

Aiding Chronic Obstructive Pulmonary Disease and Congestive Heart Failure Ultrasound-guided Management through Enhanced Point-of-Care Ultrasound (ACCUMEN-POCUS): Protocol for a Randomized Controlled Trial

Michelle Nora Grinman, Peter Nakhla, Steve Reid, Dennis Moon, Negar Dehghan Noudeh, Oladoyin Olaosebikan, Amanda Chung Yan Ip, Salomé Saunders, Ryan Kozicky, John Conly, Andrew Wallace Kirkpatrick, Jeff Round, Irene Wai Yan Ma, Suean Pascoe, Ghazwan Altabbaa

Submitted to: JMIR Research Protocols
on: April 22, 2025

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 22

 Figures 23

 Figure 1..... 24

 Figure 2..... 25

 Figure 3..... 26

 Multimedia Appendixes 27

 Multimedia Appendix 1..... 28

Aiding Chronic Obstructive Pulmonary Disease and Congestive Heart Failure Ultrasound-guided Management through Enhanced Point-of-Care Ultrasound (ACCUMEN-POCUS): Protocol for a Randomized Controlled Trial

Michelle Nora Grinman^{1,2,3} BSc, MPH, FRCPC, MD; Peter Nakhla^{2,1} BHSc, MD; Steve Reid⁴ BSc; Dennis Moon³ ACP; Negar Dehghan Noudeh⁵ BSc, MBT; Oladoyin Olaosebikan² MBBS; Amanda Chung Yan Ip² BSc, MSc; Salomé Saunders² BSc, MBT; Ryan Kozicky³ BSc, MPH; John Conly^{2,3,1,6} FACP, FSHEA, FIDSA, FAMMI, FCAHS, FRCPC, CCFP, DSc, MD; Andrew Wallace Kirkpatrick^{7,8} FACS, FRCSC, MHSc, MD; Jeff Round⁹ BA, MA, PhD; Irene Wai Yan Ma^{1,10} BSc, MSc, RDCS, RDMS, FACP, FRCPC, PhD, MD; Suean Pascoe¹¹ FAIUM, AMS, BAppScMRT; Ghazwan Altabbaa^{3,1} MSc, FRCPC, MD

¹Department of Medicine Cumming School of Medicine University of Calgary Calgary CA

²O'Brien Institute for Public Health Cumming School of Medicine University of Calgary Calgary CA

³Alberta Health Services Calgary CA

⁴Presuna Coleman CA

⁵Faculty of Medicine University of Toronto Toronto CA

⁶Snyder Institute for Chronic Diseases University of Calgary Calgary CA

⁷Department of Surgery Cumming School of Medicine University of Calgary Calgary CA

⁸TeleMentored Ultrasound Supported Medical Interventions (TMUSMI) Research Group Calgary CA

⁹Faculty of Medicine and Dentistry University of Alberta Edmonton CA

¹⁰Department of Community Health Sciences University of Calgary Calgary CA

¹¹Zedu Ultrasound Training Solutions Greensborough AU

Corresponding Author:

Michelle Nora Grinman BSc, MPH, FRCPC, MD
Department of Medicine
Cumming School of Medicine
University of Calgary
3330 Hospital Dr NW
Calgary
CA

Abstract

Background: Hospital at home (HAH) programs offer acute care at home as a substitute for inpatient hospitalization, reducing healthcare costs while maintaining safety and quality of care. Despite point-of-care ultrasound's (POCUS) validation in inpatient and emergency settings, its role in HAH care remains underexplored.

Common conditions treated on medical HAH programs such as acute exacerbation of chronic obstructive pulmonary disease (AE-COPD), acute decompensated heart failure (ADHF), and pneumonia are highly amenable to the integration of POCUS into clinical decision making and have been proven to improve healthcare utilization outcomes. POCUS' portability makes it ideal for use in HAH but its feasibility remains to be proven given the need for provider training and use in virtual settings where a non-physician practitioner is providing in-person care.

Objective: This study evaluates the feasibility and clinical utility of remotely interpreted lung and inferior vena cava (IVC) POCUS acquired by Community Paramedics (CPs) to support real-time clinical decision-making for HAH patients with AE-COPD, ADHF, and pneumonia in Calgary, Canada.

Methods: This randomized control trial (RCT) compared usual HAH care (control) to lung and IVC POCUS-enhanced HAH care (intervention). Handheld POCUS devices captured images, which were downloaded and securely shared using a cloud-based application. This enabled real-time image sharing among the clinical team, facilitating immediate decision-making by remote physicians.

A mixed-methods approach will evaluate clinical outcomes, patients' experience, healthcare utilization, and healthcare provider perceptions of POCUS integration. The primary outcome of the study is defined as length-of-stay for the index HAH admission. Quantitative analysis will assess clinical efficacy and healthcare resource use, while qualitative methods such as interviews and surveys will capture patient and provider experiences.

Results: Study funding began in April 2022, with data collection having commenced in Dec 2023. Patient recruitment was finalized on December 31, 2024. The study included a three-month follow-up for significant outcomes and will include a one-year follow-up for long-term healthcare utilization, including admissions to long-term care. A total of 20 patients were enrolled (10 intervention, 10 control).

Initial results highlighted feasibility and potential benefits of remotely-acquired POCUS imaging in HAH. Full data analysis is in progress.

Conclusions: This study is the first RCT to investigate virtually-acquired POCUS by non-physician practitioners for real-time lung and IVC remote decision-making in HAH care. Findings will provide insights into whether serial lung and IVC POCUS assessments improve ADHF, AE-COPD, and pneumonia outcomes in the HAH setting. The study will also enhance understanding of the value of POCUS integration from a provider perspective. By assessing its clinical impact and feasibility, this research may inform future guidelines for incorporating POCUS into home-based acute care, ultimately improving patient care and optimizing healthcare resource utilization. Clinical Trial: ClinicalTrials.gov NCT05423652

(JMIR Preprints 22/04/2025:76186)

DOI: <https://doi.org/10.2196/preprints.76186>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.

Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <https://preprints.jmir.org/preprint/76186>

No. Please do not make my accepted manuscript PDF available to anyone. I understand that if I later pay to participate in <https://preprints.jmir.org/preprint/76186>

Original Manuscript

Protocols/Proposals

Title: Aiding Chronic Obstructive Pulmonary Disease and Congestive Heart Failure Ultrasound-guided Management through Enhanced Point-of-Care Ultrasound (ACCUMEN-POCUS): Protocol for a Randomized Controlled Trial

Authors: MN Grinman^{1,2,8}, P Nakhla^{1,2}, S Reid⁷, D Moon⁸, N Dehghan Noudeh⁶, O Olaosebikan², A Ip², S Saunders², R Kozicky⁸, J Conly^{1,2,3,8}, AW Kirkpatrick^{4,11}, J Round⁹, IWY Ma^{1,5}, S Pascoe¹⁰, G Altabbaa^{1,8}

1. Department of Medicine, Cumming School of Medicine, University of Calgary, and Alberta Health Services, Calgary, Alberta, Canada
2. O'Brien Institute for Public Health, Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada
3. Snyder Institute for Chronic Diseases, University of Calgary, Calgary, Alberta, Canada
4. Department of Surgery, Cumming School of Medicine, University of Calgary, and Alberta Health Services, Calgary, Alberta, Canada
5. Department of Community Health Sciences, University of Calgary, Calgary, Alberta, Canada
6. Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada
7. Presuna, Alberta, Canada
8. Alberta Health Services, Calgary, Alberta, Canada
9. Faculty of Medicine & Dentistry, University of Alberta, Edmonton, Alberta, Canada
10. Zedu Ultrasound Training Solutions, Greensborough, Australia
11. TeleMentored Ultrasound Supported Medical Interventions - TMUSMI - Research Group, Calgary, Alberta, Canada

Corresponding author: Michelle Grinman

Phone: 403-943-3889

Fax: 403-943-8535

Email: michelle.grinman@ucalgary.ca

Author	Email
Michelle Grinman (corresponding author)	michelle.grinman@ucalgary.ca
Peter Nakhla	peter.nakhla@albertahealthservices.ca
Steve Reid	steve.reid@presuna.com
Dennis Moon	dennis.moon@albertahealthservices.ca
Negar Dehghan Noudeh	negar.dehghannoudeh@mail.utoronto.ca
Oladoyin Olaosebikan	doyin.olasebikan@gmail.com
Amanda Ip	amanda.ip@ucalgary.ca
Salome Saunders	salome.saunders@ucalgary.ca
Ryan Kozicky	ryan.kozicky@albertahealthservices.ca
John Conly	john.conly@albertahealthservices.ca
Andrew W Kirkpatrick	andrew.kirkpatrick@albertahealthservices.ca
Jeffrey Round	jround@ualberta.ca
Irene Ma	ima@ucalgary.ca
Suean Pascoe	suean@ultrasoundtraining.com.au
Ghazwan Altabbaa	galtabba@ucalgary.ca

Disclaimer: The views expressed in this manuscript are those of the individual researchers and not an official position of the affiliated institutions or funder.

