the title of the protocol being changed?

○ Yes ⊙ No

Does your study involve an intervention / interaction with human subjects?

NOTE: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject (45 CFR 46.102(f)).

⊙ Yes ○ No

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1. Data Forms Updates

Indicate below what forms need to be updated as part of this amendment. After clicking the save button you will be able to open any applicable forms that need to be updated/completed on the Forms page.

- ☐ Ancillary Drug
- ☐ Ancillary Non-hospital Device(s)
- ☐ Clinical Trials Registration
- ☐ Conflicts of Interest
- ☐ Diaries (e.g., Drug Diary)
- ☐ Drugs / Biologics / Dietary Supplements
- ☑ Instruments / Questionaires
- ☑ Informed Consent Form / Process
- ☑ Medical Device
- ☐ Non-Intervention / Non-Interaction Group
- ☐ Nursing Implementation
- ☐ Privacy / Confidentiality
- ☐ Radiation (Ionizing)

- ☐ Radiation (Non-Ionizing)
- ☐ Recruitment
- ☐ Remuneration
- ☐ Study Type / Classification (for example, physiologic, therapeutic, genetic)
- ☑ Study Population (for example, enrollment targets)
- ☑ Study Population - Special Populations
  - ☐ Children
  - ☑ Individuals with Impaired Decision-Making Capacity
  - ☐ Research Involving Neonates
  - ☐ Pregnant Women or Human Fetuses

Change in Protocol Status

Do you need to change the overall status of the protocol? For example, Re-Open to Enrollment or indicate that Research Interventions/Assessments Continue after telling the IRB these have ceased.

○ Yes ⊙ No

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2. New/Revised Study Documents (Attachments)

Are you submitting new or revised study-related documents? Note: If you answer 'no' to this question you will not be able to attach documents to this submission.

⊙ Yes ○ No

Indicate:.

- ☑ Consent Form(s)
- ☑ Device Manual
- ☐ Diaries
- ☑ Instruments / Questionnaires
- ☐ Investigator Drug Brochure (IDB)
- ☐ Recruitment Materials
- ☐ Response to Review
- ☐ Schema
- ☐ Other Study-Related Documents
- ☑ Protocol Summary
- ☑ Protocol

☑ Check to change the Version Name / Number of the Protocol

Enter proposed version name / number of the protocol:

v4

Are you removing any study-related documents because they are not being used, e.g., you are no longer using advertisements?

○ Yes ⊙ No

Briefly describe the proposed changes:

We have successfully run a short pilot of home hospital and would like to relaunch with several changes. Briefly, these include additional diagnoses, addition of patients who can assent but require health care proxy consent, modification of our inclusion/exclusion criteria, and addition of community health workers and community paramedics to our home hospital team. We are also adding one new instrument: a clinician burnout survey.

Provide rationale for the proposed changes:

Our proposed changes will likely boost enrollment without altering safety and quality, add novel care team members, and make for smoother logistics. We added the clinician burnout survey to make sure the culture of our team was optimized.

Will the proposed change(s) significantly alter the risk to benefit assessment the IRB relied upon to approve the protocol?

○ Yes ⊙ No

Will the proposed change(s) significantly affect the integrity of the protocol?

○ Yes ⊙ No

Study Population

How many subjects do you plan to enroll at Partners' sites?

120

NOTE: Target enrollment at Partners sites is the number of subjects you expect to provide written or verbal consent, or implied consent by voluntary completion of a survey or participation in a focus group.

How many subjects will be enrolled study-wide?

120

What is the age range of eligible subjects who will be enrolled at Partners sites?

Enter 'None' if there is no maximum age.

Minimum age:

18

Maximum age:

None

Will both males and females be enrolled?

◉ Yes ○ No

Indicate below whether the study population that is being targeted for the research is any of the following groups that require additional protections:

- ☐ Children (less than 18 years of age)
- ☐ Economically or Educationally Disadvantaged
- ☐ Embryos
- ☐ Employees under the direct supervision of the investigators conducting the research
- ☐ Employees (physician, nurses, or other healthcare workers) in the course of, or related to, their employment related duties
- ☑ Individuals with Impaired Decision-Making Capacity
- ☐ Neonates -age up to 28 days
- ☐ Non-English Speakers
- ☐ Patients from the Medical Practice of the Investigator
- ☐ Pregnant Women / Fetuses
- ☐ Prisoners
- ☐ Students of Harvard Medical School
- ☐ U.S. Military Personnel
- ☐ None of the above

Informed Consent

For guidance, refer to the PHRC web page Informed Consent of Research Subjects.

Will informed consent and authorization for participation in research be obtained verbally (oral consent), or by use of a written consent form approved by the PHRC and signed by the subject or the subject's legally authorized representative?

◉ Yes ○ No

Indicate how informed consent and authorization will be obtained:

- ⊙ Written
- ○ Verbal (oral consent)

Enter the description of the study population (as listed on page 1 of the informed consent) and move to the box on the right. Repeat if using more than one consent.

Selected hospitalized adults who would normally have been admitted to the hospital

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Indicate who will obtain the informed consent of the subject or the subject's legally authorized representative.

- ☑ Licensed Physician Investigator
- ☐ Non-Physician Investigator
- ☐ Other

Indicate from whom informed consent will be obtained. Check all that apply:

- ☑ Adult Subject
- ☐ Parent(s) / Guardian for Child
- ☑ Court-Appointed Guardian for Adult
- ☑ Surrogate for Adult, other than Guardian (e.g. health care proxy, person with durable power of attorney, spouse, adult child, or close family member).

NOTE: When surrogate consent for adults is obtained, the individuals with impaired decision-making capacity form must be completed. For guidance, refer to the following PHRC web pages, Surrogate Consent to Research for Individuals with Impaired Decision-making Capacity

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Will the research target a non-English speaking group?

○ Yes ⊙ No

NOTE: When investigators can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the research is targeting a non-English speaking group), the use of a written translation of the entire English version of the consent form is required. The PHRC must approve all written translated versions of the consent from and recommends that the written translation be done by an in-house medical translator from Interpreter Services or other qualified person or service recommended by Interpreter Services. Refer to the PHRC guidance on Obtaining And Documenting Informed Consent Of Subjects Who Do Not Speak English.

Will a study subject advocate participate in the consent process?

○ Yes ⊙ No

NOTE: A study subject advocate may be used, for example, because subjects have limited time to consider participation in a study involving significant risk, or may feel obligated to participate.

Will subjects have less than 12 hours to decide whether or not to participate?

◉ Yes ○ No

Explain why:

Patients will complete their initial treatment in the emergency department. Once the decision to admit has been made, the patient will need to decide whether or not to consent to participation in the home hospital program. A lengthy decision process [e.g., remaining in limbo in the emergency room] will jeopardize the patient's care.

NOTE: The IRB may waive the requirement to obtain a signed written consent / authorization form if it finds either: (1) the only record linking the subject and the research is the consent form and the principal risk would be potential harm resulting from a breach in confidentiality; or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

Instruments / Questionnaires

Will the research involve the development of instruments, questionnaires, surveys, interviews, and/or focus group topics?

○ Yes ◉ No

Will the research involve the use of instruments, questionnaires, surveys, interviews, and/or focus group topics?

◉ Yes ○ No

List of Instruments / Questionnaires / Surveys / Interviews / Focus Group Topics

Enter the name of the instruments, questionnaires, surveys, interview and/or focus group topics and move to the box on the right. For each name entered, the system will be looking for an attachment on the Attachments page with the Attachment type 'Instruments/Questinaires.' If you enter 7 names here the system will be looking for 7 attachments. Do not list any that are under development.

Measures compilation

Internet Surveys

Do you plan to use web-based survey or social media tools to administer a survey or questionnaire?
NOTE: Social media tools could include Facebook, Twitter, chat/text messages, message boards, interactive web pages and blogs.

○ Yes ◉ No

For guidance, please see refer to: Guidance on Research Using the Internet - Survey Research Using Web-Based Survey Tools and Guidance on Research Using the Internet - Informed Consent in Online Research.

Impaired Decision Making

Federal regulations require the IRB to provide additional protections for individuals participating in research when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as individuals with impaired decision-making capacity [45.CFR 46.111(b)]. For guidance, refer to the PHRC memo "Surrogate Consent to Research for Individuals with Impaired Decision-making Capacity" (PHS internal only link). Please complete each section as it applies to your research. Each question must be fully answered. Assessing Risks and BenefitsWhen assessing risks and benefits, consider the variability in health status of the subjects to be enrolled, their medical experiences, and the extent to which the research procedures will be a burden to the subjects in the context of their daily lives and/or routine medical care. Procedures that usually present no more than minimal risk include: urinalysis, obtaining a small amount of blood, EEGs, minor changes in diet or daily routine, and/or the use of standard psychological tests. The assessment of the probability and magnitude of the risk may be different depending on the diseases or conditions the subjects may have. Be sensitive to how a procedure that generally entails little to no physical or psychosocial risks may affect someone with limited (or no) understanding of the situation.Minimal RiskAs defined in the regulations 45 CFR 46.102(i), “minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Justification For Study Population

Explain why individuals with impaired decision-making capacity are necessary to and appropriate for the research.

Hospitalized patients often have impaired decision-making capacity, with decisions made by health care proxies. To exclude these patients from the study would lead to a major loss of generalizability. These patients may also benefit as much or more from home hospitalization, e.g., because of decreased risk of delirium at home. Previously published home hospital trials enrolled patients who could assent but not consent with health care proxy consent. We seek to do the same.

Assessment of Risks and Potential Benefits

Select the one risk / benefit category:

☐ Research not involving greater than minimal risk

☑ Research involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.

Explain what personal health benefit may accrue to subjects and why you think the risk of intervention(s) is justified by the benefit.

Patients hospitalized at home may directly benefit by having decreased risk of hospital-acquired conditions, such as fall and delirium, less loss of physical

function due to greater activity and familiar surroundings, and greater presence of family members. Prior studies of home hospital have shown equal or greater safety compared with hospitalized patients.

Explain why the risk / benefit ratio of participation is at least as favorable as that which would be afforded by available alternative approaches.

As noted above, the potential benefits of this intervention outweigh the risks, especially given the high degree of monitoring these patients will receive at home, careful patient selection process, and prior research suggesting a high degree of safety compared with available alternatives.

☐ Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Consent Process for Surrogate Consent and Assent of Subjects

Describe how capacity to consent ("competency") will be assessed; specifically who will perform the assessments (include qualifications and experience, as well as relationship to the study team); what competency measures will be used and criteria for concluding an individual is capable of consent.

If capacity of the individual to consent to the study is questioned, capacity assessment will be performed by the patients ED attending or by a psychiatric consultant if deemed necessary by the ED attending.
o In addition to the attendings knowledge of the case and patient, the attending will be provided with the results of the Eight-item Interview to Differentiate Aging and Dementia, the activities of daily living scale, and the instrumental activities of daily living scale. These instruments will be obtained by the research assistant.

Describe how and by whom capacity to understand and consent will be assessed throughout the study period.

If the patient is deemed without capacity, any of the following individuals may give consent provided they are on-site and able to sign the informed consent (the patient will assent):
court-appointed guardian with authority to consent to participation in the proposed research or authority to make decisions for a class of health care decisions inclusive of the proposed research;
health care proxy with authority to make decisions for a class of health care decisions inclusive of the proposed research;
durable powers of attorney with authority to make health care decisions inclusive of the proposed research; or
spouse, adult child, parent, or adult sibling.

The study period is brief (the duration of the hospitalization, usually a few days), but if a patient has a major improvement in mental status (and originally had proxy consent), then capacity could be reassessed by the physician seeing the patient in the home (which happens on a daily basis), potentially leading to a change from proxy to patient consent. Conversely, if a patient's mental status declines in a patient who originally gave consent personally, then capacity could be reassessed, potentially leading to a change to proxy consent for the remainder of the study period.

NOTE: When subjects regain the capacity to consent (or assent) to the research, the investigator must obtain the consent (or assent) of the individual for continued participation in the study.

Surrogate Consent

Informed consent will be obtained in writing from the following categories of surrogates (listed in general order of preference). Check all that you propose to rely on in the study:

☑ Court-appointed guardian with specific authority to make health care decisions for a class of diagnostic and therpeutic decisions inclusive of the proposed research.

☑ Health care proxy / person with durable power of attorney with specific authority for making health care decisions inclusive of the proposed research.

☑ Spouse, adult child, or other close family member who knows the subject well and has been involved in their care.

NOTE:
1. Court-appointed guardians will typically be required for research involving more than minimal risk and no prospect of direct benefit.
2. A guardian is required for any research that is within the jurisdiction of the Massachusetts Department of Mental Retardation (DMR). For guidance, refer to the Department of Mental Retardation regulation web site.

Assent of Subjects

Select one below:

☑ Assent of subjects will be required for participation.

Describe procedures for obtaining assent of subjects to enroll in the study and for continued participation throughout the course of the study.

Assent will be obtained during the written informed consent process, at the same time as consent is obtained from one of the above surrogates.

☐ Assent of subjects will be a requirement for participation in the research, unless the subject is incapable of giving assent due to his/her medical condition (e.g., subject may be in shock, delirious, intubated, and/or heavily sedated).

Medical Devices: HealthPatch

Complete a separate form for each medical device being investigated for safety or effectiveness or used as a comparator, or for non-FDA approved medical devices that are being used as a tool to study human physiology. NOTE: Do not complete this form for FDA-approved medical devices that are used for research-related ancillary tests, procedures, or monitoring in accordance with the device's FDA-approved labeling, e.g., heart, blood pressure monitors.

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1. Medical Device Information

Manufacturer:

Vital Connect

Enter the type of device, e.g., stent, AICD, catheter:

Vital signs monitoring patch

Indicate the proposed use of the medical device:

○ The device will be investigated for safety and/or effectiveness or used as a comparator, for example, compared to another device, drug or other therapeutic approach.

○ The device will be used as a Humanitarian Use Device.

⊙ The device will be used as a tool to measure data or study human physiology.

Explain the purpose and use of the device (3900 character limit):

This device measures heart rate, respiratory rate, motion, and 2-lead telemetry.

Explain the risk associated with the use of the device (3900 character limit):

This device could theoretically provide incorrect measurements, leading a home hospital team member to visit the patient's home or activate emergency services. This is unlikely given the data quality algorithm that time-averages measurements.

Coverage of Costs

Will the sponsor provide the device free-of-charge?

⊙ Yes ○ No

Biomedical Engineering Review

Will the device be used at a Partners facility (e.g., MGH, BWH, etc) or the Beth Israel Deaconess Medical Center General Clinical Research Center (sleep medicine studies only)?

⊙ Yes ○ No

Check all that apply.

☑ BWH

Indicate location:

Inpatient ward

☑ Faulkner

Indicate location:

Inpatient ward

☐ MGH

☐ SRH

- ☐ NSMC
- ☐ NWH
- ☐ McLean
- ☐ BIDMC GCRC

Is the device electrically powered (battery powered or plug in to electric wall outlet)?

◉ Yes ○ No

Has the device been reviewed previously by Biomedical Engineering (BME)?

○ Yes ◉ No

Is the device to be connected, directly or indirectly, to the hospital network?

○ Yes ◉ No

Does the device communicate wirelessly?

◉ Yes ○ No

What is the location of the device?

Patient's chest

Enter a study contact for the device:

Chris Economos

Enter contact phone number:

630-842-0267

Enter contact e-mail address:

chris.economos@physiq.com

Therapeutic Or Other Devices That Deliver Energy

Is the device therapeutic, i.e., does it deliver substances or energy to the subject?

○ Yes ◉ No

Physiologic Monitoring / Diagnostic Devices

Is the device used to acquire data and/or to inform treatment?

◉ Yes ○ No

Explain what protects against using bad data, e.g., by warning the user of potentially incorrect data?

The HealthPatch uses the same algorithms as VitalPatch. Briefly, time averaging, as well as signal quality, prevent against using bad data.

Can the device yield inaccurate data, the use of which could increase the risk to the subject?

◉ Yes ○ No

Can a device failure or operator error occur that could lead to inaccurate data?

○ Yes ◉ No

Are operators trained to recognize and act on situations of increased risk associated with the operation of the device?

◉ Yes ○ No

NOTE: Contact the Biomedical Engineering group if you have any questions about biomedical devices:
BWH: Maureen Nephew 617-525-7942;
MGH: Patricia Regal 617-643-2783;
McLean: Ken Hanrahan 617-855-2443;
NWH: 617-243-6083;
SRH: Abel Erives 617-573-2704.

Device Control and Accountability

The investigator is responsible for ensuring control of investigational devices being used in the research.

NOTE: When the sponsor (or another party) provides a medical device for use to obtain measurements, collect data, or monitor subjects, the investigator must request a zero dollar purchase order to track receipt of the medical device and to document BME inspection for electrical safety, when necessary. For more information, refer to the Zero Dollar Purchase Order Policy.

To whom are the devices shipped, and where are they stored?

David Levine; stored at BWH DGIM in a key-card controlled, locked office.

What procedures are in place for ensuring that the investigational devices are only used by the investigators participating in this research for this investigation?

The devices are stored securely, as above. Only the research team has access to them. Activating the device requires a multi-step, password protected procedure.

What is the plan for disposition of unused investigational devices at the conclusion of the study?

HealthPatch can be thrown in normal waste streams.

Who is responsible for completing the device accountability log and for disposition of unused devices at the conclusion of the study?

The PI.

NOTE: The Human Research QI Program has developed a Device Accountability Log for investigators where no log has been developed by the sponsor.

Attachments

Name	Mode
Protocol Summary	Electronic
Protocol Summary	Electronic
Detailed Protocol_01(Detailed Protocol)	Electronic
Detailed Protocol_01(Detailed Protocol)	Electronic
Consent Form_01(Consent Form)	Electronic
Consent Form_01(Consent Form)	Electronic
Instrument/Questionnaire_Compilation(Instrument/Questionnaire)	Electronic
Instrument/Questionnaire_Compilation(Instrument/Questionnaire)	Electronic
Research Assistant Guide(Manual of Operations)	Electronic
Research Assistant Guide(Manual of Operations)	Electronic
Explanation of Changes to Selection Criteria(Other)	Electronic
Explanation of Changes to Selection Criteria(Other)	Electronic
Rick Hampton's Security Assessment(Other)	Electronic
Consent Form Scans(Other)	Electronic
HealthPatch(FDA 510K)	Electronic

PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Jeffrey Schnipper, MD MPH

PROTOCOL TITLE
Hospitalization at Home: The Acute Care Home Hospital Program for Adults

FUNDING
Brigham and Women's Hospital (primary funder)
Partners Population Health Management
Vital Connect and Smiths Medical (providing in-kind donation of hardware only)

VERSION DATE
3 12 17

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Primary Aim

We will accomplish a 20% reduction in hospitalization cost for selected hospitalized adults who would normally have been admitted to the hospital.

Secondary Aims

We will accomplish the following for the above-mentioned selected hospitalized adults:

- reduce health care utilization;
  - For example: decreased length of stay, number of labs/imaging, readmissions, ED visits
- maintain or improve on patient safety;
  - For example: reduced risk of delirium, falls
- maintain or improve on quality of care;
  - For example, high-value: increase in appropriate antibiotic selection, hours of sleep
  - For example, low-value: decrease in use of urinary catheter, inappropriate medications in the elderly
- maintain or improve on functional status and quality of life; and
  - For example: increase in EuroQol-5D-5L, activities of daily living scale
- improve absolute patient experience by 20%.
  - For example: increase in 3-item care transition measure, PROMIS experience measures

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Hospitals are the standard of care for acute illness in the US, but hospital care is expensive and often unsafe, especially for older individuals.[1] While admitted, 20% suffer delirium,[2] over 5% contract hospital-acquired infections,[3] and most lose functional status that is never regained.[4] Timely access to inpatient care is poor: many hospital wards are typically over 100% capacity, and emergency department waits can be protracted. Moreover, hospital care is increasingly costly: many internal medicine admissions have a negative margin (i.e., expenditures exceed hospital revenues) and incur patient debt.

We propose a home hospital model of care that substitutes for treatment in an acute care hospital. Studies of the home hospital model have demonstrated that a sizeable proportion of acute care can be delivered in the home with equal quality and safety, 20% reduced cost, and 20% improved patient experience.[5,6] While this is the standard of care in several developed countries,[7] only 2 non-randomized demonstration projects have been conducted in the United States, each with highly local needs. Taken together, home hospital evidence is promising but falls short due to non-robust experimental design, failure to implement modern medical technology, and poor enlistment of community support. Our preliminary pilot data is reassuring.[8]

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

- Randomized controlled trial
    - Arm 1 (intervention): return home from emergency room
    - Arm 2 (control): usual care as inpatient
- 120 patients (60 per arm)
    - Adults who present to the emergency room with primary diagnosis of cellulitis, heart failure, complicated urinary tract infection, pneumonia, COPD/asthma, other infection, chronic kidney disease, malignant pain, diabetes and its complications, gout flare, hypertensive urgency, atrial fibrillation with rapid ventricular response, anticoagulation needs, surgical monitoring, or a patient who desires only medical management that requires inpatient admission (please see Detailed Protocol for a full explanation of these criteria).

- Limited to patients who live within a 5-mile or 20-minute radius of Brigham and Women's or Brigham and Women's Faulkner's emergency rooms

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

- Patients who meet our inclusion/exclusion criteria and are randomized to return home will receive the home hospital module, which consists of staff (MD, RN, case manager), diagnostics (blood tests, vital signs, telemetry, x-ray, and ultrasound), intravenous therapy, and oxygen/nebulizer therapy. On patient-tailored basis, it can also include food, home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and/or social worker.
- Primary endpoint: total cost of hospitalization
- Documentation by RN and MD will occur via intake notes, daily progress notes, and discharge notes that will be compiled (on a Partners secure share-drive) and uploaded as a pdf document to the patient's chart upon discharge. In addition, each day an outpatient MD note, lab orders, and pharmacy orders will be written in Epic by the MD. When available, the study will be able to transition to complete Epic integration, such that the daily notes completed and stored on the share-drive will no longer be necessary.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Home hospital will be able to provide treatments and diagnostics at or above the standard of care. Several improvements to the standard of care are planned: point of care diagnostics, minimally invasive continuous vital signs monitoring, video visits, lower patient to staff ratios, ambulatory portable infusion pumps, and others.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Admission to the hospital can be a physically and psychosocially difficult event, particularly for a senior. We believe home hospital will alleviate these typical risks by allowing the patient to remain in her/his home and providing improved staffing ratios and an as needed social worker.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of

improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Safety ensured through

- Continuous vital signs and activity monitoring
- Telephone, video, and in-person visit capability at any time of the day

Criteria for returning to the hospital (ending participation in the intervention arm) will be made by the clinical team and tailored to the patient. At any time a patient or clinician can halt the study.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

We foresee many of the same risks and discomforts associated with inpatient hospitalization will apply to home hospitalization, although we hope some of these risks will be less. These include drug side effects and toxicities, psychosocial risks, device complications/malfunctions.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

- Improved health outcomes
    - Reduced length of stay
    - Reduced complications while admitted
        - Less delirium
        - Fewer falls
        - Fewer health care associated infections
        - Decreases reduction in functional status
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- Remain in their home despite acute illness
    - Eat their own culturally concordant food
    - Sleep in familiar surroundings
    - Maximize time and interactions with their family and friends
- Clinical improvements to the standard of care
- Improved transitions of care

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

We are not categorically selecting for gender, race/ethnicity, or socioeconomic status during this study.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

We will include all languages for which the IRB has a short-form consent form: Arabic, Dutch, French, German, Greek, Haitian Creole, Hebrew, Italian, Portuguese, Russian, Somali, Spanish, Chinese, and Vietnamese. We will have 24/7 access to a live telephone interpreter when needed. We will use short-form consent forms for languages other than English.

For guidance, refer to the following Partners policy:

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RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

- Decision to admit made by emergency room team
- Participant is pre-screened by a research assistant for primary diagnosis, age, and residence within 5 miles/20-minutes via the electronic medical record.
- If participant meets those criteria, the emergency room team will ask the patient/caregiver if the research assistant can approach the patient regarding the home hospital study.
- If participant agrees, the research assistant will describe the program, answer initial questions, and further assess whether the participant meets inclusion/exclusion non-clinical (e.g., social) criteria. The RA will then contact the on-call MD to assess clinical criteria by EHR review.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to

study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

None.

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Guidelines for Advertisements for Recruiting Subjects
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- If the participant has interest in the program and meets inclusion/exclusion criteria, the on-call MD (either in-person or via a live video visit facilitated by the research assistant) will obtain written informed consent of the participant to enroll in the home hospital program. Alternately, if the participant does not have capacity, the MD can obtain assent of the participant and consent of the participant's health care proxy.
- If capacity of the individual to consent to the study is questioned, capacity assessment will be performed by the patient's ED attending or by a psychiatric consultant if deemed necessary by the ED attending.
    - In addition to the attending's knowledge of the case and patient, the attending will be provided with the results of the Eight-item Interview to Differentiate Aging and Dementia, the activities of daily living scale, and the instrumental activities of daily living scale. These instruments will be obtained by the research assistant.
    - If the patient is deemed without capacity, any of the following individuals may give consent provided they are on-site and able to sign the informed consent (the patient will assent):
        - court-appointed guardian with authority to consent to participation in the proposed research or authority to make decisions for a class of health care decisions inclusive of the proposed research;

- health care proxy with authority to make decisions for a class of health care decisions inclusive of the proposed research;
- durable powers of attorney with authority to make health care decisions inclusive of the proposed research; or spouse, adult child, parent, or adult sibling.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
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DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

The study's research assistant will collect all data denoted above. The PI and co-PI will monitor the source data throughout the project.

If any of the following concerning safety events occur, a blinded monitoring committee will review the event to determine attribution to the intervention: fall, medication error, DVT/PE, mortality during admission, transfer back to hospital (committee cannot be blinded for this endpoint). If any of these events are felt to be due to the home hospital intervention, they will be reported to the IRB with recommendations for appropriate actions to be taken. Decisions to modify the protocol or suspend the study will be made jointly by the study investigators, monitoring committee, and the IRB.

The physician and RNs will daily review quality and safety data as part of a rapid logistics improvement process.

Weekly, all physicians and RNs will huddle to review quality and safety data as part of a rapid logistics improvement process.
At 3 weeks into the home hospital clinical service, a blinded monitoring committee will review outcomes data and make recommendations to the study team.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

All adverse events denoted above under safety monitoring will be reported to the monitoring committee. Adverse events will be reported to the PHRC in accordance with PHRC unanticipated problems reporting guidelines.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

As above.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/DSMP_in_Human_Subjects_Research.pdf

Reporting Unanticipated Problems (including Adverse Events)
https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Reporting_Unanticipated_Problems_including_Adverse_Events.pdf

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

All data collection will be inputted on a Partners encrypted shared drive, accessible only by research staff. All personnel are trained in confidentiality and appropriate use of encrypted files.

Once data collection is complete, we will strip names from the data, using alpha-numeric codes instead. The code file will only be accessible to the PI on a separate Partners encrypted shared drive.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

N/A

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

N/A

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

N/A

PARTNERS HUMAN RESEARCH COMMITTEE
PROTOCOL SUMMARY

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR
Jeffrey Schnipper, MD MPH

PROTOCOL TITLE
Hospitalization at Home: The Acute Care Home Hospital Program for Adults

FUNDING
Brigham and Women's Hospital (primary funder)
Partners Population Health Management
Vital Connect and Smiths Medical (providing in-kind donation of hardware only)

VERSION DATE
3 12 17

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Primary Aim

We will accomplish a 20% reduction in hospitalization cost for selected hospitalized adults who would normally have been admitted to the hospital.

Secondary Aims

We will accomplish the following for the above-mentioned selected hospitalized adults:

- reduce health care utilization;
  - For example: decreased length of stay, number of labs/imaging, readmissions, ED visits
- maintain or improve on patient safety;
  - For example: reduced risk of delirium, falls
- maintain or improve on quality of care;
  - For example, high-value: increase in appropriate antibiotic selection, hours of sleep
  - For example, low-value: decrease in use of urinary catheter, inappropriate medications in the elderly
- maintain or improve on functional status and quality of life; and
  - For example: increase in EuroQol-5D-5L, activities of daily living scale
- improve absolute patient experience by 20%.
  - For example: increase in 3-item care transition measure, PROMIS experience measures

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Hospitals are the standard of care for acute illness in the US, but hospital care is expensive and often unsafe, especially for older individuals.[1] While admitted, 20% suffer delirium,[2] over 5% contract hospital-acquired infections,[3] and most lose functional status that is never regained.[4] Timely access to inpatient care is poor: many hospital wards are typically over 100% capacity, and emergency department waits can be protracted. Moreover, hospital care is increasingly costly: many internal medicine admissions have a negative margin (i.e., expenditures exceed hospital revenues) and incur patient debt.

We propose a home hospital model of care that substitutes for treatment in an acute care hospital. Studies of the home hospital model have demonstrated that a sizeable proportion of acute care can be delivered in the home with equal quality and safety, 20% reduced cost, and 20% improved patient experience.[5,6] While this is the standard of care in several developed countries,[7] only 2 non-randomized demonstration projects have been conducted in the United States, each with highly local needs. Taken together, home hospital evidence is promising but falls short due to non-robust experimental design, failure to implement modern medical technology, and poor enlistment of community support. Our preliminary pilot data is reassuring.[8]

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

- Randomized controlled trial
    - Arm 1 (intervention): return home from emergency room
    - Arm 2 (control): usual care as inpatient
- 120 patients (60 per arm)
    - Adults who present to the emergency room with primary diagnosis of cellulitis, heart failure, complicated urinary tract infection, pneumonia, COPD/asthma, other infection, chronic kidney disease, malignant pain, diabetes and its complications, gout flare, hypertensive urgency, atrial fibrillation with rapid ventricular response, anticoagulation needs, surgical monitoring, or a patient who desires only medical management that requires inpatient admission (please see Detailed Protocol for a full explanation of these criteria).

- Limited to patients who live within a 5-mile or 20-minute radius of Brigham and Women's or Brigham and Women's Faulkner's emergency rooms

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

- Patients who meet our inclusion/exclusion criteria and are randomized to return home will receive the home hospital module, which consists of staff (MD, RN, case manager), diagnostics (blood tests, vital signs, telemetry, x-ray, and ultrasound), intravenous therapy, and oxygen/nebulizer therapy. On patient-tailored basis, it can also include food, home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and/or social worker.
- Primary endpoint: total cost of hospitalization
- Documentation by RN and MD will occur via intake notes, daily progress notes, and discharge notes that will be compiled (on a Partners secure share-drive) and uploaded as a pdf document to the patient's chart upon discharge. In addition, each day an outpatient MD note, lab orders, and pharmacy orders will be written in Epic by the MD. When available, the study will be able to transition to complete Epic integration, such that the daily notes completed and stored on the share-drive will no longer be necessary.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Home hospital will be able to provide treatments and diagnostics at or above the standard of care. Several improvements to the standard of care are planned: point of care diagnostics, minimally invasive continuous vital signs monitoring, video visits, lower patient to staff ratios, ambulatory portable infusion pumps, and others.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Admission to the hospital can be a physically and psychosocially difficult event, particularly for a senior. We believe home hospital will alleviate these typical risks by allowing the patient to remain in her/his home and providing improved staffing ratios and an as needed social worker.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of

improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Safety ensured through

- Continuous vital signs and activity monitoring
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Criteria for returning to the hospital (ending participation in the intervention arm) will be made by the clinical team and tailored to the patient. At any time a patient or clinician can halt the study.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

We foresee many of the same risks and discomforts associated with inpatient hospitalization will apply to home hospitalization, although we hope some of these risks will be less. These include drug side effects and toxicities, psychosocial risks, device complications/malfunctions.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

- Improved health outcomes
    - Reduced length of stay
    - Reduced complications while admitted
        - Less delirium
        - Fewer falls
        - Fewer health care associated infections
        - Decreases reduction in functional status
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- Remain in their home despite acute illness
    - Eat their own culturally concordant food
    - Sleep in familiar surroundings
    - Maximize time and interactions with their family and friends
- Clinical improvements to the standard of care
- Improved transitions of care

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

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RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

- Decision to admit made by emergency room team
- Participant is pre-screened by a research assistant for primary diagnosis, age, and residence within 5 miles/20-minutes via the electronic medical record.
- If participant meets those criteria, the emergency room team will ask the patient/caregiver if the research assistant can approach the patient regarding the home hospital study.
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- ~~Capacity assessment will be performed by the consenting physician as part of the process of obtaining informed consent. Capacity assessment will be performed by using "read-back" of the main points of the consent form: that participation is voluntary, that patients will be randomized to usual care or home hospital, what home hospital entails, that they will be asked survey questions as part of the study, that they will have the right to decline to answer any questions they don't want to answer, that they can end their participation in the study in the study at any time. In previous studies, we have found this to be the most effective means of determining capacity to make the decision of whether to participate in a study.~~
- If capacity of the individual to consent to the study is questioned, capacity assessment will be performed by the patient's ED attending or by a psychiatric consultant if deemed necessary by the ED attending.
    - In addition to the attending's knowledge of the case and patient, the attending will be provided with the results of the Eight-item

Interview to Differentiate Aging and Dementia, the activities of daily living scale, and the instrumental activities of daily living scale. These instruments will be obtained by the research assistant.

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NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
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NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

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PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

All data collection will be inputted on a Partners encrypted shared ~~"U"~~ drive, accessible only by research staff. All personnel are trained in confidentiality and appropriate use of encrypted files.

Once data collection is complete, we will strip names from the data, using alpha-numeric codes instead. The code file will only be accessible to the PI on a separate Partners encrypted shared drive.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

N/A

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

N/A

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

N/A

Hospitalization at Home:

The Acute Care Home Hospital Program for Adults

DETAILED PROTOCOL

Version 4

BACKGROUND AND SIGNIFICANCE

Historical background

Hospitals are the standard of care for acute illness in the US, but hospital care is expensive and often unsafe, particularly for older individuals.[1] While admitted, 20% suffer delirium,[2] over 5% contract hospital-acquired infections,[3] and most lose functional status that is never regained.[4] Timely access to inpatient care is poor: many hospital wards are typically over 100% capacity, and emergency department waits can be protracted. Moreover, hospital care is increasingly costly: many internal medicine admissions have a negative margin (i.e., expenditures exceed hospital revenues) and incur patient debt.

