INVESTIGATOR STUDY PLAN - REQUIRED

Cover Page

Study Title: Evaluation of the Paramedic Evaluation for Acute COPD Exacerbation (PEACE) Intervention.

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1. TITLE
Evaluation of the Paramedic Evaluation for Acute COPD Exacerbation (PEACE) intervention.

2. EXTERNAL IRB REVIEW HISTORY*
NA

3. PRIOR APPROVALS:
NA

Conflict of Interest (COI):
NA

Clinical Engineering Department:
NA

Biohazardous Agents:
NA

Radiation*:*
NA

Students as Subjects*:*
NA

Research Informatics Core:
The Research Informatics Core will be providing support for this project including assistance with participant recruitment. Details of their involvement will be described in Section 11: Procedures Involved and Section 24: Local Recruitment Methods.

UMCCTS Protocol Review Committee (PRC)
NA

4. OBJECTIVES*

Evidence-based strategies to ensure that patients with COPD have reliable, timely, equitable access to treatment are lacking. This deficit is particularly evident in communities impacted by determinants of health that adversely impact preventive health behavior and care access.[1]

On-demand Mobile Integrated Health (MIH) teams, comprised of community paramedics supported by centralized physicians, have been developed to care for patients outside of conventional hospital settings.[2-5] These teams empower physicians to provide enhanced remote care by collecting essential clinical information about patients in their living environment, performing diagnostic testing, and administering therapy in the home.[3, 6] MIH programs decrease emergency medical

services utilization and improve patient satisfaction in select populations, but the impact of MIH programs on the outcomes of patients with COPD exacerbation has not been evaluated.[7]

In this project, the study team will implement and refine an MIH intervention for patients living with COPD. The Paramedic Evaluation for Acute COPD Exacerbation (PEACE) intervention will dispatch community paramedics to execute a home-based evaluation and treatment strategy in collaboration with a supervising physician and the patient's ambulatory medical team during and after acute COPD exacerbation to promote wellness and recovery. This intervention is intended to improve clinical outcomes and reduce acute care costs by eliminating barriers to care, generating actionable clinical data that can facilitate appropriate diagnosis, accelerating treatment, and simplifying care coordination. Our central hypothesis, based on preliminary data and input from key informants, is that an intervention that facilitates community-based management of COPD exacerbation will be acceptable and highly adoptable by patients and clinicians.

The Practical Robust Implementation and Sustainability Model (PRISM) implementation framework [8, 9] will be used to describe factors impacting project implementation, with the embedded Expanded RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) model guiding outcomes measurements.[10] Leveraging our prototypical intervention design, we will **test and Refine the prototype PEACE intervention in real clinical practice** with a cohort of patients who are at high risk of COPD exacerbation. We will use a mixed-methods approach to evaluate the usability and acceptability of each operational and clinical component of PEACE. Measures will include a systematic assessment of protocol adherence, survey instruments, and qualitative interviews to explore contextual factors impacting intervention performance.[11, 12] We will confirm our findings and adapt the protocols informed by a working group comprised of clinicians and community partners. Up to 25 patient participants will be enrolled in the intervention, plus up to 11 clinician participants will be enrolled to participate in usability/acceptability ratings and qualitative evaluations/focus groups.

5. BACKGROUND*

Chronic obstructive pulmonary disease (COPD) claims 150,000 lives every year in the United States, diminishes patient quality of life, costs billions of dollars in healthcare expenditures, and widens health disparities.[13-16] Acute COPD exacerbations cause 873,000 emergency department visits and 700,000 hospitalizations annually,[13, 17] with disproportionate morbidity and mortality in patients impacted by social and racial inequities.[1, 18-20] **Frequent assessment and early treatment are effective in mitigating COPD exacerbations** and preventing severe complications including hospitalization, worsening disability, and mortality.[21-24] **However, evidence-based strategies to ensure that patients with COPD have reliable, timely, equitable access to treatment when experiencing acute symptoms are lacking.** This project seeks to address this question and provide evidence describing the use of MIH models to care for patients living with COPD.