Funding: This work has been funded by an Alberta Boehringer Ingelheim Collaboration grant in partnership with the University Hospital Foundation.

Trial Registration: ClinicalTrials.gov NCT05423652; <https://clinicaltrials.gov/study/NCT05423652>

Word count: 3287 (excluding abstract, acknowledgements, tables, figure legends, and references)

Number of figures: 3

Number of tables: 0



Abstract

Background

Hospital at home (HAH) programs offer acute care at home as a substitute for inpatient hospitalization, reducing healthcare costs while maintaining safety and quality of care. Despite point-of-care ultrasound's (POCUS) validation in inpatient and emergency settings, its role in HAH care remains underexplored.

Common conditions treated on medical HAH programs such as acute exacerbation of chronic obstructive pulmonary disease (AE-COPD), acute decompensated heart failure (ADHF), and pneumonia are highly amenable to the integration of POCUS into clinical decision making and have been proven to improve healthcare utilization outcomes. POCUS' portability makes it ideal for use in HAH but its feasibility remains to be proven given the need for provider training and use in virtual settings where a non-physician practitioner is providing in-person care.

Objective

This study evaluates the feasibility and clinical utility of remotely interpreted lung and inferior vena cava (IVC) POCUS acquired by Community Paramedics (CPs) to support real-time clinical decision-making for HAH patients with AE-COPD, ADHF, and pneumonia in Calgary, Canada.

Methods

This randomized control trial (RCT) compared usual HAH care (control) to lung and IVC POCUS-enhanced HAH care (intervention). Handheld POCUS devices captured images, which were downloaded and securely shared using a cloud-based application. This enabled real-time image sharing among the clinical team, facilitating immediate decision-making by remote physicians.

A mixed-methods approach will evaluate clinical outcomes, patients' experience, healthcare utilization, and healthcare provider perceptions of POCUS integration. The primary outcome of the study is defined as length-of-stay for the index HAH admission. Quantitative analysis will assess clinical efficacy and healthcare resource use, while qualitative methods such as interviews and surveys will capture patient and provider experiences.

Results

Study funding began in April 2022, with data collection having commenced in Dec 2023. Patient recruitment was finalized on December 31, 2024. The study included a three-month follow-up for significant outcomes and will include a one-year follow-up for long-term healthcare utilization, including admissions to long-term care. A total of 20 patients were enrolled (10 intervention, 10 control).

Initial results highlighted feasibility and potential benefits of remotely-acquired POCUS imaging in HAH. Full data analysis is in progress.

Conclusions

This study is the first RCT to investigate virtually-acquired POCUS by non-physician practitioners for real-time lung and IVC remote decision-making in HAH care. Findings will provide insights into whether serial lung and IVC POCUS assessments improve ADHF, AE-COPD, and pneumonia outcomes in the HAH setting. The study will also enhance understanding of the value of POCUS integration from a provider perspective. By assessing its clinical impact and feasibility, this research may inform future guidelines for incorporating POCUS into home-based acute care, ultimately improving patient care and optimizing healthcare resource utilization.

Trial Registration: ClinicalTrials.gov NCT05423652

Key words: Hospital at Home; Point-of-Care Ultrasound; ADHF; AE-COPD; Pneumonia

Introduction

Acute decompensated heart failure (ADHF), acute exacerbations of chronic obstructive pulmonary disease (AE-COPD) and/or pneumonia are among the leading causes of patient morbidity and mortality worldwide. They present with dyspnea and respiratory distress[1,2]. Currently, diagnosis and management of these patients is reliant on symptoms, physical examination such as lung auscultation, radiographic imaging studies and laboratory investigations[3–5]. However, for these conditions, the above modalities have poor diagnostic rates with radiographs having false-negative rates exceeding 25% at times. Biomarkers have poor predictive value in comorbid patients with multiple physiologic derangements[6–8]. Furthermore, chest radiographs often require costly machinery housed in a hospital or radiology centre, with the potential for delays due to radiologic interpretation time[9].

Emerging literature on using point-of-care ultrasound (POCUS) for management of AE-COPD, ADHF and pneumonia show reductions in hospital length-of-stay, favourable patient outcomes and lowered healthcare costs[10–13]. These findings are often attributed to the same or higher sensitivity than physical exam and chest radiography in detecting early signs of pulmonary edema, pleural effusions, impaired diaphragmatic excursion and/or subpleural consolidation[14–16]. Radiograph are also characterized by a lack of exposure to radiation, improved portability, and conduciveness to frequent bedside use in longitudinal care[15,17,18]. Historically, the success of POCUS in clinical medicine has been limited by the need for provider training, insufficient numbers of trained providers, and variability in the acquisition and interpretation of scans[10,11,16].

Recent studies suggested that non-expert providers, and even patients themselves, could be effectively trained to acquire quality POCUS images in an acute care, emergency or intensive care unit setting, particularly by using tele-guidance methods[19–21]. Although POCUS is well established in emergency and critical care settings, its utilization has progressively expanded into community and home-based care environments[22–24]. This shift has been notably accelerated by the COVID-19 pandemic, which highlighted the need for accessible diagnostic modalities among homebound older adults and populations in geographically isolated regions. In this context, tele-ultrasound has emerged as a viable solution, supporting timely and accurate clinical decision-making within evolving models of home-based acute care.[20,25–27]. This shift has been notably accelerated by the COVID-19 pandemic, which highlighted the need for accessible diagnostic modalities among homebound older adults and populations in geographically isolated regions. In this context, tele-ultrasound has emerged as a viable solution, supporting timely and accurate clinical decision-making within evolving models of home-based acute care.[20,25–27].

This paper describes a study protocol developed to investigate the feasibility and clinical usefulness of embedding Community Paramedic-acquired lung and inferior vena cava (IVC) POCUS scans in supporting real-time remote decision-making by physicians on a Hospital at Home (HAH) program. The sharing of images, feedback and clinical decision-making was supported by a cloud-based application (Presuna) designed to extract POCUS images from handheld POCUS devices, to enable sharing of ultrasound images between clinical team members for education and clinical care.

Objectives and Aims

This study is a multi-site, two-arm, parallel, randomized controlled trial (RCT) comparing enhanced daily assessments for patients with AE-COPD, ADHF, and/or pneumonia using POCUS with a cloud-based application versus standard care provided by a HAH program at a tertiary acute care medical teaching hospital in Calgary, Alberta, Canada.

Standard care provided through this HAH program was selected as the comparator to assess patient outcomes, experience, and healthcare utilization, and to evaluate the economic feasibility of integrating POCUS into future standard care practices.

Methods

This study is approved by the Conjoint Human Research Ethics Board at the University of Calgary (REB22-0434; latest protocol amendment version: 13.0; Issue date: Mar 20, 2025) and registered as a clinical trial (NCT05423652) at clinicaltrials.gov.