Previous clinical studies

We propose a home hospital model of care that substitutes for treatment in an acute care hospital. Studies of the home hospital model have demonstrated that a sizeable proportion of acute care can be delivered in the home with equal quality and safety, 20% reduced cost, and 20% improved patient experience.[5,6] While this is the standard of care in several developed countries,[7] only 2 non-randomized demonstration projects have been conducted in the United States, each with highly local needs. Taken together, home hospital evidence is promising but falls short due to non-robust experimental design, failure to implement modern medical technology, and poor enlistment of community support. Our preliminary pilot data is reassuring.[8]

Rationale

In order to produce unbiased results, maximize patient safety, and minimize patient/caregiver burden while making the intervention as efficient as possible, our program innovates on prior home hospital models in several ways:

- Randomized controlled study and unbiased patient cohort: home hospital versus usual care in the hospital;
- Telepresence: on-demand video visits between patient and clinician 24 hours a day, 7 days a week;
- Remote wireless vital sign monitoring: mobile alerts and smart algorithms trigger video or in-person visits;
- Patient physical activity and sleep monitoring: steps taken and sleep quality for both outcome assessment and to guide treatment;
- Point of care diagnostics: blood, x-ray, and ultrasound; and

As discussed below in our aims, we expect decreased cost, improved patient experience, and similar safety and quality as compared to usual care.

SPECIFIC AIMS

Primary Aim

We will accomplish a 20% reduction in hospitalization cost for selected hospitalized adults who would normally have been admitted to the hospital.

Secondary Aims

We will accomplish the following for the above-mentioned selected hospitalized adults:

- reduce health care utilization;
    - For example: decreased length of stay, number of labs/imaging, readmissions, ED visits
- maintain or improve on patient safety;
    - For example: reduced risk of delirium, falls
- maintain or improve on quality of care;
    - For example, high-value: increase in appropriate antibiotic selection, hours of sleep
    - For example, low-value: decrease in use of urinary catheter, inappropriate medications in the elderly
- maintain or improve on functional status and quality of life; and
    - For example: increase in EuroQol-5D-5L, activities of daily living scale
- improve absolute patient experience by 20%.
    - For example: increase in 3-item care transition measure, PROMIS experience measures

Please refer to our performance measures below for more details regarding the definitions and sources for each of these measures.

SUBJECT SELECTION

Inclusion/exclusion criteria

Inclusion

- Social
    - Resides within either a 5-mile or 20 minute driving radius of BWH or BWFH emergency room
        - Driving radius will be obtained via inputting a nearby (but not exact) address into Google Maps, with average rush hour arrival timing.
    - Has capacity to consent to study OR can assent to study and has proxy who can consent (see subject enrollment, below)
    - Can identify a potential caregiver who agrees to stay with patient for first 24 hours of admission. Caregiver must be competent to call care team if a problem is evident to her/him. After 24 hours, this caregiver should be available for as-needed spot checks on the patient.
        - This criterion may be waived for highly competent patients at the patient and clinician's discretion.
- Clinical
    - >=18 years old

- Primary or possible diagnosis of cellulitis, heart failure, complicated urinary tract infection, pneumonia, COPD/asthma, other infection, chronic kidney disease, malignant pain, diabetes and its complications, gout flare, hypertensive urgency, previously diagnosed atrial fibrillation with rapid ventricular response, anticoagulation needs, or a patient who desires only medical management that requires inpatient admission, as determined by the emergency room team.
  - Regarding anticoagulation needs, this includes a patient who requires therapeutic anticoagulation and concomitant monitoring (thus requiring inpatient status)
  - Regarding a patient who desires only medical management, this includes a patient who requires acute care for symptom management, but declines any surgical intervention. This may include a patient who is about to transition to hospice care, for example, but still has the functional capacity to meet our criteria below. Under these circumstances, we would make sure that various contingencies, including possible transition to hospice care or hospital readmission, are completely understood by patients and caregivers as applicable.
  - In order to achieve enrollment goals, if <=5 patients have been enrolled in the first two weeks, we *a priori* reserve the ability to expand this criterion to include patients who fail observation status and patients who are transferred to the observation unit under the care of the emergency room observation team.

Exclusion

- Social
  - Undomiciled
  - No working heat (October-April), no working air conditioning if forecast > 80°F (June-September), or no running water
  - On methadone requiring daily pickup of medication
  - In police custody
  - Resides in facility that provides on-site medical care (e.g., skilled nursing facility)
  - Domestic violence screen positive[9]
- Clinical
  - Acute delirium, as determined by the Confusion Assessment Method[2]
  - Cannot establish peripheral access in emergency department (or access requires ultrasound guidance)
  - Secondary condition: end-stage renal disease, acute myocardial infarction, acute cerebral vascular accident, acute hemorrhage
  - Primary diagnosis requires multiple or routine administrations of intravenous narcotics for pain control
  - Cannot independently ambulate to bedside commode
  - As deemed by on-call MD, patient likely to require any of the following procedures: computed tomography, magnetic resonance imaging, endoscopic procedure, blood transfusion, cardiac stress test, or surgery
  - For pneumonia:
    - Most recent CURB65 > 3: new confusion, BUN > 19mg/dL, respiratory rate>=30/min, systolic blood pressure<90mmHg, Age>=65 (<14% 30-day mortality)[10]
    - Most recent SMRTCO > 2: systolic blood pressure < 90mmHg (2pts), multilobar CXR involvement (1pt), respiratory rate >= 30/min, heart rate >= 125, new

confusion, oxygen saturation <= 90% (<10% chance of intensive respiratory or vasopressor support)[11]
        - Absence of clear infiltrate on imaging
        - Cavitary lesion on imaging
        - Pulmonary effusion of unknown etiology
        - O_2 saturation < 90% despite 5L O_2
    - For heart failure:
        - Has a left ventricular assist device
        - GWTG-HF[12] (>10% in-hospital mortality) or ADHERE[13] (high risk or intermediate risk 1)*
        - Severe pulmonary hypertension
    - For complicated urinary tract infection:
        - Absence of pyuria
        - Most recent qSOFA > 1 (SBP≤100 mmHg, RR≥22, GCS<15 [any AMS]) (if sepsis, >10% mortality)[14]
    - For other infection
        - Most recent qSOFA > 1 (SBP≤100 mmHg, RR≥22, GCS<15 [any AMS]) (if sepsis, >10% mortality)[14]
    - For COPD
        - BAP-65 score > 3 (BUN>25, altered mental status, HR>109, age>65) (<13% chance in-hospital mortality): exercise caution
    - For asthma
        - Peak expiratory flow < 50% of normal: exercise caution
    - For diabetes and its complications
        - Requires IV insulin
    - For hypertensive urgency
        - Evidence of end-organ damage
    - For atrial fibrillation with rapid ventricular response
        - Likely to require cardioversion
        - New atrial fibrillation with rapid ventricular response
        - Unstable blood pressure, respiratory rate, or oxygenation
        - Despite IV beta and/or calcium channel blockade in the emergency department, HR remains > 125 and SBP remains different than baseline
- Home hospital census is full (maximum 5 patients at any time)

*GWTG-HF: AHA Get with the Guidelines: SBP, BUN, Na, Age, HR, Black race, COPD
ADHERE: Acute decompensated heart failure national registry: BUN, creatinine, SBP

Source of subjects and recruitment methods

All subjects will present to the Brigham and Women's Emergency Department and the Brigham and Women's Faulkner Emergency Department. Those meeting primary diagnosis, age, and residence within 5 mile requirements will be screened by our research assistants for further enrollment (below).

Subject Enrollment

Methods of enrollment, Procedures for obtaining consent

- Decision to admit made by emergency room team

- Participant is pre-screened by a research assistant for primary diagnosis, age, and residence within 5 miles or 20 minute drive via the electronic medical record.
- If participant meets those criteria, the emergency room team will ask the patient/caregiver if the research assistant can approach the patient regarding the home hospital study.
- If participant agrees, the research assistant will describe the program, answer initial questions, and further assess whether the participant meets inclusion/exclusion non-clinical (e.g., social) criteria. The RA will then contact the on-call MD to assess clinical criteria by EHR review.
- If the participant has interest in the program and meets inclusion/exclusion criteria, the on-call MD (either in-person or via a live video visit facilitated by the research assistant) will obtain written informed consent of the participant to enroll in the home hospital program.
- If capacity of the individual to consent to the study is questioned, capacity assessment will be performed by the patient's ED attending or by a psychiatric consultant if deemed necessary by the ED attending.
    - In addition to the attending's knowledge of the case and patient, the attending will be provided with the results of the Eight-item Interview to Differentiate Aging and Dementia, the activities of daily living scale, and the instrumental activities of daily living scale. These instruments will be obtained by the research assistant.
    - If the patient is deemed without capacity, any of the following individuals may give consent provided they are on-site and able to sign the informed consent (the patient will assent):
        - court-appointed guardian with authority to consent to participation in the proposed research or authority to make decisions for a class of health care decisions inclusive of the proposed research;
        - health care proxy with authority to make decisions for a class of health care decisions inclusive of the proposed research;
        - durable powers of attorney with authority to make health care decisions inclusive of the proposed research; or
        - spouse, adult child, parent, or adult sibling.
- All of these steps will occur in the emergency department or within 24 hours of placement on the floor if a patient was admitted overnight (when home hospital does not admit) or was missed in the screening protocol.

Treatment Assignment

- If the participant consents, the research assistant will proceed to randomization via concealed envelopes with
    - Concealed allocation;
    - Stratified on diagnosis;
    - Use randomization to determine arm;
- If patient/caregiver does not consent, the research assistant will ask the patient's permission to collect covariates, functional status, and a quality of life measure to determine generalizability of enrollment.

STUDY PROCEDURES

Study visits and measured parameters

Each day, the home hospital team will make visits to the patient's home. These are personnel who have been trained in home health and carry out home health as per the usual care they deliver. The home hospital module offers most of the same medical components that are standard of care in an acute care hospital (**Figure below**). The typical staff (MD, RN, case manager), diagnostics (blood tests, vital signs, telemetry, x-ray, and ultrasound), intravenous therapy, and oxygen/nebulizer therapy will all be available for home hospital. Optional deployment of a food, home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and social worker will be tailored to patient need. An enrolled subject assigned to the home hospital arm will have a conversation with study staff regarding which staff will visit their home. These staff may change as a patient's needs are further assessed throughout the admission. Home hospital improves upon the components of a typical ward's standard of care in several ways:

- Point of care blood diagnostics (results at the bedside in <5 minutes);
- Minimally invasive continuous vital signs, telemetry, and activity tracking, including clinical deterioration algorithms, steps taken, and sleep quality;
- 24/7 clinician video visits;
- 4 to 1 patient to MD ratio, compared to typical 16 to 1;
- Ambulatory/portable infusion pumps that can be worn on the hip;
- Optional access to a personal home health aide, community paramedic, and community health worker

Component	Module
Personnel	 **Registered Nurse** • Minimum 2 visits daily • Medication administration • IV access management • Education **Physician** • Minimum 1 visit daily • Medical decision making **Home Health Team** • Home health aide • Home PT/OT • Social Worker • Paramedic • CHW
Diagnostics	Point of care: BMP, Hgb/Hct, PT/INR, ultrasound, x-ray, PFTs, ECG
Pharmacy	Any inpatient medication, most any route
Equipment	Ambulatory infusion pump, peripheral IV, oxygen concentrator
Communication	Telepresence/virtual visits
Monitoring	Wireless remote vital signs, telemetry, activity tracking, sleep tracking, predictive analytics for deterioration

As denoted in the figure above, a patient or clinician can initiate a video or in-person visit at any time.

Clinical parameters measured will be at the discretion of the physician and nurse, who treat the participant following evidence-based practice guidelines, just as in the usual care setting. Please see below for all collected data points.

Documentation by RN and MD will occur via digital intake notes, daily progress notes, and discharge notes that will be compiled (on a Partners secure shared file area) and uploaded as a scanned document to the patient's chart upon discharge. In addition, each day an outpatient MD note, lab orders, and pharmacy orders will be written in Epic by the MD. When available, the study will be able to transition to complete Epic integration, such that the daily notes completed and stored in the shared-file area will no longer be necessary.

Additional personnel descriptions from those listed in the Figure:

- Community health worker (CHW): a trained and certified lay person who often shares culture and/or community with the patient. The CHW strives to improve familiarity with the plan of care, improve adherence to the plan of care (medications, appointments), improve clinical outcomes, and help the patient manage social barriers to care (e.g., applying for medication financial assistance). The CHW will make once daily visits during the admission and twice weekly visits after discharge for 30 days. The CHW will have no role in providing medical decision-making or in nursing care.
- Community paramedic: a command leader paramedic will provide in-home coverage from 6p-8a (when the nurse is not on duty). If a need arises in the off-hours that requires in-person assistance, the home hospital attending can dispatch the paramedic at their discretion with specific instructions. The paramedic will always consult the attending once on-site, often with

the use of a video visit. The paramedic can give medications under the direction of the attending should it be in the patient's best interests.

- Medical resident: a BWH PGY2 or PGY3 in internal medicine will have the option to select home hospital service as a two-week elective. They will attend a home hospital training and continue to have twice-weekly home-based medicine seminars throughout. Their role includes daily rounds for supervised medical decision-making, responses to patient needs, and documentation. They will always have to travel with another team member when visiting a patient's home. The home hospital attending will supervise the resident through direct observation and making addendums to documentation.

Drugs to be used

Only medications used in the usual care of hospitalized patients will be used. For example, a patient with pneumonia might receive guideline-based antibiotics with ceftriaxone and azithromycin.

Devices to be used

- Home hospital employs standard devices during the usual care of hospitalized patients. For example, a nebulizer machine.
- Home hospital additionally employs
    - Vital signs monitoring patch: Vital Connect VitalPatch (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])
        - Our team reserves the option to use the Vital Connect HealthPatch, which has improved blue-tooth range that becomes useful for obese patients and thick-walled homes (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])
    - Ambulatory infusion pump: Smiths Medical CADD SOLIS VIP (FDA cleared application/use)
    - Point of care diagnostic meter: Abbott iSTAT (FDA cleared application/use)

Procedures/surgical interventions

- Home hospital employs the same standard procedures used during the usual care of hospitalized patients. For example, peripheral venipuncture. Need for surgery is an exclusion criterion.

Data to be collected and when the data is to be collected

Primary Endpoint

Measure	Source	Day(s) Obtained
Total cost, hospitalization	Intervention arm: Home hospital accounting Control arm: BWH episodes of care	Discharge

Secondary and Exploratory Endpoints

Cost

Measure	Source(s)	Day(s) Obtained	Secondary vs Exploratory

Direct margin	Same as for Primary Outcome	Discharge	Secondary
Direct margin, modeled with backfill	Same as for Primary Outcome	Discharge	Secondary
Total cost, 30-day post discharge	Partners data	+30	Exploratory
Total reimbursement, 30-day post discharge	Shared-risk claims*	+30	Exploratory

*Will have this only for shared-risk patients (note our inclusion criteria are payer agnostic). Population Health Management team will provide.

Health Care Utilization

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Length of stay, days	RA via MD/RN for home patients; RA EHR review for inpatients	Discharge	Secondary
IV medication, days	As above.	Daily	Exploratory
Intravenous fluids, days	RA via EHR	Daily	Exploratory
Intravenous diuretics, days	RA via EHR	Daily	Exploratory
Intravenous antibiotics, days	RA via EHR	Daily	Exploratory
Oxygen requirement, days	RA via RN	Daily	Exploratory
Nebulizer treatment, days	RA via EHR	Daily	Exploratory
Imaging, #	As above. +30 will be cross-checked with Partners data.	Daily, +30	Secondary
Lab Orders, #	As above.	Daily, +30	Secondary
MD sessions, # of notes	As above.	Daily, +30	Exploratory
Consultant sessions, # of notes	As above.	Daily, +30	Exploratory
PT/OT sessions, # of notes	As above.	Daily, +30	Exploratory
Disposition (routine, SNF, home health, other)	RA via MD/RN for home patients; RA EHR review for inpatients	Discharge	Secondary
PCP follow-up within 14 days, y/n	RA via pt phone call, cross-checked with Partners data.	+30	Exploratory
SNF utilization, days	As above.	+30	Exploratory
Home health utilization, days	As above.	+30	Exploratory
All-cause readmission(s) after index, # and y/n + date	As above.	+30	Secondary
Unplanned readmission(s) after index, # and y/n + date	As above.	+30	Secondary
ED observation stay(s), # and y/n + date	As above.	+30	Secondary
ED visit(s), # and y/n + date	As above.	+30	Secondary

RA: Research assistant

Safety

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Fall	RA via MD/RN for home patients; MD EHR review for inpatients	Daily	Exploratory

Delirium	RNs in home and inpatient settings calculate the CAM (standard of care in both). RA will obtain the home patient CAM via the home RN; RA will obtain the inpatient CAM via EHR.	Daily	Secondary
DVT/PE	RA via MD/RN for home patients; MD EHR review for inpatients	Daily	Exploratory
New pressure ulcer	As above.	Daily	Exploratory
Thrombophlebitis at peripheral IV site	As above.	Daily	Exploratory
Hospital Acquired Condition			
CAUTI	As above.	Daily	Exploratory
Clostridium difficile	As above.	Daily	Exploratory
MRSA	As above.	Daily	Exploratory
Transfer back to hospital[a]	RA via MD/RN	Discharge	Secondary
All-cause mortality during admission	RA via MD/RN for home patients; MD EHR review for inpatients	Discharge	Exploratory
Unplanned mortality during admission	RA via MD/RN for home patients; MD EHR review for inpatients	Discharge	Exploratory
All-cause 30-day mortality	RA via pt/caregiver call	+30	Exploratory
Unplanned 30-day mortality	RA via pt/caregiver call	+30	Exploratory
Heart Failure			
New arrhythmia	RA via MD/RN for home patients; MD EHR review for inpatients	Daily	Exploratory
Hypokalemia	As above.	Daily	Exploratory
Acute kidney injury	As above.	Daily	Exploratory

[a]: intervention arm only

Quality: High-Value Care

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Pain management	RA via MD/RN for home patients; RA EHR review for inpatients	Daily	Exploratory
Hours of sleep per day	RA via activity tracker	Daily	Secondary
Hours of sleep per night	RA via activity tracker	Daily	Exploratory
Hours of activity per day	RA via activity tracker	Daily	Secondary
Hours of activity per night	RA via activity tracker	Daily	Exploratory
Hours of sitting upright per day	RA via activity tracker	Daily	Secondary
Hours of sitting upright per night	RA via activity tracker	Daily	Exploratory
Daily steps	RA via activity tracker	Daily	Secondary
Pneumonia			
Pneumococcal vaccination if appropriate	RA via EHR	Discharge	Exploratory

Influenza vaccination if appropriate	RA via EHR	Discharge	Exploratory
Smoking cessation counseling if appropriate	RA via EHR	Discharge	Exploratory
Heart Failure			
Evaluation of ejection fraction scheduled or completed if not done within 1 year	RA via EHR	Discharge	Exploratory
ACEI/ARB for HFrEF (EF < 40%)	RA via EHR, pt (post discharge)	Discharge, +30	Exploratory
Beta blocker for HFrEF (EF < 40%)	As above.	Discharge, +30	Exploratory
Aldosterone antagonist for HFrEF (EF < 40%)	As above.	Discharge, +30	Exploratory
Lipid lowering for CAD, PVD, CVA, or diabetes	As above.	Discharge, +30	Exploratory
Smoking cessation counseling if appropriate	As above.	Discharge	Exploratory
Smoking status post-discharge	RA via pt	+30	Exploratory

Quality: Low-Value Care

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Use of inappropriate medications in the elderly	RA via EHR/MAR	Daily	Exploratory
Use of foley catheter	RA via MD/RN for home patients; EHR review for inpatients	Daily	Exploratory
Use of restraints	RA via MD/RN for home patients; EHR review for inpatients	Daily	Exploratory
>3 medications added to medication list	RA via EHR/MAR	Discharge	Exploratory

Patient Functional Status and Quality of Life

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
EuroQol -5D-5L	RA via patient	Admission, discharge, +30	Secondary
SF-1	RA via patient	-30, admission, discharge, +30	Secondary
Activities of daily living	RA via patient	-30, admission, discharge, +30	Secondary
Instrumental activities of daily living	RA via patient	-30, admission, discharge, +30	Secondary
Patient Health Questionnaire-2	RA via patient	Admission, discharge, +30	Exploratory
PROMIS Emotional Support Short Form 4a	RA via patient	Admission, discharge, +30	Exploratory
Days at home since discharge	RA via	+30	Exploratory

	patient		
Milestones			
Walk around ward/home	RA via RN	Discharge	Exploratory
Get to (non-commode) bathroom	RA via RN	Discharge	Exploratory
Walk 1 flight of stairs	RA via RN	Discharge	Exploratory
Visit with friends/family	RA via patient	Discharge	Exploratory
Walk outside around my home	RA via patient	+30	Exploratory
Go shopping	RA via patient	+30	Exploratory

Patient and Family Experience

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
3-item Care Transition Measure	RA via patient	+30	Secondary
Picker Experience Questionnaire	RA via patient	+30	Secondary
Global satisfaction	RA via patient	+30	Exploratory
Qualitative interviews	See Below	+30	Exploratory

Process Measures

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Time from admission decision to assessment by RA	RA	Admission	Exploratory
Time from RA assessment to dismissal	RA	Admission	Exploratory
Time from arrival home or to floor and MD evaluation	RA via MD	Admission	Exploratory
Time from arrival home or to floor and RN evaluation	RA via RN	Admission	Exploratory
RN to patient ratio	RA via census	Daily	Exploratory
Number of RN visits	RA via RN/EHR	Daily	Exploratory
Number of “on call” MD interactions (video or phone)	RA via MD	Daily	Exploratory
Number of “on call” MD in-person visits	RA via MD	Daily	Exploratory
Duration of 1st RN visit	RA via RN	Daily	Exploratory
Duration of subsequent RN visit	RA via RN	Daily	Exploratory
Clinician Burnout	All clinicians	Pre/post study	Exploratory

Covariates of Interest

Measure	Source	Day(s) Obtained
Age	RA via EHR[a]	Admission
Gender	RA via EHR	Admission
Race/ethnicity	RA via patient	Admission
Primary language	RA via EHR	Admission
Health insurance status, public/private/none	RA via EHR	Admission

BMI	RA via EHR	Admission
Comorbidities, type and #	RA via EHR and H&P	Admission
Partner status	RA via patient	Admission
Education	RA via patient	Admission
Zip code	RA via EHR	Admission
Employment	RA via H&P	Admission
Smoking status	RA via H&P	Admission
Medications used as outpatient, #	RA via EHR	Admission
DNR/I code status	RA via H&P	Admission
Home health aide prior to admission	RA via patient	Admission
Readmission risk score on discharge (HOSPITAL)	RA via EHR	Discharge
Elective and urgent admissions in the previous year, #	RA via EHR and patient	Admission
ED visits in the previous 6 months, #	RA via EHR and patient	Admission
Interqual disease-specific leveling	MD	Admission
PRISMA-7	RA via patient	Admission
Eight-item Interview to Differentiate Aging and Dementia	RA via patient or proxy	Admission
Would you be surprised if this patient died in the next year?	RA via MD	Admission
BRIEF health literacy screening tool	RA via patient	Admission
Caregiver burden	RA via caregiver	Admission, +30

[a]: Note that RA will recheck covariates after MD H&P completed to ensure comorbidities and other covariates correctly captured

Standard Operating Procedure for Problematic Situations

Clinically Emergent Patient Condition

Should a matter be emergent (that is, requiring in-person assistance in less than 15 minutes), then 9-1-1 will be called and the patient will be returned to the hospital immediately. An example of an emergent patient condition is severe new-onset shortness of breath.

Clinically Urgent Patient Condition

Should a matter be urgent (that is, a condition that does not require assistance in under 15 minutes), the patient and/or nurse and/or physician may choose to communicate via phone or video (either of the 3 persons can initiate either medium). If this is unsuccessful, the nurse and/or physician will visit the patient in their home. If there is no way to rectify the situation, then the patient will be transported to the hospital. An example of an urgent situation is new-onset non-severe pain.

Unsafe Home Situation

Should an unsafe home situation be discovered during a home hospital admission, the home hospital team will assess if said situation poses a harm or threat to either the participant or the home hospital personnel. If it does, and after an attempt to rectify said situation, the situation persists, then the home hospital team will end the study and return the patient to the hospital. An example of an unsafe home situations includes lack of basic sanitation.

Intoxication

Should intoxication occur in the home of a participant, the home hospital team will assess if said intoxication poses a harm or threat to either the participant or the home hospital personnel. If it does, and after an attempt to rectify said intoxication, the situation persists, then the home hospital team will end the study and return the patient to the hospital.

Neglect or child abuse

Should neglect or child abuse be observed, the home hospital team will act as mandatory reporters. The home hospital team, in coordination with the hotline team, will assess if said neglect or child abuse poses an immediate harm or threat to either the participant, children in the home, or the home hospital personnel. If it does, then the home hospital team will end the study and return the patient to the hospital.

BIOSTATISTICAL ANALYSIS

Specific data variables being collected

Please see above.

Study endpoints

As described above, the study's primary endpoint is total hospitalization cost. We aim for 20% cost reduction. Several secondary endpoints are listed above.

Statistical methods

Quantitative

The primary outcome (hospitalization cost) will be assessed using log-transformed multivariable linear regression adjusted for medical condition, age, comorbidity score, and several other covariates (see above list for details). We will use this same multivariable regression approach for secondary outcomes, using logistic regression for binary outcomes (e.g., ED visits, readmissions, delirium, falls) and non-transformed linear regression for normally distributed continuous outcomes (e.g., measures of quality of life and patient experience) as appropriate.

We *a priori* plan to perform a subgroup analysis that does not involve any outlier participants in either study arm, should this occur. We also *a priori* plan subgroup analyses by diagnosis, by age group, by disposition, and by daily activity level. We also *a priori* plan to analyze our outcomes with means, but

also with median and interquartile ranges, which are less subject to outlier effects. We may choose to employ non-parametric tests of significance should our data be nonparametric.

Qualitative

During and after the intervention period, we will interview a sample of patients and caregivers 7-30 days after discharge (irrespective of their experimental arm) regarding their opinions of their hospitalization. We will use this data to both iteratively improve home hospital and make detailed qualitative comparisons between home hospital and usual care.

In all cases, we will use semi-structured interview guides to ask questions regarding the hospitalization experience. Interviews will be recorded, transcribed, and then analyzed using NVivo qualitative analysis software. Drs. Schnipper and Levine will perform dual coding of all themes, and all differences will be discussed and reconciled. We will use an a priori analytic framework based on the Systems Engineering Initiative for Patient Safety Model (SEIPS), which describes processes and outcomes as products of the interactions among patients, technology and tools, the health care organization, the tasks at hand, and the physical environment.[15]

Power analysis

Our preliminary pilot data suggests that median direct cost of the acute care episode for home patients was 52% lower than for control patients. At 90% power, we would require 19 patients in each arm.

Secondary outcomes require larger samples sizes at 80% power. At 60 patients in each arm, we will be powered to detect significant differences in activity, steps, worsening in iADLs, laboratory use, Picker, and consultant use.

RISKS AND DISCOMFORTS

Uncommon: Complications of surgical and non-surgical procedures

Standard hospital procedures carry small risks and discomforts. For example, venipuncture can be painful and can lead to thrombophlebitis, but this is uncommon and readily rectifiable.

Uncommon: Device complications/malfunctions

IV pumps, vital signs monitoring patches, and the other devices used during home hospital uncommonly have malfunctions.

Uncommon: Radiation risks

Patients can receive radiography while admitted to home hospital, much the same as when they are admitted in the hospital. We do not anticipate that home hospital will in any way change the prevailing risk of radiation.

Common (but unchanged from usual care): Drug side effects and toxicities

Drug side effects and toxicities do occur during inpatient medicine, despite following best practices and evidence based medicine. We do not anticipate that home hospital will in any way change the prevailing

rate of drug side effects and toxicities compared to usual care. For example, acute kidney injury can occur in patients receiving antibiotics, even when correct dosing occurs. Home hospital is equipped to monitor and respond to the common drug side effects and toxicities much the same as the standard of care (monitoring, diagnostics, fluids, etc).

Common (but improved from usual care): Psychosocial risks

Admission to the hospital can be a psychosocially difficult event, particularly for a senior. We believe home hospital will alleviate these typical risks. Home hospital is equipped to assist patients with psychosocial stressors through improved staffing ratios and a social worker.

POTENTIAL BENEFITS

Potential benefits to participating individuals

- Remain in their home despite acute illness
    - Eat their own culturally concordant food
    - Sleep in familiar surroundings
    - Maximize time and interactions with their family and friends
- Improved health outcomes (we anticipate these from previous literature)
    - Reduced length of stay
    - Reduced complications while admitted
        - Less delirium
        - Fewer falls
        - Fewer health care associated infections
        - Decreases reduction in functional status
    - Improved patient experience
- Clinical improvements to the standard of care
    - Point of care blood diagnostics (results at the bedside in <5 minutes);
    - Minimally invasive continuous vital signs, telemetry, and activity tracking, including clinical deterioration algorithms, steps taken, and sleep quality;
    - On-demand 24/7 clinician virtual video visits;
    - 4 to 1 patient to MD ratio, compared to typical 16 to 1;
    - Ambulatory/portable infusion pumps that can be worn on the hip;
    - Optional access to a personal home health aide, community health worker, and community paramedic
- Improved transitions of care
    - Ability to coach patients on their post-discharge care plan in the appropriate environment, with caregivers available, and with adequate time for teaching given provider to patient ratio

Potential benefits to society

- New evidence-based care paradigm for acute care hospitalization.
- Lower total medical expenditure. Allows for redirection of resources to areas in need.
- Might eventually lead to reduction in total hospitals in the U.S.

- Provide needed randomized controlled data on the home hospital intervention to inform payment methods moving forward.

MONITORING AND QUALITY ASSURANCE

Independent monitoring of source data

The study's research assistant will collect all data denoted above. The PI and co-PI will monitor the source data throughout the project.

Safety monitoring

If any of the following concerning safety events occur, a blinded monitoring committee will review the event to determine attribution to the intervention: fall, medication error, DVT/PE, mortality during admission, transfer back to hospital (committee cannot be blinded for this endpoint). If any of these events are felt to be due to the home hospital intervention, they will be reported to the IRB with recommendations for appropriate actions to be taken. Decisions to modify the protocol or suspend the study will be made jointly by the study investigators, monitoring committee, and the IRB.

Outcomes monitoring

The physician and RNs will daily review quality and safety data as part of a rapid logistics improvement process.

Weekly, all physicians and RNs will huddle to review quality and safety data as part of a rapid logistics improvement process.

At 3 weeks into the home hospital clinical service, a blinded monitoring committee will review outcomes data and make recommendations to the study team.

Adverse event reporting guidelines

All adverse events denoted above under safety monitoring will be reported to the monitoring committee.

APPENDIX

Risk Scores

CURB 65 – 30-day mortality prediction

- Cohort: 1068pts of CAP in the UK, New Zealand, and the Netherlands in 1998-1999
- 30-day mortality by points
    - score 0, 0.7%
    - score 1, 3.2%
    - score 2, 3%
    - score 3, 17%
    - score 4, 41.5%
    - score 5, 57%

No of	Sensitivity	Specificity	PPV (%)	NPV (%)

features	(%)	(%)		
>0	100	0	9.6	NA
>1	98.6	21.0	11.7	99.3
>2	92.8	49.2	16.2	98.5
>3	68.1	74.9	22.4	95.7
>4	39.1	93.1	37.5	93.5
>5	1.4	99.1	14.3	90.4

SMRTCO – chance of intensive respiratory or vasopressor support (IRVS)

- Cohort: 5 databases (7464 patients), 1991-2001
- IRVS by points
    - Score 0, ~0%
    - Score 1, 5%
    - Score 2, 10%
    - Score 3, 17%
    - Score >=4, 33%

Study Staff

- Jeffrey Schnipper, MD MPH, has conducted research since 2002 aimed at improving health information technology, predicting hospital readmission, improving medication safety during transitions in care, and improving discharge. He has over 100 peer-reviewed publications, including a dual-site randomized controlled trial of an electronic medication reconciliation tool and process redesign on patient safety, generally regarded as the most rigorous study to date of electronic medication reconciliation tools. More recently, his group completed a two-site randomized controlled trial of pharmacist counseling and follow-up on cardiac patients with low health literacy (the PILL-CVD study). He was the principal investigator of the Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS), an AHRQ-funded study at five US hospitals to design and implement an evidence-based toolkit to improve medication reconciliation and is now the PI of an AHRQ-funded study to continue that work at 18 additional hospitals. Dr. Schnipper's recent PCORI-funded readmission avoidance project involved community health workers. He also has expertise in decision support, electronic dashboards, and the novel use of patient portals.
- David Levine, MD MA, is a clinical attending physician and research fellow in the division of general internal medicine and primary care at Brigham and Women's Hospital. He has expertise in design, implementation, and evaluation of innovative and disruptive medical programs with experience in house calls, digital health, and community health worker programs. Currently leading projects on national quality measurement, disparities in quality, virtual visits, seniors' use of digital health, and house calls. As coinvestigator of this project, his role is in design, implementation, and evaluation.
- 3 research assistants – TBD

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Hospitalization at Home:

The Acute Care Home Hospital Program for Adults

DETAILED PROTOCOL

Version 4

BACKGROUND AND SIGNIFICANCE

Historical background

Hospitals are the standard of care for acute illness in the US, but hospital care is expensive and often unsafe, particularly for older individuals.[1] While admitted, 20% suffer delirium,[2] over 5% contract hospital-acquired infections,[3] and most lose functional status that is never regained.[4] Timely access to inpatient care is poor: many hospital wards are typically over 100% capacity, and emergency department waits can be protracted. Moreover, hospital care is increasingly costly: many internal medicine admissions have a negative margin (i.e., expenditures exceed hospital revenues) and incur patient debt.

Previous clinical studies

We propose a home hospital model of care that substitutes for treatment in an acute care hospital. Studies of the home hospital model have demonstrated that a sizeable proportion of acute care can be delivered in the home with equal quality and safety, 20% reduced cost, and 20% improved patient experience.[5,6] While this is the standard of care in several developed countries,[7] only 2 non-randomized demonstration projects have been conducted in the United States, each with highly local needs. Taken together, home hospital evidence is promising but falls short due to non-robust experimental design, failure to implement modern medical technology, and poor enlistment of community support. Our preliminary pilot data is reassuring.[8]

Rationale

In order to produce unbiased results, maximize patient safety, and minimize patient/caregiver burden while making the intervention as efficient as possible, our program innovates on prior home hospital models in several ways:

- Randomized controlled study and unbiased patient cohort: home hospital versus usual care in the hospital;
- Telepresence: on-demand video visits between patient and clinician 24 hours a day, 7 days a week;
- Remote wireless vital sign monitoring: mobile alerts and smart algorithms trigger video or in-person visits;
- Patient physical activity and sleep monitoring: steps taken and sleep quality for both outcome assessment and to guide treatment;
- Point of care diagnostics: blood, x-ray, and ultrasound; and

As discussed below in our aims, we expect decreased cost, improved patient experience, and similar safety and quality as compared to usual care.

SPECIFIC AIMS

Primary Aim

We will accomplish a 20% reduction in hospitalization cost for selected hospitalized adults who would normally have been admitted to the hospital.

