DETAILED PROTOCOL

Hospital-Level Care at Home for Acutely Ill Adults in Rural and Ultra-Rural Settings: Proof of Concept

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Sponsor: Rx Foundation

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1.0 BACKGROUND AND SIGNIFICANCE

1.1 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. An acute illness that traditionally requires inpatient hospitalization represents a common critical moment in people's lives. Many people worldwide lack access to acute care, some face intense travel burdens to obtain care, while others simply go without. Even those who may receive their care in a hospital will encounter an environment that may be unsafe and expensive. Maintaining high quality acute care facilities in rural areas is a major burden to health care systems.

1.1.1 Previous Clinical studies

We have designed, implemented, evaluated, and continue improving on home-based acute care (e.g., a "home hospital") for dense urban environments. The home hospital model of care provides in-home acute care to acutely ill patients who would normally be admitted to a traditional 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, reduced cost, and improved patient experience.[5,6] In late 2016, we launched a randomized controlled trial (RCT) of home hospital care, the first RCT to be performed in the US context. With this pilot we showed that hospital-level care could be delivered with similar or better quality and safety but at lower cost.[7] We subsequently completed a larger RCT that corroborated the pilot's findings, additionally demonstrating reduced readmissions for those home hospitalized. Since conclusion of this larger RCT, we have enrolled over 500 patients in home hospital care.

1.1.2 Rationale

About 1 in 5 Americans live in rural areas, totaling nearly 60 million people.[8] Living in a rural area is associated with higher mortality[9] and poor access to health care, with 23% reporting an average 34-minute drive to their nearest hospital.[10] An acute illness that traditionally requires hospitalization represents a common critical moment in nearly every person's life. While some in rural areas face intense travel burdens to obtain acute care, others simply go without. Even those who receive care in a hospital may encounter an environment that is unsafe, of poor quality or experience, and expensive.[11] This may be particularly true of rural hospitals.[12,13] In response to this unacceptable geographic disparity, over the last year, our team has designed and refined the rural home hospital (RHH) model through background research, workflow mapping, prototyping, and rapid cycle testing. We conducted a simulation of RHH through a series of "mock admissions" with stable but chronically ill patients in rural Utah. We evaluated the processes, workflows, and technologies involved in RHH and collected qualitative data from the patients, caregivers, and RHH clinical team.

Building on the success of these detailed planning exercises, we propose deploying RHH to care for acutely ill patients in rural and ultra-rural settings in Utah as a proof of concept. This study will evaluate the feasibility and acceptability of the RHH intervention with 3 patients and synthesize key learnings which will be used to refine the RHH model and inform an implementation strategy going forward. If the home hospital model can be successfully deployed in rural and ultra-rural settings, a paradigm shift in access to acute care will occur, providing this care model to rural patients and clinicians.

2.0 SPECIFIC AIMS

2.1 Primary Aim
Assess the feasibility of home hospital care in rural and ultra-rural settings in the United States by deploying a home hospital team to care for acutely ill rural patients at home.

2.2 Secondary Aims
Asses RHH for its acceptability, experience, quality, and safety.

3.0 SUBJECT SELECTION

3.1 Inclusion

Patient inclusion criteria:

Patient clinical inclusion criteria:

- >=18 years old
- Any infectious process (e.g., pneumonia, diverticulitis, cellulitis, complicated urinary tract infection)
- Heart failure exacerbation
- Asthma and chronic obstructive pulmonary disease exacerbation
- Atrial fibrillation with rapid ventricular response
- Diabetes and its complications
- Venous thromboembolism
    - This includes a patient who requires therapeutic anticoagulation and concomitant monitoring (thus requiring inpatient status)
- Gout exacerbation
- Chronic kidney disease with volume overload
- Hypertensive urgency
- End of life / desires only medical management
    - 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.

Patient social inclusion criteria:

- Lives in rural or ultra-rural area (see definitions in Appendix) that can be served by one of our RHH clinicians.
- Has capacity to consent to study
- 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.

Patient caregiver inclusion criteria: (not required for patient participation):

- Age >= 18 years old
- Has capacity to consent to study
- Lives with or nearby to patient

Clinician inclusion criteria:

- Any member of the rural home hospital (RHH) clinical team (MD, RN, paramedic, NP) who will be participating in the screening and recruitment of patients for the rural home hospital intervention and/or providing care to rural patients that enroll in the intervention.