Study Setting

The Calgary Zone Virtual Home Hospital (previously the Complex Care Hub)[28] is a HAH program that provides substitutive acute care in patients' homes for a General Internal Medicine (GIM) population at two hospitals, the Rockyview General Hospital and South Health Campus. Patients can be admitted to HAH from a Brick-and-Mortar (BAM) hospital, either directly from the Emergency Department or the medical inpatient wards, as well as from community settings such as specialty clinics and family medicine referrals.

There are two collaborating teams:

- 1) The hospital-based team consists of a hospital physician (GIM or Family Medicine Hospitalist), Nurse Navigators (NN) and a pharmacist. This team performs case-finding, in-person assessments and interventions in a dedicated clinic space and oversees the care plan. Physicians also conduct virtual visits for patients admitted to the program, either directly leveraging digital remote patient monitoring technology or via a virtual consult with home-visiting Community Paramedics (CPs).

- 2) The home-based team consists of highly skilled CPs who collaborate with patients and their caregivers in the home. CPs perform the majority of home visits, assessments, and interventions under remote guidance by the HAH physician.

Patient Recruitment

Patients admitted to HAH with ADHF, AE-COPD and/or pneumonia were identified as potentially eligible either by HAH NNs or through the research team's screening of the patient charts (under a waiver of consent). NNs or CPs offered eligible patients the opportunity to be contacted by the research team to learn about the research study. Following initial contact, consenting patients were contacted by research assistants for enrollment into the study, obtaining written or verbal informed consent via Research Electronic Data Capture (REDCap) or email.

Inclusion criteria were: 1) Primary active diagnosis of ADHF, AE-COPD and/or pneumonia that required home-based acute care at the time of enrollment; 2) Patients must already have been admitted to HAH; 3) Patients were also required to be willing to participate in the study and to provide informed consent. Patients were excluded from the study if they did not have one of the three index conditions, had new unstable rib fractures, a prior history of allergy to ultrasound gel, or chronic lung diseases that would confound POCUS imaging (pulmonary fibrosis, fibrothorax, lung cancer or other intra-pulmonary malignancy, pleural plaques, pneumothorax, or pulmonary embolus). These conditions were confirmed on imaging done in BAM before admission to HAH, including radiographs and/or Computed Tomography.

REDCap's randomization function was used to allocate enrolled study patients to either the intervention arm (HAH care enhanced with serial POCUS assessment) or the control arm (usual HAH care) (Figure 1).

Randomization and Allocation Concealment

Randomization through the intrinsic REDCap functionality allocated participants to their respective study arms. Data analysts, including economists, are being blinded to study allocation. The master list of the clinical and study codes will be kept in an encrypted file on the University of Calgary server and managed by the research study team.

Provider Recruitment

HAH providers were recruited based on an expressed willingness to participate in the study after being provided with information about the study's aims and methods. Study staff then obtained informed consent, via email or in person. When a physician did not want to participate in the study, two physicians from the research team who regularly attend on HAH assumed care of study patients for the week(s) in which there was a non-participating physician.

In preparation for the RCT, we previously trained 6 CPs in POCUS image acquisition for lung and IVC using a hybrid protocol consisting of in-person didactic lectures and bedside teaching, online modules from the Canadian Point of Care Ultrasound Society (CPOCUS)[29], and asynchronous mentorship. The latter was used to evaluate their POCUS images' quality and clinical usability based on a rubric developed with consultation from POCUS experts.

There were two groups of physician participants, a mix of non-POCUS experts and POCUS experts who regularly rotate through the service. Those defined as POCUS experts are physicians certified in POCUS use and capable of providing consultative support to other clinicians/trainees. They only required an orientation to using the cloud-based application to interpret images. Initially, we intended to train non-POCUS expert physicians in acquiring and interpreting lung and IVC POCUS using the same training program described above for CPs. However, the post-pandemic challenges of high patient volumes, multiple competing priorities and physician burnout made it infeasible for physicians to complete the training. As such, we pivoted to train two physicians from the research team to be able to provide real-time POCUS interpretation support for non-POCUS expert physicians. (Figure 2). While certain physicians leveraged this support and the rubric on the cloud-based application to aid them in learning about POCUS, this was not common and was not evaluated in the study.

Intervention

Patients randomized to the interventional study arm received serial lung and IVC POCUS assessments throughout their admission to HAH. These images were acquired by CPs in their home and transmitted to HAH physicians via Presuna, a cloud-based application. Presuna allowed for extraction and secure sharing of the images captured by the handheld POCUS. CPs used a Phillips Lumify C5-2 curved array ultrasound transducer connected to a Samsung tablet to extract the images from the Lumify App and upload them to the Presuna App (which is encrypted). Once on Presuna, the images were instantaneously available for HAH physicians to interpret, either on a hospital computer or their personal cell phones, facilitating immediate decision-making by remote physicians (Figure 2).

For each POCUS study, CPs acquired images for a minimum 8 out of 10 lung zones (Figure 3). They attempted to acquire two views of IVC (longitudinal and transverse) with measurements at end inspiration and expiration to derive the IVC collapsibility index.

Data Collection

Confidentiality

All data on Presuna is encrypted in transit with modern Transport Layer Security and while at rest (storage) with modern Advanced Encryption Standard 256-bit encryption. Patient study IDs were used as the only method of patient identification. As such, no identifiable patient information was stored on Presuna. Furthermore, Presuna uses the 'least access principle', so providers could only access the data needed to perform their workflows and inform their decisions. In addition, all practitioners accessing Presuna had their codes to protect them as provider participants in the study, but also to reduce the identifiable linkages of patients with their providers.

All other study data was collected and managed using REDCap electronic data capture tools hosted

at the Centre for Health Informatics (CHI), Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada[30,31]. REDCap is a secure, web-based application designed to support data capture for research studies providing an intuitive interface for validated data capture; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to standard statistical packages, and procedures for data integration and interoperability with external sources. The Principal Investigator and the research team members involved in data analysis will be given access to the cleaned data sets. To ensure confidentiality, data dispersed to research team members will be blinded of any identifying participant information.

Study Outcomes

The study's demographic summary includes date-of-birth, age, sex and/or gender, co-morbid diagnoses, Charlson comorbidity Index, education level, employment status, race, smoking history, medication history, home medications, goals-of-care status and overall functional status. This serves to stratify endpoints based on potentially extraneous variables, thus minimizing their confounding effect in the final analysis. Study outcomes are intended to capture the most clinically significant causes of patient morbidity and mortality.

Primary

Outcome

The primary outcome is defined as length-of-stay (LOS) for the index HAH admission, measured from the date of admission until discharge based on ADHF studies showing decreased LOS in BAM inpatient care[12]. Since the program has an acute (hospital substitution) and subacute arm (post-acute care), LOS on each arm will also be reported.

Secondary

Outcomes

Secondary outcomes consist of patient-specific clinical outcomes, self-reported patient experience ratings (qualitative and quantitative), provider experience ratings (qualitative and quantitative) for physicians and paramedics, metrics of healthcare resource utilization, and assessment of feasibility within the HAH model.

Patient-specific secondary clinical outcomes include health-related quality of life (EuroQuoL-5-Dimension-5-Level (EQ-5D-5L) at the time of randomization, within one week following HAH discharge, at three months post-discharge and at six months post-discharge, and other objective metrics relating to disease progression/resolution while minimizing the subjectivity in relying on symptomatology alone.

Objective disease-related metrics for pneumonia include time to resolution of infection, defined as return to baseline oxygen saturation (considering home oxygen in some patients), normalization of white blood cell count, and for intervention-group participants the normalization of pathologic B-lines due to consolidative pneumonia. For ADHF patients, time to decongestion is defined as absence of crackles on lung auscultation, return to baseline oxygen saturations, and for intervention-group participants the absence of pathologic B-lines and/or pleural effusions on ultrasound. For AE-COPD patients, time to reduction in dynamic hyper-inflation is defined as absence of wheeze and return to baseline respiratory effort and oxygen levels, and absence of new pulmonary findings. POCUS monitoring in this population was intended to proactively identify new findings (e.g.: pneumonia) that could complicate the AE-COPD. Relevant biochemical parameters include change in N-terminal pro-B-type natriuretic peptide on admission relative established 'time of decongestion', change in troponin from maximum to minimum as measured during the enrollment period, change in creatinine and estimated glomerular filtration rate during the enrollment period, change in hemoglobin and white blood cell count during the enrollment period.