Secondary Aims

We will accomplish the following for the above-mentioned selected hospitalized adults:

- reduce health care utilization;
    - For example: decreased length of stay, number of labs/imaging, readmissions, ED visits
- maintain or improve on patient safety;
    - For example: reduced risk of delirium, falls
- maintain or improve on quality of care;
    - For example, high-value: increase in appropriate antibiotic selection, hours of sleep
    - For example, low-value: decrease in use of urinary catheter, inappropriate medications in the elderly
- maintain or improve on functional status and quality of life; and
    - For example: increase in EuroQol-5D-5L, activities of daily living scale
- improve absolute patient experience by 20%.
    - For example: increase in 3-item care transition measure, PROMIS experience measures

Please refer to our performance measures below for more details regarding the definitions and sources for each of these measures.

SUBJECT SELECTION

Inclusion/exclusion criteria

Inclusion

- Social
    - Resides within either a 5-mile or 20 minute driving radius of BWH or BWFH emergency room
        - Driving radius will be obtained via inputting a nearby (but not exact) address into Google Maps, with average rush hour arrival timing.
    - ~~o~~ Has capacity to consent to study OR can assent to study and has ~~health care~~ proxy who can consent (see subject enrollment, below)~~has capacity to consent to study as determined by home hospital physician~~
    - ~~Capacity assessment will be performed by using "read-back" of the main points of the consent form: that participation is voluntary, that patients will be randomized to usual care or home hospital, what home hospital entails, that they will be asked survey questions as part of the study, that they will have the right to decline to answer any questions they don't want to answer, that they can end their participation in the study in the study at any time.~~
    - Can identify a potential caregiver who agrees to stay with patient for first 24 hours of admission. Caregiver must be competent to call care team if a problem is evident to

her/him. After 24 hours, this caregiver should be available for as-needed spot checks on the patient.
    - This criterion may be waived for highly competent patients at the patient and clinician's discretion.
- Clinical
    - >=18 years old
    - Primary or possible diagnosis of cellulitis, heart failure, complicated urinary tract infection, pneumonia, COPD/asthma, other infection, chronic kidney disease, malignant pain, diabetes and its complications, gout flare, hypertensive urgency, previously diagnosed atrial fibrillation with rapid ventricular response, anticoagulation needs, ~~surgical monitoring,~~ or a patient who desires only medical management that requires inpatient admission, as determined by the emergency room team.
        - Regarding anticoagulation needs, this includes a patient who requires therapeutic anticoagulation and concomitant monitoring (thus requiring inpatient status)
        - Regarding a patient who desires only medical management, this includes a patient who requires acute care for symptom management, but declines any surgical intervention. This may include a patient who is about to transition to hospice care, for example, but still has the functional capacity to meet our criteria below. Under these circumstances, we would make sure that various contingencies, including possible transition to hospice care or hospital readmission, are completely understood by patients and caregivers as applicable.
        - In order to achieve enrollment goals, if <=5 patients have been enrolled in the first two weeks, we *a priori* reserve the ability to expand this criterion to include patients who fail observation status and patients who are transferred to the observation unit under the care of the emergency room observation team.

Exclusion

- Social
    - Undomiciled
    - No working heat (October-April), no working air conditioning if forecast > 80°F (June-September), or no running water
    - On methadone requiring daily pickup of medication
    - In police custody
    - Resides in facility that provides on-site medical care (e.g., skilled nursing facility)
    - Domestic violence screen positive[9]
- Clinical
    - Acute delirium, as determined by the Confusion Assessment Method[2]
    - Cannot establish peripheral access in emergency department (or access requires ultrasound guidance)
    - Secondary condition: end-stage renal disease, acute myocardial infarction, acute cerebral vascular accident, acute hemorrhage
    - Primary diagnosis requires multiple or routine administrations of intravenous narcotics for pain control
    - Cannot independently ambulate to bedside commode
    - As deemed by on-call MD, patient likely to require any of the following procedures: computed tomography, magnetic resonance imaging, endoscopic procedure, blood transfusion, cardiac stress test, or surgery

- For pneumonia:
  - Most recent CURB65 > 3: new confusion, BUN > 19mg/dL, respiratory rate>=30/min, systolic blood pressure<90mmHg, Age>=65 (<14% 30-day mortality)[10]
  - Most recent SMRTCO > 2: systolic blood pressure < 90mmHg (2pts), multilobar CXR involvement (1pt), respiratory rate >= 30/min, heart rate >= 125, new confusion, oxygen saturation <= 90% (<10% chance of intensive respiratory or vasopressor support)[11]
  - Absence of clear infiltrate on imaging
  - Cavitary lesion on imaging
  - Pulmonary effusion of unknown etiology
  - O_2 saturation < 90% despite 5L O_2
- For heart failure:
  - Has a left ventricular assist device
  - GWTG-HF[12] (>10% in-hospital mortality) or ADHERE[13] (high risk or intermediate risk 1)*
  - Severe pulmonary hypertension
- For complicated urinary tract infection:
  - Absence of pyuria
  - Most recent qSOFA > 1 (SBP≤100 mmHg, RR≥22, GCS<15 [any AMS]) (if sepsis, >10% mortality)[14]
- For other infection
  - Most recent qSOFA > 1 (SBP≤100 mmHg, RR≥22, GCS<15 [any AMS]) (if sepsis, >10% mortality)[14]
- For COPD
  - BAP-65 score > 3 (BUN>25, altered mental status, HR>109, age>65) (<13% chance in-hospital mortality): exercise caution
- For asthma
  - Peak expiratory flow < 50% of normal: exercise caution
- For diabetes and its complications
  - Requires IV insulin
- For hypertensive urgency
  - Evidence of end-organ damage
- For atrial fibrillation with rapid ventricular response
  - Likely to require cardioversion
  - New atrial fibrillation with rapid ventricular response
  - Unstable blood pressure, respiratory rate, or oxygenation
  - Despite IV beta and/or calcium channel blockade in the emergency department, HR remains > 125 and SBP remains different than baseline

- Home hospital census is full (maximum 5 patients at any time)

*GWTG-HF: AHA Get with the Guidelines: SBP, BUN, Na, Age, HR, Black race, COPD
ADHERE: Acute decompensated heart failure national registry: BUN, creatinine, SBP

Source of subjects and recruitment methods

All subjects will present to the Brigham and Women's Emergency Department and the Brigham and Women's Faulkner Emergency Department. Those meeting primary diagnosis, age, and residence within 5 mile requirements will be screened by our research assistants for further enrollment (below).

Subject Enrollment

Methods of enrollment, Procedures for obtaining consent

- Decision to admit made by emergency room team
- Participant is pre-screened by a research assistant for primary diagnosis, age, and residence within 5 miles or 20 minute drive via the electronic medical record.
- If participant meets those criteria, the emergency room team will ask the patient/caregiver if the research assistant can approach the patient regarding the home hospital study.
- If participant agrees, the research assistant will describe the program, answer initial questions, and further assess whether the participant meets inclusion/exclusion non-clinical (e.g., social) criteria. The RA will then contact the on-call MD to assess clinical criteria by EHR review.
- If the participant has interest in the program and meets inclusion/exclusion criteria, the on-call MD (either in-person or via a live video visit facilitated by the research assistant) will obtain written informed consent of the participant to enroll in the home hospital program.
- If capacity of the individual ~~or the individual's health care proxy~~ to consent to the study is questioned, capacity assessment will be performed by the patient's ED attending or by a psychiatric consultant if deemed necessary by the ED attending.
    - In addition to the attending's knowledge of the case and patient, the attending will be provided with the results of the Eight-item Interview to Differentiate Aging and Dementia, the activities of daily living scale, and the instrumental activities of daily living scale. These instruments will be obtained by the research assistant.~~using "read-back" of the main points of the consent form: that participation is voluntary. , that patients will be randomized to usual care or home hospital, what home hospital entails, that they will be asked survey questions as part of the study, that they will have the right to decline to answer any questions they don't want to answer, that they can end their participation in the study at any time.~~
    - If the patient is deemed without capacity, any of the following individuals may give consent provided they are on-site and able to sign the informed consent (the patient will assent):
        - court-appointed guardian with authority to consent to participation in the proposed research or authority to make decisions for a class of health care decisions inclusive of the proposed research;
        - health care proxy with authority to make decisions for a class of health care decisions inclusive of the proposed research;
        - durable powers of attorney with authority to make health care decisions inclusive of the proposed research; or
        - spouse, adult child, parent, or adult sibling.
- All of these steps will occur in the emergency department or within 24 hours of placement on the floor if a patient was admitted overnight (when home hospital does not admit) or was missed in the screening protocol.

Treatment Assignment

- If the participant consents, the research assistant will proceed to randomization via concealed envelopes with
    - Concealed allocation;
    - Stratified on diagnosis;
    - Use randomization to determine arm;
- If patient/caregiver does not consent, the research assistant will ask the patient's permission to collect covariates, functional status, and a quality of life measure to determine generalizability of enrollment.

STUDY PROCEDURES

Study visits and measured parameters

Each day, the home hospital team will make visits to the patient's home. These are personnel who have been trained in home health and carry out home health as per the usual care they deliver. The home hospital module offers most of the same medical components that are standard of care in an acute care hospital (**Figure below**). The typical staff (MD, RN, case manager), diagnostics (blood tests, vital signs, telemetry, x-ray, and ultrasound), intravenous therapy, and oxygen/nebulizer therapy will all be available for home hospital. Optional deployment of a food, home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and social worker will be tailored to patient need. An enrolled subject assigned to the home hospital arm will have a conversation with study staff regarding which staff will visit their home. These staff may change as a patient's needs are further assessed throughout the admission. Home hospital improves upon the components of a typical ward's standard of care in several ways:

- Point of care blood diagnostics (results at the bedside in <5 minutes);
- Minimally invasive continuous vital signs, telemetry, and activity tracking, including clinical deterioration algorithms, steps taken, and sleep quality;
- 24/7 clinician video visits;
- 4 to 1 patient to MD ratio, compared to typical 16 to 1;
- Ambulatory/portable infusion pumps that can be worn on the hip;
- Optional access to a personal home health aide, community paramedic, and community health worker

Component	Module
Personnel	 **Registered Nurse** • Minimum 2 visits daily • Medication administration • IV access management • Education **Physician** • Minimum 1 visit daily • Medical decision making **Home Health Team** • Home health aide • Home PT/OT • Social Worker • Paramedic • CHW
Diagnostics	Point of care: BMP, Hgb/Hct, PT/INR, ultrasound, x-ray, PFTs, ECG
Pharmacy	Any inpatient medication, most any route
Equipment	Ambulatory infusion pump, peripheral IV, oxygen concentrator
Communication	Telepresence/virtual visits
Monitoring	Wireless remote vital signs, telemetry, activity tracking, sleep tracking, predictive analytics for deterioration

As denoted in the figure above, a patient or clinician can initiate a video or in-person visit at any time.

Clinical parameters measured will be at the discretion of the physician and nurse, who treat the participant following evidence-based practice guidelines, just as in the usual care setting. Please see below for all collected data points.

Documentation by RN and MD will occur via digital intake notes, daily progress notes, and discharge notes that will be compiled (on a Partners secure shared file area) and uploaded as a scanned document to the patient's chart upon discharge. In addition, each day an outpatient MD note, lab orders, and pharmacy orders will be written in Epic by the MD. When available, the study will be able to transition to complete Epic integration, such that the daily notes completed and stored in the shared-file area will no longer be necessary.

Additional personnel descriptions from those listed in the Figure:

- Community health worker (CHW): a trained and certified lay person who often shares culture and/or community with the patient. The CHW strives to improve familiarity with the plan of care, improve adherence to the plan of care (medications, appointments), improve clinical outcomes, and help the patient manage social barriers to care (e.g., applying for medication financial assistance). The CHW will make once daily visits during the admission and twice weekly visits after discharge for 30 days. The CHW will have no role in providing medical decision-making or in nursing care.
- Community paramedic: a command leader paramedic will provide in-home coverage from 6p-8a (when the nurse is not on duty). If a need arises in the off-hours that requires in-person assistance, the home hospital attending can dispatch the paramedic at their discretion with specific instructions. The paramedic will always consult the attending once on-site, often with

the use of a video visit. The paramedic can give medications under the direction of the attending should it be in the patient's best interests.

- Medical resident: a BWH PGY2 or PGY3 in internal medicine will have the option to select home hospital service as a two-week elective. They will attend a home hospital training and continue to have twice-weekly home-based medicine seminars throughout. Their role includes daily rounds for supervised medical decision-making, responses to patient needs, and documentation. They will always have to travel with another team member when visiting a patient's home. The home hospital attending will supervise the resident through direct observation and making addendums to documentation.

Drugs to be used

Only medications used in the usual care of hospitalized patients will be used. For example, a patient with pneumonia might receive guideline-based antibiotics with ceftriaxone and azithromycin.

Devices to be used

- Home hospital employs standard devices during the usual care of hospitalized patients. For example, a nebulizer machine.
- Home hospital additionally employs
    - Vital signs monitoring patch: Vital Connect VitalPatch (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])
        - Our team reserves the option to use the Vital Connect HealthPatch, which has improved blue-tooth range that becomes useful for obese patients and thick-walled homes (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])
    - Ambulatory infusion pump: Smiths Medical CADD SOLIS VIP (FDA cleared application/use)
    - Point of care diagnostic meter: Abbott iSTAT (FDA cleared application/use)

Procedures/surgical interventions

- Home hospital employs the same standard procedures used during the usual care of hospitalized patients. For example, peripheral venipuncture. Need for surgery is an exclusion criterion.

Data to be collected and when the data is to be collected

Primary Endpoint

Measure	Source	Day(s) Obtained
Total cost, hospitalization	Intervention arm: Home hospital accounting Control arm: BWH episodes of care	Discharge

Secondary and Exploratory Endpoints

Cost

Measure	Source(s)	Day(s) Obtained	Secondary vs Exploratory

Direct margin	Same as for Primary Outcome	Discharge	Secondary
Direct margin, modeled with backfill	Same as for Primary Outcome	Discharge	Secondary
Total cost, 30-day post discharge	Partners data	+30	Exploratory
Total reimbursement, 30-day post discharge	Shared-risk claims*	+30	Exploratory

*Will have this only for shared-risk patients (note our inclusion criteria are payer agnostic). Population Health Management team will provide.

Health Care Utilization

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Length of stay, days	RA via MD/RN for home patients; RA EHR review for inpatients	Discharge	Secondary
IV medication, days	As above.	Daily	Exploratory
Intravenous fluids, days	RA via EHR	Daily	Exploratory
Intravenous diuretics, days	RA via EHR	Daily	Exploratory
Intravenous antibiotics, days	RA via EHR	Daily	Exploratory
Oxygen requirement, days	RA via RN	Daily	Exploratory
Nebulizer treatment, days	RA via EHR	Daily	Exploratory
Imaging, #	As above. +30 will be cross-checked with Partners data.	Daily, +30	Secondary
Lab Orders, #	As above.	Daily, +30	Secondary
MD sessions, # of notes	As above.	Daily, +30	Exploratory
Consultant sessions, # of notes	As above.	Daily, +30	Exploratory
PT/OT sessions, # of notes	As above.	Daily, +30	Exploratory
Disposition (routine, SNF, home health, other)	RA via MD/RN for home patients; RA EHR review for inpatients	Discharge	Secondary
PCP follow-up within 14 days, y/n	RA via pt phone call, cross-checked with Partners data.	+30	Exploratory
SNF utilization, days	As above.	+30	Exploratory
Home health utilization, days	As above.	+30	Exploratory
All-cause readmission(s) after index, # and y/n + date	As above.	+30	Secondary
Unplanned readmission(s) after index, # and y/n + date	As above.	+30	Secondary
ED observation stay(s), # and y/n + date	As above.	+30	Secondary
ED visit(s), # and y/n + date	As above.	+30	Secondary

RA: Research assistant

Safety

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Fall	RA via MD/RN for home patients; MD EHR review for inpatients	Daily	Exploratory

Delirium	RNs in home and inpatient settings calculate the CAM (standard of care in both). RA will obtain the home patient CAM via the home RN; RA will obtain the inpatient CAM via EHR.	Daily	Secondary
DVT/PE	RA via MD/RN for home patients; MD EHR review for inpatients	Daily	Exploratory
New pressure ulcer	As above.	Daily	Exploratory
Thrombophlebitis at peripheral IV site	As above.	Daily	Exploratory
Hospital Acquired Condition			
CAUTI	As above.	Daily	Exploratory
Clostridium difficile	As above.	Daily	Exploratory
MRSA	As above.	Daily	Exploratory
Transfer back to hospital[a]	RA via MD/RN	Discharge	Secondary
All-cause mortality during admission	RA via MD/RN for home patients; MD EHR review for inpatients	Discharge	Exploratory
Unplanned mortality during admission	RA via MD/RN for home patients; MD EHR review for inpatients	Discharge	Exploratory
All-cause 30-day mortality	RA via pt/caregiver call	+30	Exploratory
Unplanned 30-day mortality	RA via pt/caregiver call	+30	Exploratory
Heart Failure			
New arrhythmia	RA via MD/RN for home patients; MD EHR review for inpatients	Daily	Exploratory
Hypokalemia	As above.	Daily	Exploratory
Acute kidney injury	As above.	Daily	Exploratory

[a]: intervention arm only

Quality: High-Value Care

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Pain management	RA via MD/RN for home patients; RA EHR review for inpatients	Daily	Exploratory
Hours of sleep per day	RA via activity tracker	Daily	Secondary
Hours of sleep per night	RA via activity tracker	Daily	Exploratory
Hours of activity per day	RA via activity tracker	Daily	Secondary
Hours of activity per night	RA via activity tracker	Daily	Exploratory
Hours of sitting upright per day	RA via activity tracker	Daily	Secondary
Hours of sitting upright per night	RA via activity tracker	Daily	Exploratory
Daily steps	RA via activity tracker	Daily	Secondary
Pneumonia			
Pneumococcal vaccination if appropriate	RA via EHR	Discharge	Exploratory

Influenza vaccination if appropriate	RA via EHR	Discharge	Exploratory
Smoking cessation counseling if appropriate	RA via EHR	Discharge	Exploratory
Heart Failure			
Evaluation of ejection fraction scheduled or completed if not done within 1 year	RA via EHR	Discharge	Exploratory
ACEI/ARB for HFrEF (EF < 40%)	RA via EHR, pt (post discharge)	Discharge, +30	Exploratory
Beta blocker for HFrEF (EF < 40%)	As above.	Discharge, +30	Exploratory
Aldosterone antagonist for HFrEF (EF < 40%)	As above.	Discharge, +30	Exploratory
Lipid lowering for CAD, PVD, CVA, or diabetes	As above.	Discharge, +30	Exploratory
Smoking cessation counseling if appropriate	As above.	Discharge	Exploratory
Smoking status post-discharge	RA via pt	+30	Exploratory

Quality: Low-Value Care

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Use of inappropriate medications in the elderly	RA via EHR/MAR	Daily	Exploratory
Use of foley catheter	RA via MD/RN for home patients; EHR review for inpatients	Daily	Exploratory
Use of restraints	RA via MD/RN for home patients; EHR review for inpatients	Daily	Exploratory
>3 medications added to medication list	RA via EHR/MAR	Discharge	Exploratory

Patient Functional Status and Quality of Life

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
EuroQol -5D-5L	RA via patient	Admission, discharge, +30	Secondary
SF-1	RA via patient	-30, admission, discharge, +30	Secondary
Activities of daily living	RA via patient	-30, admission, discharge, +30	Secondary
Instrumental activities of daily living	RA via patient	-30, admission, discharge, +30	Secondary
Patient Health Questionnaire-2	RA via patient	Admission, discharge, +30	Exploratory
PROMIS Emotional Support Short Form 4a	RA via patient	Admission, discharge, +30	Exploratory
Days at home since discharge	RA via	+30	Exploratory

	patient		
Milestones			
Walk around ward/home	RA via RN	Discharge	Exploratory
Get to (non-commode) bathroom	RA via RN	Discharge	Exploratory
Walk 1 flight of stairs	RA via RN	Discharge	Exploratory
Visit with friends/family	RA via patient	Discharge	Exploratory
Walk outside around my home	RA via patient	+30	Exploratory
Go shopping	RA via patient	+30	Exploratory

Patient and Family Experience

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
3-item Care Transition Measure	RA via patient	+30	Secondary
Picker Experience Questionnaire	RA via patient	+30	Secondary
Global satisfaction	RA via patient	+30	Exploratory
Qualitative interviews	See Below	+30	Exploratory

Process Measures

Measure	Source	Day(s) Obtained	Secondary vs Exploratory
Time from admission decision to assessment by RA	RA	Admission	Exploratory
Time from RA assessment to dismissal	RA	Admission	Exploratory
Time from arrival home or to floor and MD evaluation	RA via MD	Admission	Exploratory
Time from arrival home or to floor and RN evaluation	RA via RN	Admission	Exploratory
RN to patient ratio	RA via census	Daily	Exploratory
Number of RN visits	RA via RN/EHR	Daily	Exploratory
Number of “on call” MD interactions (video or phone)	RA via MD	Daily	Exploratory
Number of “on call” MD in-person visits	RA via MD	Daily	Exploratory
Duration of 1st RN visit	RA via RN	Daily	Exploratory
Duration of subsequent RN visit	RA via RN	Daily	Exploratory
Clinician Burnout	All clinicians	Pre/post study	Exploratory

Covariates of Interest

Measure	Source	Day(s) Obtained
Age	RA via EHR[a]	Admission
Gender	RA via EHR	Admission
Race/ethnicity	RA via patient	Admission
Primary language	RA via EHR	Admission
Health insurance status, public/private/none	RA via EHR	Admission

BMI	RA via EHR	Admission
Comorbidities, type and #	RA via EHR and H&P	Admission
Partner status	RA via patient	Admission
Education	RA via patient	Admission
Zip code	RA via EHR	Admission
Employment	RA via H&P	Admission
Smoking status	RA via H&P	Admission
Medications used as outpatient, #	RA via EHR	Admission
DNR/I code status	RA via H&P	Admission
Home health aide prior to admission	RA via patient	Admission
Readmission risk score on discharge (HOSPITAL)	RA via EHR	Discharge
Elective and urgent admissions in the previous year, #	RA via EHR and patient	Admission
ED visits in the previous 6 months, #	RA via EHR and patient	Admission
Interqual disease-specific leveling	MD	Admission
PRISMA-7	RA via patient	Admission
Eight-item Interview to Differentiate Aging and Dementia	RA via patient or proxy	Admission
Would you be surprised if this patient died in the next year?	RA via MD	Admission
BRIEF health literacy screening tool	RA via patient	Admission
Caregiver burden	RA via caregiver	Admission, +30

[a]: Note that RA will recheck covariates after MD H&P completed to ensure comorbidities and other covariates correctly captured

Standard Operating Procedure for Problematic Situations

Clinically Emergent Patient Condition

Should a matter be emergent (that is, requiring in-person assistance in less than 15 minutes), then 9-1-1 will be called and the patient will be returned to the hospital immediately. An example of an emergent patient condition is severe new-onset shortness of breath.

Clinically Urgent Patient Condition

Should a matter be urgent (that is, a condition that does not require assistance in under 15 minutes), the patient and/or nurse and/or physician may choose to communicate via phone or video (either of the 3 persons can initiate either medium). If this is unsuccessful, the nurse and/or physician will visit the patient in their home. If there is no way to rectify the situation, then the patient will be transported to the hospital. An example of an urgent situation is new-onset non-severe pain.

Unsafe Home Situation

Should an unsafe home situation be discovered during a home hospital admission, the home hospital team will assess if said situation poses a harm or threat to either the participant or the home hospital personnel. If it does, and after an attempt to rectify said situation, the situation persists, then the home hospital team will end the study and return the patient to the hospital. An example of an unsafe home situations includes lack of basic sanitation.

Intoxication

Should intoxication occur in the home of a participant, the home hospital team will assess if said intoxication poses a harm or threat to either the participant or the home hospital personnel. If it does, and after an attempt to rectify said intoxication, the situation persists, then the home hospital team will end the study and return the patient to the hospital.

Neglect or child abuse

Should neglect or child abuse be observed, the home hospital team will act as mandatory reporters. The home hospital team, in coordination with the hotline team, will assess if said neglect or child abuse poses an immediate harm or threat to either the participant, children in the home, or the home hospital personnel. If it does, then the home hospital team will end the study and return the patient to the hospital.

BIOSTATISTICAL ANALYSIS

Specific data variables being collected

Please see above.

Study endpoints

As described above, the study's primary endpoint is total hospitalization cost. We aim for 20% cost reduction. Several secondary endpoints are listed above.

Statistical methods

Quantitative

The primary outcome (hospitalization cost) will be assessed using log-transformed multivariable linear regression adjusted for medical condition, age, comorbidity score, and several other covariates (see above list for details). We will use this same multivariable regression approach for secondary outcomes, using logistic regression for binary outcomes (e.g., ED visits, readmissions, delirium, falls) and non-transformed linear regression for normally distributed continuous outcomes (e.g., measures of quality of life and patient experience) as appropriate.

We *a priori* plan to perform a subgroup analysis that does not involve any outlier participants in either study arm, should this occur. We also *a priori* plan subgroup analyses by diagnosis, by age group, by disposition, and by daily activity level. We also *a priori* plan to analyze our outcomes with means, but

also with median and interquartile ranges, which are less subject to outlier effects. We may choose to employ non-parametric tests of significance should our data be nonparametric.

Qualitative

During and after the intervention period, we will interview a sample of patients and caregivers 7-30 days after discharge (irrespective of their experimental arm) regarding their opinions of their hospitalization. We will use this data to both iteratively improve home hospital and make detailed qualitative comparisons between home hospital and usual care.

In all cases, we will use semi-structured interview guides to ask questions regarding the hospitalization experience. Interviews will be recorded, transcribed, and then analyzed using NVivo qualitative analysis software. Drs. Schnipper and Levine will perform dual coding of all themes, and all differences will be discussed and reconciled. We will use an a priori analytic framework based on the Systems Engineering Initiative for Patient Safety Model (SEIPS), which describes processes and outcomes as products of the interactions among patients, technology and tools, the health care organization, the tasks at hand, and the physical environment.[15]

Power analysis

Our preliminary pilot data suggests that median direct cost of the acute care episode for home patients was 52% lower than for control patients. At 90% power, we would require 19 patients in each arm.

Secondary outcomes require larger samples sizes at 80% power. At 60 patients in each arm, we will be powered to detect significant differences in activity, steps, worsening in iADLs, laboratory use, Picker, and consultant use.

RISKS AND DISCOMFORTS

Uncommon: Complications of surgical and non-surgical procedures

Standard hospital procedures carry small risks and discomforts. For example, venipuncture can be painful and can lead to thrombophlebitis, but this is uncommon and readily rectifiable.

Uncommon: Device complications/malfunctions

IV pumps, vital signs monitoring patches, and the other devices used during home hospital uncommonly have malfunctions.

Uncommon: Radiation risks

Patients can receive radiography while admitted to home hospital, much the same as when they are admitted in the hospital. We do not anticipate that home hospital will in any way change the prevailing risk of radiation.

Common (but unchanged from usual care): Drug side effects and toxicities

Drug side effects and toxicities do occur during inpatient medicine, despite following best practices and evidence based medicine. We do not anticipate that home hospital will in any way change the prevailing

rate of drug side effects and toxicities compared to usual care. For example, acute kidney injury can occur in patients receiving antibiotics, even when correct dosing occurs. Home hospital is equipped to monitor and respond to the common drug side effects and toxicities much the same as the standard of care (monitoring, diagnostics, fluids, etc).

Common (but improved from usual care): Psychosocial risks

Admission to the hospital can be a psychosocially difficult event, particularly for a senior. We believe home hospital will alleviate these typical risks. Home hospital is equipped to assist patients with psychosocial stressors through improved staffing ratios and a social worker.

POTENTIAL BENEFITS

Potential benefits to participating individuals

- Remain in their home despite acute illness
    - Eat their own culturally concordant food
    - Sleep in familiar surroundings
    - Maximize time and interactions with their family and friends
- Improved health outcomes (we anticipate these from previous literature)
    - Reduced length of stay
    - Reduced complications while admitted
        - Less delirium
        - Fewer falls
        - Fewer health care associated infections
        - Decreases reduction in functional status
    - Improved patient experience
- Clinical improvements to the standard of care
    - Point of care blood diagnostics (results at the bedside in <5 minutes);
    - Minimally invasive continuous vital signs, telemetry, and activity tracking, including clinical deterioration algorithms, steps taken, and sleep quality;
    - On-demand 24/7 clinician virtual video visits;
    - 4 to 1 patient to MD ratio, compared to typical 16 to 1;
    - Ambulatory/portable infusion pumps that can be worn on the hip;
    - Optional access to a personal home health aide, community health worker, and community paramedic
- Improved transitions of care
    - Ability to coach patients on their post-discharge care plan in the appropriate environment, with caregivers available, and with adequate time for teaching given provider to patient ratio

Potential benefits to society

- New evidence-based care paradigm for acute care hospitalization.
- Lower total medical expenditure. Allows for redirection of resources to areas in need.
- Might eventually lead to reduction in total hospitals in the U.S.

- Provide needed randomized controlled data on the home hospital intervention to inform payment methods moving forward.

MONITORING AND QUALITY ASSURANCE

Independent monitoring of source data

The study's research assistant will collect all data denoted above. The PI and co-PI will monitor the source data throughout the project.

Safety monitoring

If any of the following concerning safety events occur, a blinded monitoring committee will review the event to determine attribution to the intervention: fall, medication error, DVT/PE, mortality during admission, transfer back to hospital (committee cannot be blinded for this endpoint). If any of these events are felt to be due to the home hospital intervention, they will be reported to the IRB with recommendations for appropriate actions to be taken. Decisions to modify the protocol or suspend the study will be made jointly by the study investigators, monitoring committee, and the IRB.

Outcomes monitoring

The physician and RNs will daily review quality and safety data as part of a rapid logistics improvement process.

Weekly, all physicians and RNs will huddle to review quality and safety data as part of a rapid logistics improvement process.

At 3 weeks into the home hospital clinical service, a blinded monitoring committee will review outcomes data and make recommendations to the study team.

Adverse event reporting guidelines

All adverse events denoted above under safety monitoring will be reported to the monitoring committee.

APPENDIX

Risk Scores

CURB 65 – 30-day mortality prediction

- Cohort: 1068pts of CAP in the UK, New Zealand, and the Netherlands in 1998-1999
- 30-day mortality by points
    - score 0, 0.7%
    - score 1, 3.2%
    - score 2, 3%
    - score 3, 17%
    - score 4, 41.5%
    - score 5, 57%

No of	Sensitivity	Specificity	PPV (%)	NPV (%)

features	(%)	(%)		
>0	100	0	9.6	NA
>1	98.6	21.0	11.7	99.3
>2	92.8	49.2	16.2	98.5
>3	68.1	74.9	22.4	95.7
>4	39.1	93.1	37.5	93.5
>5	1.4	99.1	14.3	90.4

SMRTCO – chance of intensive respiratory or vasopressor support (IRVS)

- Cohort: 5 databases (7464 patients), 1991-2001
- IRVS by points
    - Score 0, ~0%
    - Score 1, 5%
    - Score 2, 10%
    - Score 3, 17%
    - Score >=4, 33%

Study Staff

- Jeffrey Schnipper, MD MPH, has conducted research since 2002 aimed at improving health information technology, predicting hospital readmission, improving medication safety during transitions in care, and improving discharge. He has over 100 peer-reviewed publications, including a dual-site randomized controlled trial of an electronic medication reconciliation tool and process redesign on patient safety, generally regarded as the most rigorous study to date of electronic medication reconciliation tools. More recently, his group completed a two-site randomized controlled trial of pharmacist counseling and follow-up on cardiac patients with low health literacy (the PILL-CVD study). He was the principal investigator of the Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS), an AHRQ-funded study at five US hospitals to design and implement an evidence-based toolkit to improve medication reconciliation and is now the PI of an AHRQ-funded study to continue that work at 18 additional hospitals. Dr. Schnipper's recent PCORI-funded readmission avoidance project involved community health workers. He also has expertise in decision support, electronic dashboards, and the novel use of patient portals.
- David Levine, MD MA, is a clinical attending physician and research fellow in the division of general internal medicine and primary care at Brigham and Women's Hospital. He has expertise in design, implementation, and evaluation of innovative and disruptive medical programs with experience in house calls, digital health, and community health worker programs. Currently leading projects on national quality measurement, disparities in quality, virtual visits, seniors' use of digital health, and house calls. As coinvestigator of this project, his role is in design, implementation, and evaluation.
- 3 research assistants – TBD

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Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Hospitalization at Home: The Acute Care Home Hospital Program for Adults

Principal Investigator: Jeffrey Schnipper, MD MPH

Site Principal Investigator: Jeffrey Schnipper, MD MPH

Description of Subject Population: Selected suddenly ill patient presenting to the emergency department

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

INSTRUCTIONS: Include the following paragraph **only** if some or all of the adult subjects are incapable of providing consent and permission for their participation will be obtained from their authorized representative. Delete the following paragraph when all subjects are adults capable of providing consent.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital (within 5 miles or 20 minute drive) and have a diagnosis that the research doctors consider safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.) or HealthPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

About 1200 patients will take part in this study at Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital.

This study is funded by Brigham and Women's Hospital and Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are partially subsidizing the costs of these products.

How long will I take part in this research study?

Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission.

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

What will happen in this research study?

This is a randomized study, which means we will assign you by chance (like a coin toss) to the Home Hospitalization group or the Standard Admission group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the Home Hospitalization group You will have a 1 in 2 chance of being assigned to the Standard Admission group.

- **Standard admission:** your care will be just like normal at Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital. Our research team will ask that you wear an activity tracker and will ask you questions about your hospital stay.
    - About 16 subject patients to every 1 MD

- **Home hospital:** your care will be in your home with a set of services tailored to your medical needs:
    - In-home visit by a Brigham and Women's or Brigham and Women's Faulkner physician at least once a day
        - Available 24 hours every day by video, phone, or in-person
    - In-home Partners nurse at least twice a day
    - Remote wireless vital signs (such as heart rate), telemetry (your heart's rhythm), activity, and sleep monitoring
    - In-home intravenous infusions (for IV fluids or medications) as needed
    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and social worker as medically needed
    - About 4 subject patients to every 1 MD

Whether or not you are assigned to receive care at Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to

learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

What are the risks and possible discomforts from being in this research study?