6. INCLUSION AND EXCLUSION CRITERIA*

Inclusion Criteria/Exclusion Criteria for Patient Subjects:

- Inclusion Criteria: 1) Diagnosis of COPD, 2) At least one COPD exacerbation resulting in ED utilization in the six months prior to enrollment, 3) Over 18 years of age, 4) Speaks English, 5) Resides in the geographical catchment area allowed by the UMass Memorial Medical Center MIH Program's license 6) Referred by a clinician at UMMH to the Wellinks pulmonary rehabilitation program

- Exclusion Criteria: 1) No prior diagnosis of COPD, 2) Under 18 years of age, 3) Does not speak English, 4) Pregnancy, 5) Cannot provide informed consent 6) Not referred to Wellinks pulmonary rehabilitation program

Inclusion Criteria/Exclusion Criteria for clinician subjects:

- Inclusion Criteria: 1) Pulmonologist, primary care physician, emergency physician, or paramedic affiliated with the UMMH system, 2) Has provided care to an enrolled patient subject, 3) Speaks English, and 4) Over 18 years of age.
- Exclusion Criteria: 1) Has not provided care to an enrolled patient subject 2) Does not speak English, 3) Under 18 years of age, and 4) Cannot provide informed consent.

Justifications for Criteria:

-Our intervention targets community-dwelling patients who have a diagnosis of COPD, so patients who do not meet this criteria are necessarily excluded.

a. Children are excluded as they rarely have a diagnosis of COPD and will not meet any inclusion criteria as clinician subjects

b. prisoners represent a special population that is routinely excluded from similar research studies. They represent an inaccessible population. Additionally, they will be excluded as they are not residing in a community setting. They will not meet any inclusion criteria as clinician subjects

c. COPD is rare in young women of childbearing age, thus pregnant women are extremely unlikely to be eligible as patient subjects for this study. Pregnant women will be ineligible for inclusion as patient subjects. They will be eligible as clinician subjects as the components of the study in which they participate are minimal risk and will have no bearing on their pregnancy.

d. The commercial products that are used as part of this study, specifically the Wellinks telepulmonary rehabilitation program, are only available in English, thus necessitating that only English-speaking participants are included in this small pilot study

7. STUDY-WIDE NUMBER OF SUBJECTS*

NA

8. STUDY-WIDE RECRUITMENT METHODS*

NA

9. STUDY TIMELINES*

Overall timeline: Recruitment will begin upon the disbursement of study funding and will be completed within 18 months of that date. Primary analyses will be completed no later than two years from the disbursement of funds.

Involvement of Subjects in PEACE Beta Testing:

1.0 Recruitment (Day 0)

1.1 Informed consent

1.2 Patient-facing education
1.3 Data Intake Patients
1.3.1 Demographic and Background Survey
1.3.2 Baseline COPD Assessment Test
1.3.3 Baseline Data collection

2.0 Intervention Period I (~Day 1-182)
2.1 The subject will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team
2.2 Subjects will be asked to fill out a survey within 7 days of each PEACE encounter
2.3 PEACE visits and Healthcare utilization will be tracked by the research team

3.0 Working Group 1 (~Day 182)
3.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview on Zoom

4.0 Intervention Period II (~Day 182-365)
4.1 The patient will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team
4.2 Subjects will be asked to fill out a survey within 7 days of each PEACE encounter
4.3 PEACE visits and Healthcare utilization will be tracked

5.0 Working Group 2 (~365)
5.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview.
5.2 Follow-up COPD Assessment Test (patient subjects only)

6.0 Follow-up Data Collection (~Day 365-Day 730)
6.1 Records review only, no subject interaction

10. STUDY ENDPOINTS*

Our primary outcome The primary feasibility measure will be the recruitment rate. The primary process outcome will be the number of PEACE referrals during the study period. Additional qualitative outcomes are described below in Table 1, organized by PRISM domain. Primary and secondary outcome measures, their timing, and how they will be measured are summarized in Tables 1 and 2 below.

There are no primary or secondary safety measures being recorded for this study.