Imaging modalities performed as a function of routine clinical care were used to support diagnosis prior to enrollment, as well as during clinical status changes during the index HAH admission, including chest x-rays, CT, and ventilation-perfusion scans to rule out pulmonary embolism.

Study participants' medication burden was assessed at time of randomization, until one week following discharge from HAH. Admission to facility living, including long-term care or supportive

living will be assessed up to 12 months following discharge from the index HAH admission.

Changes in patient status were analyzed in terms of their severity and impact. Escalation of care is defined as the incidence ratio of transfer back to a BAM hospital ward from HAH for a reason concerning clinical stability. The transfers included in this metric are from the date of randomization until discharge from the index HAH admission. Adverse events that are measured in standard monitoring of the program include venous thromboembolism, falls, new infection, and mortality.

Qualitative analysis of patient experience of the index HAH admission was collected via survey format. The analysis is comprised of inquiries into patients' perceived experience with the clinical care model and the various technologies employed by HAH (digital remote patient monitoring, videoconferencing, and POCUS for the intervention arm). To achieve analytical granularity, we utilized a non-dichotomous but nominal rating scale: 'yes', 'yes to some extent', 'no' and 'unsure'. Responses were collected upon discharge from the index HAH admission.

We collected data on the overall experience of healthcare providers via qualitative means, including nurse practitioners, CPs, and physicians. Qualitative surveys were administered to inquire into providers' experience with the HAH model and various technologies employed for its duration (digital remote patient monitoring, videoconferencing, as well as POCUS-Presuna for the intervention arm). Participants were asked to score their responses on a Likert scale allowing entries in the form of 'strongly disagree,' 'disagree', 'neither agree nor disagree' and 'strongly agree'. We also embedded survey questions on Presuna for CPs and physicians to complete regarding their confidence in interpreting images (both in terms of their own confidence and the image quality), usability and clinical usefulness of POCUS for each encounter.

Statistical Analysis

Öhman et al.[32] showed a 46% reduction in hospital LOS in the standard care group versus the treatment arm that used cardiothoracic ultrasound to guide clinical decision-making for inpatient care (6.85 days, standard deviation: 4.22 versus 3.72 days, standard deviation: 2.02). For our study, we will use a conservative 30% reduction in LOS on HAH for the intervention arm versus the control arm, powered at 80% with an alpha level of 0.05. In designing the study, we estimated that we would require a sample size of 22 patients per study arm within the time frame of this project.

For analysis of the net resource effectiveness, economic data that still requires collection will be analyzed via the headroom model which is a method that quantifies the greatest cost at which an intervention would continue to demonstrate a net economic benefit. In this study, the headroom analysis will compare the control group, defined above as standard practice HAH care, with the POCUS/Presuna (intervention) group in ADHF, AE-COPD and pneumonia patients. Secondary patient outcomes will be analyzed via t-test comparing difference in biomarker or imaging values between control and intervention groups, set to the same power 0.80 and alpha 0.05.

Quality Assurance, Adverse Event Monitoring, and Steering Committee

Several measures were enacted to improve adherence to intervention protocols and ensure patient safety. Quality assurance of randomly selected scans was performed by the research team in consultation with a POCUS expert physician. This involved asynchronous mentorship leveraging the Presuna platform and Zedu Ultrasound Training Solutions. We created a POCUS acquisition/interpretation evaluation rubric to evaluate the presence of proper anatomic landmarks, image quality, and systematic analysis of the scans to identify the presence/absence of pathologic findings.

Adverse events were stratified under frequency and severity of venous thromboembolism, new infections (focal or systemic), falls, delirium and medication-related reactions, or other clinically significant events. They were recorded from the date of randomization up to discharge from HAH. Mortality outcomes will be stratified under time-to death and cause of death from date of randomization until participant mortality up to one year post-discharge.

A Data and Safety Monitoring Board (DSMB) reviewed adverse events during the study. The DSMB was comprised of two GIM specialists who work on HAH and were trained in POCUS for this study and two expert POCUS expert physicians. These two expert POCUS physicians (a GIM physician who works at a different hospital and a thoracic surgeon) have extensive experience in the design and deployment of ultrasound-based training curriculums.

Lastly, a steering committee for the project met monthly to discuss project operations and updates as well as providing direction and guidance to the research team. This committee consisted of the research team and co-investigators, a human factors evaluation team, the CP manager, POCUS experts, advisors, and a health economics analyst.

Results

Study funding began in April 2022, with data collection commencing in Dec 2023. Patient recruitment was finalized on December 31, 2024. The study includes a three-month follow-up for major outcomes and a one-year follow-up for long-term healthcare utilization, including admissions to long-term care. A total of 20 patients were enrolled (10 intervention, 10 control).

Preliminary findings were presented in poster format at the World Hospital at Home Congress (March 2025). Initial results of an analysis of patient and provider experience highlighted feasibility and potential benefits of remotely acquired POCUS imaging in HAH. Full data analysis is in progress, with results to be disseminated through journal publication and future scientific conferences.

Discussion

Our sample size calculations suggested a minimum of 22 patients per study arm to detect a statistically significant difference in length-of-stay. However, HAH experienced a shift in the expected diagnoses admitted to the program in the post-COVID-19 pandemic period. This resulted in lower numbers of patients with ADHF, AE-COPD and pneumonia than expected. While we implemented multiple strategies to increase recruitment, including adding the second site and obtaining a no-cost extension from the funder, we were only able to recruit 10 patients per study arm. While this will impact the analysis of the primary outcome, the rest of the metrics and particularly the semi-quantitative and qualitative data will be highly informative for future research in POCUS-enhanced HAH services.

Conclusions

This study is the first RCT investigating virtually acquired POCUS for lung and IVC real-time decision-making in HAH care. Findings will provide insights into whether serial lung and IVC POCUS assessments improve outcomes for ADHF, AE-COPD, and pneumonia in the HAH setting. The study will also enhance understanding of the value of POCUS integration from a provider perspective. By assessing its clinical impact and feasibility, this research may inform future guidelines for incorporating POCUS into home-based acute care, ultimately improving patient care and optimizing healthcare resource utilization.

Acknowledgements

We would like to acknowledge the Calgary Zone Virtual Home Hospital nurse navigators, physicians and leaders for supporting the implementation of this initiative and the development of this protocol for the RCT.

Author Statement

MG, SR, GA, NDN, OO, AI, RK, JC, AK, IM, JR and SP participated in designing the study. MG, GA, DM, OO, AI, SS, and SP conducted the study. AI, MG, GA, JR, and JC will be involved in data

analysis and methods. MG, PN, and AI drafted and revised the manuscript in response to co-author feedback. All authors were involved in reviewing and editing serial versions of the manuscript prior to submission.

Conflicts of Interest

The research team has no conflicts of interest to declare relevant to the work entailed in this research protocol. SR is the founder and owner of Presuna, who was provided with reimbursement for the cost of participation in the study. Presuna did not profit from this study but benefitted from iterative feedback from the research and clinical team to refine the software to be more responsive and usable for clinical teams embedding POCUS into their care. SP is the owner of Zedu Ultrasound Solutions and contributed her time in kind to the development of the rubric to evaluate and provide quality assurance for the acquisition and interpretation of POCUS images for lung and inferior vena cava POCUS. SP was only reimbursed for her time providing remote mentorship to the clinicians. Both SR and SP will not be involved in data analysis and preparation of results presentations. IM declares receiving an editorial honorarium from Elsevier and is funded by the John A. Buchanan Chair in General Internal Medicine at the University of Calgary, both unrelated to the manuscript. IM serves as a volunteer on the executive of the American Institute of Ultrasound in Medicine.