3.2 Exclusion

Patient exclusion criteria:

Patient exclusion clinical criteria:

- Acute delirium, as determined by the Confusion Assessment Method
- Cannot establish peripheral access (or access requires ultrasound guidance, unless ultrasound guidance is available)
- Secondary condition: active non-melanoma/prostate cancer, end-stage renal disease, acute myocardial infarction, acute cerebral vascular accident, acute hemorrhage
- Primary diagnosis requires controlled substances
- Cannot independently ambulate to bedside commode
- As deemed by on-call MD, patient likely to require any of the following procedures that have not already occurred: 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)[15]

    - 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)[16]
    - 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[17] (>10% in-hospital mortality) or ADHERE[18] (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)[19]
- For other infection
    - Most recent qSOFA > 1 (SBP≤100 mmHg, RR≥22, GCS<15 [any AMS]) (if sepsis, >10% mortality)[19]
- 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
    - Systolic blood pressure > 190 mmHg
    - Evidence of end-organ damage; for example, acute kidney injury, focal neurologic deficits, myocardial infarction
- 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
    - Less than 1 hour of time has elapsed with HR < 125 and SBP similar or higher than baseline
- For patients with end-stage renal disease on peritoneal dialysis
    - Peritoneal catheter malfunction
    - Requires temporary hemodialysis
- Home hospital census is full (maximum 3 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

Patient social exclusion criteria:

- Non-english speaking
- 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[8]

3.3 Source of subjects and recruitment methods

All subjects will be associated with the University of Utah Health system. The University of Utah Health has agreed to serve as research collaborator.

A patient may be considered for RHH care if they are acutely ill at home, present acutely ill to a clinic or emergency department, or if they are admitted and require additional days of acute care ("early transfer"):

- If at home: this patient phenotype is well-known to her/his physician and has an acute illness of highly likely etiology (e.g., heart failure or chronic obstructive pulmonary disease exacerbation). The patient's care team (perhaps primary care or a specialist) will receive a call from the patient describing acute symptoms. The care team will call the RHH nurse practitioner (NP) to describe the case. If appropriate, the RHH NP will call the patient to determine eligibility and interest. If eligible, the RHH MD will make the decision to admit and the MD or NP will consent the patient.
- If presenting acutely ill to a clinic: after appropriate assessment by the clinic care team, and if the team believes the patient requires admission, the clinic care team will call the RHH NP to describe the case. If appropriate, the RHH NP will call the patient to determine eligibility and interest. If eligible, the RHH MD or NP will consent the patient. The patient will be transported home in an appropriate transport (personal car, chair car, or ambulance). The RHH nurse/paramedic will meet the patient in their home.
- If presenting acutely ill to an emergency department: after appropriate assessment by the emergency department team, and if the team believes the patient requires admission, the emergency department care team will call the RHH NP to describe the case. If appropriate, the RHH NP will call the patient to determine eligibility and interest. If eligible, the RHH MD or NP will consent the patient. The patient will be transported home in an appropriate transport (personal car, chair car, or ambulance). The RHH nurse/paramedic will meet the patient in their home.
- If admitted and requiring additional days of acute care ("early transfer"): an ideal patient for this setting is a patient with a heart failure exacerbation requiring additional days of IV diuresis and close monitoring including daily electrolyte and telemetry monitoring. Patients who require additional days of acute care but could be cared for with RHH will

be approached for enrollment after discussion with the RHH NP, RHH MD, and hospital care team, ensuring it is an appropriate time to approach for enrollment. If the patient and all stakeholders are in agreement with RHH, the patient will be enrolled and consented to RHH by the RHH MD or NP. The patient will be transported home in an appropriate transport (personal car, chair car, or ambulance). The RHH nurse/paramedic will meet the patient in their home.

4.0 SUBJECT ENROLLMENT

4.1 Screening and recruitment

Patients:

- Acutely ill patient is screened and recruited as above.
- If participant agrees, the RHH MD will further describe the program, answer initial questions, and further assess whether the participant meets inclusion/exclusion non-clinical (e.g., social) and clinical criteria (please see the subject eligibility checklist)

Clinicians

- Members of the rural home hospital clinical team (MD, RN, paramedic, NP) that have expressed interest in participating in research activities and meet inclusion criteria will be approached by a member of the study team.

4.2 Methods of enrollment and procedures for obtaining consent/ informed consent

Clinicians:

- If the clinician meets inclusion criteria, then the study team will invite them to participate. The research assistant will explain the purpose of the study, answer initial questions, and seek written informed consent from clinician participants.