Table 1: Beta Testing Outcome by PRISM Domain			
PRISM Domain	**Outcome**	**Data Source**	**Analysis**
Patient Characteristics	• Sample Demographic characteristics • Excluded/Declined Demographics	Study Records Interviews	Descriptive Qualitative
Organizational Characteristics	• Participating clinic size/structure	Interviews	Descriptive Qualitative
Intervention *Clinician and Patient Perspective*	• Affective Attitude • Intervention Coherence • Self-Efficacy • Ethicality • Burden and anticipated cost • Opportunity cost • Fidelity to PEACE protocol	Video review Interviews *Intervention Usability Scale* *Acceptability E-*	Qualitative Descriptive
External Environment	• Institutional, local, and state resources that could be leveraged for intervention delivery	Interviews Literature Review	Descriptive
Implementation and Sustainability Infrastructure	• Staff Fidelity to Intervention (see Figure 3) • Cost of intervention	Clinical Records Interviews Study Records	Descriptive Qualitative

Table 2: Feasibility and Clinical Measures				
Outcome	**Measure**	**Frequency**		
		0	6	12
Sample Description	*Demographic Characteristics of Study Sample*: Participant age, gender identity, race and ethnicity, education level, smoking status, insurance type, employment status, living arrangements, driving status, and comorbidities	**X**		
	Sample COPD Severity: Gold Score, ED visits and hospitalizations in year before enrollment	**X**		
Feasibility Outcomes	***Recruitment and enrollment:*** **Number of participants approached, met eligibility, and randomized; reason for refusal of nonparticipants (primary feasibility outcome)**	**X**		
	Baseline Measures: Completeness of data collection	**X**		
	Retention: Loss to follow-up, perceived reason for discontinuation, completeness of post-intervention data collection		**X**	**X**
	PEACE Referrals during study period: **Number of encounters requested (Primary process outcome)**		**X**	**X**
Clinical Outcomes	*PEACE Visits and Disposition:* Number of PEACE visits completed and rate of home treatment versus ED referral		**X**	**X**
	Ambulatory Visits: Number of ambulatory visits for COPD (routine/acute)		**X**	**X**
	EMS Utilization: Number of prehospital encounters related to COPD		**X**	**X**
	Hospitalizations: Number and length of hospitalizations for COPD		**X**	**X**

	Other institutional stays: Number and length of stay in skilled nursing facilities or acute rehabilitation settings		**X**	**X**
	COPD Assessment Test (CAT): health-related quality of life and COPD symptom severity assessment	**X**	**X**	**X**
	Unanticipated ED visits: ED visits within 72 hours after PEACE visit		**X**	**X**
	Mortality: Death will be ascertained through chart review		**X**	**X**
	Exacerbation Relapse: An event where COPD symptoms worsen and require a second pharmacological intervention[25]		**X**	**X**
	COPD related medication changes: Number of adjustments made to study participants' treatment regimen (initiation, discontinuation, dosage adjustment, or substitution of medications aimed at managing COPD)		**X**	**X**

11. PROCEDURES INVOLVED*

Subject Screening (day -1)

→ The UMass Chan research informatics core will identify eligible patients by creating an automated report that flags patients who meet the inclusion criteria (filtering by diagnosis, city of residence, and use of Wellinks)

→ The RIC will securely (via encrypted secure excel document) provide the study team with reports containing the contact information for potentially eligible patients

» STUDY00002240_PEACE_HIPAA Waiver of Authorization

Enrollment & Intake Visit of Patient Subjects:

- ***Recruitment:*** *See Section 24*.
  → ***Documents:***
    - STUDY00002240_PEACE_HIPAA Waiver of Authorization
    - STUDY00002240_PEACE_SCREENER
    - STUDY00002240_PEACE_DeclinedIneligibleLog
      STUDY00002240_SOLICITATIONMESSAGEPATIENTSUBJECT

- ***Consent:*** *See Sections 30 & 31*. Study Staff will obtain at least three ways (email address, primary phone number and mailing address) to contact participants to schedule interviews and fill out ad-hoc surveys.
  → ***Documents:***
    - STUDY00002240_PEACE_Consent
    - STUDY00002069_PEACE_PATIENTMASTERCODE

- ***Intake:*** After obtaining consent, the study staff will access EMRs to obtain baseline data. Patients will also be asked to complete a baseline COPD Assessment Test.