Abbreviations

ADHF: acute decompensated heart failure
AE-COPD: acute exacerbation of chronic obstructive pulmonary disease
BAM: brick-and-mortar
CHI: Centre For Health Informatics
CP: community paramedic
CPOCUS: Canadian Point of Care Ultrasound Society
DSMB: data and safety monitoring board
EQ-5D-5L: Euroquol-5-Dimension-5-Level
GIM: general internal medicine
HAH: Hospital At Home
IVC: inferior vena cava
NN: nurse navigator
RCT: randomized controlled trial
REDCap: Research Electronic Data Capture
POCUS: point-of-care ultrasound

Figures

Figure 1: Randomization and study protocol



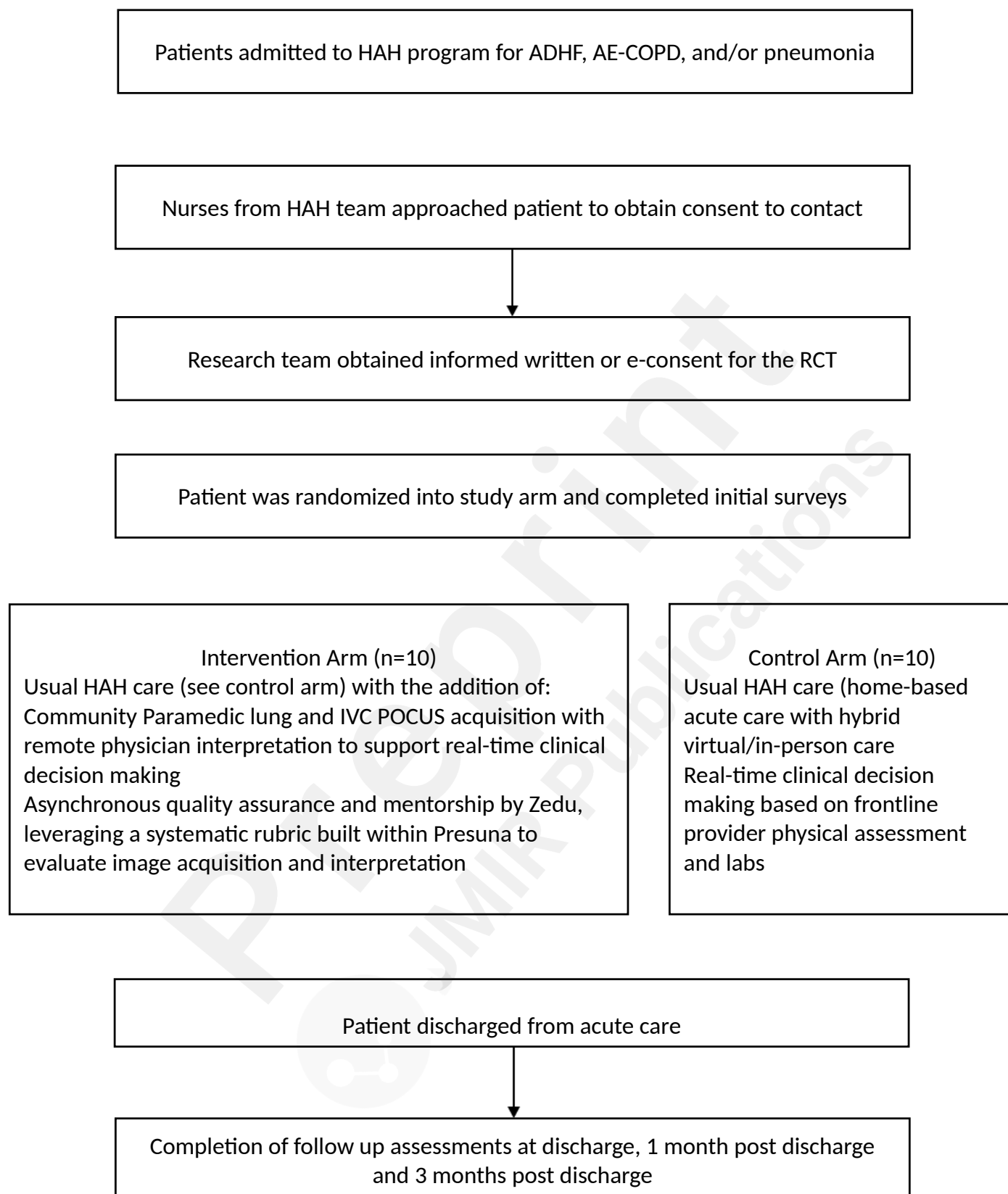


Figure 2: Process for Remote Acquisition, Interpretation and Real-Time Learning of IVC and Lung POCUS

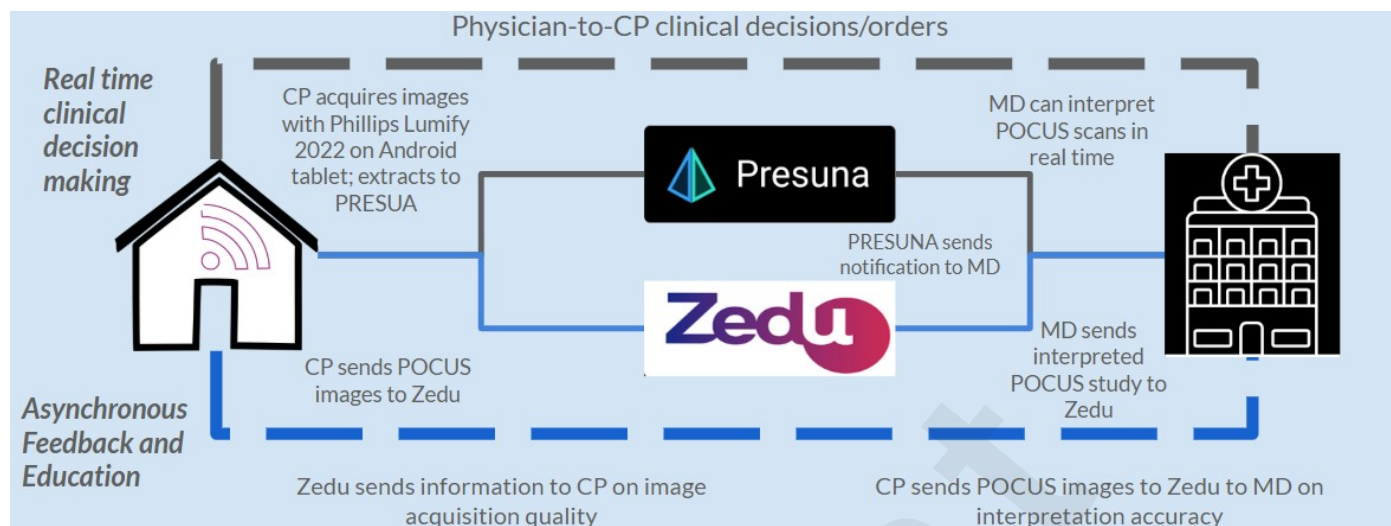
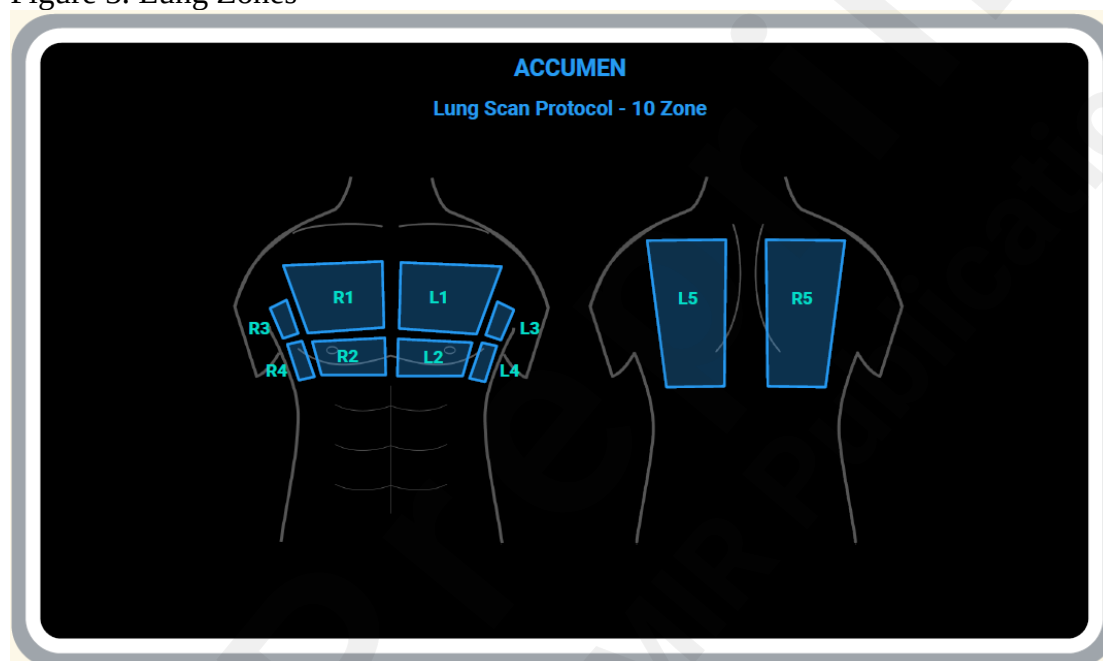