Patients:

- If the participant has interest in the program and meets inclusion/exclusion criteria, the MD (either over the phone or via a live video visit) or NP will obtain written informed consent of the participant to enroll in the RHH study.
- The MD will make the final decision to admit the patient to home hospital.

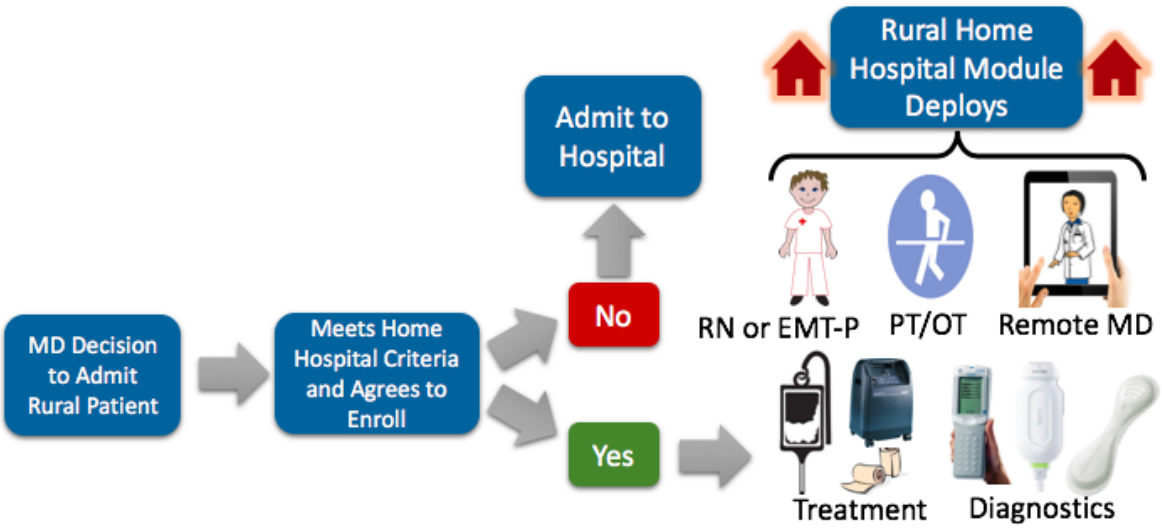

Figure 1.

4.4 Treatment Assignment

All eligible and agreeable patients will be enrolled in RHH.

5.0 STUDY PROCEDURES

5.1 Study visits and measured parameters

Each day, the RHH clinical team will make in-person and/or virtual 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 RHH module offers most of the same medical components that are standard of care in an acute care hospital (**Table below**). The typical staff (MD, RN or paramedic), diagnostics (blood tests, vital signs, telemetry), intravenous therapy, and oxygen/nebulizer therapy will all be available for home hospital.

RHH 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
- 24/7 clinician video visits;
- Ambulatory/portable infusion pumps that can be worn on the hip;

Component	Module
Personnel	 **Nurse/Paramedic** • 2 daily visits (1 in-person; 1 virtual) • Medication administration • IV access management • Education   **Physician** • 1 daily interaction • Medical decision making
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

Table 1.

As denoted in the table above, the physician will make at least one daily virtual visit to the patient's home, facilitated by the nurse/paramedic. At the discretion of the physician and nurse/paramedic, the physician can make additional virtual visits should the patient's clinical condition require it. Similarly, the nurse/paramedic will make at least two daily visits to the patient's home. At the discretion of the physician and nurse/paramedic, the nurse/paramedic can make additional visits should the patient's clinical condition require it. This will be an ongoing twice daily discussion among clinicians, patient, and caregivers, as applicable. A patient or clinician can initiate a video visit at any time. As denoted in the table above, the RHH team uses a suite of communication software to communicate with the patient and among team members.

For patients with chronic/stable dementia, they will receive mental status assessments (eg, Confusion Assessment Method) by the home hospital RN/paramedic at each visit (at least 2 daily). As is standard of care, we will take measures to avoid delirium: open blinds to allow light in during the day, minimize environmental noise, encourage typical routines to optimize eating and sleeping, and reassess medication list for culprit medications.