→ ***Documents:***
- STUDY00002240_PEACE_DemographicsData
- STUDY00002240_PEACE_COPD_Assessment Test

Enrollment of clinician subjects:

- ***Recruitment:*** *See Section 24.*
  → ***Documents:***
  - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS
  - STUDY0002240_PEACE_QualitativeIntake
  - STUDY00002240_PEACE_DeclinedIneligibleLogClinician

- ***Consent:*** *See Sections 30 & 31*
  → ***Documents***
  - STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS

- **Master Code *Contact Information:*** Study Staff will obtain at least two ways (primary phone number and mailing address) to contact participants to schedule interviews and prompt participants to complete surveys.
  → ***Documents:***
  - STUDY00002069_PEACE_CLINICIANMASTERCODE

- **Intervention Period I (~Day 1-182)**
  → The patient will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team.
  1..1 *The Paramedic Evaluation for Acute COPD Exacerbation (PEACE)* intervention is a mobile integrated health home visit specifically designed to manage acute COPD exacerbation in the community. PEACE was developed using high-quality literature, stakeholder feedback, and observations from the UMMHC pilot MIH studies.
  1..2 Ambulatory teams are empowered to refer patients for PEACE visits when patients need more focused, in-person care but a brick-and-mortar setting is inaccessible or inappropriate. PEACE visits are available 7 days a week/24 hours a day. All clinical teams participating in this study are familiar with the MIH program as they have engaged with it for other purposes
  1..3 Once a visit is requested via an electronic health record (EHR) order, a community paramedic presents to the patient's home within 2 hours, evaluates the patient using mobile diagnostic testing, and initiates pharmacological therapy if necessary. A standardized clinical approach and documentation strategy is used including a focused history and physical exam, venous blood gas, trending pulse-oximetry, medication reconciliation, smoking cessation resources, mobile x-ray etc.
  1..4 The community paramedic is supervised in real-time by a physician to establish a care plan and disposition- either treatment at home with ambulatory follow-up or, if the patient is too acutely ill to be treated in place, transfer to the ED. While often used during periods of acute

exacerbation, PEACE can also be used to support post-acute care and augment telepulmonary rehabilitation services.

→ PEACE visits and Healthcare utilization will be tracked throughout the beta testing period.
→ Every time a patient undergoes a PEACE visit, the study team will ask the patient, their primary care physician, pulmonologist, and the treating paramedic (if enrolled in the study) to complete a post-visit evaluation survey.

1..1 Documents:
1..1.1 Study00002240 PEACE Visit Data
1..1.2 STUDY002240 PEACE Post Visit Form
1..1.3 STUDY00002240_PostVisitFormClinician

7.0 Working Group 1 (~Day 182)

7.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview in a focus group-type setting
7.2 The focus of these focus groups will be on 1) Selecting and engaging patients most likely to benefit from the PEACE intervention 2) Determining the best timing of the PEACE intervention in each patient's healthcare trajectory, 3) optimizing the clinical and diagnostic capabilities of the mobile intervention 4) establishing relationships between the mobile clinical team and other members of patients' personal and medical care team, and 5) measurements of the effectiveness of the program.
7.2.1 Patient subjects will be informed that if they choose to participate in the focus groups, they may be asked to discuss their health and health information regarding their diagnosis of COPD with other patients and clinicians in the mixed-subject focus groups.
7.3 Structured interviews will be scheduled at a mutually convenient time for subjects and study staff.
7.4 Each subject will participate on one day for approximately 1-2 hours.
7.5 Interviews may be held in person or via secure zoom video chat
7.6 Interviews will be held in groups of 3-4 with a mix of subject types in each group
7.7 After a brief reiteration of the study purpose, the interviewer will confirm consent to record the interview for transcription and analysis purposes before proceeding. Interview responses will be recorded by hand on the interview guide or typed into a document on the interviewer's encrypted computer, and also digitally recorded to capture verbatim content and professionally transcribed by a member of the study team for later qualitative analysis.
7.8 At the end of the interview, all participants will be asked to fill out a brief (10 minute) structured Redcap Survey.
7.9 All interviews will be digitally recorded using the Zoom recording application with Microsoft Teams as a backup. This program will be run on a computer present in the room for in-person interviews or on the computer of the study team member conducting any Zoom interviews. Only audio recording will take place. No video recording will take place at any time.

7.9.1 Immediately following each interview, the recording will be transcribed, and the original recording subsequently deleted once transcription is complete.