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected

child/elder/disabled abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
    - Eat your own food
    - Sleep in your own bed
    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example
    - Less risk for developing delirium (confusion)
    - Fewer falls
    - Fewer health care associated infections
    - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
    - Lab test results at the bedside in less than 5 minutes
    - Continuous (around the clock**)** vital signs, telemetry (heart rhythm patterns), and physical activity tracking
    - Video visits with physician
    - IV medication pumps that can be worn on the hip

If you are assigned to the control group, some of the possible benefits include:

- Standard care in a hospital, which is known to be an effective treatment for your condition
- Proximity to care
    - Around-the-clock nursing care
    - Quick ability to transfer to intensive care or receive emergency care, should you become sicker

We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-

payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject

- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)

- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: None

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____	_____	_____
Signature	Date	Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent Form Version: 4

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Hospitalization at Home: The Acute Care Home Hospital Program for Adults

Principal Investigator: Jeffrey Schnipper, MD MPH

Site Principal Investigator: Jeffrey Schnipper, MD MPH

Description of Subject Population: Selected suddenly ill patient presenting to the emergency department

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

INSTRUCTIONS: Include the following paragraph **only** if some or all of the adult subjects are incapable of providing consent and permission for their participation will be obtained from their authorized representative. Delete the following paragraph when all subjects are adults capable of providing consent.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the study.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital (within 5 miles or 20 minute drive) and have a diagnosis that the research doctors consider safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.) or HealthPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

About 1200 patients will take part in this study at Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital.

This study is funded by Brigham and Women's Hospital and Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are partially subsidizing the costs of these products.~~have no sponsorship of this study.~~

How long will I take part in this research study?

Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission. ~~Each day, our home hospital team will make several visits to your home.~~

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

What will happen in this research study?

This is a randomized study, which means we will assign you by chance (like a coin toss) to the Home Hospitalization group or the Standard Admission group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the Home Hospitalization group You will have a 1 in 2 chance of being assigned to the Standard Admission group.

- **Standard admission:** your care will be just like normal at Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital. Our research team will ask that you wear an activity tracker and will ask you questions about your hospital stay.
    - About 16 subject patients to every 1 MD

- **Home hospital:** your care will be in your home with a set of services tailored to your medical needs:
    - In-home visit by a Brigham and Women's or Brigham and Women's Faulkner physician at least once a day
        - Available 24 hours every day by video, phone, or in-person
    - In-home Partners nurse at least twice a day
    - Remote wireless vital signs (such as heart rate), telemetry (your heart's rhythm), activity, and sleep monitoring
    - In-home intravenous infusions (for IV fluids or medications) as needed
    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and social worker as medically needed
    - About 4 subject patients to every 1 MD

Whether or not you are assigned to receive care at Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to

learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital or Brigham and Women's Faulkner Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

What are the risks and possible discomforts from being in this research study?

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected

child/elder/disabled abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
  - Eat your own food
  - Sleep in your own bed
  - Rest on your own schedule
  - Spend more time with your family and friends
  - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example
  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes
  - Continuous (around the clock**)** vital signs, telemetry (heart rhythm patterns), and physical activity tracking
  - Video visits with physician
  - IV medication pumps that can be worn on the hip

If you are assigned to the control group, some of the possible benefits include:

- Standard care in a hospital, which is known to be an effective treatment for your condition
- Proximity to care
  - Around-the-clock nursing care
  - Quick ability to transfer to intensive care or receive emergency care, should you become sicker

We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-

payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject

- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)

- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other: None

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Guardian or Authorized Representative for Adult:

I give my consent for the person I am authorized to represent to take part in this research study and agree to allow his/her health information to be used and shared as described above.

_____

Print Name (check applicable box below)

- ☐ Court-appointed Guardian
- ☐ Health Care Proxy
- ☐ Durable Power of Attorney
- ☐ Family Member/Next-of-Kin

_____	_____	_____
Signature	Date	Time (optional)

Relationship to Subject:_____

Assent

Statement of Person Giving Assent

- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions, and my questions have been answered.

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Consent Form Version: 4

Hospitalization at Home:

The Acute Care Home Hospital Program for Adults

Screening instruments

Hurt, Insulted, Threatened with Harm and Screamed (HITS): Domestic violence screening tool

How often does your partner...	1 = Never	2 = Rarely	3 = Sometimes	4 = Fairly Often	5 = Frequently
...physically hurt you?					
...insult or talk down to you?					
...threaten you with harm?					
...scream or curse at you?					

Total score (range 4-20): ____
For females, >=10 suggests domestic violence. For males, >=11 suggests domestic violence.

Source: Sherin KM, Sinacore JM, Li XQ, Zitter RE, Shakil A. (1998). HITS: A short domestic violence screening tool for use in a family practice setting. Family Medicine, 30, 508-12.

Confusion Assessment Method (CAM)

Feature 1: Acute Onset and Fluctuating Course
This feature is usually obtained from a family member or nurse and is shown by positive responses to the following questions: Is there evidence of an acute change in mental status from the patient's baseline? Did the (abnormal) behavior fluctuate during the day, that is, tend to come and go, or increase and decrease in severity?

Feature 2: Inattention
This feature is shown by a positive response to the following question: Did the patient have difficulty focusing attention, for example, being easily distractible, or having difficulty keeping track of what was being said?

Feature 3: Disorganized thinking
This feature is shown by a positive response to the following question: Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?

Feature 4: Altered Level of consciousness
This feature is shown by any answer other than "alert" to the following question: Overall, how would you rate this patient's level of consciousness? (alert [normal]), vigilant [hyperalert], lethargic [drowsy, easily aroused], stupor [difficult to arouse], or coma [unarousable]).

Delirium present if features 1 and 2 and either 3 or 4 present.

Source: Inouye, S., van Dyck, C., Alessi, C., Balkin, S., Siegal, A. & Horwitz, R. (1990). Clarifying confusion: The confusion assessment method. Annals of Internal Medicine, 113(12), 941-948.

Quick Sepsis Related Organ Failure Assessment (QSOFA)

	0 = No	1 = Yes
Systolic blood pressure <= 100mgHg		
Respiratory rate >= 22		
Glasgow come scale < 15 (any altered mental status)		

Total score (range 0-3): ____
Sepsis suggested for score > 1

Source: Seymour CW, Liu VX, Iwashyna TJ, et al. Assessment of Clinical Criteria for Sepsis: For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):762-74.

Pneumonia: CURB65

	0 = No	1 = Yes
Confusion		
BUN > 19mg/dL		
Respiratory rate>=30		
Systolic blood pressure < 90		
Age>=65		

Total score (range 0-5): ____
Score > 3 suggests ICU requirement

Source: Chalmers JD, Singanayagam A, Hill AT. Systolic blood pressure is superior to other haemodynamic predictors of outcome in community acquired pneumonia. *Thorax*. 2008;63(8):698-702.

Pneumonia: SMRTCO

	0 = No	1/2 = Yes
Systolic blood pressure < 90mmHg (2pts)		
Multilobar CXR involvement		
Respiratory rate>=30		
Heart rate >= 125		
New confusion		
Oxygen saturation <= 90%		

Total score (range 0-7): ____
Score > 2 suggests likelihood of intensive respiratory or vasopressor support too high for home hospital

Source: Charles PGP, Wolfe R, Whitby M, et al. SMART-COP: a tool for predicting the need for intensive respiratory or vasopressor support in community-acquired pneumonia. *Clin Infect Dis*. 2008;47(3):375-384.

Systolic BP	Points	BUN	Points	Sodium	Points	Age	Points
50-59	28	≤9	0	≤130	4	≤19	0
60-69	26	10-19	2	131	3	20-29	3
70-79	24	20-29	4	132	3	30-39	6
80-89	23	30-39	6	133	3	40-49	8
90-99	21	40-49	8	134	2	50-59	11
100-109	19	50-59	9	135	2	60-69	14
110-119	17	60-69	11	136	2	70-79	17
120-129	15	70-79	13	137	1	80-89	19
130-139	13	80-89	15	138	1	90-99	22
140-149	11	90-99	17	≥139	0	100-109	25
150-159	9	100-109	19			≥110	28
160-169	8	110-119	21				
170-179	6	120-129	23				
180-189	4	130-139	25				
190-199	2	140-149	27				
≥200	0	≥150	28				

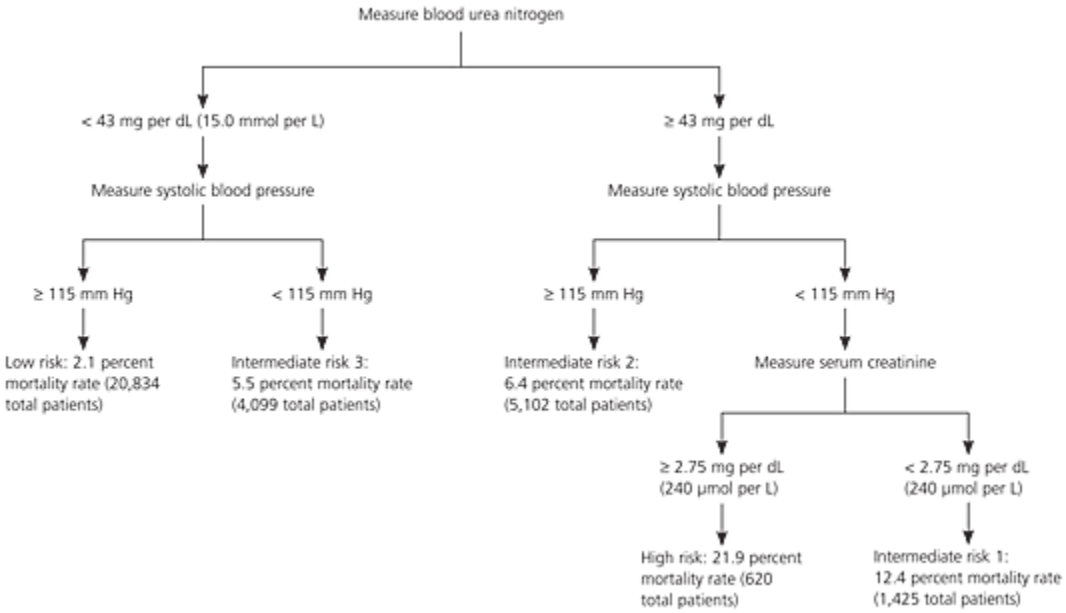
Heart Rate	Points	Black Race	Points	COPD	Points
≤79	0	Yes	0	Yes	2
80-84	1	No	3	No	0
85-89	3				
90-94	4				
95-99	5				
100-104	6				
≥105	8				

Total Score	Probability of Death
0-33	**<1%**
34-50	**1-5%**
51-57	**>5-10%**
58-61	**>10-15%**
62-65	**>15-20%**
66-70	**>20-30%**
71-74	**>30-40%**
75-78	**>40-50%**
≥79	**>50%**

Score > 57 suggests acuity level too high for home hospital (>10% in-hospital mortality).

Source: Peterson PN, Rumsfeld JS, Liang L, et al. A validated risk score for in-hospital mortality in patients with heart failure from the American Heart Association get with the guidelines program. *Circ Cardiovasc Qual Outcomes*. 2010;3(1):25-32.

Acute Decompensated Heart Failure National Registry (ADHERE)



Score of "high-risk" (>~20% in-hospital mortality) and intermediate risk 1 (~12% in-hospital mortality) suggests acuity level too high for home hospital.

Source: Fonarow GC, Adams KF, Abraham WT, Yancy CW, Boscardin WJ. Risk stratification for in-hospital mortality in acutely decompensated heart failure: classification and regression tree analysis. *JAMA*. 2005;293(5):572-580.

PRISMA-7

	0 = No	1 = Yes
1. Are you more than 85 years?		
2. Male?		
3. In general do you have any health problems that require you to limit your activities?		
4. Do you need someone to help you on a regular basis?		
5. In general do you have any health problems that require you to stay at home?		
6. In case of need can you count on someone close to you?		
7. Do you regularly use a stick, walker or wheelchair to get about?		

Score >= 3 suggests frailty and need for further assessment.

Source: Raîche M, Hébert R, Dubois MF. PRISMA-7: a case-finding tool to identify older adults with moderate to severe disabilities. Arch Gerontol Geriatr. 2008;47(1):9-18.

Eight-item Interview to Differentiate Aging and Dementia

Remember, "Yes, a change" indicates that there has been a change in the last several years caused by cognitive (thinking and memory) problems.

	YES, a change	NO, no change	N/A, Don't know
1. Problems with judgment (e.g., problems making decisions, bad financial decisions, problems with thinking)			
2. Less interest in hobbies/activities			
3. Repeats the same things over and over (questions, stories, or statements)			
4. Trouble learning how to use a tool, appliance, or gadget (e.g., VCR, computer, microwave, remote control)			
5. Forgets correct month or year			
6. Trouble handling complicated financial affairs (e.g., balancing checkbook, income taxes, paying bills)			
7. Trouble remembering appointments			
8. Daily problems with thinking and/or memory			

Score: ___ (sum of YES's)

Score >=2 indicates cognitive impairment is likely present

Source: Galvin JE, Roe CM, Powlishta KK et al. The AD8: a brief informant interview to detect dementia. Neurology. 2005. 65(4):559-564.

BRIEF Health Literacy Screener

Please choose the answer that best represents your response:

1. How often do you have someone help you read hospital materials?	1=Always	2=Often	3=Sometimes	4=Occasionally	5=Never
2. How often do you have problems learning about your medical condition because of difficulty understanding written information?	1=Always	2=Often	3=Sometimes	4=Occasionally	5=Never
3. How often do you have a problem understanding what is told to you about your medical condition?	1=Always	2=Often	3=Sometimes	4=Occasionally	5=Never
4. How confident are you filling out medical forms by yourself?	1=Not at all	2=A little bit	3=Somewhat	4=Quite a bit	5=Extremely

Score: ___ (sum of responses)

Literacy	Score	Skills and Abilities
Limited	**4-12**	Not able to read most low literacy health materials; will need repeated oral instructions; materials should be composed of illustrations or video tapes. Will need low literacy materials; may not be able to read a prescription label.
Marginal	**13-16**	May need assistance; may struggle with patient education materials.
Adequate	**17-20**	Will be able to read and comprehend most patient education materials.

Source: Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36(8):588-94.

Endpoint instruments

EuroQol – 5D – 5L 1.5min

Under each heading, please check the ONE box that best describes your health TODAY.

MOBILITY

I have no problems walking ❑
I have slight problems walking ❑
I have moderate problems walking ❑
I have severe problems walking ❑
I am unable to walk ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

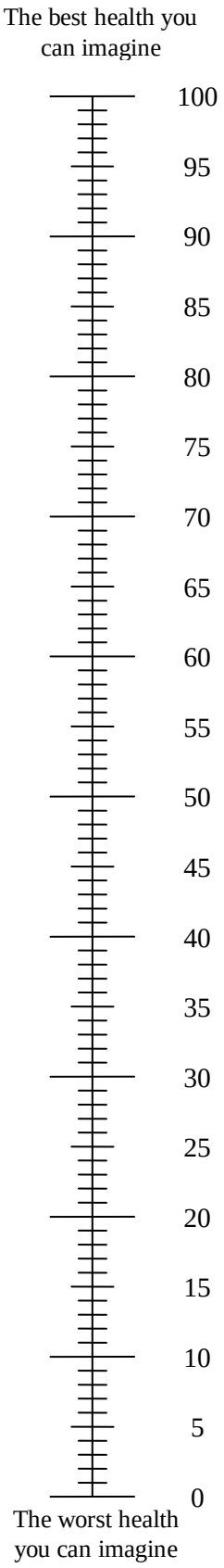
I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑

Levine and Schnipper

I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Activities of daily living

Activity	1 = Independence *No supervision, direction, or personal assistance*	0 = Dependence *With supervision, direction, personal assistance or total care*
Bathing	Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
Dressing	Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	Needs help with dressing self or needs to be completely dressed.
Toileting	Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
Transferring	Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable.	Needs help in moving from bed to chair or requires a complete transfer.
Continence	Exercises complete self-control over urination and defecation.	Is partially or totally incontinent of bowel or bladder.
Feeding	Gets food from plate into mouth without help. Preparation of food may be done by another person.	Needs partial or total help with feeding or requires parenteral feeding.

Score: ____ (6 = High [patient independent]; 0 = Low [patient very dependent])

Source: Katz, S., Down, T.D., Cash, H.R., & Grotz, R.C. (1970) Progress in the development of the index of ADL. The Gerontologist, 10(1), 20-30.

Instrumental Activities of daily living

Activity	1 = Independent	0 = Dependent
Use telephone	Operates telephone on own initiative; looks up and dials numbers Dials a few well-known numbers Answers telephone, but does not dial	Does not use telephone at all
Shopping	Takes care of all shopping needs independently	Shops independently for small purchases Needs to be accompanied on any shopping trip Completely unable to shop
Food Preparation	Plans, prepares, and serves adequate meals independently	Prepares adequate meals if supplied with ingredients Heats and serves prepared meals or prepares meals but does not maintain adequate diet Needs to have meals prepared and served
Housekeeping	Maintains house alone with occasional assistance (heavy work) Performs light daily tasks such as dishwashing, bed making Performs light daily tasks, but cannot maintain acceptable level of cleanliness Needs help with all home maintenance tasks	Does not participate in any housekeeping tasks
Laundry	Does personal laundry completely Launders small items, rinses socks, stockings, etc	All laundry must be done by others
Transportation	Travels independently on public transportation or drives own car Arranges own travel via taxi, but does not otherwise use public transportation Travels on public transportation when assisted or accompanied by another	Travel limited to taxi or automobile with assistance of another Does not travel at all
Responsibility for Own Medications	Is responsible for taking medication in correct dosages at correct time	Takes responsibility if medication is prepared in advance in separate dosages Is not capable of dispensing own medication
Ability to Handle Finances	Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income Manages day-to-day purchases, but needs help with banking, major purchases, etc	Incapable of handling money

Score: ____ (7 = High [patient independent]; 0 = Low [patient very dependent])

Source: Lawton, M.P., & Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. The Gerontologist, 9(3), 179-186.

Patient Health Questionnaire 2

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

	Not at All	Several Days	More than Half the Days	Nearly Every Day
Little interest or pleasure in doing things.	0	1	2	3
Feeling down, depressed, or hopeless.	0	1	2	3

Score of >=3 suggests depression

Source: Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care 2003; 41:1284-92.

PROMIS Emotional Support – Short Form 4a

Please respond to each item:

	1 = Never	2 = Rarely	3 = Sometimes	4 = Usually	5 = Always
I have someone who will listen to me when I need to talk					
I have someone to confide in or talk to about myself or my problems					
I have someone who makes me feel appreciated					
I have someone to talk with when I have a bad day					

Source: PROMIS Item Bank v2.0 - Emotional Support – Short Form 4a

Milestones

If the answer to the question is “no,” do not continue with subsequent questions. Assume they are “no” as well.

For home hospital arm:

1. Have you walked to the bathroom, not including the commode?
2. Have you walked around your home, not including walking to the bathroom?
3. Have you walked one flight of stairs?

For control arm:

1. Have you walked to the bathroom, not including the commode?
2. Have you walked around the hospital ward other than to the bathroom?
3. Have you walked one flight of stairs?

3-Item Care Transition Measure

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

Strongly disagree	Disagree	Agree	Strongly agree	Don't know/Don't remember/Not applicable

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

Strongly disagree	Disagree	Agree	Strongly agree	Don't know/Don't remember/Not applicable

3. When I left the hospital, I clearly understood the purpose for taking each of my medications.

Strongly disagree	Disagree	Agree	Strongly agree	Don't know/Don't remember/Not applicable

Score: sum divided by questions answered; use linear transformation to convert to 0-100 scale

Source: Parry C, Mahoney E, Chalmers SA, Coleman EA. Assessing the quality of transitional care: further applications of the care transitions measure. Med Care. 2008;46(3):317-22.

Picker Experience Questionnaire 15 (PPE-15)

1. When you had important questions to ask a doctor, did you get answers that you could understand? Yes, always/Yes, sometimes/No/I had no need to ask
2. When you had important questions to ask a nurse, did you get answers that you could understand? Yes, always/Yes, sometimes/No/I had no need to ask
3. Sometimes in a hospital, one doctor or nurse will say one thing and another will say something quite different. Did this happen to you? Yes, often/Yes, sometimes/No
4. If you had any anxieties or fears about your condition or treatment, did a doctor discuss them with you? Yes, completely/Yes, to some extent/No/I didn't have any anxieties or fears
5. Did doctors talk in front of you as if you weren't there? Yes, often/Yes sometimes/No
6. Did you want to be more involved in decisions made about your care and treatment? Yes, definitely/Yes, to some extent/No
7. Overall, did you feel you were treated with respect and dignity while you were in hospital? Yes, always/Yes, sometimes/No
8. If you had any anxieties or fears about your condition or treatment, did a nurse discuss them with you? Yes, completely/Yes, to some extent/No/I didn't have any anxieties or fears
9. Did you find someone on the hospital staff to talk to about your concerns? Yes, definitely/Yes, to some extent/No/I had no concerns
10. Were you ever in pain? Yes/No If yes . . . Do you think the hospital staff did everything they could to help control your pain? Yes, definitely/Yes, to some extent/No
11. If your family or someone else close to you wanted to talk to a doctor, did they have enough opportunity to do so? Yes, definitely/Yes, to some extent/No/No family or friends were involved/My family didn't want or need information/I didn't want my family or friends to talk to a doctor
12. Did the doctors or nurses give your family or someone close to you all the information they needed to help you recover? Yes, definitely/Yes, to some extent/No/No family or friends were involved/My family or friends didn't want or need information
13. Did a member of staff explain the purpose of the medicines you were to take at home in a way you could understand? Yes, completely/Yes, to some extent/No/I didn't need an explanation/I had no medicines—go to question 15
14. Did a member of staff tell you about medication side effects to watch for when you went home? Yes, completely/Yes, to some extent/No/I didn't need an explanation
15. Did someone tell you about danger signals regarding your illness or treatment to watch for after you went home? Yes, completely/Yes, to some extent/No

Source Jenkinson C, Coulter A, Bruster S. The Picker Patient Experience Questionnaire: development and validation using data from in-patient surveys in five countries. Int J Qual Health Care. 2002 Oct;14(5):353-8.

Global Experience

Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?

Would you recommend this hospital to your friends and family?

- Definitely no
- Probably no
- Probably yes
- Definitely yes

Qualitative Post-Discharge Interview

Date of Interview:_____

Interview began at: _____

Interview completed at: _____

Mr./Ms._____, thank you for taking the time to talk with me and for agreeing to participate in this study.

My name is Dr. _____, a physician at Brigham and Women's Hospital and Harvard Medical School.

This study was a first step toward changing the way we take care of older adults who become acutely ill. Having recently been admitted, you are truly a (home) hospital expert. We are hoping to gain insight into your (home) hospital experience so that we can improve it moving forward.

All of your responses will be kept anonymous and confidential. Your name will not be linked to the responses when we present our findings. If it is acceptable to you, I would like to tape our conversation today. This helps me go back to recall everything you said. Is it okay if I tape our conversation?

As this interview has open-ended questions, it could take anywhere from 15 minutes to an hour, is that all right?

Do you have any questions before we begin?

1. Please share with me your experience during your (home) hospital admission.
    a. Could you discuss your experiences with the physician(s)?
    b. Could you discuss your experiences with the nurses?
    c. How comfortable were you during your admission?
        i. Consider probing on room, bed, food, sleep, activity, pain, connection with family/friends, connection with care team.
    d. How safe did you feel during your admission?
2. Could you describe what went smoothly during your (home) hospital admission?
3. Could you describe what difficulties you came across during your (home) hospital admission?
    a. How could the (home) hospital team have made that better for you?
4. What surprises were there during your (home) hospital admission? Can you talk a little about those?
5. Could you describe what improvements to (home) hospital could be made?
6. If heaven-forbid you had to be hospitalized again and you could choose home hospital or regular hospital, which would you choose? Why?
    a. What would you tell someone else who was making this decision?
7. Is there anything else you think we should know about your (home) hospital experience?

Thank you very much for your time. If you have any further comments or questions, please reach out to the study coordinators.

Clinician Burnout

- Please do ***NOT*** put your name on this form.
- Please send your completed form to <third party administrative assistant>. S/he will assure anonymity when compiling the forms.
- Our entire team will see average aggregated responses regarding sections on team and program evaluation. Only the PI and the person evaluated will see the team-member evaluation section.

Team Evaluation

I felt like my opinions were heard.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we have improved including your voice?

I knew what the goal of our team was.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we have improved our goal-orientation?

I felt like our team valued each of its participants.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we have better valued each of our participants?

Program Evaluation

The logistics of patient care worked optimally.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve logistics?

Nursing care was delivered optimally.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve nursing care?

Physician care was delivered optimally.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve physician care?

I had sufficient support to carry out my duties.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we support you better?

Patients were cared for safely.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve patient safety?

Patient experience was optimal.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve patient experience?

I prefer home hospital work to my standard job.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

Why did you reply the way you did?

Next time, home hospital should... (Think of anything you would like to add: New diagnosis? New radius? New protocol?)

*Next time, home hospital should **not**... (Think of anything you would like to change.)*

Overall, I am satisfied with home hospital:	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree
I feel a great deal of stress because of home hospital:	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree

Using your own definition of "burnout," please circle one of the answers below with respect to home hospital:

a. I enjoy my work. I have no symptoms of burnout.
b. I am under stress, and don't always have as much energy as I did, but I don't feel burned out.
c. I am definitely burning out and have one or more symptoms of burnout, e.g., emotional exhaustion.
d. The symptoms of burnout that I am experiencing won't go away. I think about work frustrations a lot.
e. I feel completely burned out. I am at the point where I may need to seek help.

My control over my workload for home hospital is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal
Sufficiency of time for documentation for home hospital is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal

Which number best describes the atmosphere for home hospital?	1 Calm	2	3 Busy, but reasonable	4	5 Hectic, chaotic
My professional values are well aligned with those of home hospital leaders:	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly Agree
The degree to which my home hospital care team works efficiently together is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal
The amount of time I spend on the electronic health record (EHR) at home for home hospital is:	1 Excessive	2 Moderately high	3 Satisfactory	4 Modest	5 Minimal/none
My proficiency with EHR use is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal

Team-Member Evaluation

- If you did not interact with a particular person sufficiently, please skip entirely.
- Be sure to evaluate yourself!

Team Member Name Here

What are this person's biggest strengths, and how should they build on these?

What are this person's areas for improvement, and how should they improve these?

Do you have any other comments?

Spanish language assessments

Hurt, Insulted, Threatened with Harm and Screamed (HITS): Domestic violence screening tool
La HIAG escala

Hay veces que las parejas no están de acuerdo, aunque se lleven muy bien. Las parejas usan muchas maneras para resolver sus diferencias. Las siguientes son preguntas sobre las cosas que le han pasado a usted en su relación con su pareja.

Use los siguientes códigos para contestar las siguientes preguntas:

¿Con qué frecuencia su compañero…	1 = Nunca	2 = Casi nunca	3 = A veces	4 = Muchas veces	5 = Frecuentemente
... la golpea físicamente?					
... la insulta o le habla de una manera que la hace sentirse mal?					
... la amenaza con causarle daño físico?					
... le grita o la maldice?					

Total score (range 4-20): ____
For females, >=10 suggests domestic violence. For males, >=11 suggests domestic violence.

Source: Chen PH, Rovi S, Vega M, Jacobs A, Johnson MS. Screening for domestic violence in a predominantly Hispanic clinical setting. Fam Pract. 2005;22(6):617-23.

Confusion Assessment Method (CAM)
Método para la evaluación de la confusión

1. Inicio agudo y curso fluctuante
    a. ¿Hay evidencia de un cambio agudo en el estado mental del paciente con respecto a su estado basal?
    b. ¿Se produjeron fluctuaciones en la conducta (anormal) durante el día, es decir, los trastornos conductuales tienden a aparecer y desaparecer o su gravedad aumenta y disminuye?
2. Inatención
    a. ¿Tuvo el paciente dificultad para enfocar la atención? Por ejemplo, ¿se distrajo fácilmente o tuvo dificultad para seguir lo que se decía?
3. Pensamiento desorganizado
    a. ¿Fue desorganizado o incoherente el pensamiento del paciente? Por ejemplo: ¿Presentó un discurso inconexo o irrelevante, un flujo de ideas poco claro o ilógico, o cambió de manera imprevista de un tema a otro?
4. Nivel de conciencia alterado
    a. En general, ¿cómo calificaría el nivel de conciencia del paciente? Alerta (normal), hiperalerta (hiperreactivo), letárgico (somnoliento, despierta fácilmente), estuporoso (difícil de despertar), o dudoso.

Delirium present if features 1 and 2 and either 3 or 4 present.

Source: MAPI Institute and Inouye, S., van Dyck, C., Alessi, C., Balkin, S., Siegal, A. & Horwitz, R. (1990). Clarifying confusion: The confusion assessment method. Annals of Internal Medicine, 113(12), 941-948.

PRISMA-7

	0 = No	1 = Sí
1. ¿Tiene usted más de 85 años?		
2. ¿Caballero?		
3. En general, ¿tiene algún problema de salud que requieren que limite sus actividades?		
4. ¿Necesita alguien que le ayude en una base regular?		
5. En general, ¿tiene algún problema de salud que le obliguen a quedarse en casa?		
6. En caso de necesidad, ¿se puede contar con alguien cercano a usted?		
7. ¿Utiliza regularmente un bastón, andador, o una silla de ruedas para moverse?		

Score >= 3 suggests frailty and need for further assessment.

Source: Raîche M, Hébert R, Dubois MF. PRISMA-7: a case-finding tool to identify older adults with moderate to severe disabilities. Arch Gerontol Geriatr. 2008;47(1):9-18.

Eight-item Interview to Differentiate Aging and Dementia
Cuestionario AD8

Recuerde: «Sí, ha cambiado» significa que usted piensa que ha habido un cambio en los siguientes aspectos en los últimos años, causado por problemas cognitivos (razonamiento y memoria)

	Sí, ha cambiado	No, no ha cambiado	No sabe / No contesta
Problemas para emitir juicios y tomar decisiones adecuadas (p. ej., le engañan o timan, toma decisiones financieras erróneas, hace regalos inapropiados, etc.)			
Pérdida de interés en sus aficiones y actividades (p. ej., ha dejado de hacer actividades que le gustaban)			
Repite las preguntas, los comentarios o las cosas que cuenta			
Dificultad para aprender a usar herramientas, aparatos o dispositivos (p. ej., vídeo o DVD, ordenador, microondas, mandos a distancia, teléfono móvil o inalámbrico)			
Olvida el mes o año correcto			
Dificultad para manejar asuntos financieros complicados (p. ej., ajustar cuentas, talones, impuestos, facturas, recibos, etc.)			
Dificultad para recordar las citas y cosas que tiene que hacer			
Los problemas de razonamiento y/o memoria son cotidianos y no ocasionales			

Score: ___ (sum of YES's)

Score >=2 indicates cognitive impairment is likely present

EuroQol – 5D – 5L

Debajo de cada encabezamiento, marque UNA casilla, la que mejor describe su salud HOY.

MOVILIDAD

- No tengo problemas para caminar ❑
- Tengo problemas leves para caminar ❑
- Tengo problemas moderados para caminar ❑
- Tengo problemas graves para caminar ❑
- No puedo caminar ❑

CUIDADO PERSONAL

- No tengo problemas para lavarme o vestirme solo/a ❑
- Tengo problemas leves para lavarme o vestirme solo/a ❑
- Tengo problemas moderados para lavarme o vestirme solo/a ❑
- Tengo problemas graves para lavarme o vestirme solo/a ❑
- No puedo lavarme o vestirme solo/a ❑

ACTIVIDADES DE TODOS LOS DÍAS *(Ej.: trabajar, estudiar, hacer las tareas domésticas, actividades familiares o actividades de ocio)*

- No tengo problemas para realizar mis actividades de todos los días ❑
- Tengo problemas leves para realizar mis actividades de todos los días ❑
- Tengo problemas moderados para realizar mis actividades de todos los días ❑
- Tengo problemas graves para realizar mis actividades de todos los días ❑
- No puedo realizar mis actividades de todos los días ❑

DOLOR / MALESTAR

- No tengo dolor ni malestar ❑
- Tengo dolor o malestar leve ❑
- Tengo dolor o malestar moderado ❑
- Tengo dolor o malestar intenso ❑
- Tengo dolor o malestar extremo ❑

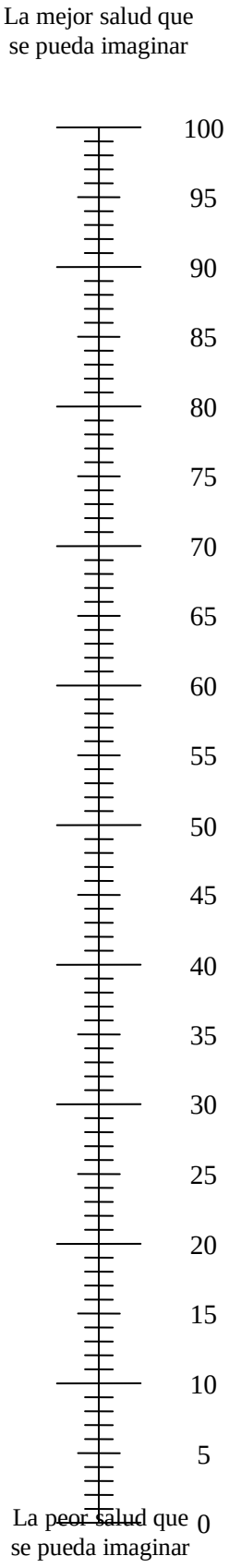
ANSIEDAD / DEPRESIÓN

- No estoy ansioso/a ni deprimido/a ❑
- Estoy levemente ansioso/a o deprimido/a ❑
- Estoy moderadamente ansioso/a o deprimido/a ❑
- Estoy muy ansioso/a o deprimido/a ❑
- Estoy extremadamente ansioso/a o deprimido/a ❑

- Nos gustaría saber lo buena o mala que es su salud HOY.
- La escala está numerada de 0 a 100.
- 100 representa la mejor salud que se pueda imaginar.
  0 representa la peor salud que se pueda imaginar.
- Por favor haga una X en la escala para indicar cuál es su estado de salud HOY.

SU SALUD HOY = ☐

- Ahora, por favor escriba en la casilla que encontrará a continuación el número que ha marcado en la escala.



Activities of daily living
Índice de actividades de la vida diaria

Actividad	1 = Independence *No supervision, direction, or personal assistance*	0 = Dependence *With supervision, direction, personal assistance or total care*
Lavado	No recibe ayuda (entra y sale solo de la bañera si esta es la forma habitual de bañarse) o recibe ayuda en la limpieza de una sola parte de su cuerpo (espalda o piernas por ejemplo)	Recibe ayuda en el aseo de más de una parte de su cuerpo para entrar o salir de la bañera
Vestido	Toma la ropa y se viste completamente sin ayuda. Se viste sin ayuda excepto para atarse los zapatos.	Recibe ayuda para coger la ropa y ponérsela o permanece parcialmente vestido.
Uso de retrete	Va al retrete, se limpia y se ajusta la ropa sin ayuda (puede usar bastón, andador y silla de ruedas).	Recibe ayuda para ir al retrete, limpiarse, ajustarse la ropa o en el uso nocturno del orinal. No va al retrete.
Movilización	Entra y sale de la cama, se sienta y se levanta sin ayuda (puede usar bastón o andador).	Entra y sale de la cama, se sienta y se levanta con ayuda. No se levanta de la cama.
Continencia	Control completo de ambos esfínteres	Incontinencia ocasional. Necesita supervisión. Usa sonda vesical o es incontinente
Alimentación	Sin ayuda. Ayuda solo para cortar la carne o untar el pan.	Necesita ayuda para comer o es alimentado parcial o completamente usando sondas o fluidos intravenosos.