Figure 3. Lung Zones



References

1. Chen H, Luo X, Du Y, He C, Lu Y, Shi Z, Zhou J. Association between chronic obstructive pulmonary disease and cardiovascular disease in adults aged 40 years and above: data from NHANES 2013–2018. BMC Pulm Med 2023 Aug 31;23(1):318. doi: 10.1186/s12890-023-02606-1
2. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021 (GBD 2021) Cause-Specific Mortality 1990–2021. Seattle; 2021. doi: <https://doi.org/10.6069/4fgf-3t54>
3. Meyer T, Colucci W, Dardas T. Approach to diagnosis and evaluation of acute decompensated heart failure in adults - UpToDate. Approach to diagnosis and evaluation of acute decompensated heart failure in adults. 2024. Available from: <https://www.uptodate.com/contents/approach-to-diagnosis-and-evaluation-of-acute-decompensated-heart-failure-in-adults> [accessed Apr 16, 2025]
4. Stoller JK, Hatipoglu U. COPD exacerbations: Management - UpToDate. COPD exacerbations: Management. 2025. Available from: <https://www.uptodate.com/contents/copd-exacerbations-management> [accessed Apr 16, 2025]

5. Ramirez JA. Overview of community-acquired pneumonia in adults - UpToDate. Overview of community-acquired pneumonia in adults. 2024. Available from: <https://www.uptodate.com/contents/overview-of-community-acquired-pneumonia-in-adults> [accessed Apr 16, 2025]
6. Makhnevich A, Sinvani L, Cohen SL, Feldhamer KH, Zhang M, Lesser ML, McGinn TG. The Clinical Utility of Chest Radiography for Identifying Pneumonia: Accounting for Diagnostic Uncertainty in Radiology Reports. *American Journal of Roentgenology* 2019 Dec;213(6):1207–1212. doi: 10.2214/AJR.19.21521
7. Collins SP, Lindsell CJ, Storrow AB, Abraham WT. Prevalence of negative chest radiography results in the emergency department patient with decompensated heart failure. *Ann Emerg Med* 2006 Jan;47(1):13–18. PMID:16387212
8. Pivetta E, Goffi A, Nazerian P, Castagno D, Tozzetti C, Tizzani P, Tizzani M, Porrino G, Ferreri E, Busso V, Morello F, Paglieri C, Masoero M, Cassine E, Bovaro F, Grifoni S, Maule MM, Lupia E, Paolo B, Alessia B, Giuseppina B, Andrea C, Andrea C, Ottavio D, Paola DR, Andrea E, Paolo FP, Patrizia F, Daniela F, Francesca G, Grazia GM, Sara G, Alda L, Davide L, Franca M, Franco M, Corrado M, Giulia N, Luca P, Sonia P, Paolo Q, Claudia S, Elisa S, Elisabetta S, Flavia S, Fabio S, Michela S, Francesca S, Cristina T, Grazia VM, Marco A, Laura B, Sofia B, Ernesta B, Barbara C, Matteo C, Melisenda C, Beatrice D, Grazia F, Roberto F, Giuseppe G, Chiara G, Simona G, Eriola H, Juri M, Federico M, Andrea N, Maddalena O, Andrea P, Giuseppe P, Stefano P, Michele R, Francesca S, Francesco TP, Federica T, Vanni S, Gabriele V. Lung ultrasound integrated with clinical assessment for the diagnosis of acute decompensated heart failure in the emergency department: a randomized controlled trial. *Eur J Heart Fail* 2019 Jun 1;21(6):754–766. PMID:30690825
9. Omofoye TS, Vlahos I, Marom EM, Bassett R, Blasinska K, Ye X, Tan BS, Yang WT. Backlogs in formal interpretation of radiology examinations: a pilot global survey. *Clin Imaging* 2024 Feb 1;106. PMID:38070475
10. Duggan NM, Jowkar N, Ma IWY, Schulwolf S, Selame LA, Fischetti CE, Kapur T, Goldsmith AJ. Novice-performed point-of-care ultrasound for home-based imaging. *Sci Rep* 2022 Dec 1;12(1). PMID:36443355
11. Naddaf N, Dianati Maleki N, Goldschmidt ME, Kalogeropoulos AP. Point of Care Ultrasound (POCUS) in the Management of Heart Failure: A Narrative Review. *J Pers Med* 2024 Jul 18;14(7):766. doi: 10.3390/jpm14070766
12. Van Schaik GWW, Van Schaik KD, Murphy MC. Point-of-Care Ultrasonography (POCUS) in a Community Emergency Department: An Analysis of Decision Making and Cost Savings Associated With POCUS. *Journal of Ultrasound in Medicine* 2019 Aug 28;38(8):2133–2140. doi: 10.1002/jum.14910
13. Zieleskiewicz L, Cornesse A, Hammad E, Haddam M, Brun C, Vigne C, Meyssignac B, Remacle A, Chaumoitre K, Antonini F, Martin C, Leone M. Implementation of lung ultrasound in polyvalent intensive care unit: Impact on irradiation and medical cost. *Anaesth Crit Care Pain Med* 2015 Feb;34(1):41–44. doi: 10.1016/j.accpm.2015.01.002
14. Maw AM, Hassanin A, Ho PM, McInnes MDF, Moss A, Juarez-Colunga E, Soni NJ, Miglioranza MH, Platz E, DeSanto K, Sertich AP, Salame G, Daugherty SL. Diagnostic Accuracy of Point-of-Care Lung Ultrasonography and Chest Radiography in Adults With Symptoms Suggestive of Acute Decompensated Heart Failure. *JAMA Netw Open* 2019 Mar 15;2(3):e190703. doi: 10.1001/jamanetworkopen.2019.0703
15. Nakao S, Vaillancourt C, Taljaard M, Nemnom M-J, Woo MY, Stiell IG. Diagnostic Accuracy of Lung Point-Of-Care Ultrasonography for Acute Heart Failure Compared With Chest X-Ray Study Among Dyspneic Older Patients in the Emergency Department. *J Emerg Med* 2021 Aug;61(2):161–168. doi: 10.1016/j.jemermed.2021.02.019
16. Bhagra A, Tierney DM, Sekiguchi H, Soni NJ. Point-of-Care Ultrasonography for Primary Care Physicians and General Internists. *Mayo Clin Proc* 2016 Dec;91(12):1811–1827. doi:

- 10.1016/j.mayocp.2016.08.023
17. Volpicelli G, Elbarbary M, Blaivas M, Lichtenstein DA, Mathis G, Kirkpatrick AW, Melniker L, Gargani L, Noble VE, Via G, Dean A, Tsung JW, Soldati G, Copetti R, Bouhemad B, Reissig A, Agricola E, Rouby J-J, Arbelot C, Liteplo A, Sargsyan A, Silva F, Hoppmann R, Breikreutz R, Seibel A, Neri L, Storti E, Petrovic T. International evidence-based recommendations for point-of-care lung ultrasound. *Intensive Care Med* 2012 Apr 6;38(4):577–591. doi: 10.1007/s00134-012-2513-4
 18. Demi L, Wolfram F, Klersy C, De Silvestri A, Ferretti VV, Muller M, Miller D, Feletti F, Wehnicki M, Buda N, Skoczylas A, Pomiecko A, Damjanovic D, Olszewski R, Kirkpatrick AW, Breikreutz R, Mathis G, Soldati G, Smargiassi A, Inchingolo R, Perrone T. New International Guidelines and Consensus on the Use of Lung Ultrasound. *Journal of Ultrasound in Medicine* 2023 Feb 22;42(2):309–344. doi: 10.1002/jum.16088
 19. Tierney D, Rosborough T, Sipsley L, Hanson K, Smith C, Boland L, Miner R. Association of Internal Medicine Point of Care Ultrasound (POCUS) with Length of Stay, Hospitalization Costs, and Formal Imaging: a Prospective Cohort Study. *POCUS Journal* 2023 Nov 27;8(2):184–192. doi: 10.24908/pocus.v8i2.16791
 20. Uschnig C, Recker F, Blaivas M, Dong Y, Dietrich CF. Tele-ultrasound in the Era of COVID-19: A Practical Guide. *Ultrasound Med Biol* 2022 Jun;48(6):965–974. doi: 10.1016/j.ultrasmedbio.2022.01.001
 21. Jindal SK, Lee T, Agrawal A, Demers L, Schwartz AW. A National Survey on Point of Care Ultrasonography Use Among Veterans Affairs Clinicians in Home Care and Skilled Nursing Facilities. *J Am Med Dir Assoc* 2024 Jun;25(6):104930. doi: 10.1016/j.jamda.2023.12.018
 22. Peris A, Tutino L, Zagli G, Batacchi S, Cianchi G, Spina R, Bonizzoli M, Migliaccio L, Perretta L, Bartolini M, Ban K, Balik M. The Use of Point-of-Care Bedside Lung Ultrasound Significantly Reduces the Number of Radiographs and Computed Tomography Scans in Critically Ill Patients. *Anesth Analg* 2010 Sep;111(3):687–692. doi: 10.1213/ANE.0b013e3181e7cc42
 23. Mjølstad OC, Andersen GN, Dalen H, Graven T, Skjetne K, Kleinau JO, Haugen BO. Feasibility and reliability of point-of-care pocket-size echocardiography performed by medical residents. *Eur Heart J Cardiovasc Imaging* 2013 Dec;14(12):1195–1202. doi: 10.1093/ehjci/jet062
 24. Lichtenstein DA, Mezière GA. Relevance of Lung Ultrasound in the Diagnosis of Acute Respiratory Failure*: The BLUE Protocol. *Chest* 2008 Jul;134(1):117–125. doi: 10.1378/chest.07-2800
 25. Kirkpatrick AW, McKee JL, Ball CG, Ma IWY, Melniker LA. Empowering the willing: the feasibility of tele-mentored self-performed pleural ultrasound assessment for the surveillance of lung health. *Ultrasound J* 2022 Jan 3;14(1):2. doi: 10.1186/s13089-021-00250-6
 26. Kirkpatrick AW, McKee JL. Lung ultrasonography in a woman with COVID-19: This examination could be remote. *Can Med Assoc J* 2020 Apr 20;192(16):E435–E435. doi: 10.1503/cmaj.75302
 27. Kirkpatrick AW, McKee JL, Conly JM. Longitudinal remotely mentored self-performed lung ultrasound surveillance of paucisymptomatic Covid-19 patients at risk of disease progression. *Ultrasound J* 2021 Dec 30;13(1):27. doi: 10.1186/s13089-021-00231-9
 28. Grinman M, Kozicky R, Smith M, Proceviat K, Bettcher L, Amlani S, Ewa V, Shankel MJ, Goertzen J, Wodinski L, Motehayerarani A, Altabbaa G, Haws J, Delcastilho C, Reimche L, Gohel B. Bringing Acute General Internal Medicine Outside of Hospital Walls. *Canadian Journal of General Internal Medicine* 2022 Mar 14;17(1):94–104. doi: 10.22374/cjgim.v17i1.548
 29. Acute Care CORE - CPoCUS - Canadian Point of Care Ultrasound Society. Available from: <https://cpocus.ca/acute-care-core/> [accessed Apr 16, 2025]
 30. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009 Apr;42(2):377–381. doi: 10.1016/j.jbi.2008.08.010
 31. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O’Neal L, McLeod L, Delacqua G,

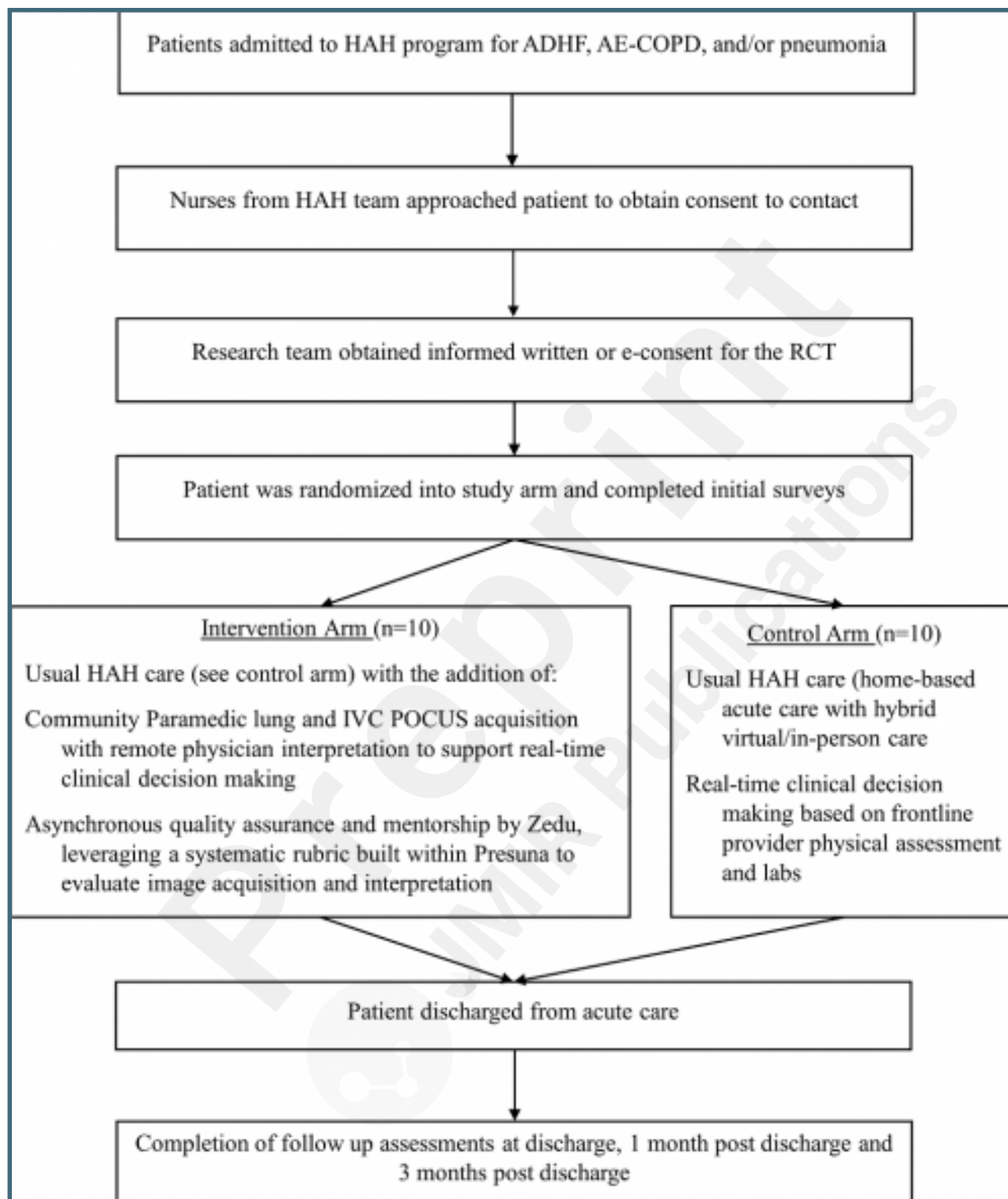
- Delacqua F, Kirby J, Duda SN. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform* 2019 Jul;95:103208. doi: 10.1016/j.jbi.2019.103208
32. Öhman J, Harjola V, Karjalainen P, Lassus J. Focused echocardiography and lung ultrasound protocol for guiding treatment in acute heart failure. *ESC Heart Fail* 2018 Feb 28;5(1):120–128. doi: 10.1002/ehf2.12208