Clinical parameters measured will be at the discretion of the physician and nurse/paramedic, who treat the participant following evidence-based practice guidelines, just as in the usual care setting. Monitoring and data collection will be performed by RHH clinicians. The clinical home hospital team manually checks vital signs at least daily. If deemed necessary based on a patient's acuity, the home hospital team can visit additional times. At all times, the patient and care team have 24/7 access to the RHH attending physician.

On top of this "on-the-ground" team, the home hospital attending is notified with an alarm should there be delayed data transfer. Such an alarm would cause the attending to contact the patient as deemed clinically appropriate.

Please see below for all collected data points.

Documentation by RN/paramedic and MD will occur via digital intake notes, daily progress notes, and discharge notes that will be compiled (on a secure shared drive) and uploaded as a scanned document to the patient's chart upon discharge.

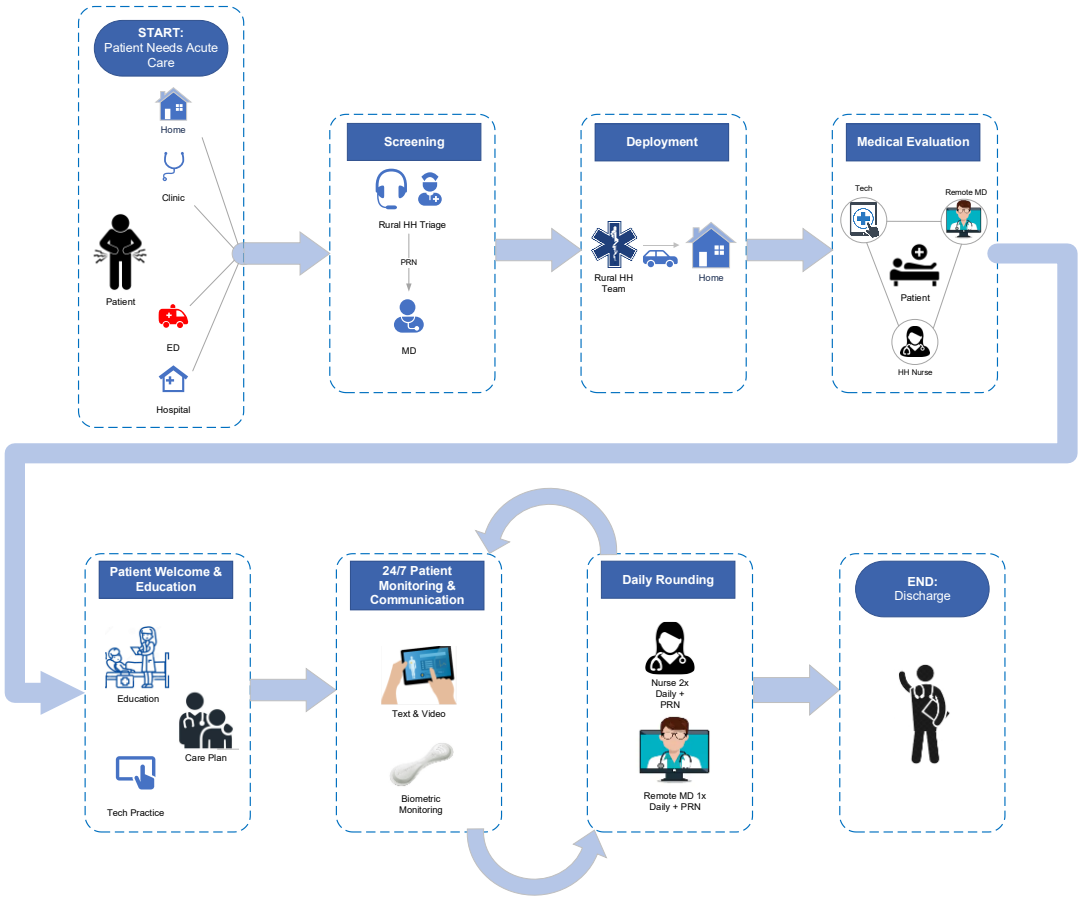

Figure 2 RHH flow. Note a patient may **enter** this flow from their home, a clinic, the emergency department, or the hospital floor. The patient is **triaged** by the RHH nurse with as needed assistance of the RHH MD. The RHH nurse/paramedic **deploys** in the patient's home, facilitates a medical evaluation by a remote MD, welcomes and educates the patient, and sets up monitoring and communication technology. The nurse **rounds** at least once to twice daily in person, facilitating an interaction with the RHH MD. Finally, the patient is **discharged** using the same criteria for discharge as would be used in a traditional hospital (ability to perform activities of daily living given supports in the home).