Score: ____ (6 = High [patient independent]; 0 = Low [patient very dependent])

Source: María Trigás-Ferrín M, Ferreira-González L, Meijide-Míguez H. Escalas de valoración funcional en el anciano. Galicia Clin 2011; 72(1): 11-16.

Instrumental activities of daily living
Escala de actividades instrumentales de la vida diaria

Activity	1 = Independent	0 = Dependent
Uso de teléfono	Opera el teléfono con su propia iniciativa; ve y marca los números Marca unos pocos números bien conocidos Contesta el teléfono pero no marca	No usa el teléfono
Shopping	Toma cuidado de todas las necesidades de compra independientemente	Compra independientemente por compras pequeñas Necesita ser acompañado en cualquier compra Completamente incapaz de comprar
Preparación de alimentos	Planea, prepara y sirve adecuadamente las comidas independientemente	Prepara adecuadamente las comidas si abastecen ingredientes Calienta y sirve comida preparada, o prepara comida pero no mantiene una dieta adecuada Necesita tener comida preparada y servida
Trabajos domésticos	Mantiene la casa sola o con asistencia ocasional (por ejemplo para trabajo pesado) Realiza trabajos leves diariamente, como lavado de platos y tender la cama Realiza trabajos ligeros diariamente pero no puede mantener un nivel aceptable de limpieza Necesita ayuda con toda la limpieza	No participa en ninguna tarea de trabajo doméstico
Ropa sucia	Hace ropa personal completo Lava pequeños artículos, enjuaga calcetines, medias, etc	Necesita tener toda la ropa hecho por otros
Transportation	Viaja independientemente en transporte público o maneja su propio carro Arregla su propio viaje por taxi pero no de otra manera usa transporte público Viaja en transporte público cuando es asistido o acompañado por otro	Viaja solo por taxi o carro con asistencia o acompañado por otro No viaja
Responsabilidad por medicaciones	Es responsable de tomar su propia medicación en dosis correcta al tiempo correcto	Toma responsabilidad si el medicamento esta preparado por adelantado en dosis separadas No es capaz de distribuir su propio medicamento
Capacidad para manejar las finanzas	Maneja materia financiera independientemente (presupuesta, escribe cheques, paga la renta, va al banco); colecta y sigue manteniendo sus ingresos Maneja día a día sus compras pero necesita ayuda en bancos, compras mayores, etc	Incapaz de manejo de dinero

Score: ____ (8 = High function [patient independent]; 0 = Low function [patient dependent])

Source: Lawton, M.P., & Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. The Gerontologist, 9(3), 179-186.

Cuestionario Sobre La Salud Del Paciente-2

Durante las últimas 2 semanas, ¿qué tan seguido ha tenido molestias debido a los siguientes problemas?

	Ningún día	Varios días	Más de la mitad de los días	Casi todos los días
Poco interés o placer en hacer cosas.	0	1	2	3
Se ha sentido decaído(a), deprimido(a) o sin esperanzas.	0	1	2	3

Score of >=3 suggests depression

Source: Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care 2003; 41:1284-92.

PROMIS Apoyo emocional – Cuestionario abreviado 4a

Responda a cada pregunta:

	1 = Nunca	2 = Rara vez	3 = Algunas veces	4 = A menudo	5 = Siempre
Tengo quien me escuche cuando necesito hablar.					
Tengo a quién confiarle mis asuntos personales o hablarle de mí o de mis problemas.					
Tengo quien me hace sentir apreciado/a.					
Tengo con quién hablar cuando tengo un mal día.					

Source: PROMIS Item Bank v2.0 - Emotional Support – Short Form 4a

Milestones
Escalones

If the answer to the question is “no,” do not continue with subsequent questions. Assume they are “no” as well.

For home hospital arm:

1. ¿Ha caminado al baño, sin incluir la tapa del inodoro?
2. ¿Ha caminado alrededor de su casa, sin incluir caminar al baño?
3. ¿Ha caminado un tramo de escaleras?

For control arm:

1. ¿Ha caminado al baño, sin incluir la tapa del inodoro?
2. ¿Ha caminado alrededor de la sala del hospital, sin incluir caminar al baño?
3. ¿Ha caminado un tramo de escaleras?

3-Item Care Transition Measure
Encuesta de la transición de cuidados médicos

1. Al salir del hospital, el personal del mismo tomó en cuenta mis preferencias y las de mi familia o personas que me cuidan al decidir cuales son mis necesidades de cuidado médico

Estoy en completo desacuerdo	Estoy en desacuerdo	Estoy de acuerdo	Estoy en completo acuerdo	No sé/ No recuerdo/ No corresponde

2. Al salir del hospital, tuve un buen entendimiento de las cosas de las que yo tenía que tomar responsabilidad para el control de mi salud.

Estoy en completo desacuerdo	Estoy en desacuerdo	Estoy de acuerdo	Estoy en completo acuerdo	No sé/ No recuerdo/ No corresponde

3. Al salir del hospital, entendí claramente porque debo tomar cada una de mis medicinas.

Estoy en completo desacuerdo	Estoy en desacuerdo	Estoy de acuerdo	Estoy en completo acuerdo	No sé/ No recuerdo/ No corresponde

Score: sum divided by questions answered; use linear transformation to convert to 0-100 scale

Source: Parry C, Mahoney E, Chalmers SA, Coleman EA. Assessing the quality of transitional care: further applications of the care transitions measure. Med Care. 2008;46(3):317-22.

Picker Experience Questionnaire 15 (PPE-15)

1. ¿Cuándo tuvo preguntas que hacer a algún médico, ¿recibió usted respuestas claras, fáciles de entender? Sí, siempre / Sí, a veces / No / No tuve necesidad de preguntar / NS/NC
2. ¿Cuándo tuvo preguntas que hacer a alguna enfermera, ¿recibió usted respuestas claras, fáciles de entender? Sí, siempre / Sí, a veces / No / No tuve necesidad de preguntar / NS/NC
3. A veces en el hospital un médico o enfermera pueden decir una cosa y otros decir lo contrario, ¿le ha pasado esto a usted? Sí, muy a menudo / sí, alguna vez / No / NS/NC
4. Si tuvo alguna preocupación o miedo sobre su estado de salud o su tratamiento, ¿algún médico habló de ese tema con usted? Sí, totalmente / Sí, hasta cierto punto / No / No tuve ninguna preocupación o miedo / NS/NC
5. ¿Hablaron los médicos delante de usted como si no estuviera allí? Sí, muy a menudo / sí, alguna vez / No / NS/NC
6. ¿Hubiese querido participar más en las decisiones tomadas sobre sus cuidados y tratamientos? Sí, totalmente / Sí, hasta cierto punto / No / NS/NC
7. En general, ¿se sintió usted tratado con respeto mientras estuvo en el Hospital? Sí, siempre / Sí, a veces / No / NS/NC
8. Si tuvo alguna preocupación o miedo sobre su estado de salud o tratamiento, ¿alguna enfermera habló de ese tema con usted? Sí, totalmente / Sí, hasta cierto punto / No / No tuve ninguna preocupación o miedo / NS/NC
9. ¿Encontró a alguien, del personal del hospital, con quien hablar de sus preocupaciones? Sí, totalmente / Sí, hasta cierto punto / No / No tuve ninguna preocupación / NS/NC
10. ¿Sintió usted dolor en algún momento? Sí/No. If yes... ¿Cree que el personal del hospital hizo todo lo que pudo para calmar su dolor? Sí, totalmente / Sí, hasta cierto punto / No / NS/NC
11. Si su familia, o alguien cercano a usted, quiso hablar con el me´dico, ¿tuvieron oportunidad de hacerlo? Sí, totalmente / Sí, hasta cierto punto / No hubo familiares ni amigos implicados / Mi familia no quiso o necesitó información / No quise que mis familiares ni amigos hablaran con el médico / NS/NC
12. ¿Los médicos o enfermeras dieron a su familia, o a alguien cercano a usted, la información necesaria para ayudarle a recuperarse? Sí, totalmente / Sí, hasta cierto punto / Mi familia no quiso o necesitó información / No quise que mis familiares ni amigos hablaran con el médico / No / No hubo familiares ni amigos implicados / NS/NC
13. ¿Algún miembro del personal del hospital le explicó para qué servían los medicamentos que tenía que tomar en casa de manera que usted lo pudiera comprender? Sí, totalmente / Sí, hasta cierto punto / No necesité explicaciones / No tuve que tomar medicamentos / No / NS/NC
14. ¿Algún profesional le explicó los posibles efectos secundarios de la medicación que debía tener en cuenta? Sí, totalmente / Sí, hasta cierto punto / No / No necesité explicaciones / NS/NC
15. ¿Le habló alguien de los posibles signos de alarma, relacionados con su enfermedad o tratamiento, a los que tenía que estar atento cuando volviera a casa? Sí, totalmente / Sí, hasta cierto punto / No / NS/NC

Source: Barrio-Cantalejo IM, Simón-Lorda P, Sánchez Rodríguez C, Molina-Ruiz A, Tamayo-Velázquez MI, Suess A, Jiménez-Martín JM. [Cross-cultural adaptation and validation of the Picker Patient Experience Questionnaire-15 for use in the Spanish population]. Rev Calid Asist. 2009;24(5):192-206. PMID: 19717076.

Global Experience

Usando un número del 0 al 10, el 0 siendo el peor hospital posible y el 10 el mejor hospital posible, ¿qué número usaría para calificar este hospital durante esta vez que estuvo en el hospital?

¿Le recomendaría este hospital a sus amigos y familiares?

- Definitivamente no
- Probablemente no
- Probablemente sí
- Definitivamente sí

Qualitative Discharge Interview

Will be performed by Spanish speaking interview or with interpreter line.

Hospitalization at Home:

The Acute Care Home Hospital Program for Adults

Screening instruments

Hurt, Insulted, Threatened with Harm and Screamed (HITS): Domestic violence screening tool

How often does your partner...	1 = Never	2 = Rarely	3 = Sometimes	4 = Fairly Often	5 = Frequently
...physically hurt you?					
...insult or talk down to you?					
...threaten you with harm?					
...scream or curse at you?					

Total score (range 4-20): ____
For females, >=10 suggests domestic violence. For males, >=11 suggests domestic violence.

Source: Sherin KM, Sinacore JM, Li XQ, Zitter RE, Shakil A. (1998). HITS: A short domestic violence screening tool for use in a family practice setting. Family Medicine, 30, 508-12.

Confusion Assessment Method (CAM)

Feature 1: Acute Onset and Fluctuating Course
This feature is usually obtained from a family member or nurse and is shown by positive responses to the following questions: Is there evidence of an acute change in mental status from the patient's baseline? Did the (abnormal) behavior fluctuate during the day, that is, tend to come and go, or increase and decrease in severity?

Feature 2: Inattention
This feature is shown by a positive response to the following question: Did the patient have difficulty focusing attention, for example, being easily distractible, or having difficulty keeping track of what was being said?

Feature 3: Disorganized thinking
This feature is shown by a positive response to the following question: Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?

Feature 4: Altered Level of consciousness
This feature is shown by any answer other than "alert" to the following question: Overall, how would you rate this patient's level of consciousness? (alert [normal]), vigilant [hyperalert], lethargic [drowsy, easily aroused], stupor [difficult to arouse], or coma [unarousable]).

Delirium present if features 1 and 2 and either 3 or 4 present.

Source: Inouye, S., van Dyck, C., Alessi, C., Balkin, S., Siegal, A. & Horwitz, R. (1990). Clarifying confusion: The confusion assessment method. Annals of Internal Medicine, 113(12), 941-948.

Quick Sepsis Related Organ Failure Assessment (QSOFA)

	0 = No	1 = Yes
Systolic blood pressure <= 100mgHg		
Respiratory rate >= 22		
Glasgow come scale < 15 (any altered mental status)		

Total score (range 0-3): ____
Sepsis suggested for score > 1

Source: Seymour CW, Liu VX, Iwashyna TJ, et al. Assessment of Clinical Criteria for Sepsis: For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):762-74.

Pneumonia: CURB65

	0 = No	1 = Yes
Confusion		
BUN > 19mg/dL		
Respiratory rate>=30		
Systolic blood pressure < 90		
Age>=65		

Total score (range 0-5): ____
Score > 3 suggests ICU requirement

Source: Chalmers JD, Singanayagam A, Hill AT. Systolic blood pressure is superior to other haemodynamic predictors of outcome in community acquired pneumonia. *Thorax*. 2008;63(8):698-702.

Pneumonia: SMRTCO

	0 = No	1/2 = Yes
Systolic blood pressure < 90mmHg (2pts)		
Multilobar CXR involvement		
Respiratory rate>=30		
Heart rate >= 125		
New confusion		
Oxygen saturation <= 90%		

Total score (range 0-7): ____
Score > 2 suggests likelihood of intensive respiratory or vasopressor support too high for home hospital

Source: Charles PGP, Wolfe R, Whitby M, et al. SMART-COP: a tool for predicting the need for intensive respiratory or vasopressor support in community-acquired pneumonia. *Clin Infect Dis*. 2008;47(3):375-384.

Systolic BP	Points	BUN	Points	Sodium	Points	Age	Points
50-59	28	≤9	0	≤130	4	≤19	0
60-69	26	10-19	2	131	3	20-29	3
70-79	24	20-29	4	132	3	30-39	6
80-89	23	30-39	6	133	3	40-49	8
90-99	21	40-49	8	134	2	50-59	11
100-109	19	50-59	9	135	2	60-69	14
110-119	17	60-69	11	136	2	70-79	17
120-129	15	70-79	13	137	1	80-89	19
130-139	13	80-89	15	138	1	90-99	22
140-149	11	90-99	17	≥139	0	100-109	25
150-159	9	100-109	19			≥110	28
160-169	8	110-119	21				
170-179	6	120-129	23				
180-189	4	130-139	25				
190-199	2	140-149	27				
≥200	0	≥150	28				

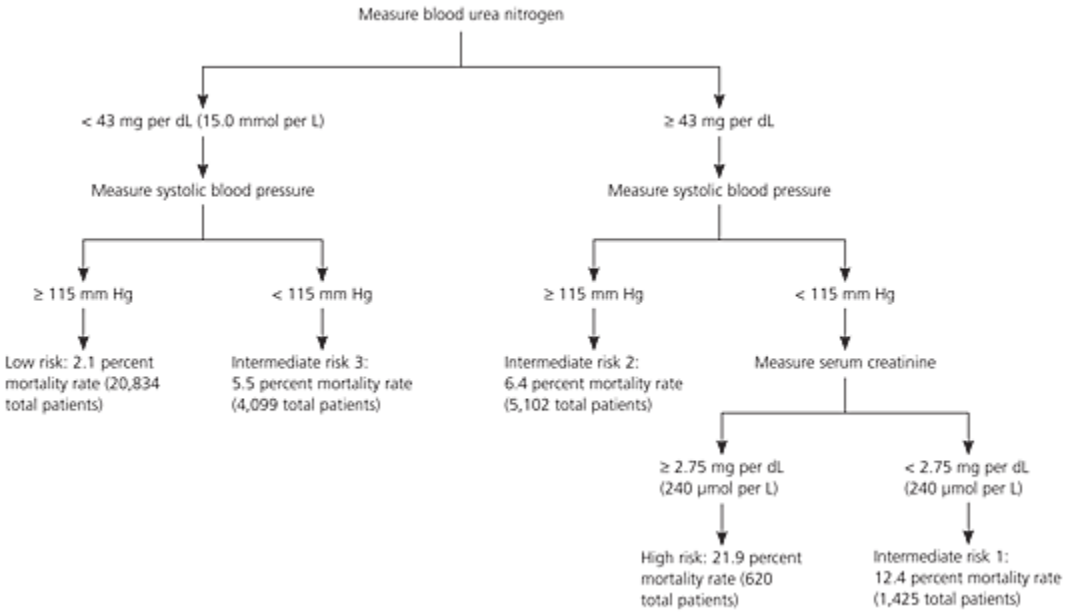
Heart Rate	Points	Black Race	Points	COPD	Points
≤79	0	Yes	0	Yes	2
80-84	1	No	3	No	0
85-89	3				
90-94	4				
95-99	5				
100-104	6				
≥105	8				

Total Score	Probability of Death
0-33	**<1%**
34-50	**1-5%**
51-57	**>5-10%**
58-61	**>10-15%**
62-65	**>15-20%**
66-70	**>20-30%**
71-74	**>30-40%**
75-78	**>40-50%**
≥79	**>50%**

Score > 57 suggests acuity level too high for home hospital (>10% in-hospital mortality).

Source: Peterson PN, Rumsfeld JS, Liang L, et al. A validated risk score for in-hospital mortality in patients with heart failure from the American Heart Association get with the guidelines program. *Circ Cardiovasc Qual Outcomes*. 2010;3(1):25-32.

Acute Decompensated Heart Failure National Registry (ADHERE)



Score of "high-risk" (>~20% in-hospital mortality) and intermediate risk 1 (~12% in-hospital mortality) suggests acuity level too high for home hospital.

Source: Fonarow GC, Adams KF, Abraham WT, Yancy CW, Boscardin WJ. Risk stratification for in-hospital mortality in acutely decompensated heart failure: classification and regression tree analysis. *JAMA*. 2005;293(5):572-580.

PRISMA-7

	0 = No	1 = Yes
1. Are you more than 85 years?		
2. Male?		
3. In general do you have any health problems that require you to limit your activities?		
4. Do you need someone to help you on a regular basis?		
5. In general do you have any health problems that require you to stay at home?		
6. In case of need can you count on someone close to you?		
7. Do you regularly use a stick, walker or wheelchair to get about?		

Score >= 3 suggests frailty and need for further assessment.

Source: Raîche M, Hébert R, Dubois MF. PRISMA-7: a case-finding tool to identify older adults with moderate to severe disabilities. Arch Gerontol Geriatr. 2008;47(1):9-18.

Eight-item Interview to Differentiate Aging and Dementia

Remember, "Yes, a change" indicates that there has been a change in the last several years caused by cognitive (thinking and memory) problems.

	YES, a change	NO, no change	N/A, Don't know
1. Problems with judgment (e.g., problems making decisions, bad financial decisions, problems with thinking)			
2. Less interest in hobbies/activities			
3. Repeats the same things over and over (questions, stories, or statements)			
4. Trouble learning how to use a tool, appliance, or gadget (e.g., VCR, computer, microwave, remote control)			
5. Forgets correct month or year			
6. Trouble handling complicated financial affairs (e.g., balancing checkbook, income taxes, paying bills)			
7. Trouble remembering appointments			
8. Daily problems with thinking and/or memory			

Score: ___ (sum of YES's)

Score >=2 indicates cognitive impairment is likely present

Source: Galvin JE, Roe CM, Powlishta KK et al. The AD8: a brief informant interview to detect dementia. Neurology. 2005. 65(4):559-564.

BRIEF Health Literacy Screener

Please choose the answer that best represents your response:

1. How often do you have someone help you read hospital materials?	1=Always	2=Often	3=Sometimes	4=Occasionally	5=Never
2. How often do you have problems learning about your medical condition because of difficulty understanding written information?	1=Always	2=Often	3=Sometimes	4=Occasionally	5=Never
3. How often do you have a problem understanding what is told to you about your medical condition?	1=Always	2=Often	3=Sometimes	4=Occasionally	5=Never
4. How confident are you filling out medical forms by yourself?	1=Not at all	2=A little bit	3=Somewhat	4=Quite a bit	5=Extremely

Score: ___ (sum of responses)

Literacy	Score	Skills and Abilities
Limited	**4-12**	Not able to read most low literacy health materials; will need repeated oral instructions; materials should be composed of illustrations or video tapes. Will need low literacy materials; may not be able to read a prescription label.
Marginal	**13-16**	May need assistance; may struggle with patient education materials.
Adequate	**17-20**	Will be able to read and comprehend most patient education materials.

Source: Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. Fam Med. 2004;36(8):588-94.

Endpoint instruments

EuroQol – 5D – 5L 1.5min

Under each heading, please check the ONE box that best describes your health TODAY.

MOBILITY

I have no problems walking ❑
I have slight problems walking ❑
I have moderate problems walking ❑
I have severe problems walking ❑
I am unable to walk ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

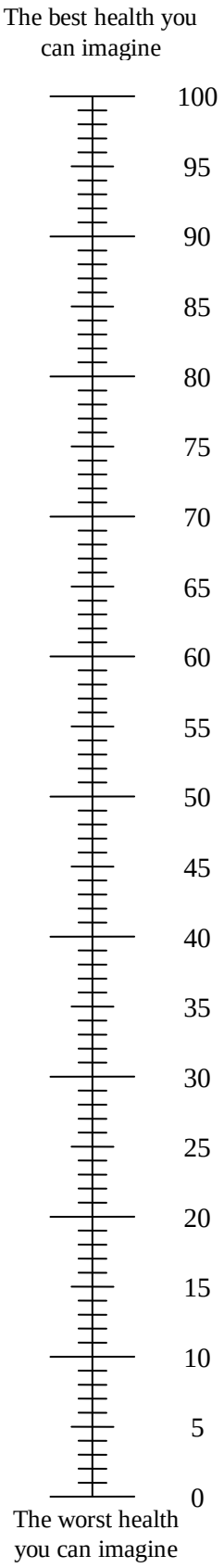
I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑

Levine and Schnipper

I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Activities of daily living

Activity	1 = Independence *No supervision, direction, or personal assistance*	0 = Dependence *With supervision, direction, personal assistance or total care*
Bathing	Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	Need help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
Dressing	Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	Needs help with dressing self or needs to be completely dressed.
Toileting	Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
Transferring	Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable.	Needs help in moving from bed to chair or requires a complete transfer.
Continence	Exercises complete self-control over urination and defecation.	Is partially or totally incontinent of bowel or bladder.
Feeding	Gets food from plate into mouth without help. Preparation of food may be done by another person.	Needs partial or total help with feeding or requires parenteral feeding.

Score: ____ (6 = High [patient independent]; 0 = Low [patient very dependent])

Source: Katz, S., Down, T.D., Cash, H.R., & Grotz, R.C. (1970) Progress in the development of the index of ADL. The Gerontologist, 10(1), 20-30.

Instrumental Activities of daily living

Activity	1 = Independent	0 = Dependent
Use telephone	Operates telephone on own initiative; looks up and dials numbers Dials a few well-known numbers Answers telephone, but does not dial	Does not use telephone at all
Shopping	Takes care of all shopping needs independently	Shops independently for small purchases Needs to be accompanied on any shopping trip Completely unable to shop
Food Preparation	Plans, prepares, and serves adequate meals independently	Prepares adequate meals if supplied with ingredients Heats and serves prepared meals or prepares meals but does not maintain adequate diet Needs to have meals prepared and served
Housekeeping	Maintains house alone with occasional assistance (heavy work) Performs light daily tasks such as dishwashing, bed making Performs light daily tasks, but cannot maintain acceptable level of cleanliness Needs help with all home maintenance tasks	Does not participate in any housekeeping tasks
Laundry	Does personal laundry completely Launders small items, rinses socks, stockings, etc	All laundry must be done by others
Transportation	Travels independently on public transportation or drives own car Arranges own travel via taxi, but does not otherwise use public transportation Travels on public transportation when assisted or accompanied by another	Travel limited to taxi or automobile with assistance of another Does not travel at all
Responsibility for Own Medications	Is responsible for taking medication in correct dosages at correct time	Takes responsibility if medication is prepared in advance in separate dosages Is not capable of dispensing own medication
Ability to Handle Finances	Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income Manages day-to-day purchases, but needs help with banking, major purchases, etc	Incapable of handling money

Score: ____ (7 = High [patient independent]; 0 = Low [patient very dependent])

Source: Lawton, M.P., & Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. The Gerontologist, 9(3), 179-186.

Patient Health Questionnaire 2

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

	Not at All	Several Days	More than Half the Days	Nearly Every Day
Little interest or pleasure in doing things.	0	1	2	3
Feeling down, depressed, or hopeless.	0	1	2	3

Score of >=3 suggests depression

Source: Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care 2003; 41:1284-92.

PROMIS Emotional Support – Short Form 4a

Please respond to each item:

	1 = Never	2 = Rarely	3 = Sometimes	4 = Usually	5 = Always
I have someone who will listen to me when I need to talk					
I have someone to confide in or talk to about myself or my problems					
I have someone who makes me feel appreciated					
I have someone to talk with when I have a bad day					

Source: PROMIS Item Bank v2.0 - Emotional Support – Short Form 4a

Milestones

If the answer to the question is “no,” do not continue with subsequent questions. Assume they are “no” as well.

For home hospital arm:

1. Have you walked to the bathroom, not including the commode?
2. Have you walked around your home, not including walking to the bathroom?
3. Have you walked one flight of stairs?

For control arm:

1. Have you walked to the bathroom, not including the commode?
2. Have you walked around the hospital ward other than to the bathroom?
3. Have you walked one flight of stairs?

3-Item Care Transition Measure

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

Strongly disagree	Disagree	Agree	Strongly agree	Don't know/Don't remember/Not applicable

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

Strongly disagree	Disagree	Agree	Strongly agree	Don't know/Don't remember/Not applicable

3. When I left the hospital, I clearly understood the purpose for taking each of my medications.

Strongly disagree	Disagree	Agree	Strongly agree	Don't know/Don't remember/Not applicable

Score: sum divided by questions answered; use linear transformation to convert to 0-100 scale

Source: Parry C, Mahoney E, Chalmers SA, Coleman EA. Assessing the quality of transitional care: further applications of the care transitions measure. Med Care. 2008;46(3):317-22.

Picker Experience Questionnaire 15 (PPE-15)

1. When you had important questions to ask a doctor, did you get answers that you could understand? Yes, always/Yes, sometimes/No/I had no need to ask
2. When you had important questions to ask a nurse, did you get answers that you could understand? Yes, always/Yes, sometimes/No/I had no need to ask
3. Sometimes in a hospital, one doctor or nurse will say one thing and another will say something quite different. Did this happen to you? Yes, often/Yes, sometimes/No
4. If you had any anxieties or fears about your condition or treatment, did a doctor discuss them with you? Yes, completely/Yes, to some extent/No/I didn't have any anxieties or fears
5. Did doctors talk in front of you as if you weren't there? Yes, often/Yes sometimes/No
6. Did you want to be more involved in decisions made about your care and treatment? Yes, definitely/Yes, to some extent/No
7. Overall, did you feel you were treated with respect and dignity while you were in hospital? Yes, always/Yes, sometimes/No
8. If you had any anxieties or fears about your condition or treatment, did a nurse discuss them with you? Yes, completely/Yes, to some extent/No/I didn't have any anxieties or fears
9. Did you find someone on the hospital staff to talk to about your concerns? Yes, definitely/Yes, to some extent/No/I had no concerns
10. Were you ever in pain? Yes/No If yes . . . Do you think the hospital staff did everything they could to help control your pain? Yes, definitely/Yes, to some extent/No
11. If your family or someone else close to you wanted to talk to a doctor, did they have enough opportunity to do so? Yes, definitely/Yes, to some extent/No/No family or friends were involved/My family didn't want or need information/I didn't want my family or friends to talk to a doctor
12. Did the doctors or nurses give your family or someone close to you all the information they needed to help you recover? Yes, definitely/Yes, to some extent/No/No family or friends were involved/My family or friends didn't want or need information
13. Did a member of staff explain the purpose of the medicines you were to take at home in a way you could understand? Yes, completely/Yes, to some extent/No/I didn't need an explanation/I had no medicines—go to question 15
14. Did a member of staff tell you about medication side effects to watch for when you went home? Yes, completely/Yes, to some extent/No/I didn't need an explanation
15. Did someone tell you about danger signals regarding your illness or treatment to watch for after you went home? Yes, completely/Yes, to some extent/No

Source Jenkinson C, Coulter A, Bruster S. The Picker Patient Experience Questionnaire: development and validation using data from in-patient surveys in five countries. Int J Qual Health Care. 2002 Oct;14(5):353-8.

Global Experience

Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?

Would you recommend this hospital to your friends and family?

- Definitely no
- Probably no
- Probably yes
- Definitely yes

Qualitative Post-Discharge Interview

Date of Interview:_____

Interview began at: _____

Interview completed at: _____

Mr./Ms._____, thank you for taking the time to talk with me and for agreeing to participate in this study.

My name is Dr. _____, a physician at Brigham and Women's Hospital and Harvard Medical School.

This study was a first step toward changing the way we take care of older adults who become acutely ill. Having recently been admitted, you are truly a (home) hospital expert. We are hoping to gain insight into your (home) hospital experience so that we can improve it moving forward.

All of your responses will be kept anonymous and confidential. Your name will not be linked to the responses when we present our findings. If it is acceptable to you, I would like to tape our conversation today. This helps me go back to recall everything you said. Is it okay if I tape our conversation?

As this interview has open-ended questions, it could take anywhere from 15 minutes to an hour, is that all right?

Do you have any questions before we begin?

1. Please share with me your experience during your (home) hospital admission.
    a. Could you discuss your experiences with the physician(s)?
    b. Could you discuss your experiences with the nurses?
    c. How comfortable were you during your admission?
        i. Consider probing on room, bed, food, sleep, activity, pain, connection with family/friends, connection with care team.
    d. How safe did you feel during your admission?
2. Could you describe what went smoothly during your (home) hospital admission?
3. Could you describe what difficulties you came across during your (home) hospital admission?
    a. How could the (home) hospital team have made that better for you?
4. What surprises were there during your (home) hospital admission? Can you talk a little about those?
5. Could you describe what improvements to (home) hospital could be made?
6. If heaven-forbid you had to be hospitalized again and you could choose home hospital or regular hospital, which would you choose? Why?
    a. What would you tell someone else who was making this decision?
7. Is there anything else you think we should know about your (home) hospital experience?

Thank you very much for your time. If you have any further comments or questions, please reach out to the study coordinators.

Clinician Burnout

- Please do ***NOT*** put your name on this form.
- Please send your completed form to <third party administrative assistant>. S/he will assure anonymity when compiling the forms.
- Our entire team will see average aggregated responses regarding sections on team and program evaluation. Only the PI and the person evaluated will see the team-member evaluation section.

Team Evaluation

I felt like my opinions were heard.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we have improved including your voice?

I knew what the goal of our team was.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we have improved our goal-orientation?

I felt like our team valued each of its participants.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we have better valued each of our participants?

Program Evaluation

The logistics of patient care worked optimally.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve logistics?

Nursing care was delivered optimally.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve nursing care?

Physician care was delivered optimally.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve physician care?

I had sufficient support to carry out my duties.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we support you better?

Patients were cared for safely.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve patient safety?

Patient experience was optimal.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

How could we improve patient experience?

I prefer home hospital work to my standard job.	1 Not at all	2 Slightly	3 Moderately	4 Very much	5 Entirely

Why did you reply the way you did?

Next time, home hospital should... (Think of anything you would like to add: New diagnosis? New radius? New protocol?)

*Next time, home hospital should **not**... (Think of anything you would like to change.)*

Overall, I am satisfied with home hospital:	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree
I feel a great deal of stress because of home hospital:	1 Strongly disagree	2 Disagree	3 Neutral	4 Agree	5 Strongly Agree

Using your own definition of "burnout," please circle one of the answers below with respect to home hospital:

a. I enjoy my work. I have no symptoms of burnout.
b. I am under stress, and don't always have as much energy as I did, but I don't feel burned out.
c. I am definitely burning out and have one or more symptoms of burnout, e.g., emotional exhaustion.
d. The symptoms of burnout that I am experiencing won't go away. I think about work frustrations a lot.
e. I feel completely burned out. I am at the point where I may need to seek help.

My control over my workload for home hospital is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal
Sufficiency of time for documentation for home hospital is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal

Which number best describes the atmosphere for home hospital?	1 Calm	2	3 Busy, but reasonable	4	5 Hectic, chaotic
My professional values are well aligned with those of home hospital leaders:	1 Strongly disagree	2 Disagree	3 Neither agree nor disagree	4 Agree	5 Strongly Agree
The degree to which my home hospital care team works efficiently together is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal
The amount of time I spend on the electronic health record (EHR) at home for home hospital is:	1 Excessive	2 Moderately high	3 Satisfactory	4 Modest	5 Minimal/none
My proficiency with EHR use is:	1 Poor	2 Marginal	3 Satisfactory	4 Good	5 Optimal

Team-Member Evaluation

- If you did not interact with a particular person sufficiently, please skip entirely.
- Be sure to evaluate yourself!

Team Member Name Here

What are this person's biggest strengths, and how should they build on these?

What are this person's areas for improvement, and how should they improve these?

Do you have any other comments?

Spanish language assessments

Hurt, Insulted, Threatened with Harm and Screamed (HITS): Domestic violence screening tool
La HIAG escala

Hay veces que las parejas no están de acuerdo, aunque se lleven muy bien. Las parejas usan muchas maneras para resolver sus diferencias. Las siguientes son preguntas sobre las cosas que le han pasado a usted en su relación con su pareja.

Use los siguientes códigos para contestar las siguientes preguntas:

¿Con qué frecuencia su compañero…	1 = Nunca	2 = Casi nunca	3 = A veces	4 = Muchas veces	5 = Frecuentemente
... la golpea físicamente?					
... la insulta o le habla de una manera que la hace sentirse mal?					
... la amenaza con causarle daño físico?					
... le grita o la maldice?					

Total score (range 4-20): ____
For females, >=10 suggests domestic violence. For males, >=11 suggests domestic violence.

Source: Chen PH, Rovi S, Vega M, Jacobs A, Johnson MS. Screening for domestic violence in a predominantly Hispanic clinical setting. Fam Pract. 2005;22(6):617-23.

Confusion Assessment Method (CAM)
Método para la evaluación de la confusión

1. Inicio agudo y curso fluctuante
    a. ¿Hay evidencia de un cambio agudo en el estado mental del paciente con respecto a su estado basal?
    b. ¿Se produjeron fluctuaciones en la conducta (anormal) durante el día, es decir, los trastornos conductuales tienden a aparecer y desaparecer o su gravedad aumenta y disminuye?
2. Inatención
    a. ¿Tuvo el paciente dificultad para enfocar la atención? Por ejemplo, ¿se distrajo fácilmente o tuvo dificultad para seguir lo que se decía?
3. Pensamiento desorganizado
    a. ¿Fue desorganizado o incoherente el pensamiento del paciente? Por ejemplo: ¿Presentó un discurso inconexo o irrelevante, un flujo de ideas poco claro o ilógico, o cambió de manera imprevista de un tema a otro?
4. Nivel de conciencia alterado
    a. En general, ¿cómo calificaría el nivel de conciencia del paciente? Alerta (normal), hiperalerta (hiperreactivo), letárgico (somnoliento, despierta fácilmente), estuporoso (difícil de despertar), o dudoso.