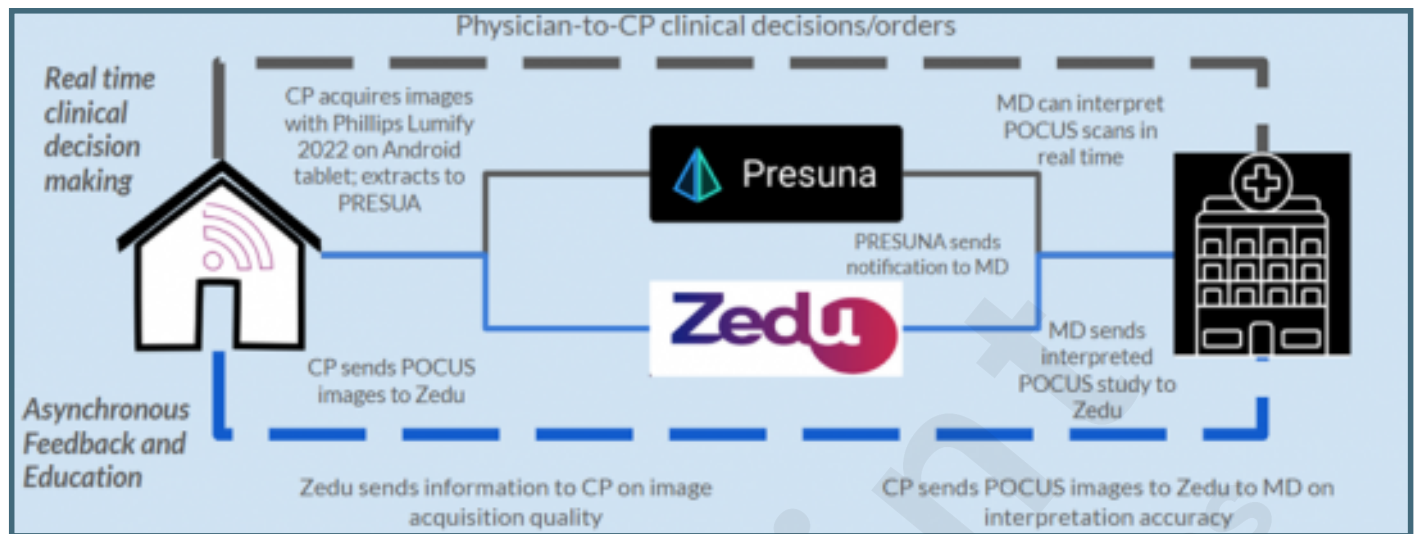
Supplementary Files

Figures

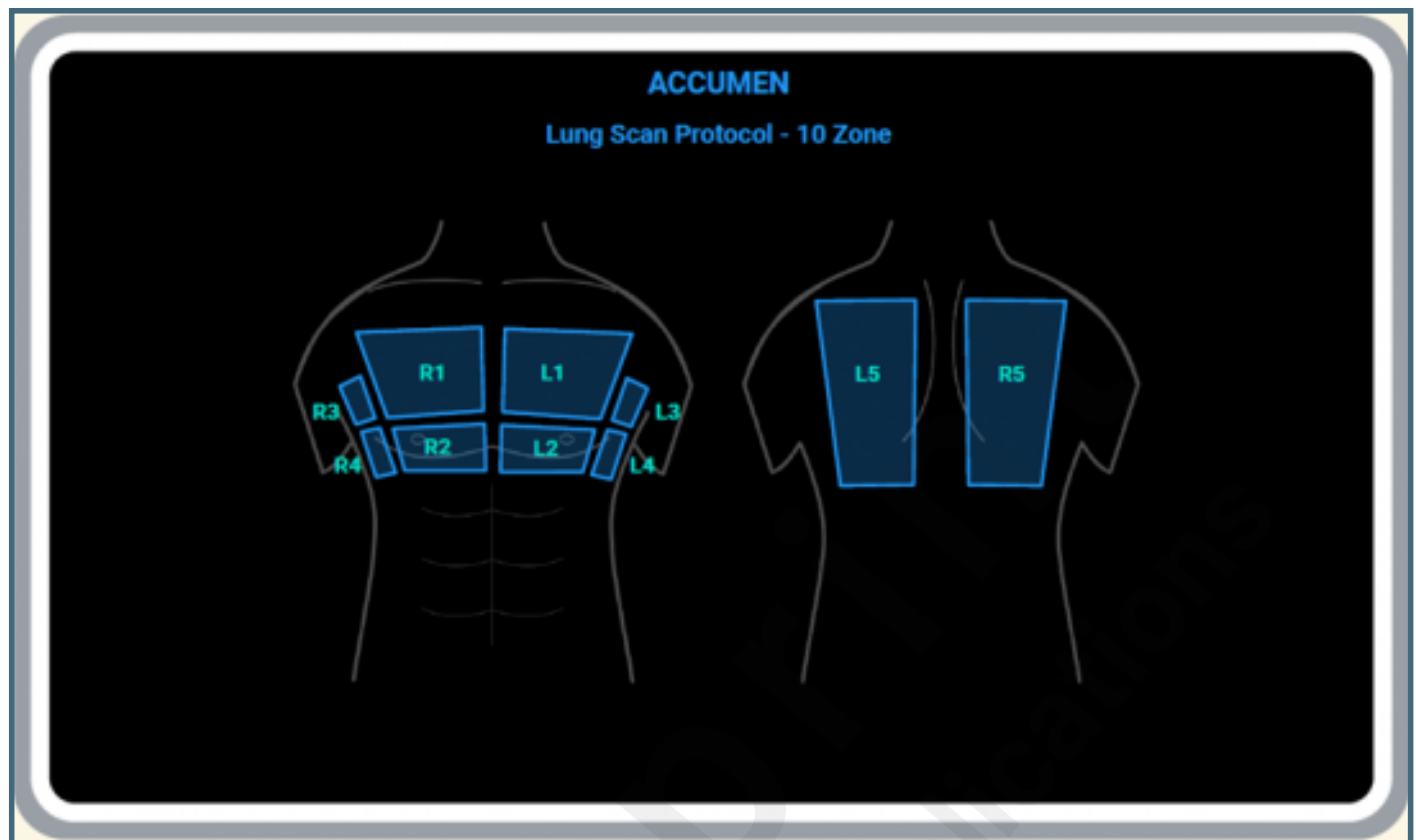
Randomization and study protocol.



Process for remote acquisition, interpretation and real-time learning of IVC and lung POCUS.



Lung zones.



Multimedia Appendixes

Peer-reviewed documentation of the research protocol.

URL: <http://asset.jmir.pub/assets/f9a4a52892a268dff78bc91eb5fb13bb.pdf>