5.2 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.

5.3 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) or BioIntellisense BioSticker (FDA cleared application/use)
    - Ambulatory infusion pump: Smiths Medical CADD Solis VIP (FDA cleared application/use)
    - Point of care diagnostic meter: Abbott iSTAT (FDA cleared application/use) or Siemens EPOC (FDA cleared application/use)

5.4 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.

5.5 Data to be collected and when the data will be collected

5.5.1 Primary endpoint

Outcome measure	Data sources	Day(s) Obtained
RHH admission, daily care, and discharge processes accomplished	Process checklist (attachment) and semi-structured interviews with clinicians	Daily

5.5.2 Secondary endpoints

Outcome measure	Data sources	Day(s) Obtained
3-item Care Transition Measure	RA via patient	Within 1 week of discharge
Picker Experience Questionnaire	RA via patient	Within 1 week of discharge
Global satisfaction	RA via patient	Within 1 week of discharge
Perceived acceptability of RHH care	Post-discharge semi-structured interviews with clinicians, patients, and caregivers	Within 1 month of discharge
Perceived safety, quality of care, caregiver burden	Post-discharge semi-structured interviews with clinicians, patients, caregivers	Within 1 month of discharge
Escalation of care to hospital	RA via RN/EMTP	Daily
Adverse event*	RA via RN/EMTP	Daily
Unplanned mortality during admission	RA via RN/EMTP	Daily

Lab Orders, #	RA via RHH records	Daily
Length of stay	RA via RHH records	Discharge
Unplanned readmission(s) after index, # and y/n	RA via patient	30-days post-discharge
ED visit(s) after index, # and y/n	RA via patient	30-days post-discharge

*: see appendix

5.5.3 Covariates of Interest

Outcome measure	Data sources	Day(s) Obtained
Age	RA via patient	Admission
Gender	RA via patient	Admission
Race/ethnicity	RA via patient	Admission
Primary language	RA via patient	Admission
Health insurance status, public/private/none	RA via patient	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 patient	Admission
Employment	RA via patient	Admission
Smoking status	RA via H&P	Admission
Medications used as outpatient, #	RA via patient	Admission
DNR/I code status	RA via H&P	Admission
Home health aide prior to admission	RA via patient	Admission
Elective and urgent admissions in the previous year, #	RA via patient	Admission
ED visits in the previous 6 months, #	RA via patient	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
Lives alone	RA via patient	Admission

5.6 Standard Operating Procedures for problematic situations

Any subjects presenting with problematic situations will be immediately transferred to the most appropriate hospital and formally withdrawn from the study

Clinically Emergent Patient Condition

Should a matter be emergent, then 9-1-1 will be called and the patient will be brought 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, the patient and/or nurse/paramedic 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/paramedic will attempt to 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 transport 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 transfer 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 transport the patient to the hospital.

Refusal of care
Should an enrolled subject refuse standard care at their home despite a clear discussion with the home hospital team, then the subject will be transferred back to the treating hospital and formally withdrawn from the study.

6.0 BIOSTATISTICAL ANALYSIS

6.1 Quantitative
Given our small planned enrollment of 3 patients, we will present our quantitative findings either as individual data points or with medians and interquartile ranges. We plan no formal statistical testing.

6.2 Qualitative
We will conduct qualitative interviews with the RHH clinical care team, patient, and caregivers daily during admission and post-discharge. Semi-structured interviews will be recorded,

transcribed, and then analyzed using NVivo qualitative analysis software. We will audio record interviews to a local microphone system and send them for transcription to a HIPAA-compliant transcription service. Qualitative data will be analyzed using descriptive content analysis, two researchers will code the data independently. Following initial descriptive coding, themes and recurrent patterns may be identified with any differences resolved by consensus.

7.0 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.

8.0 POTENTIAL BENEFITS

- 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;
    - Ambulatory/portable infusion pumps that can be worn on the hip;
- 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.

9.0 MONITORING AND QUALITY ASSURANCE

Independent monitoring of source data
The study's research assistant will collect all data denoted above. The 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 RHH 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 MD and RN/paramedics will daily review quality and safety data as part of a rapid logistics improvement process.

Weekly, the MD and RN/paramedic will huddle to review quality and safety data as part of a rapid logistics improvement process.