Delirium present if features 1 and 2 and either 3 or 4 present.

Source: MAPI Institute and Inouye, S., van Dyck, C., Alessi, C., Balkin, S., Siegal, A. & Horwitz, R. (1990). Clarifying confusion: The confusion assessment method. Annals of Internal Medicine, 113(12), 941-948.

PRISMA-7

	0 = No	1 = Sí
1. ¿Tiene usted más de 85 años?		
2. ¿Caballero?		
3. En general, ¿tiene algún problema de salud que requieren que limite sus actividades?		
4. ¿Necesita alguien que le ayude en una base regular?		
5. En general, ¿tiene algún problema de salud que le obliguen a quedarse en casa?		
6. En caso de necesidad, ¿se puede contar con alguien cercano a usted?		
7. ¿Utiliza regularmente un bastón, andador, o una silla de ruedas para moverse?		

Score >= 3 suggests frailty and need for further assessment.

Source: Raîche M, Hébert R, Dubois MF. PRISMA-7: a case-finding tool to identify older adults with moderate to severe disabilities. Arch Gerontol Geriatr. 2008;47(1):9-18.

Eight-item Interview to Differentiate Aging and Dementia
Cuestionario AD8

Recuerde: «Sí, ha cambiado» significa que usted piensa que ha habido un cambio en los siguientes aspectos en los últimos años, causado por problemas cognitivos (razonamiento y memoria)

	Sí, ha cambiado	No, no ha cambiado	No sabe / No contesta
Problemas para emitir juicios y tomar decisiones adecuadas (p. ej., le engañan o timan, toma decisiones financieras erróneas, hace regalos inapropiados, etc.)			
Pérdida de interés en sus aficiones y actividades (p. ej., ha dejado de hacer actividades que le gustaban)			
Repite las preguntas, los comentarios o las cosas que cuenta			
Dificultad para aprender a usar herramientas, aparatos o dispositivos (p. ej., vídeo o DVD, ordenador, microondas, mandos a distancia, teléfono móvil o inalámbrico)			
Olvida el mes o año correcto			
Dificultad para manejar asuntos financieros complicados (p. ej., ajustar cuentas, talones, impuestos, facturas, recibos, etc.)			
Dificultad para recordar las citas y cosas que tiene que hacer			
Los problemas de razonamiento y/o memoria son cotidianos y no ocasionales			

Score: ___ (sum of YES's)

Score >=2 indicates cognitive impairment is likely present

EuroQol – 5D – 5L

Debajo de cada encabezamiento, marque UNA casilla, la que mejor describe su salud HOY.

MOVILIDAD

- No tengo problemas para caminar ❑
- Tengo problemas leves para caminar ❑
- Tengo problemas moderados para caminar ❑
- Tengo problemas graves para caminar ❑
- No puedo caminar ❑

CUIDADO PERSONAL

- No tengo problemas para lavarme o vestirme solo/a ❑
- Tengo problemas leves para lavarme o vestirme solo/a ❑
- Tengo problemas moderados para lavarme o vestirme solo/a ❑
- Tengo problemas graves para lavarme o vestirme solo/a ❑
- No puedo lavarme o vestirme solo/a ❑

ACTIVIDADES DE TODOS LOS DÍAS *(Ej.: trabajar, estudiar, hacer las tareas domésticas, actividades familiares o actividades de ocio)*

- No tengo problemas para realizar mis actividades de todos los días ❑
- Tengo problemas leves para realizar mis actividades de todos los días ❑
- Tengo problemas moderados para realizar mis actividades de todos los días ❑
- Tengo problemas graves para realizar mis actividades de todos los días ❑
- No puedo realizar mis actividades de todos los días ❑

DOLOR / MALESTAR

- No tengo dolor ni malestar ❑
- Tengo dolor o malestar leve ❑
- Tengo dolor o malestar moderado ❑
- Tengo dolor o malestar intenso ❑
- Tengo dolor o malestar extremo ❑

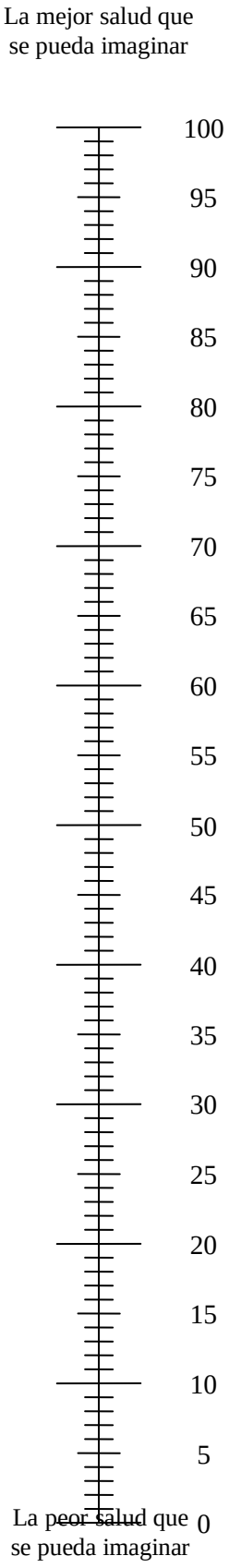
ANSIEDAD / DEPRESIÓN

- No estoy ansioso/a ni deprimido/a ❑
- Estoy levemente ansioso/a o deprimido/a ❑
- Estoy moderadamente ansioso/a o deprimido/a ❑
- Estoy muy ansioso/a o deprimido/a ❑
- Estoy extremadamente ansioso/a o deprimido/a ❑

- Nos gustaría saber lo buena o mala que es su salud HOY.
- La escala está numerada de 0 a 100.
- 100 representa la mejor salud que se pueda imaginar.
  0 representa la peor salud que se pueda imaginar.
- Por favor haga una X en la escala para indicar cuál es su estado de salud HOY.

SU SALUD HOY = ☐

- Ahora, por favor escriba en la casilla que encontrará a continuación el número que ha marcado en la escala.



Activities of daily living
Índice de actividades de la vida diaria

Actividad	1 = Independence *No supervision, direction, or personal assistance*	0 = Dependence *With supervision, direction, personal assistance or total care*
Lavado	No recibe ayuda (entra y sale solo de la bañera si esta es la forma habitual de bañarse) o recibe ayuda en la limpieza de una sola parte de su cuerpo (espalda o piernas por ejemplo)	Recibe ayuda en el aseo de más de una parte de su cuerpo para entrar o salir de la bañera
Vestido	Toma la ropa y se viste completamente sin ayuda. Se viste sin ayuda excepto para atarse los zapatos.	Recibe ayuda para coger la ropa y ponérsela o permanece parcialmente vestido.
Uso de retrete	Va al retrete, se limpia y se ajusta la ropa sin ayuda (puede usar bastón, andador y silla de ruedas).	Recibe ayuda para ir al retrete, limpiarse, ajustarse la ropa o en el uso nocturno del orinal. No va al retrete.
Movilización	Entra y sale de la cama, se sienta y se levanta sin ayuda (puede usar bastón o andador).	Entra y sale de la cama, se sienta y se levanta con ayuda. No se levanta de la cama.
Continencia	Control completo de ambos esfínteres	Incontinencia ocasional. Necesita supervisión. Usa sonda vesical o es incontinente
Alimentación	Sin ayuda. Ayuda solo para cortar la carne o untar el pan.	Necesita ayuda para comer o es alimentado parcial o completamente usando sondas o fluidos intravenosos.

Score: ____ (6 = High [patient independent]; 0 = Low [patient very dependent])

Source: María Trigás-Ferrín M, Ferreira-González L, Meijide-Míguez H. Escalas de valoración funcional en el anciano. Galicia Clin 2011; 72(1): 11-16.

Instrumental activities of daily living
Escala de actividades instrumentales de la vida diaria

Activity	1 = Independent	0 = Dependent
Uso de teléfono	Opera el teléfono con su propia iniciativa; ve y marca los números Marca unos pocos números bien conocidos Contesta el teléfono pero no marca	No usa el teléfono
Shopping	Toma cuidado de todas las necesidades de compra independientemente	Compra independientemente por compras pequeñas Necesita ser acompañado en cualquier compra Completamente incapaz de comprar
Preparación de alimentos	Planea, prepara y sirve adecuadamente las comidas independientemente	Prepara adecuadamente las comidas si abastecen ingredientes Calienta y sirve comida preparada, o prepara comida pero no mantiene una dieta adecuada Necesita tener comida preparada y servida
Trabajos domésticos	Mantiene la casa sola o con asistencia ocasional (por ejemplo para trabajo pesado) Realiza trabajos leves diariamente, como lavado de platos y tender la cama Realiza trabajos ligeros diariamente pero no puede mantener un nivel aceptable de limpieza Necesita ayuda con toda la limpieza	No participa en ninguna tarea de trabajo doméstico
Ropa sucia	Hace ropa personal completo Lava pequeños artículos, enjuaga calcetines, medias, etc	Necesita tener toda la ropa hecho por otros
Transportation	Viaja independientemente en transporte público o maneja su propio carro Arregla su propio viaje por taxi pero no de otra manera usa transporte público Viaja en transporte público cuando es asistido o acompañado por otro	Viaja solo por taxi o carro con asistencia o acompañado por otro No viaja
Responsabilidad por medicaciones	Es responsable de tomar su propia medicación en dosis correcta al tiempo correcto	Toma responsabilidad si el medicamento esta preparado por adelantado en dosis separadas No es capaz de distribuir su propio medicamento
Capacidad para manejar las finanzas	Maneja materia financiera independientemente (presupuesta, escribe cheques, paga la renta, va al banco); colecta y sigue manteniendo sus ingresos Maneja día a día sus compras pero necesita ayuda en bancos, compras mayores, etc	Incapaz de manejo de dinero

Score: ____ (8 = High function [patient independent]; 0 = Low function [patient dependent])

Source: Lawton, M.P., & Brody, E.M. (1969). Assessment of older people: Self-maintaining and instrumental activities of daily living. The Gerontologist, 9(3), 179-186.

Cuestionario Sobre La Salud Del Paciente-2

Durante las últimas 2 semanas, ¿qué tan seguido ha tenido molestias debido a los siguientes problemas?

	Ningún día	Varios días	Más de la mitad de los días	Casi todos los días
Poco interés o placer en hacer cosas.	0	1	2	3
Se ha sentido decaído(a), deprimido(a) o sin esperanzas.	0	1	2	3

Score of >=3 suggests depression

Source: Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. Med Care 2003; 41:1284-92.

PROMIS Apoyo emocional – Cuestionario abreviado 4a

Responda a cada pregunta:

	1 = Nunca	2 = Rara vez	3 = Algunas veces	4 = A menudo	5 = Siempre
Tengo quien me escuche cuando necesito hablar.					
Tengo a quién confiarle mis asuntos personales o hablarle de mí o de mis problemas.					
Tengo quien me hace sentir apreciado/a.					
Tengo con quién hablar cuando tengo un mal día.					

Source: PROMIS Item Bank v2.0 - Emotional Support – Short Form 4a

Milestones
Escalones

If the answer to the question is “no,” do not continue with subsequent questions. Assume they are “no” as well.

For home hospital arm:

1. ¿Ha caminado al baño, sin incluir la tapa del inodoro?
2. ¿Ha caminado alrededor de su casa, sin incluir caminar al baño?
3. ¿Ha caminado un tramo de escaleras?

For control arm:

1. ¿Ha caminado al baño, sin incluir la tapa del inodoro?
2. ¿Ha caminado alrededor de la sala del hospital, sin incluir caminar al baño?
3. ¿Ha caminado un tramo de escaleras?

3-Item Care Transition Measure
Encuesta de la transición de cuidados médicos

1. Al salir del hospital, el personal del mismo tomó en cuenta mis preferencias y las de mi familia o personas que me cuidan al decidir cuales son mis necesidades de cuidado médico

Estoy en completo desacuerdo	Estoy en desacuerdo	Estoy de acuerdo	Estoy en completo acuerdo	No sé/ No recuerdo/ No corresponde

2. Al salir del hospital, tuve un buen entendimiento de las cosas de las que yo tenía que tomar responsabilidad para el control de mi salud.

Estoy en completo desacuerdo	Estoy en desacuerdo	Estoy de acuerdo	Estoy en completo acuerdo	No sé/ No recuerdo/ No corresponde

3. Al salir del hospital, entendí claramente porque debo tomar cada una de mis medicinas.

Estoy en completo desacuerdo	Estoy en desacuerdo	Estoy de acuerdo	Estoy en completo acuerdo	No sé/ No recuerdo/ No corresponde

Score: sum divided by questions answered; use linear transformation to convert to 0-100 scale

Source: Parry C, Mahoney E, Chalmers SA, Coleman EA. Assessing the quality of transitional care: further applications of the care transitions measure. Med Care. 2008;46(3):317-22.

Picker Experience Questionnaire 15 (PPE-15)

1. ¿Cuándo tuvo preguntas que hacer a algún médico, ¿recibió usted respuestas claras, fáciles de entender? Sí, siempre / Sí, a veces / No / No tuve necesidad de preguntar / NS/NC
2. ¿Cuándo tuvo preguntas que hacer a alguna enfermera, ¿recibió usted respuestas claras, fáciles de entender? Sí, siempre / Sí, a veces / No / No tuve necesidad de preguntar / NS/NC
3. A veces en el hospital un médico o enfermera pueden decir una cosa y otros decir lo contrario, ¿le ha pasado esto a usted? Sí, muy a menudo / sí, alguna vez / No / NS/NC
4. Si tuvo alguna preocupación o miedo sobre su estado de salud o su tratamiento, ¿algún médico habló de ese tema con usted? Sí, totalmente / Sí, hasta cierto punto / No / No tuve ninguna preocupación o miedo / NS/NC
5. ¿Hablaron los médicos delante de usted como si no estuviera allí? Sí, muy a menudo / sí, alguna vez / No / NS/NC
6. ¿Hubiese querido participar más en las decisiones tomadas sobre sus cuidados y tratamientos? Sí, totalmente / Sí, hasta cierto punto / No / NS/NC
7. En general, ¿se sintió usted tratado con respeto mientras estuvo en el Hospital? Sí, siempre / Sí, a veces / No / NS/NC
8. Si tuvo alguna preocupación o miedo sobre su estado de salud o tratamiento, ¿alguna enfermera habló de ese tema con usted? Sí, totalmente / Sí, hasta cierto punto / No / No tuve ninguna preocupación o miedo / NS/NC
9. ¿Encontró a alguien, del personal del hospital, con quien hablar de sus preocupaciones? Sí, totalmente / Sí, hasta cierto punto / No / No tuve ninguna preocupación / NS/NC
10. ¿Sintió usted dolor en algún momento? Sí/No. If yes... ¿Cree que el personal del hospital hizo todo lo que pudo para calmar su dolor? Sí, totalmente / Sí, hasta cierto punto / No / NS/NC
11. Si su familia, o alguien cercano a usted, quiso hablar con el me´dico, ¿tuvieron oportunidad de hacerlo? Sí, totalmente / Sí, hasta cierto punto / No hubo familiares ni amigos implicados / Mi familia no quiso o necesitó información / No quise que mis familiares ni amigos hablaran con el médico / NS/NC
12. ¿Los médicos o enfermeras dieron a su familia, o a alguien cercano a usted, la información necesaria para ayudarle a recuperarse? Sí, totalmente / Sí, hasta cierto punto / Mi familia no quiso o necesitó información / No quise que mis familiares ni amigos hablaran con el médico / No / No hubo familiares ni amigos implicados / NS/NC
13. ¿Algún miembro del personal del hospital le explicó para qué servían los medicamentos que tenía que tomar en casa de manera que usted lo pudiera comprender? Sí, totalmente / Sí, hasta cierto punto / No necesité explicaciones / No tuve que tomar medicamentos / No / NS/NC
14. ¿Algún profesional le explicó los posibles efectos secundarios de la medicación que debía tener en cuenta? Sí, totalmente / Sí, hasta cierto punto / No / No necesité explicaciones / NS/NC
15. ¿Le habló alguien de los posibles signos de alarma, relacionados con su enfermedad o tratamiento, a los que tenía que estar atento cuando volviera a casa? Sí, totalmente / Sí, hasta cierto punto / No / NS/NC

Source: Barrio-Cantalejo IM, Simón-Lorda P, Sánchez Rodríguez C, Molina-Ruiz A, Tamayo-Velázquez MI, Suess A, Jiménez-Martín JM. [Cross-cultural adaptation and validation of the Picker Patient Experience Questionnaire-15 for use in the Spanish population]. Rev Calid Asist. 2009;24(5):192-206. PMID: 19717076.

Global Experience

Usando un número del 0 al 10, el 0 siendo el peor hospital posible y el 10 el mejor hospital posible, ¿qué número usaría para calificar este hospital durante esta vez que estuvo en el hospital?

¿Le recomendaría este hospital a sus amigos y familiares?

- Definitivamente no
- Probablemente no
- Probablemente sí
- Definitivamente sí

Qualitative Discharge Interview

Will be performed by Spanish speaking interview or with interpreter line.

HOME HOSPITAL GUIDE

Brigham and Women's

Home Hospital Research Study

Highly effective teaming

Highly effective care

Healthy, satisfied patients

Research Assistant

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Thursday	9:45-6:00	Data collection Clinician Check-Ins	Off (required until 1)	9:45-5: Track board and enroll
Friday	9:45-6:00	Track board and enroll Clinician Check-Ins	Off (required)	Off (required)
Saturday	9:45-6:00	Off	Off	Track board and enroll Clinician Check-Ins
Total hours		39	19.625	19.625

*Team meeting at 12p

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- Anything with patient information must be placed in a certified shredder bin, not in a regular trash/recycling bin.
- Only use HipaaChat for text messages. No patient information can be texted with regular texts.
- Only use your Partners email account for emails.

Enrollment

Your ability to enroll patients is the lifeblood of this project. We are relying on you!

Timing overview

Action	Description	Time Low (min)	Time High (min)
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RA enrollment	Screening that cannot be done via EHR, program description, Q&A	6	16
Consent review	Patient and family review written consent form	5	10
MD enrollment	Further Q&A, consent, randomization, begin plan of care discussion (if applicable)	5	15
Transport pickup	Leave ED in patient-tailored transport (if applicable)	5	30
	TOTAL	21	71

Pre-Screening – know patients in alpha, bravo, charlie, and extra beds. If unsure, ask home hospital attending.

- Delete excluded age (<18)
- Delete excluded problems (psychiatric evaluation, suicidal, trauma, motor vehicle accident, joint complaints)
- Delete excluded towns/zip codes (click LPOC tab; see Appendix)
- Delete if not one of 14 approved languages (click Pt Story tab)
- Patients you haven't deleted are "potential participants." Add them to the Potentials tab.
    - Check medication list for methadone
    - Check problem list for end stage renal disease
    - Check for incomplete notes
    - Check ED-administered narcotic (hydromorphone, oxycodone, morphine, etc)
    - Calculate risk scores
        - If heart failure, calculate GWTG-HF and ADHERE
        - If pneumonia, calculate CURB65 and SMRTCO
        - If any other infection, calculate qSOFA
        - If COPD, calculate BAP-65
        - If asthma, check peak flow
    - Compile "potential participants" email
        - By 10am, email on-call hospitalist, cardiology fellow (see Appendix), and home hospital attending
        - Annotate as appropriate: awaiting risk scoring, awaiting CXR read, etc
- Update this list throughout the day with new data and new patients (new patients have short length of stay)
    - Re-email on-call hospitalist and home hospital attending the list of potential participants at ~1pm.

Potential participant is recommended by hospitalist

- Hospitalist will call/text/email you to attempt enrollment. Mark what time you receive this call. Move ASAP to enroll!

Potential participant who was excellent candidate is admitted (appears on admit board), but wasn't recommended by hospitalist

- Ask hospitalist then ED attending if both patient and facility factors are suitable for home hospital enrollment. Mark what time you approach attending.
    - If so, ask resident/PA to introduce you to patient.
    - If not, immediately remove admitting hold

Enroll

- Text Home hospital attending: “I am starting enrollment on patient XXX.”
- Bring in the room
    - 3 copies of the consent form
    - Tablet for video visit if Home hospital attending off site
    - Envelope for randomization
    - Admission questionnaires: AD8, EQ-5D, ADL, iADL, PHQ2, social support
- Mark what time you enter room
- Give your enrollment pitch
    - “I’m [your first name], the home hospital program associate. Brigham and Women’s is offering a home hospital program where patients like you {your loved one} who are going to be admitted can enroll. Participants will be randomized (similar to a coin flip) to usual care upstairs or to return home with services tailored to your {loved-one’s} needs, including Brigham doctors and Partners nurses in your home, monitoring technology, intravenous medicine, and more that I’d like to explain. It’s an alternative to being hospitalized upstairs. There is no additional cost to you {your loved one} for the home hospital service.”
    - “This is a research study, could I describe it further for you?”
        - If they say no, kindly depart
        - If they say yes, continue
    - “Before I describe things further, let me ask you a few questions to make sure you {your loved one} qualify for the study:
        - We can only accept patients that live within 5-miles of Brigham’s {or Faulkner’s} emergency room. Where do you {does your loved one} live?
            - Follow-ups:
                - Is that a skilled nursing facility or your own home?
                - Is there running water, electricity, and air-conditioning?
        - Do you {Does your loved one} live alone or with someone?
            - If alone: could a family member or friend stay with you {your loved one} at home for the next 24 hours if needed?
            - Is she/he able to make a phone call if a problem is happening?
        - For everyone’s safety, we ask if your {your loved one’s} partner has…
            - ...physically hurt you?
            - ...insulted or talked down to you?
            - ...threatened you with harm?
            - ...screamed or cursed at you?
        - Just to double-check, why did you {your loved one} come to the emergency room?
            - Follow-up, as necessary: what have doctors diagnosed you {your loved one} with?
        - If screens out, kindly depart and remove admitting hold ASAP
        - If screens in, continue
    - “Dr. [insert name], the attending physician for the home hospital program, will be here shortly. Before s/he arrives, I would like to give you more details about our home hospital program research study.
        - This is a randomized study, which means by chance (similar to a coin flip), you {your loved one} will either be selected for standard admission or for the home hospital program:
        - Home hospital program: your {loved one’s} care will be in your {loved one’s} home with the following set of highly specialized services tailored to you {your loved one}:
            - In-home visit by a Brigham and Women’s physician at least once a day who is also available 24 hours every day by phone, video, or in-person.
            - In-home visit by a Partners nurse at least twice a day.
            - Remote wireless vital signs monitor (measuring things like your heart rate and breathing rate), heart rhythm monitoring, activity monitoring, and sleep monitoring
            - In-home intravenous infusions (for IV fluids or medications) as needed

- In-home testing: blood tests [faster than in the hospital], x-ray, ultrasound all in the home as needed
- We of course want you {your loved one} to eat home-cooked meals, but if that's not an option, we can provide food delivery as needed
- In-home personal home health aide and physical therapist as needed
- After assessing you {your loved one}, the attending will have a conversation with you {your loved one} regarding which services are best for you {your loved one}.

▪ Standard admission: your {loved one's} care will be delivered upstairs, just like normal. We will ask you {your loved one} to wear an activity tracker and will ask you {your loved one} questions at discharge and once you are home about your stay.

- What questions can I answer?
- While we are waiting for Home hospital attending, please review this consent form. I will be just outside if you have any questions.

Frequently asked questions

- Will I see the doctor more or less if I go home?
  - More. We only have up to 4 patients and always one doctor in the home hospital program at any one time, much better than in the hospital. Plus, you will have the direct phone number to Home hospital attending and direct video access at all hours of the day.
- What is the mortality rate?
  - The same as if had you been in the hospital, based on prior studies.
- Are pets at home a problem?
  - No.
- Will this cost more?
  - No. You will be expected to pay the same or less had you been in the hospital.
  - Follow-up: how will my insurance be billed?
    - Only a daily home visit will be billed. No medications or other hospital charges will be billed. The home hospital program grant will cover these costs.
- What if I don't use technology?
  - Not a problem. We can always use the telephone. Most of our technology requires little to no input from you.
- What are the benefits to home hospital?
  - Direct their attention to the consent form, where there is a list of benefits.
- What if there is a crisis (or emergency) at home?
  - In an absolute emergency, our protocol is to call 911. In an urgent situation, your home hospital nurse or doctor will be able to come to your home in under 20 minutes.
- What happens if I call 911?
  - Although we would like you to call us first because we will be able to come to your home quickly and know your case well, if you call 911 an ambulance will arrive and take you to the nearest emergency room, just like normal.
- Am I too sick for this?
  - We have selected you specifically based on risk scores and all of your clinical conditions. We would not have approached you had we thought you were too sick.
- Will this effect length of care (length of stay)?
  - When this has been done elsewhere, being home was associated with a shorter recovery time.
- Will I be hooked up to wires?
  - No. All of our monitoring equipment is wireless.
- Has this been done before? Where?
  - Yes, previous studies like this have shown equal safety, equal quality, and increased patient satisfaction. If requested, give article abstract.
  - Locations: Mt Sinai in New York City, University of Pennsylvania in Philadelphia, and others.
- Is it safe?

    - Yes, previous studies similar to this have shown equal safety. Only 1-5% of patients have to return to the hospital for additional care. In addition, we are using monitoring technology that we believe may add additional safety.
- What happens if I'm not comfortable with this and want to go back to the hospital once I'm home?
    - You, your family, your doctor, or your nurse can request that the study be stopped at any time. If this happens, you will be returned to the hospital.
- Where's the food from?
    - A non-profit organization Community Servings provides the food. It is tailored to your medical needs and is really quite delicious!

Confirmed participant ready for admission

- Mark when you begin enrollment
- Use Admission Worksheet and enter data in the Admission tab of data collection spreadsheet (on encrypted share drive).
    - Note that fields have details if you hover over the cell
- Open envelope to reveal randomization
    - If usual care
        - Ask ED attending to put in admission order
        - Notify hospitalist
        - Place vital patch
        - Visit patient upstairs to ensure tablet is plugged in at desk
    - If home
        - Determine transport needs with home hospital attending; if necessary call Fallon Ambulance to transport
            - Call 1-888-PHS-TRAN (1-888-141-8726)
            - Tell them this is a home hospital pilot patient
            - Later, send an email to Greg Davis (see Appendix)
        - Handoff
            - Ask ED nurse to call the on-call home hospital nurse
            - Ask ED PA/resident to call the on-call home hospital physician
        - Ask PA/resident to place discharge order
        - Discharge logistics
            - If necessary, obtain oxygen concentrator, nebulizer, walker, and/or commode from storage area
            - If necessary, obtain medications from ED pharmacy and package with patient
            - Place patient stickers in envelope
            - Complete ListRunner App entry
            - Complete Home Hospital EMR spreadsheet
                - Use report: Facesheet
            - Discuss with patient
                - Prepare all medications from around the house in one central location
                - Conceal any weapons
                - Leash or cage any pets
                - If living alone: keys to physician for safety at night

Discharge

Home hospital attending will call/text you when a patient is going to be discharged. Please do the following:

- "Hi [Mr/Ms patient's last name], this is [your full name], one of the home hospital program associates. Home hospital attending just told me you are being discharged. Congratulations, that is great! Glad to hear you are on the mend. To help us determine how successful the home hospital program has been, I have a few questions to ask; in total this should take 10 minutes. Is now a good time?
    - If so, use the discharge worksheet and enter data in the Discharge tab of data collection spreadsheet (on encrypted share drive).
    - If not, reschedule for another time, hopefully today.
    - If responses are contradictory, patient has diagnosis of dementia or another cognitive disorder, or patient is often unsure, ask permission to speak to the patient's family, friend, or health care proxy (okay to obtain a different phone number that the patient provides) in order to corroborate responses.
- At the end of the questionnaire, schedule a time around 30 days from discharge for a follow-up conversation. Put this date/time in the Post-Discharge tab of data collection spreadsheet (on encrypted share drive).
- Thank the patient profusely for their participation.

Post-Discharge

Call the patient on the scheduled date/time for a post-discharge follow-up. Please do the following:

- "Hi [Mr/Ms patient's last name], this is [your full name], one of the home hospital program associates. I am calling because when you were discharged you had said this might be a good time to ask some follow-up questions. I have only a few questions. Is now a good time?
    - If so, use the post-discharge worksheet and enter data in the Discharge tab of data collection spreadsheet (on encrypted share drive).
    - If not, reschedule for another time.
    - If responses are contradictory, patient has diagnosis of dementia or another cognitive disorder, or patient is often unsure, ask permission to speak to the patient's family, friend, or health care proxy (okay to obtain a different phone number that the patient provides) in order to corroborate responses.
- Thank the patient profusely for their participation.

Clinician Check-Ins

Each day you will obtain important quality data from the nurse and physician.

- Text the nurse/physician to make sure they are free and can start their check-in.
- Go through the Daily tab of data collection spreadsheet (on encrypted share drive).

Ordering Patient Food

Community Servings provides food for patients when needed. We will need your help to order it:

- Please send the following referral email:
  - To: lbronstein@servings.org; apyke@servings.org
  - CC: home hospital attending
  - Subject: BWH Home Hospital Referral **[send secure]**
  - Body:
    - Dear Andrea and Lindsay,
    - We have a referral for you!
    - Patient name:
    - Delivery address:
    - Contact phone # for delivery:
    - Delivery notes: <IE – door code, special instructions, alternate contact if different from patient>
    - Diet selection: <Choose 1: __Regular / __Diabetic / __Cardiac / __Vegetarian / __Soft>
    - Milk selection: <Choose 1: __Skim / __1% / __2% / __Lactaid / __No Milk>
- Delivery timing
  - Monday – Thursday, referrals received by 3pm will be delivered by 5pm to the patient's address. Referrals made after 3pm will be delivered the following day by approximately 11am.
  - Friday referrals made by 3pm will be delivered by 5pm. Referrals made after 3pm will need to be picked up Saturday at Community Servings by a member of the Home Hospital team and the meal bag will be ready by 11am for pick up.
  - Saturday referrals made by 12pm will be available for pick up between 2-3pm at Community Servings by a member of the Home Hospital team.
  - Referrals made after noon on Saturday and anytime on Sunday will be delivered on Monday by 11am.
  - Referrals made between Saturday October 8th after 12pm and Monday October 10th at 5pm will be delivered Tuesday Oct. 11th by 11am.
- Someone will need to be home to receive the delivery. We will not be able to leave the meal bag at the door of a patient for food safety reasons. If no one is home to receive the delivery, we will not be able to redeliver; however, a member of the home hospital team may pick up the bag at Community Servings by 5pm for a missed morning delivery or by 11am the following day for a missed afternoon delivery. The referral source will be notified by e-mail within 1 hour of a missed delivery.

Appendix

Exhibit 1. On-Call Schedule

Hospitalists

- Go to amion.com
- Enter hosp75
- Find “medicine consult”

Cardiology Fellows

- Go to ppd.partners.org
- Find B team and consult fellow and attending

Exhibit 2. Email to Fallon Ambulance

To: gdavis@fallonambulance.com
CC: dmlevine@partners.org; home hospital attending
Subject: Home Hospital Transfer Notification [send secure]
Body:
Dear Greg,

Fallon is assisting us in transporting the following patient home for home hospitalization. As requested, please do not bill the patient if insurance does not reimburse. Instead bill the home hospital program.

Date of Transport:
First Name:
Last Name:
DOB:

Thank you!

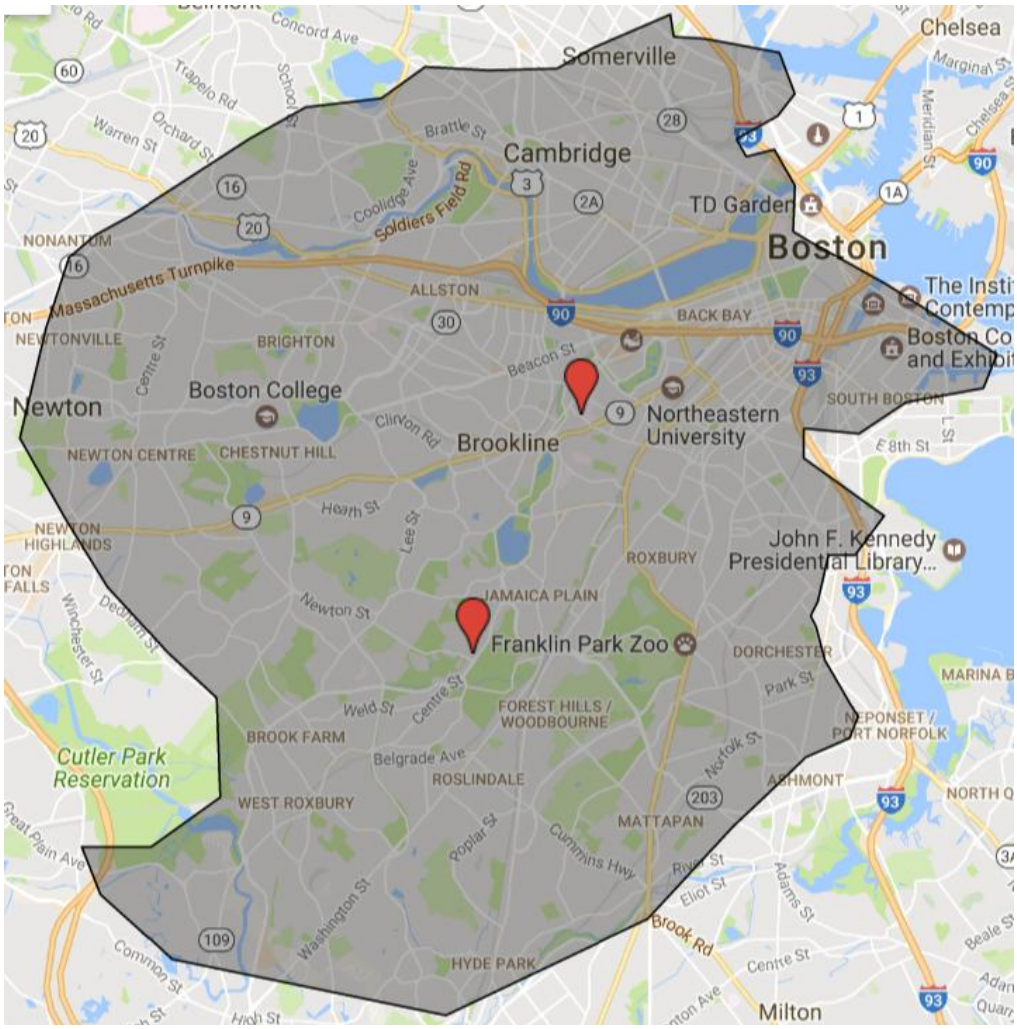
Sincerely,

[RA name]
Cell: [RA cell phone]

Exhibit 3. Laboratory Directions

Bring the sample(s) and requisition in a biohazard bag to the specimen drop off area as soon as you walk through the doors on Amory 2.

Figure 1. Approximate Catchment Area



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  - No.
- Will this cost more?
  - No. You will be expected to pay the same or less had you been in the hospital.
  - Follow-up: how will my insurance be billed?
    - Only a daily home visit will be billed. No medications or other hospital charges will be billed. The home hospital program grant will cover these costs.
- What if I don't use technology?
  - Not a problem. We can always use the telephone. Most of our technology requires little to no input from you.
- What are the benefits to home hospital?
  - Direct their attention to the consent form, where there is a list of benefits.
- What if there is a crisis (or emergency) at home?
  - In an absolute emergency, our protocol is to call 911. In an urgent situation, your home hospital nurse or doctor will be able to come to your home in under 20 minutes.
- What happens if I call 911?
  - Although we would like you to call us first because we will be able to come to your home quickly and know your case well, if you call 911 an ambulance will arrive and take you to the nearest emergency room, just like normal.
- Am I too sick for this?
  - We have selected you specifically based on risk scores and all of your clinical conditions. We would not have approached you had we thought you were too sick.
- Will this effect length of care (length of stay)?
  - When this has been done elsewhere, being home was associated with a shorter recovery time.
- Will I be hooked up to wires?
  - No. All of our monitoring equipment is wireless.
- Has this been done before? Where?
  - Yes, previous studies like this have shown equal safety, equal quality, and increased patient satisfaction. If requested, give article abstract.
  - Locations: Mt Sinai in New York City, University of Pennsylvania in Philadelphia, and others.
- Is it safe?

    - Yes, previous studies similar to this have shown equal safety. Only 1-5% of patients have to return to the hospital for additional care. In addition, we are using monitoring technology that we believe may add additional safety.
- What happens if I'm not comfortable with this and want to go back to the hospital once I'm home?
    - You, your family, your doctor, or your nurse can request that the study be stopped at any time. If this happens, you will be returned to the hospital.
- Where's the food from?
    - A non-profit organization Community Servings provides the food. It is tailored to your medical needs and is really quite delicious!

Confirmed participant ready for admission

- Mark when you begin enrollment
- Use Admission Worksheet and enter data in the Admission tab of data collection spreadsheet (on encrypted share drive).
    - Note that fields have details if you hover over the cell
- Open envelope to reveal randomization
    - If usual care
        - Ask ED attending to put in admission order
        - Notify hospitalist
        - Place vital patch
        - Visit patient upstairs to ensure tablet is plugged in at desk
    - If home
        - Determine transport needs with home hospital attending; if necessary call Fallon Ambulance to transport
            - Call 1-888-PHS-TRAN (1-888-141-8726)
            - Tell them this is a home hospital pilot patient
            - Later, send an email to Greg Davis (see Appendix)
        - Handoff
            - Ask ED nurse to call the on-call home hospital nurse
            - Ask ED PA/resident to call the on-call home hospital physician
        - Ask PA/resident to place discharge order
        - Discharge logistics
            - If necessary, obtain oxygen concentrator, nebulizer, walker, and/or commode from storage area
            - If necessary, obtain medications from ED pharmacy and package with patient
            - Place patient stickers in envelope
            - Complete ListRunner App entry
            - Complete Home Hospital EMR spreadsheet
                - Use report: Facesheet
            - Discuss with patient
                - Prepare all medications from around the house in one central location
                - Conceal any weapons
                - Leash or cage any pets
                - If living alone: keys to physician for safety at night

Discharge

Home hospital attending will call/text you when a patient is going to be discharged. Please do the following:

- "Hi [Mr/Ms patient's last name], this is [your full name], one of the home hospital program associates. Home hospital attending just told me you are being discharged. Congratulations, that is great! Glad to hear you are on the mend. To help us determine how successful the home hospital program has been, I have a few questions to ask; in total this should take 10 minutes. Is now a good time?
    - If so, use the discharge worksheet and enter data in the Discharge tab of data collection spreadsheet (on encrypted share drive).
    - If not, reschedule for another time, hopefully today.
    - If responses are contradictory, patient has diagnosis of dementia or another cognitive disorder, or patient is often unsure, ask permission to speak to the patient's family, friend, or health care proxy (okay to obtain a different phone number that the patient provides) in order to corroborate responses.
- At the end of the questionnaire, schedule a time around 30 days from discharge for a follow-up conversation. Put this date/time in the Post-Discharge tab of data collection spreadsheet (on encrypted share drive).
- Thank the patient profusely for their participation.

Post-Discharge

Call the patient on the scheduled date/time for a post-discharge follow-up. Please do the following:

- "Hi [Mr/Ms patient's last name], this is [your full name], one of the home hospital program associates. I am calling because when you were discharged you had said this might be a good time to ask some follow-up questions. I have only a few questions. Is now a good time?
    - If so, use the post-discharge worksheet and enter data in the Discharge tab of data collection spreadsheet (on encrypted share drive).
    - If not, reschedule for another time.
    - If responses are contradictory, patient has diagnosis of dementia or another cognitive disorder, or patient is often unsure, ask permission to speak to the patient's family, friend, or health care proxy (okay to obtain a different phone number that the patient provides) in order to corroborate responses.
- Thank the patient profusely for their participation.

Clinician Check-Ins

Each day you will obtain important quality data from the nurse and physician.

- Text the nurse/physician to make sure they are free and can start their check-in.
- Go through the Daily tab of data collection spreadsheet (on encrypted share drive).

Ordering Patient Food

Community Servings provides food for patients when needed. We will need your help to order it:

- Please send the following referral email:
  - To: lbronstein@servings.org; apyke@servings.org
  - CC: home hospital attending
  - Subject: BWH Home Hospital Referral **[send secure]**
  - Body:
    - Dear Andrea and Lindsay,
    - We have a referral for you!
    - Patient name:
    - Delivery address:
    - Contact phone # for delivery:
    - Delivery notes: <IE – door code, special instructions, alternate contact if different from patient>
    - Diet selection: <Choose 1: __Regular / __Diabetic / __Cardiac / __Vegetarian / __Soft>
    - Milk selection: <Choose 1: __Skim / __1% / __2% / __Lactaid / __No Milk>
- Delivery timing
  - Monday – Thursday, referrals received by 3pm will be delivered by 5pm to the patient's address. Referrals made after 3pm will be delivered the following day by approximately 11am.
  - Friday referrals made by 3pm will be delivered by 5pm. Referrals made after 3pm will need to be picked up Saturday at Community Servings by a member of the Home Hospital team and the meal bag will be ready by 11am for pick up.
  - Saturday referrals made by 12pm will be available for pick up between 2-3pm at Community Servings by a member of the Home Hospital team.
  - Referrals made after noon on Saturday and anytime on Sunday will be delivered on Monday by 11am.
  - Referrals made between Saturday October 8th after 12pm and Monday October 10th at 5pm will be delivered Tuesday Oct. 11th by 11am.
- Someone will need to be home to receive the delivery. We will not be able to leave the meal bag at the door of a patient for food safety reasons. If no one is home to receive the delivery, we will not be able to redeliver; however, a member of the home hospital team may pick up the bag at Community Servings by 5pm for a missed morning delivery or by 11am the following day for a missed afternoon delivery. The referral source will be notified by e-mail within 1 hour of a missed delivery.

Appendix

Exhibit 1. On-Call Schedule

Hospitalists

- Go to amion.com
- Enter hosp75
- Find “medicine consult”

Cardiology Fellows

- Go to ppd.partners.org
- Find B team and consult fellow and attending

Exhibit 2. Email to Fallon Ambulance

To: gdavis@fallonambulance.com
CC: dmlevine@partners.org; home hospital attending
Subject: Home Hospital Transfer Notification [send secure]
Body:
Dear Greg,

Fallon is assisting us in transporting the following patient home for home hospitalization. As requested, please do not bill the patient if insurance does not reimburse. Instead bill the home hospital program.

Date of Transport:
First Name:
Last Name:
DOB:

Thank you!

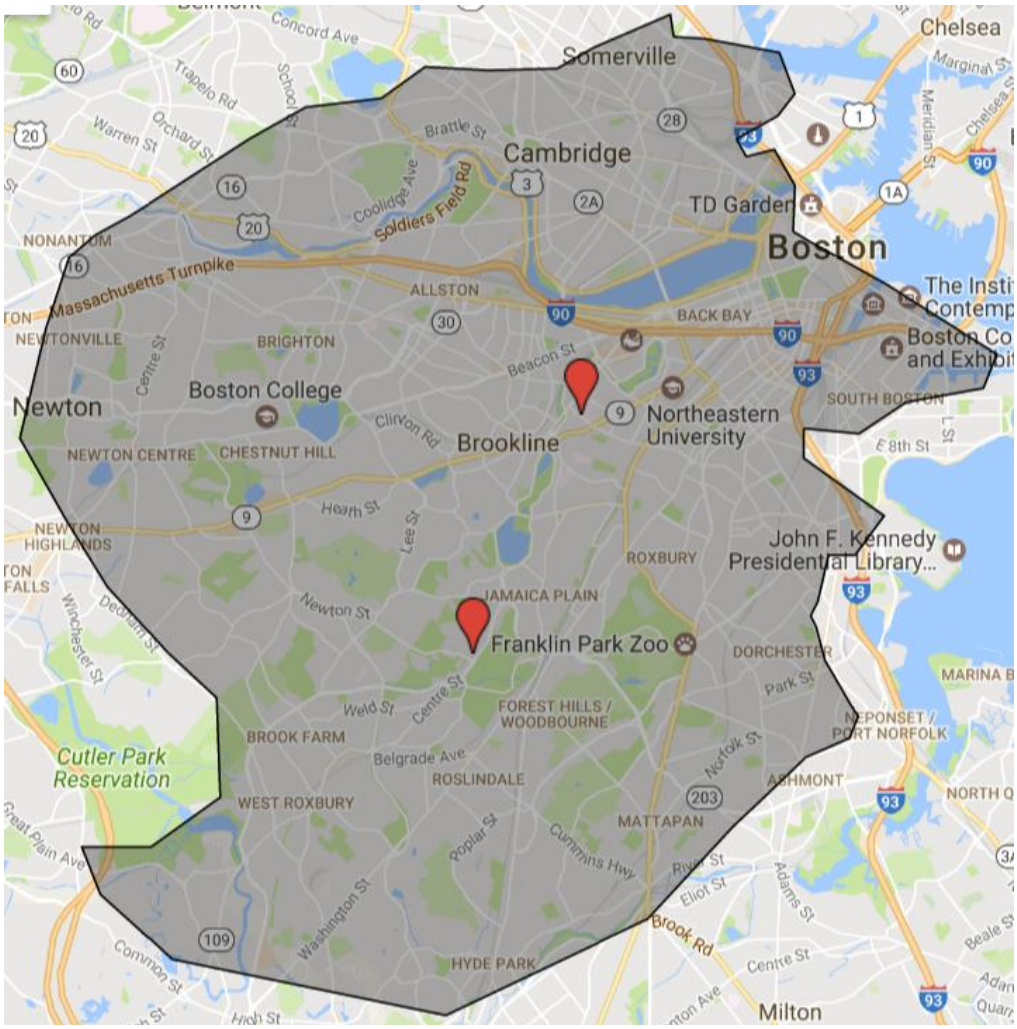
Sincerely,

[RA name]
Cell: [RA cell phone]

Exhibit 3. Laboratory Directions

Bring the sample(s) and requisition in a biohazard bag to the specimen drop off area as soon as you walk through the doors on Amory 2.

Figure 1. Approximate Catchment Area



Explanation of and rationale for changes

To selection criteria:

- Add 20-minute driving radius: we found that estimating the driving time, rather than the distance, was more important during our initial pilot and ensured we could arrive at a patient's home in a safe amount of time.
- Add patients who can assent with HCP consent: throughout the pilot, we were unable to enroll patients with dementia. Previous published home hospital programs have all enrolled such patients without safety issues. We believe these patients would be well-served remaining at home and receiving acute-care services in their home. We were asked to initially begin conservatively, with the potential to enroll these patients after experience with this protocol. We would now like to add these patients with the additional safeguard of providing a full-time home health aide for patients who do not have family in the home.
- Add diagnoses
    - Chronic kidney disease (CKD): patients with CKD often require diuretic adjustment and monitoring, all of which can be provided at home.
    - Diabetes and its complications: insulin titration and diabetic infections can all be provided for at home with the existing exclusion criteria in place (e.g., need for MRI).
    - Gout flare: we are able to provide NSAID-based pain control, steroids, and physical therapy often required in these attacks.
    - Hypertensive urgency: blood pressure medication titration can be performed at home
    - Atrial fibrillation with rapid ventricular response: cardiac monitoring and medication titration can be performed at home.
    - Anticoagulation needs: all anticoagulants, telemetry, and monitoring can be provided for at home.
- Remove "uninsured." With our current funding, this is not an issue.
- Remove "cared for by a private PCP..." The main PCP group that was previously a concern wants the option to participate in home hospital.
- Remove active cancer: in collaboration with oncology, we will provide oncology patient care at home, maintaining all of the exclusion criteria.
- Add intravenous: we will add the ability to prescribe PO narcotics, but not IV narcotics.
- Delete paced rhythm: this was a prior concern of our telemetry algorithm but is no longer an issue.
- Delete >20lbs of weight... In consultation with our cardiology colleagues, we would like to remove this. It is often difficult to ascertain, and it is not as powerful a marker of acuity as we would have hoped.
- Add various exclusion criteria: these are to ensure we are bringing home patients who do not have a high acuity level and are in line with prior home hospital programs.

To Instruments:

- Add staff burnout survey
    - Voluntary survey of all home hospital staff, to be used to further improve staff processes and the culture of the team.

To home hospital care team:

- Add community health worker (CHW): a trained and certified lay person who often shares culture and/or community with the patient. The CHW strives to improve familiarity with the

plan of care, improve adherence to the plan of care (medications, appointments), improve clinical outcomes, and help the patient manage social barriers to care (e.g., applying for medication financial assistance). The CHW will make once daily visits during the admission and twice weekly visits after discharge for 30 days. The CHW will have no role in providing medical decision-making or in nursing care.

- Add community paramedic: a command leader paramedic will provide in-home coverage from 6p-8a (when the nurse is not on duty). If a need arises in the off-hours that requires in-person assistance, the home hospital attending can dispatch the paramedic at their discretion with specific instructions. The paramedic will always consult the attending once on-site, often with the use of a video visit. The paramedic can give medications under the direction of the attending should it be in the patient's best interests.

- Add medical resident: a BWH PGY2 or PGY3 in internal medicine will have the option to select home hospital service as a two-week elective. They will attend a home hospital training and continue to have twice-weekly home-based medicine seminars throughout. Their role includes daily rounds for supervised medical decision-making, responses to patient needs, and documentation. They will always have to travel with another team member when visiting a patient's home. The home hospital attending will supervise the resident through direct observation and making addendums to documentation.

To monitoring capability:

- Option to use the Vital Connect HealthPatch, which has improved blue-tooth range that becomes useful for obese patients and thick-walled homes (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])

To analysis:

- We *a priori* plan to perform a subgroup analysis that does not involve any outlier participants in either study arm, should this occur. We also *a priori* plan subgroup analyses by diagnosis, by age group, by disposition, and by daily activity level. We also *a priori* plan to analyze our outcomes with means, but also with median and interquartile ranges, which are less subject to outlier effects. We may choose to employ non-parametric tests of significance should our data be nonparametric.

Explanation of and rationale for changes

To selection criteria:

- Add 20-minute driving radius: we found that estimating the driving time, rather than the distance, was more important during our initial pilot and ensured we could arrive at a patient's home in a safe amount of time.
- Add patients who can assent with HCP consent: throughout the pilot, we were unable to enroll patients ~~who presented mildly altered or~~ with dementia. Previous published home hospital programs have all enrolled such patients without safety issues. We believe these patients would be well-served remaining at home and receiving acute-care services in their home. We were asked to initially begin conservatively, with the potential to enroll these patients after experience with this protocol. We would now like to add these patients with the additional safeguard of providing a full-time home health aide for patients who do not have family in the home.
- Add diagnoses
    - Chronic kidney disease (CKD): patients with CKD often require diuretic adjustment and monitoring, all of which can be provided at home.
    - Diabetes and its complications: insulin titration and diabetic infections can all be provided for at home with the existing exclusion criteria in place (e.g., need for MRI).
    - Gout flare: we are able to provide NSAID-based pain control, steroids, and physical therapy often required in these attacks.
    - Hypertensive urgency: blood pressure medication titration can be performed at home
    - Atrial fibrillation with rapid ventricular response: cardiac monitoring and medication titration can be performed at home.
    - Anticoagulation needs: all anticoagulants, telemetry, and monitoring can be provided for at home.
    - ~~Surgical monitoring: laboratory and surgical wound monitoring can be provided for at home.~~
- Remove "uninsured." With our current funding, this is not an issue.
- Remove "cared for by a private PCP..." The main PCP group that was previously a concern wants the option to participate in home hospital.
- Remove active cancer: in collaboration with oncology, we will provide oncology patient care at home, maintaining all of the exclusion criteria.
- Add intravenous: we will add the ability to prescribe PO narcotics, but not IV narcotics.
- Delete paced rhythm: this was a prior concern of our telemetry algorithm but is no longer an issue.
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To monitoring capability:

- Option to use the Vital Connect HealthPatch, which has improved blue-tooth range that becomes useful for obese patients and thick-walled homes (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])

To analysis:

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IRB Review for Experimental Devices Containing Wireless and Radio Components

Investigation Title: Hospitalization at Home: The Acute Care Home Hospital Program for Adults	Principle Investigator: Schnipper, Jeffrey	Protocol Number: 2016P001337
Version: 4	Version Date: 10/5/16	Primary Contact: David Levine

1) Overview:
   a) The primary goal of the protocol is to accomplish a 20% reduction in hospitalization cost for selected hospitalized adults who would normally have been admitted to the hospital.
   b) Patients who meet the inclusion/exclusion criteria and are randomized to return home will receive the home hospital module, which consists of staff (MD, RN, case manager), diagnostics (blood tests, vital signs, telemetry, x-ray, and ultrasound), intravenous therapy, and oxygen/nebulizer therapy. On patient-tailored basis, it can also include food, home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and/or social worker.
      i) Exclusion criteria does not include patients with pacemakers or other implanted/body-worn medical devices.
   c) Each day, the home hospital team will make visits to the patient's home. These are personnel who have been trained in home health and carry out home health as per the usual care they deliver. The home hospital module offers most of the same medical components that are standard of care in an acute care hospital. The typical staff (MD, RN, case manager), diagnostics (blood tests, vital signs, telemetry, x-ray, and ultrasound), intravenous therapy, and oxygen/nebulizer therapy will all be available for home hospital. Optional deployment of a food, home health aide, physical therapist, occupational therapist, community health worker, community paramedic, and social worker will be tailored to patient need.
   d) Documentation by RN and MD will occur via intake notes, daily progress notes, and discharge notes that will be compiled (on a Partners secure share-drive) and uploaded as a pdf document to the patient's chart upon discharge. In addition, each day an outpatient MD note, lab orders, and pharmacy orders will be written in Epic by the MD. When available, the study will be able to transition to complete Epic integration, such that the daily notes completed and stored on the share-drive will no longer be necessary.
   e) Safety ensured through
      i) Participant is pre-screened by a research assistant for primary diagnosis, age, and residence within 5 miles or 20 minute drive via the electronic medical record.
      ii) Continuous vital signs and activity monitoring
      iii) A patient or clinician can initiate a video or in-person visit at any time.
      iv) Telepresence: on-demand video visits between patient and clinician 24 hours a day, 7 days a week;
      v) Remote wireless vital sign monitoring: mobile alerts and smart algorithms trigger video or in-person visits;
   f) Equipment to be used:
      i) Wireless:
         (1) VitalConnect VitalPatch
         (2) VitalConnect HealthPatch MD
         (3) Samsung Tab E
      ii) Non-wireless:

(1) Ambulatory infusion pump: Smiths Medical CADD SOLIS VIP
(2) Point of care diagnostic meter: Abbott iSTAT

2) List each wireless devices and components:
   a) VitalConnect Inc.
      224 Airport Parkway, Suite 300
      San Jose, CA 95110
      TEL: (408) 963-4600
      info@vitalconnect.com
      www.vitalconnect.com
      i) Vital Connect Inc.
         900 East Hamilton Ave. Suite 500
         Campbell, CA 95008
      ii) Vital Connect Inc. Grantee Code: SPO
         https://apps.fcc.gov/oetcf/eas/reports/GenericSearchResult.cfm?RequestTimeout=500
   b) VitalPatch
      i) FCC Regulatory Information
         (1) FCC ID: SPO-VCI-VP1
         (2) Bluetooth: BT4.1
         (3) Transmit power: ≤ 10dbm
      ii) Security:
         (1) Bluetooth Low Energy (BLE) [NIST recommends Mode1 Level 3 for BLE]
         (2) Security mode: 1
         (3) Security level: 3
         (4) Bluetooth profiles: Custom profile used only for their patch devices
         (5) Pairing Method/Patch Authentication:
            (a) Authentication between the Patch and the Relay (Phone or Tablet) is achieved using a challenge-response scheme with HMAC based One-Time-Password algorithm (HOTP).
            (b) Once authenticated all sensor data is encrypted.
            (c) The authentication is based on a pre-shared secret key between the Patch and Relay.
         (6) Data Encryption:
            (a) Encryption of data between the Patch and Relay is provided using a Counter with Cipher Block Chaining-Message Authentication (CCM) mode in conjunction with AES-128 block cipher.
            (b) This layer of encryption is above (and in addition to) the encryption provided by the Bluetooth LE (BLE) standard and encrypts the sensor data packets as compared to the BLE standard providing encryption at the BLE link layer.
      iii) FDA Regulatory Information
         (1) FDA 510(k) Number: K152139
            (a) Proprietary Name: HealthPatch MD; VitalConnect Platform; VitalPatch
            (b) Classification Product Code: DRG
               (i) Sec. 870.2910 Radiofrequency physiological signal transmitter and receiver.
               (ii) Decision Date: 12/06/2015
            (c) Subsequent Product Codes: DSI
               (i) Device: detector and alarm, arrhythmia
               (ii) Sec. 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).

(d) Subsequent Product Codes: MHX
(i) Device: monitor, physiological, patient(with arrhythmia detection or alarms)
(ii) Sec. 870.1025 Arrhythmia detector and alarm (including ST-segment measurement and alarm).
(2) Vital signs monitoring patch: Vital Connect VitalPatch (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])

c) HealthPatch
i) FCC ID: SPO-VCI-Module
ii) The HealthPatch uses a slightly higher-gain antenna; 4 dBm vs. 0 dBm for VitalPatch
iii) The researchers reserve the option to use the Vital Connect HealthPatch, which has improved blue-tooth range that becomes useful for obese patients and thick-walled homes (FDA cleared application/use, except arrhythmia detection and predictive analytics [cleared for home-based patients but not hospital-based patients])
iv) FDA regulatory information same as for VitalPatch

d) Samsung Tab E
i) FCC ID: A3LSMT377A

3) Areas of Concern
a) Diagnostic and/or therapeutic decisions
i) The wireless medical devices will be used for remote monitoring and indicate need for diagnostic and therapeutic decisions.
ii) Clinicians will perform in-person assessments of patients when before acting upon results of remote monitoring.

b) FCC Regulations
i) All wireless devices have FCC approval and have been issued FCC ID numbers.

c) Radio Frequency (RF) Safety
i) Since all devices have FCC IDs, each should meet requirements for occupational exposure and Specific Absorption Rate.

d) FDA Regulations
i) The VitalPatch and VitalHealth monitoring patches are regulated by the FDA.
ii) Other, non-wireless medical devices, e.g. Smiths Medical CADD SOLIS VIP ambulatory infusion pump and Abbott iSTAT point of care diagnostic meter, will be used.
iii) Protocol indicates all medical devices will be used within their intended use.
iv) Protocol includes multiple actions/strategies to mitigate patient safety risks from wireless and medical device failure.
v) VitalPatch/HealthPatch User Manuals contain the following information/notifications:
(1) Contraindications:
(a) The device is not intended for use on users who have implanted defibrillators or pacemakers.
(b) The device is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis.
(2) Warnings:
(a) Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous or real-time monitoring. Data will be stored on the VitalConnect Sensor module for transfer once connectivity is reestablished.
(3) Precautions:

(a) Healthcare providers must be aware if uninterrupted continuous data monitoring is necessary for patient safety, treatment in home setting may not be appropriate. If considered medically necessary, additional measures may be taken to ensure appropriate care and monitoring is provided to meet the clinical need.
(b) If connected to other devices/system through the same user interface (i.e. mobile phone), while connected to the VitalConnect System via a Bluetooth connection, please note that performance of either or both Bluetooth connected devices/system could potentially be affected.
(c) Similar devices may cause signal interference during data transmission. If you experience this affect, steer clear of interfering devices.

e) RF Interference potential
   i) The subjects will use a smartphone, wireless and non-wireless medical devices in their homes.
      (1) Study staff should educate patients that while the probability of interference to other medical devices is very low, they should keep the smartphone at least 3 feet from any medical device in the household. They should also contact the study staff if they notice unusual behavior of any medical device they believe may be caused by the smartphone. See Resources List.
   ii) The study staff may use these wireless devices in the clinical setting to educate the patients in their proper use.
      (1) Study staff should review and adhere to hospital policy on the use of wireless devices in proximity to electronic medical devices. See Resources List.

f) Data Security
   i) PHI/PII is collected with and stored in the wireless medical devices during the study.
   ii) Data is encrypted before being passed via Bluetooth to the Samsung Tab E and via the cellular network to the VisIQ servers.
   iii) Samsung Tab E will need to be encrypted, according to PHS security policies. See Resources List.
   iv) Bluetooth security meets or exceeds NIST SP800-121R1 recommendations.
   v) Wireless devices will be used in patient's/study subject's homes and will not connect directly to the PHS networks.
   vi) Maureen Buck will complete Information Security assessment.

4) Resources
   a) Hospital policies:
      i) BWH:
         (1) https://hospitalpolicies.ellucid.com/documents/view/10038
         (2) https://hospitalpolicies.ellucid.com/documents/view/2673
   b) Research Information Security Office Review/BYOD Encryption – Open up a ticket in ServiceNOW for the "enterprise mobility management - phs" queue. (riso@partners.org)
      i) For this study, Maureen Buck will address the requirement. (Buck, Maureen E.)
   c) FDA
      i) Wireless Medical Devices http://www.fda.gov/medicaldevices/digitalhealth/wirelessmedicaldevices/default.htm
      i) Cutting the Wires: FDA Provides Industry Guidance http://blogs.fda.gov/fdavoice/index.php/tag/wireless-medical-devices/

5) Summary:
   a) There are diagnostic and therapeutic components to this protocol.

i) There should be minimal/acceptable patient safety risks associated with the use of the described wireless devices in this study.
ii) Protocol includes multiple actions/strategies to mitigate patient safety risks from wireless and medical device failure.

b) Since all wireless devices have been approved by the FCC and FDA, there should be minimal/acceptable interference risks when the following are accomplished:
i) BWH Hospital policies for use of cellular phones and electronic devices apply when these devices are used in the hospital for patient education. See Resources section.
ii) Research staff should follow VitalConnect User Instructions and exclude from the study any individuals with pacemakers, defibrillators and other implanted and body-worn electronic medical devices.
iii) Research staff should review the appropriate policies to reduce interference risks to devices not considered by the protocol. See Resources section.
iv) Research staff should educate patients that while the probability of interference to other medical devices is very low, they should keep the smartphone at least 3 feet from any medical device in the household. The patients should also contact the study staff if they notice unusual behavior of any medical device they believe may be caused by the smartphone. See Resources List.

c) Data security risks from the wireless devices should be minimal/acceptable. PHI/PII is being collected, stored or transmitted by the devices being used. The required Bluetooth and cellular links use encryption and authentication meeting or exceeding NIST recommendations.

d) The researchers should contact Maureen Buck in Information Security for completion and documentation of a security audit according to Partners HealthCare policies.

6) Reviewer: Rick Hampton, Wireless Communications Manager, PHS IS
7) Date: 3/10/2017

About this consent form

Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital (within 5 miles) and have a diagnosis of either cellulitis, pneumonia, complicated urinary tract infection, or heart failure. The research doctors consider these health problems safe to take care of at home.

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Informed Consent and Authorization

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_____ _____ _____

Date Time (optional)

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Adult Date Time (optional)

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Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine 9/28/16

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

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Version 2, July 26, 2016

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(see brief consent) _____ _____ _____

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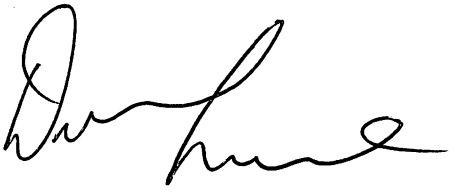

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10/1/16 — Date
_____ — Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ — Hospital Medical Interpreter
_____ — Date
_____ — Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

[redacted]

_____ — Time (optional)

Título del estudio de investigación (*Title of Research Study*):
Hospital en casa: Programa de hospital para adultos

Investigador principal (*Principal Investigator*):
Jeffrey Schnipper, MD MPH

CONSENTIMIENTO A PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Consent to participate in research - Spanish

Se le está pidiendo que participe en un estudio de investigación.

Antes de que usted acceda a participar, el investigador tienen que informarle de:

i) los propósitos, los procedimientos y la duración del estudio;
ii) los procedimientos que sean experimentales;
iii) los riesgos, molestias o beneficios de la investigación, que sean razonablemente previsibles;
iv) procedimientos o tratamientos alternativos que sean potencialmente beneficioso; y de
v) qué medidas se tomarán para proteger el carácter confidencial de la información.

Si aplica, el investigador también tiene que informarle sobre:

i) cualquier tipo de recompensa o de tratamiento médico que esté disponible en caso de lesión;
ii) cualquier posibilidad de riesgos que no se puedan anticipar;
iii) circunstancias bajo las cuales el investigador podría descontinuar su participación en el estudio;
iv) cualquier gasto adicional que usted pueda tener;
v) qué ocurre si usted decide descontinuar su participación;
vi) cuándo se le informará sobre nuevos hallazgos que pudieran afectar su voluntad de participar;
vii) cuántas personas participarán en el estudio.

Si usted accede a participar, el investigador tiene que entregarle una copia firmada de este documento y, por escrito, un resumen de la investigación.

Si tiene preguntas sobre el estudio puede comunicarse en cualquier momento con
David Levine MD MPH, llamando al teléfono 617.278.0639
(Name of contact for questions about study) *(Telephone)*

Si tiene preguntas sobre sus derechos al participar en un estudio (al ser sujeto de estudio), o sobre qué hacer si sufre alguna lesión, puede comunicarse en cualquier momento con:
Partners Human Research Committee office, llamando al teléfono 617-424-4100.
(Name of contact for questions about rights or injury) *(Telephone)*

Su participación en el estudio es voluntaria, y no será sancionado ni perderá prestaciones si rehúsa participar o si decide descontinuar su participación en el estudio de investigación.

Al firmar este documento da fe de que el estudio de investigación, incluyendo la información enumerada [redacted] scrito verbalmente y que usted accede voluntariamente a participar.

Firma del participante
Participant's signature

10/1/16
Fecha
Date

Firma del intérprete
Signature of Interpreter

Fecha
Date

1/16

Signature of Non-Interpreter Witness

About this consent form

Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital (within 5 miles) and have a diagnosis of either cellulitis, pneumonia, complicated urinary tract infection, or heart failure. The research doctors consider these health problems safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. About 60 patients will take part in this study at Brigham and Women's Hospital.

The majority of this study is funded by Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are providing the hardware for this study free of charge.

How long will I take part in this research study?

Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission. Each day, our home hospital team will make several visits to your home.

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

What will happen in this research study?

This is a randomized study, which means we will assign you by chance (like a coin toss) to the Home Hospitalization group or the Standard Admission group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the Home Hospitalization group You will have a 1 in 2 chance of being assigned to the Standard Admission group.

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    - About 16 subjects patients to every 1 MD

- **Home hospital:** your care will be in your home with a set of services tailored to your medical needs:
    - In-home visit by a Brigham and Women's physician at least once a day
        - Available 24 hours every day by video, phone, or in-person
    - In-home Partners nurse at least twice a day
    - Remote wireless vital signs (such as heart rate), telemetry (your heart's rhythm), activity, and sleep monitoring
    - In-home intravenous infusions (for IV fluids or medications) as needed
    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, and social worker as medically needed
    - About 4 subject patients to every 1 MD

Whether or not you are assigned to receive care at Brigham and Women's Hospital or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

What are the risks and possible discomforts from being in this research study?

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child/elder/disabled abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
    - Eat your own food
    - Sleep in your own bed
    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
  - Continuous (around the clock) vital signs, telemetry (heart rhythm patterns), and physical activity tracking;
  - Video visits with physician;
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We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if

appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

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Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

Informed Consent and Authorization

Signature of Subject:

[redacted] ny health information to

[redacted]

_____
Time (optional)

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Adult	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

David Levine

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine | 10/6/16 | _____
Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

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Informed Consent and Authorization

[redacted] health information to

_____
Time (optional)

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Adult	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine | 10/14/16 | _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

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Name | Date | Time (optional)

Version 2, July 26, 2016

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- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
  - Continuous (around the clock) vital signs, telemetry (heart rhythm patterns), and physical activity tracking;
  - Video visits with physician;
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We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
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You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if

appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

If I have questions or concerns about this research study, whom can I call?

Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

(see brief consent) _____ _____ _____

Subject Date Time (optional)

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

_____ _____ _____

Adult Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent: 

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine | 10/17/16 | _____
Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ | _____ | _____
Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

[redacted] | 10/17/16 | _____
Date | Time (optional)

Título del estudio de investigación (*Title of Research Study*):
Hospital en casa: Programa de hospital para adultos

Investigador principal (*Principal Investigator*):
Jeffrey Schnipper, MD MPH

CONSENTIMIENTO A PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Consent to participate in research - Spanish

Se le está pidiendo que participe en un estudio de investigación.

Antes de que usted acceda a participar, el investigador tienen que informarle de:

i) los propósitos, los procedimientos y la duración del estudio;
ii) los procedimientos que sean experimentales;
iii) los riesgos, molestias o beneficios de la investigación, que sean razonablemente previsibles;
iv) procedimientos o tratamientos alternativos que sean potencialmente beneficioso; y de
v) qué medidas se tomarán para proteger el carácter confidencial de la información.