Adverse event reporting guidelines
All adverse events denoted above under safety monitoring will be reported to the monitoring committee.

10.0 APENDIX

Rural definition and Ultra- rural definition:

Rural:

- Centers for Medicare & Medicaid Services (CMS) ambulance fee schedule: EMS super rural
- Rural-Urban Commuting Area Codes (RUCA) 4-10
- Frontier and Remote Area Codes (FAR) less than or equal to 4

Ultra-rural:

- Centers for Medicare & Medicaid Services (CMS) ambulance fee schedule: EMS super rural
- Rural-Urban Commuting Area Codes (RUCA) 10
- Frontier and Remote Area Codes (FAR) 4

Adverse events

- Fall
- Delirium
- Potentially preventable VTE
- New pressure ulcer
- Thrombophlebitis at peripheral IV site

11.0 REFERENCES

1. Hung WW, Ross JS, Farber J, Siu AL. Evaluation of the Mobile Acute Care of the Elderly (MACE) service. *JAMA Intern Med*. 2013;173(11):990-996. doi:10.1001/jamainternmed.2013.478.
2. Fong TG, Tulebaev SR, Inouye SK. Delirium in elderly adults: diagnosis, prevention and treatment. *Nat Rev Neurol*. 2009;5(4):210-220. doi:10.1038/nrneurol.2009.24.
3. *2014 National and State Healthcare-Associated Infections Progress Report*.; 2016. http://www.cdc.gov/hai/surveillance/progress-report/index.html. Accessed April 19, 2016.
4. Counsell SR, Holder CM, Liebenauer LL, et al. Effects of a Multicomponent Intervention

on Functional Outcomes and Process of Care in Hospitalized Older Patients: A Randomized Controlled Trial of Acute Care for Elders (ACE) in a Community Hospital. *J Am Geriatr Soc*. 2000;48(12):1572-1581. doi:10.1111/j.1532-5415.2000.tb03866.x.

5. Leff B, Burton L, Mader SL, et al. Hospital at home: feasibility and outcomes of a program to provide hospital-level care at home for acutely ill older patients. *Ann Intern Med*. 2005;143(11):798-808. http://www.ncbi.nlm.nih.gov/pubmed/16330791. Accessed February 15, 2016.
6. Cryer L, Shannon SB, Van Amsterdam M, Leff B. Costs for "hospital at home" patients were 19 percent lower, with equal or better outcomes compared to similar inpatients. *Health Aff (Millwood)*. 2012;31(6):1237-1243. doi:10.1377/hlthaff.2011.1132.
7. Levine DM, Ouchi K, Blanchfield B, Diamond K, Licurse A, Pu CT, and Schnipper JL. Hospital-Level Care at Home for Acutely Ill Adults: A Pilot Randomized Controlled Trial. *J Gen Intern Med*. 2018; 33(5):729-736. doi: 10.1007/s11606-018-4307-z
8 Bureau UC. What is Rural America?https://www.census.gov/library/stories/2017/08/rural-america.html. Published 2017. Accessed May 31, 2019.
9 Garcia MC, Rossen LM, Bastian B, et al. Potentially Excess Deaths from the Five Leading Causes of Death in Metropolitan and Nonmetropolitan Counties — United States, 2010–2017. MMWR Surveill Summ. 2019;68(10):1-11. doi:10.15585/mmwr.ss6810a1
10 Parker K, Horowitz J, Brown A, Fry R, Cohn D, Igielnik R. What Unites and Divides Urban, Suburban and Rural Communities.; 2018. https://www.pewsocialtrends.org/wpcontent/uploads/sites/3/2018/05/Pew-Research-Center-Community-Type-Full-Report-FINAL.pdf. Accessed May 31, 2019
11. Creditor MC. Hazards of hospitalization of the elderly. Ann Intern Med. 1993;118(3):219-223. http://www.ncbi.nlm.nih.gov/pubmed/8417639. Accessed May 31, 2019.
12. Joynt KE, Orav EJ, Jha AK. Mortality rates for Medicare beneficiaries admitted to critical access and non-critical access hospitals, 2002-2010. JAMA. 2013;309(13):1379-1387. doi:10.1001/jama.2013.2366
13 Joynt KE, Harris Y, Orav EJ, Jha AK. Quality of Care and Patient Outcomes in Critical Access Rural Hospitals. JAMA. 2011;306(1):45-52. doi:10.1001/jama.2011.902