Si aplica, el investigador también tiene que informarle sobre:

i) cualquier tipo de recompensa o de tratamiento médico que esté disponible en caso de lesión;
ii) cualquier posibilidad de riesgos que no se puedan anticipar;
iii) circunstancias bajo las cuales el investigador podría descontinuar su participación en el estudio;
iv) cualquier gasto adicional que usted pueda tener;
v) qué ocurre si usted decide descontinuar su participación;
vi) cuándo se le informará sobre nuevos hallazgos que pudieran afectar su voluntad de participar;
vii) cuántas personas participarán en el estudio.

Si usted accede a participar, el investigador tiene que entregarle una copia firmada de este documento y, por escrito, un resumen de la investigación.

Si tiene preguntas sobre el estudio puede comunicarse en cualquier momento con
David Levine, MD MPH, llamando al teléfono 617.278.0639
(Name of contact for questions about study) *(Telephone)*

Si tiene preguntas sobre sus derechos al participar en un estudio (al ser sujeto de estudio), o sobre qué hacer si sufre alguna lesión, puede comunicarse en cualquier momento con:
Partners Human Research Committee office, llamando al teléfono 617-424-4100.
(Name of contact for questions about rights or injury) *(Telephone)*

Su participación en el estudio es voluntaria, y no será sancionado ni perderá prestaciones si rehúsa participar o si decide descontinuar su participación en el estudio de investigación.

Al firmar este documento da fe de que el estudio de investigación, incluyendo la información enumerada [redacted] iamente a participar.

[redacted] 1/9/2016

[redacted]
Date

Spanish

Firma del intérprete
Signature of Interpreter

Fecha
Date

O

[redacted]érprete

Fecha
Date

10/17/16

About this consent form

Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital (within 5 miles) and have a diagnosis of either cellulitis, pneumonia, complicated urinary tract infection, or heart failure. The research doctors consider these health problems safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. About 60 patients will take part in this study at Brigham and Women's Hospital.

The majority of this study is funded by Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are providing the hardware for this study free of charge.

How long will I take part in this research study?

Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission. Each day, our home hospital team will make several visits to your home.

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

What will happen in this research study?

This is a randomized study, which means we will assign you by chance (like a coin toss) to the Home Hospitalization group or the Standard Admission group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the Home Hospitalization group You will have a 1 in 2 chance of being assigned to the Standard Admission group.

- **Standard admission:** your care will be just like normal at Brigham and Women's Hospital. Our research team will ask that you wear an activity tracker and will ask you questions about your hospital stay.
    - About 16 subjects patients to every 1 MD

- **Home hospital:** your care will be in your home with a set of services tailored to your medical needs:
    - In-home visit by a Brigham and Women's physician at least once a day
        - Available 24 hours every day by video, phone, or in-person
    - In-home Partners nurse at least twice a day
    - Remote wireless vital signs (such as heart rate), telemetry (your heart's rhythm), activity, and sleep monitoring
    - In-home intravenous infusions (for IV fluids or medications) as needed
    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, and social worker as medically needed
    - About 4 subject patients to every 1 MD

Whether or not you are assigned to receive care at Brigham and Women's Hospital or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

What are the risks and possible discomforts from being in this research study?

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child/elder/disabled abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
    - Eat your own food
    - Sleep in your own bed
    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
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  - Fewer health care associated infections
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What other treatments or procedures are available for my condition?

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Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

[redacted]

_____
Time (optional)

[redacted]formation to be used

[redacted]

_____
Time (optional)

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Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Lawe — 10/17/16 — _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

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Hospital Medical Interpreter | Date | Time (optional)

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Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to

[redacted]

_____
Time (optional)

[redacted]formation to be used

[redacted]

_____
Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine	10/23/16	
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

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Name	Date	Time (optional)

Version 2, July 26, 2016

Título del estudio de investigación (*Title of Research Study*):
Hospital en casa: Programa de hospital para adultos

Investigador principal (*Principal Investigator*):
Jeffrey Schnipper, MD MPH

CONSENTIMIENTO A PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Consent to participate in research - Spanish

Se le está pidiendo que participe en un estudio de investigación.

Antes de que usted acceda a participar, el investigador tienen que informarle de:

i) los propósitos, los procedimientos y la duración del estudio;
ii) los procedimientos que sean experimentales;
iii) los riesgos, molestias o beneficios de la investigación, que sean razonablemente previsibles;
iv) procedimientos o tratamientos alternativos que sean potencialmente beneficioso; y de
v) qué medidas se tomarán para proteger el carácter confidencial de la información.

Si aplica, el investigador también tiene que informarle sobre:

i) cualquier tipo de recompensa o de tratamiento médico que esté disponible en caso de lesión;
ii) cualquier posibilidad de riesgos que no se puedan anticipar;
iii) circunstancias bajo las cuales el investigador podría descontinuar su participación en el estudio;
iv) cualquier gasto adicional que usted pueda tener;
v) qué ocurre si usted decide descontinuar su participación;
vi) cuándo se le informará sobre nuevos hallazgos que pudieran afectar su voluntad de participar;
vii) cuántas personas participarán en el estudio.

Si usted accede a participar, el investigador tiene que entregarle una copia firmada de este documento y, por escrito, un resumen de la investigación.

Si tiene preguntas sobre el estudio puede comunicarse en cualquier momento con
David Levine, MD MPH, llamando al teléfono 617.278.0639
(Name of contact for questions about study) *(Telephone)*

Si tiene preguntas sobre sus derechos al participar en un estudio (al ser sujeto de estudio), o sobre qué hacer si sufre alguna lesión, puede comunicarse en cualquier momento con:
Partners Human Research Committee office, llamando al teléfono 617-424-4100.
(Name of contact for questions about rights or injury) *(Telephone)*

Su participación en el estudio es voluntaria, y no será sancionado ni perderá prestaciones si rehúsa participar o si decide descontinuar su participación en el estudio de investigación.

Al firmar este documento da fe de que el estudio de investigación, incluyendo la información enumerada [redacted] lmente y que usted accede voluntariamente a participar.

[redacted]

11/2/16
Fecha
Date

Firma del intérprete
Signature of Interpreter

Fecha
Date

O

Firma
Signa

11/2/16
Fecha
Date

About this consent form

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- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
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Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

(See brief consent) _____ _____ _____

Subject Date Time (optional)

Signature of Adult:

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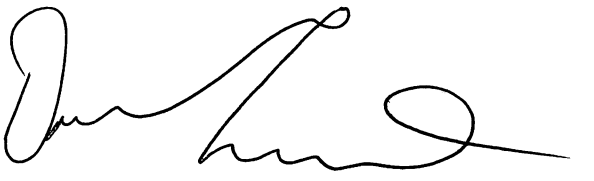
_____ _____ _____

Adult Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent: 

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- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine _____ 11/2/16 _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

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_____
Time (optional)

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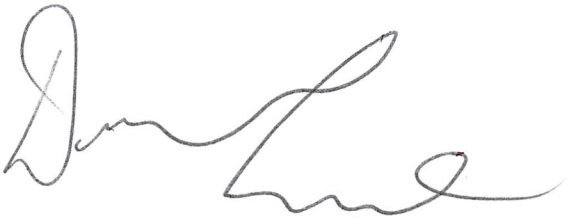

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David Levine — Study Doctor or Person Obtaining Consent
11/11/16 — Date
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Version 2, July 26, 2016

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I give my consent to take part in this research study and agree to allow my health information to

[redacted]

_____
Time (optional)

[redacted]ormation to be used

[redacted]

_____
Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

	9/14/16	
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

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Name	Date	Time (optional)

Version 2, July 26, 2016

About this consent form

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We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital (within 5 miles) and have a diagnosis of either cellulitis, pneumonia, complicated urinary tract infection, or heart failure. The research doctors consider these health problems safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. About 60 patients will take part in this study at Brigham and Women's Hospital.

The majority of this study is funded by Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are providing the hardware for this study free of charge.

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Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission. Each day, our home hospital team will make several visits to your home.

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

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    - About 16 subjects patients to every 1 MD

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    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, and social worker as medically needed
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Whether or not you are assigned to receive care at Brigham and Women's Hospital or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

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What are the risks and possible discomforts from being in this research study?

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If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
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    - Sleep in your own bed
    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
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We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

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What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

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We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if

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Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

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Time (optional)

formation to be used

2:25
2 P
Time (optional)

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David Levine | 10/2/16 | _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

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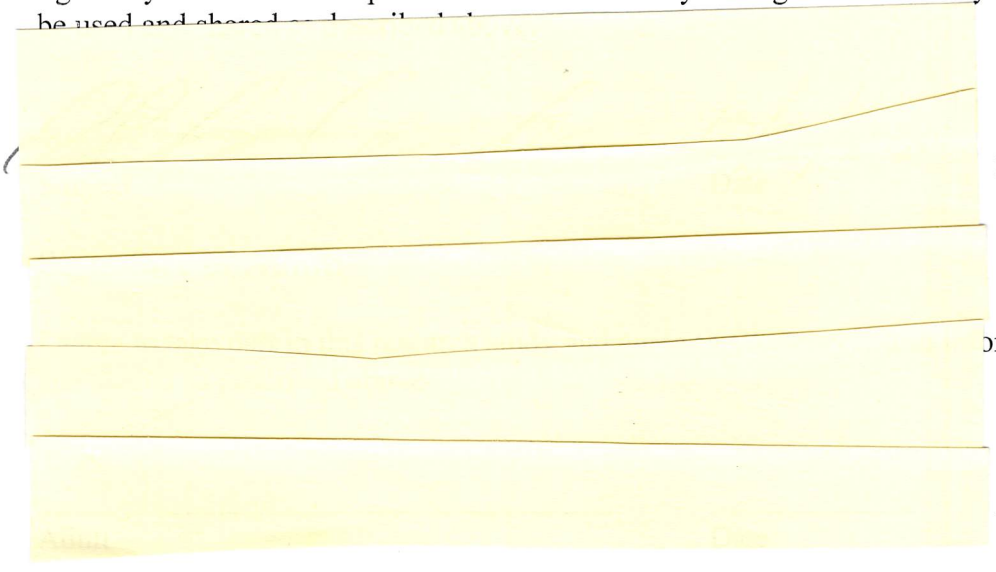

_____
Time (optional)

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10/5/2016

Statement of Study Doctor or Person Obtaining Consent

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Ken Quail, MD	10/5/16	
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appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

If I have questions or concerns about this research study, whom can I call?

Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to

[redacted]

Time (optional)

[redacted]

ɪrmation to be used

[redacted]

Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

I have answered all questions about this research study to the best of my ability.

[signature] Leonard MD	10/8/16	3PM
[signature]	10/8/16	
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

Version 2, July 26, 2016

About this consent form

Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital (within 5 miles) and have a diagnosis of either cellulitis, pneumonia, complicated urinary tract infection, or heart failure. The research doctors consider these health problems safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. About 60 patients will take part in this study at Brigham and Women's Hospital.

The majority of this study is funded by Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are providing the hardware for this study free of charge.

How long will I take part in this research study?

Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission. Each day, our home hospital team will make several visits to your home.

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

What will happen in this research study?

This is a randomized study, which means we will assign you by chance (like a coin toss) to the Home Hospitalization group or the Standard Admission group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the Home Hospitalization group You will have a 1 in 2 chance of being assigned to the Standard Admission group.

- **Standard admission:** your care will be just like normal at Brigham and Women's Hospital. Our research team will ask that you wear an activity tracker and will ask you questions about your hospital stay.
    - About 16 subjects patients to every 1 MD

- **Home hospital:** your care will be in your home with a set of services tailored to your medical needs:
    - In-home visit by a Brigham and Women's physician at least once a day
        - Available 24 hours every day by video, phone, or in-person
    - In-home Partners nurse at least twice a day
    - Remote wireless vital signs (such as heart rate), telemetry (your heart's rhythm), activity, and sleep monitoring
    - In-home intravenous infusions (for IV fluids or medications) as needed
    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, and social worker as medically needed
    - About 4 subject patients to every 1 MD

Whether or not you are assigned to receive care at Brigham and Women's Hospital or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

What are the risks and possible discomforts from being in this research study?

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child/elder/disabled abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
    - Eat your own food
    - Sleep in your own bed
    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
  - Continuous (around the clock) vital signs, telemetry (heart rhythm patterns), and physical activity tracking;
  - Video visits with physician;
  - IV medication pumps that can be worn on the hip;

We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

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Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study. I agree to allow my health information to be used as described above.

5:16
Time (optional)

I agree to allow my health information to be used as described above.

Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine | 10/17/16 | _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

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Statement of Hospital Medical Interpreter

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_____ | _____ | _____

Hospital Medical Interpreter | Date | Time (optional)

OR

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_____ | _____ | _____

Name | Date | Time (optional)

Version 2, July 26, 2016

Título del estudio de investigación (*Title of Research Study*):
Hospital en casa: Programa de hospital para adultos

Investigador principal (*Principal Investigator)*:
Jeffrey Schnipper, MD MPH

CONSENTIMIENTO A PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Consent to participate in research - Spanish

Se le está pidiendo que participe en un estudio de investigación.

Antes de que usted acceda a participar, el investigador tienen que informarle de:

i) los propósitos, los procedimientos y la duración del estudio;
ii) los procedimientos que sean experimentales;
iii) los riesgos, molestias o beneficios de la investigación, que sean razonablemente previsibles;
iv) procedimientos o tratamientos alternativos que sean potencialmente beneficioso; y de
v) qué medidas se tomarán para proteger el carácter confidencial de la información.

Si aplica, el investigador también tiene que informarle sobre:

i) cualquier tipo de recompensa o de tratamiento médico que esté disponible en caso de lesión;
ii) cualquier posibilidad de riesgos que no se puedan anticipar;
iii) circunstancias bajo las cuales el investigador podría descontinuar su participación en el estudio;
iv) cualquier gasto adicional que usted pueda tener;
v) qué ocurre si usted decide descontinuar su participación;
vi) cuándo se le informará sobre nuevos hallazgos que pudieran afectar su voluntad de participar;
vii) cuántas personas participarán en el estudio.

Si usted accede a participar, el investigador tiene que entregarle una copia firmada de este documento y, por escrito, un resumen de la investigación.

Si tiene preguntas sobre el estudio puede comunicarse en cualquier momento con
David Levine, MD MPH, llamando al teléfono 617.278.0639
(Name of contact for questions about study) *(Telephone)*

Si tiene preguntas sobre sus derechos al participar en un estudio (al ser sujeto de estudio), o sobre qué hacer si sufre alguna lesión, puede comunicarse en cualquier momento con:
Partners Human Research Committee office, llamando al teléfono 617-424-4100.
(Name of contact for questions about rights or injury) *(Telephone)*

Su participación en el estudio es voluntaria, y no será sancionado ni perderá prestaciones si rehúsa participar o si decide descontinuar su participación en el estudio de investigación.

Al firmar [redacted] el estudio de investigación, incluyendo la información enumerada en este do[redacted]almente y que usted accede voluntariamente a participar.

[redacted]

Firma de[redacted]
Participant'

10/22/16
Fecha
Date

Firma del intérprete
Signature of Interpreter

Fecha
Date

O

See English consent

Firma del testigo que no es intérprete
Signtaure of Non-Interpreter Witness

Fecha
Date

About this consent form

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What other treatments or procedures are available for my condition?

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What will I have to pay for if I take part in this research study?

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Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

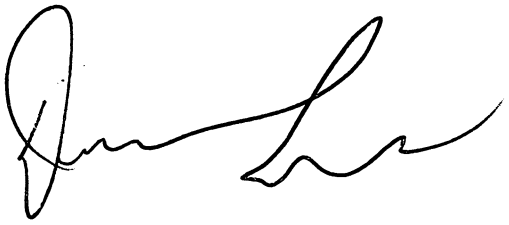
See Short Consent		
Subject	Date	Time (optional)

Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

Adult	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:



Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine — 10/22/16 — _____

Study Doctor or Person Obtaining Consent — Date — Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ — _____ — _____

Hospital Medical Interpreter — Date — Time (optional)

OR

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Ve[illegible]

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- Your initially diagnosed condition was incorrect
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What are the risks and possible discomforts from being in this research study?

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    - Sleep in your own bed
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    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
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We hope this research may have future benefits such as:

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Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

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Informed Consent and Authorization

Signature of Subject:

[redacted] consent to take part in this research study and agree to allow my health information to

[redacted] Time (optional)

[redacted] ormation to be used

[redacted] Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine | 10/26/16 | _____
Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ | _____ | _____
Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

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Time (optional)

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David Levine | 10/23/16 | _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

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Name | Date | Time (optional)

Version 2, July 26, 2016

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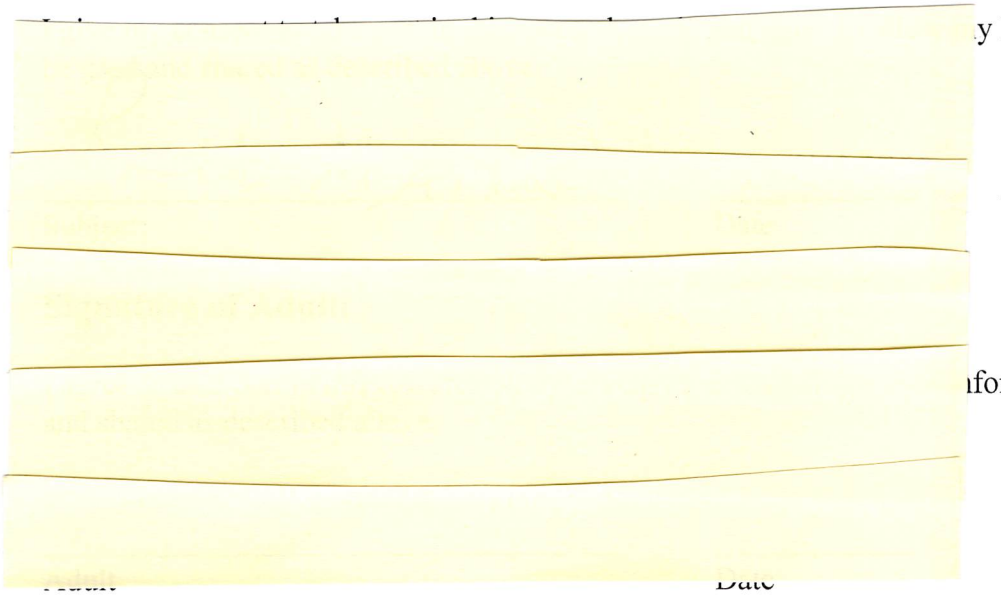
Signature of Subject:



y health information to

Time (optional)

iformation to be used

Time (optional)

Signature of Study Doctor or Person Obtaining Consent: KEL OWOH! MD

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Kei Ouchi	11/4/16	
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At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
- You have an adverse reaction to treatment

A record of your admission will be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

What are the risks and possible discomforts from being in this research study?

Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

During this study, we may learn information from you that must be reported to public health or public safety authorities. We are required by law to report known or suspected child/elder/disabled abuse. If we make such report, the public health and safety authorities can use the information as they see fit and may end up sharing it with other government agencies.

If we learn information from you during this study that indicates intent to seriously harm others or yourself, we may be required by law to share that information with third parties, including public safety or law enforcement authorities, and may take other precautions to protect against such harm.

What are the possible benefits from being in this research study?

If you are assigned to the home hospital group, some of the possible benefits include:

- Remaining in your home during your acute illness
    - Eat your own food
    - Sleep in your own bed
    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
  - Continuous (around the clock) vital signs, telemetry (heart rhythm patterns), and physical activity tracking;
  - Video visits with physician;
  - IV medication pumps that can be worn on the hip;

We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if

appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

If I have questions or concerns about this research study, whom can I call?

Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

Informed Consent and Authorization

Signature of Subject:

health information to

_____
Time (optional)

rmation to be used

_____
Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine — 11/8/16 — _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ — _____ — _____

Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ — _____ — _____

Name | Date | Time (optional)

Version 2, July 26, 2016

Título del estudio de investigación (*Title of Research Study*):
Hospital en casa: Programa de hospital para adultos

Investigador principal (*Principal Investigator*):
Jeffrey Schnipper, MD MPH

CONSENTIMIENTO A PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Consent to participate in research - Spanish

Se le está pidiendo que participe en un estudio de investigación.

Antes de que usted acceda a participar, el investigador tienen que informarle de:

i) los propósitos, los procedimientos y la duración del estudio;
ii) los procedimientos que sean experimentales;
iii) los riesgos, molestias o beneficios de la investigación, que sean razonablemente previsibles;
iv) procedimientos o tratamientos alternativos que sean potencialmente beneficioso; y de
v) qué medidas se tomarán para proteger el carácter confidencial de la información.

Si aplica, el investigador también tiene que informarle sobre:

i) cualquier tipo de recompensa o de tratamiento médico que esté disponible en caso de lesión;
ii) cualquier posibilidad de riesgos que no se puedan anticipar;
iii) circunstancias bajo las cuales el investigador podría descontinuar su participación en el estudio;
iv) cualquier gasto adicional que usted pueda tener;
v) qué ocurre si usted decide descontinuar su participación;
vi) cuándo se le informará sobre nuevos hallazgos que pudieran afectar su voluntad de participar;
vii) cuántas personas participarán en el estudio.

Si usted accede a participar, el investigador tiene que entregarle una copia firmada de este documento y, por escrito, un resumen de la investigación.

Si tiene preguntas sobre el estudio puede comunicarse en cualquier momento con
David Levine, MD MPH, llamando al teléfono 617.278.0639
(Name of contact for questions about study) *(Telephone)*

Si tiene preguntas sobre sus derechos al participar en un estudio (al ser sujeto de estudio), o sobre qué hacer si sufre alguna lesión, puede comunicarse en cualquier momento con:
Partners Human Research Committee office, llamando al teléfono 617-424-4100.
(Name of contact for questions about rights or injury) *(Telephone)*

Su participación en el estudio es voluntaria, y no será sancionado ni perderá prestaciones si rehúsa participar o si decide descontinuar su participación en el estudio de investigación.

[redacted] de que el estudio de investigación, incluyendo la información enumerada [redacted] escrito verbalmente y que usted accede voluntariamente a participar.

[redacted]

11/9/16
Fecha
Date

Firma del intérprete
Signature of Interpreter

Fecha
Date

O

(See full consent)

Firma del testigo que no es intérprete
Signtaure of Non-Interpreter Witness

Fecha
Date

About this consent form

Throughout the consent form, "you" always refers to the person who takes part in the study.

Why is this research study being done?

We are doing this research to see if providing hospital care at home ("home hospitalization") will cost less than regular "inpatient" hospitalization. We also want to find out if home hospitalization will provide the same or better hospital experience for adults. When an adult has to be hospitalized, it can be uncomfortable, and there may be risks to patient safety. This research project will compare the overall costs and experience of a group of patients where doctor visits, nursing care, medications, tests, and monitoring all occur at home to another group of patients who are admitted to the hospital for their treatment as per standard of care. Other studies have shown reduced costs as well as the same safety, same quality, and improved patient satisfaction. We would like to see if the same is true at Brigham and Women's Hospital.

We are asking you to take part in this study because you are an adult who lives close by to Brigham and Women's Hospital (within 5 miles) and have a diagnosis of either cellulitis, pneumonia, complicated urinary tract infection, or heart failure. The research doctors consider these health problems safe to take care of at home.

In addition to expert clinical staff from Brigham and Women's Hospital and Partners Healthcare who come to your home, we will be using state-of-the-art technology during the home hospitalization: remote vital-sign monitoring (checking things like heart rate with a skin patch), video visits with doctors and nurses, medicine pumps, and bedside bloodwork. We will monitor vital-signs with the VitalPatch™ (Vital Connect, Inc.), which is FDA approved for home use. Its detection of abnormal heart rhythms is pending FDA approval. We will administer IV medications with the CADD® Solis VIP (Smiths Medical, Inc.), which is FDA approved for home use. We will check bedside bloodwork with the iSTAT™ (Abbott Laboratories, Inc), which is FDA approved for portable use.

This is a pilot study. Pilot studies are done on a small group of subjects to learn if a larger study would be useful. About 60 patients will take part in this study at Brigham and Women's Hospital.

The majority of this study is funded by Partners Population Health Management. The makers of the remote vital-sign monitoring system and medicine pumps are providing the hardware for this study free of charge.

How long will I take part in this research study?

Your enrollment in the study will start on admission and continue until discharge. Depending on your condition, we expect this to take two to five days, similar to a typical hospital admission. Each day, our home hospital team will make several visits to your home.

30 days after your hospitalization is complete, we will call you to ask your thoughts on your experience.

What will happen in this research study?

This is a randomized study, which means we will assign you by chance (like a coin toss) to the Home Hospitalization group or the Standard Admission group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the Home Hospitalization group You will have a 1 in 2 chance of being assigned to the Standard Admission group.

- **Standard admission:** your care will be just like normal at Brigham and Women's Hospital. Our research team will ask that you wear an activity tracker and will ask you questions about your hospital stay.
    - About 16 subjects patients to every 1 MD

- **Home hospital:** your care will be in your home with a set of services tailored to your medical needs:
    - In-home visit by a Brigham and Women's physician at least once a day
        - Available 24 hours every day by video, phone, or in-person
    - In-home Partners nurse at least twice a day
    - Remote wireless vital signs (such as heart rate), telemetry (your heart's rhythm), activity, and sleep monitoring
    - In-home intravenous infusions (for IV fluids or medications) as needed
    - In-home testing as needed: blood tests, x-ray, ultrasound
    - In-home personal home health aide, physical therapist, occupational therapist, and social worker as medically needed
    - About 4 subject patients to every 1 MD

Whether or not you are assigned to receive care at Brigham and Women's Hospital or at home, we will collect information from your medical record so that we can measure the quality and safety of the care you received. We will also ask you some questions at the beginning and end of the hospitalization and 30 days after discharge to learn more about your experience of the care you received. All of this information will remain confidential (see below).

At any time, you can choose to stop taking part in this study. If you are in the home hospital group, you may either remain home or return to the hospital. The study team may choose to end your participation in the study if you become too ill for home hospital and need to go to Brigham and Women's Hospital for further care.
This may happen because:

- Your condition does not respond to standard treatments
- Your condition requires advanced imaging (like a CT or MRI)
- Your initially diagnosed condition was incorrect
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In both study groups, we will collect information about what happens to you during and for 30 days after your hospitalization. For example, we will determine the cost of your hospitalization, how long your hospitalization lasted, if you used an emergency room after your hospitalization, the quality of care you received, your quality of life, and how satisfied you were with your hospitalization.

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Any time a person is admitted to the hospital, there are risks of physical impairment and death, emotional distress, costs, and discomfort from both the disease as well as procedures during the admission. Any of these same risks apply when being hospitalized at home. An additional risk of being hospitalized at home is that in the case of an acute emergency, your physician and nurse are further from you than in traditional hospital care. However, our study team is within 5 miles of your home, and you can reach them 24 hours a day. If necessary, we will call emergency medical services to your home. Study staff will make sure you are comfortable using the study devices to reach the study staff at any time. We will also explain to you what our plan is for handling any unexpected problems or events.

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    - Rest on your own schedule
    - Spend more time with your family and friends
    - Not share a room with another patient
- You may have, but are not guaranteed to have, better health outcomes, for example

  - Less risk for developing delirium (confusion)
  - Fewer falls
  - Fewer health care associated infections
  - Better strength after discharge
- You may be more satisfied with your care
- Some of the devices in this study may provide results to you and your staff sooner than if you were in the hospital
  - Lab test results at the bedside in less than 5 minutes;
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  - Video visits with physician;
  - IV medication pumps that can be worn on the hip;

We hope this research may have future benefits such as:

- If home hospital is shown to benefit patients, then this may become a common alternative to traditional hospitalization for many adults.
- This model may also reduce future health care costs in the U.S.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to be treated for your medical condition. Taking part in this study is voluntary.

If you do not want to take part in the study, you will be admitted to the hospital as an inpatient and you will be treated according to standard of care for your condition.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care, just as you normally would.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

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If I have questions or concerns about this research study, whom can I call?

Jeffrey Schnipper, MD MPH is the person in charge of this research study. You can call him at 617-732-7063, 24 hours each day, 7 days per week with questions about this research study. You can also call David Levine, MD MA at 617-278-0639 24 hours each day, 7 days per week with questions about this research study.

Informed Consent and Authorization

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

(See brief consent) _____ _____ _____

Subject Date Time (optional)

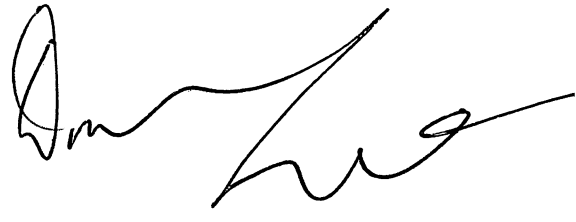
Signature of Adult:

I agree to take part in this research study and agree to allow my health information to be used and shared as described above.

_____ _____ _____

Adult Date Time (optional)

Signature of Study Doctor or Person Obtaining Consent:



Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

David Levine | 11/9/16 | _____

Study Doctor or Person Obtaining Consent | Date | Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

_____ | _____ | _____

Hospital Medical Interpreter | Date | Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's [illegible] rtunity to ask questions.

[illegible] 11/9/16 | _____

[illegible]ate | Time (optional)

1 Vital Connect Platform Description -IRB Sample

Device Description

The Vital Connect Platform is a wireless physiological monitoring system. The Vital Connect Platform was developed with an Application Programming Interface intended to allow development of user interface applications enabling healthcare professionals to access collected vital information. The platform consists of:

- Vital Connect Sensor (includes adhesive Patch and Sensor Module)
- Relay Software Library
- Server Software Library (Optional)

The Vital Connect Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver, worn on the torso to record heart rate, electrocardiography (ECG), heart rate variability R-R interval, respiratory rate, skin temperature, fall detection, step count and posture. The Vital Connect Sensor continuously gathers physiological data from the person being monitored and then transmits encrypted data via bi-directional communication to the relay device when in range of the relay. The encrypted wireless data provided by the Sensor may be downloaded from the relay device for storage, or integrated into a Third-Party Relay Application via the APIs of the Relay Software Library. In addition, the wireless data may be transferred to the Vital Connect Secure Server where they are stored for analysis with the deployment of the server.

During normal operation, data are collected on the Vital Connect Sensor and transmitted to the Relay immediately. A continuous connection is needed between the Sensor and the Relay in order to facilitate continuous data transmission. The continuous wireless transmission of the data occurs with a delay or latency of seconds between continuous data collection and transmission. Data can be stored and downloaded from the Relay. Data can continue be transferred to the Vital Connect Server with a server connection.

Authorized healthcare professionals can configure the system parameters via the API to generate notification of changes in measured data. With the connection to the Secure Server, a notification is triggered when configured physiologic data parameters are exceeded. Notification can be transmitted to a generic display device (i.e. smartphone, tablet, PC or monitor).

Figure 1: HealthPatch MD

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**
Sponsor Name:
PI Name: **Schnipper, Jeffrey L** Protocol #: **2016P001337** Type: **Amendment (AME8)**
Date Received: **June 15, 2017**

Study Staff Added

Name	Role	Degree	Organization	Citi Certified
Boateng, Megan	Research Assistant		BWH > Medicine > General Medicine	May 26, 2017
Brito, Cristina	Research Assistant		BWH > Medicine > General Medicine	May 17, 2017
Burke, Kimberly	Research Assistant		BWH > Medicine	April 04, 2017

Study Staff Removed

Name	Role	Degree	Organization
Thiagalingam, Natasha	Research Assistant		BWH > Medicine

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: June 05, 2017

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add Non-Partners collaborators <u>unless</u> they are engaged in the conduct of the research at a Partners institution <u>or</u> they plan to rely on the Partners IRB, and not their own IRB.**

◉ Yes ○ No

Are you changing the principal investigator?

○ Yes ◉ No

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**
Sponsor Name:
PI Name: **Schnipper, Jeffrey L** Protocol #: **2016P001337** Type: **Amendment (AME9)**
Date Received: **July 31, 2017**

Study Staff Added

Name	Role	Degree	Organization	Citi Certified
Brochier, Annelise	Research Assistant		BWH > Medicine > General Medicine	July 06, 2017
Cannon, Brittnie	Intern/Student		BWH	May 21, 2017

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: July 21, 2017

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB.**

◉ Yes ○ No

Are you changing the principal investigator?

○ Yes ◉ No

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**
Sponsor Name:
PI Name: **Schnipper, Jeffrey L** Protocol #: **2016P001337** Type: **Amendment (AME10)**
Date Received: **August 09, 2017**

Study Staff Added

Name	Role	Degree	Organization	Citi Certified
Saenz, Agustina	Co-Investigator		BWH > Medicine > Primary Care	July 20, 2017

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: August 08, 2017

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB.**

◉ Yes ○ No

Are you changing the principal investigator?

○ Yes ◉ No

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**
Sponsor Name:
PI Name: **Schnipper, Jeffrey L** Protocol #: **2016P001337** Type: **Amendment (AME11)**
Date Received: **September 06, 2017**

Study Staff Added

Name	Role	Degree	Organization	Citi Certified
Pian, Julia	Intern/Student		BWH > Medicine > General Medicine	April 19, 2016

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: September 06, 2017

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB.**

◉ Yes ○ No

Are you changing the principal investigator?

○ Yes ◉ No

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**
Sponsor Name:
PI Name: **Schnipper, Jeffrey L** Protocol #: **2016P001337** Type: **Amendment (AME12)**
Date Received:

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add Non-Partners collaborators unless they are engaged in the conduct of the research at a Partners institution or they plan to rely on the Partners IRB, and not their own IRB.**

◉ Yes ○ No

Are you changing the principal investigator?

○ Yes ◉ No

Title: **Hospitalization at Home: The Acute Care Home Hospital Program for Adults**
Sponsor Name:
PI Name: **Schnipper, Jeffrey L** Protocol #: **2016P001337** Type: **Amendment (AME13)**
Date Received: **November 03, 2017**

Study Staff Added

Name	Role	Degree	Organization	Citi Certified
Gupte, Anu	Data Coordinator/Manager		BWH > Medicine	October 09, 2017
Paz, Mary	Research Assistant		BWH > Medicine	September 27, 2017

Study Staff Removed

Name	Role	Degree	Organization
Brito, Cristina	Research Assistant		BWH > Medicine > General Medicine
Brochier, Annelise	Research Assistant		BWH > Medicine > General Medicine
Medoff, Jeffrey	Research Assistant		BWH > Medicine > General Medicine

Signatures

PI Name: Schnipper, Jeffrey L, MD, MPH
Authenticated: November 03, 2017

Amendment

Performance Sites

Are you adding or removing a performance site?

○ Yes ◉ No

Study Staff Amendment

Are you adding or removing study staff? **REMINDER: Do not add Non-Partners collaborators <u>unless</u> they are engaged in the conduct of the research at a Partners institution <u>or</u> they plan to rely on the Partners IRB, and not their own IRB.**

◉ Yes ○ No

Are you changing the principal investigator?

○ Yes ◉ No