7.9.2 Documents

7.9.2.1 STUDY00002240_PEACE_SampleInterviewGuide

7.9.2.2 Transcribed Interviews

7.9.2.3 STUDY00002240_PEACE_QUALITATIVEINTERVIEWPOSTSURVEY

8.0 Intervention Period II (~Day 182-365)

8.1 The patient will have on-demand access to PEACE Intervention via their primary care or subspecialty clinicians as well as the Wellinks team as described above

8.2 PEACE visits and Healthcare utilization will be tracked

8.3 Every time a patient undergoes a PEACE visit, the study team will ask the patient, their primary care physician, pulmonologist, and the treating paramedic (if enrolled in the study) to complete a post-visit evaluation survey.

8.3.1 Documents:

8.3.1.1 Study00002240 PEACE visit form

8.3.1.2 Study00002240_PEACE_POSTVISITINSTRUMENT

8.3.1.3 STUDY00002240_PostVisitFormClinician

9.0 Working Group 2 (~365)

9.1 Qualitative working group. All subjects will be asked to attend a single (~1-2 hour) structured interview in a focus group setting as described above
At the end of the interview, all participants will be asked to fill out a brief (10 minute) structured Redcap Survey.

9.2 Patient subjects will be asked to also complete a follow up COPD Assessment Test

9.2.1 Documents:

9.2.1.1 STUDY00002240_PEACE_SampleInterviewGuide

9.2.1.2 Transcribed Interviews

9.2.1.3 STUDY00002240_PEACE_QUALITATIVEINTERVIEWPOSTSURVEY

9.2.1.4 STUDY00002240_PEACE_COPD_Assessment Test 2

10.0 Follow-up Data Collection (~Day 365-Day 548)

10.1 Records review only, no subject interaction. The study team will query the EHR to collect follow-up data points about enrolled subjects

→ *Documents:*

- *Study00002240_PEACE_Utilizationsummary*

12. DATA AND SPECIMEN BANKING*

NA

13. Data Analysis and Management*

Sample Size:

Analysis Strategy:

Quantitative Analysis: As is appropriate for a pilot study, quantitative data including demographic data, exploratory clinical outcomes data, and subject usability and acceptability ratings as well as the evaluation of fidelity to each intervention component will be analyzed and reported descriptively.

Qualitative Analysis: Analysis of qualitative data will be conducted using ATLAS.ti qualitative software. Three independent coders will inductively develop a preliminary set of codes organized by PRISM domain.[8] The codebook will be elaborated upon based on emergent themes and adjusted as the interviews proceed. The entire qualitative team will subsequently review each transcript and develop a revised codebook after reviewing ~ 20% of the interviews together. We will apply the codebook to all interviews, using constant comparison methods to generate higher-level themes and synthesize our results into a formative evaluation report of the key findings.

Data Management Plan:

All study data will be recorded on a REDCap database established on a secure encrypted server on Amazon Web Services. All access to the database will be through permissions established by the IT REDCap administrator. Investigators will have to log into the REDCap database to enter or view data. Logic data checks will be built into the data entry process to help clean the data at entry. Quality control edits will be run to identify inconsistencies and questionable values in the data. The audit trail will be activated for the duration of the study.

Data for analysis will be downloaded directly from REDCap and converted to SAS, STATA, datasets or R data frames for analysis. The downloaded datasets will be deidentified and are HIPPA as well as 21 CFR Part 11 compliant.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

All unanticipated adverse events will be reported, and the study PI will closely monitor all aspects of the study.

The PI will be responsible for monitoring adverse events during the study. If an adverse event occurs, their role will be to identify the concern, to develop an appropriate response to alleviate or minimize any adverse event, and to ensure that the adverse event is reported in a timely manner to the appropriate authority. We anticipate that these adverse will be rare in this minimal risk study. We will assess whether an undesirable experience (adverse event) occurred and will record details of all adverse events on an adverse event case report form. We do not anticipate that any serious adverse events (death, life threatening illness, new serious or permanent disability) will occur. However, should such an event occur, we will report the event within five business days to the University of Massachusetts Chan Medical School (UMCMS) Institutional Review Board per HRP-103-Investigator Manual guidelines.

The adverse event case report form will include a description of all undesirable experiences, required interventions, and an assessment of the participant after the event if possible. An estimate of the extent of injury and prevention strategies will be reported. The principal investigators will classify the relationship of the study protocol to the event as follows:

• Not related: The event is clearly related to factors not related to the study protocol.
• Remote: The event was most likely related to factors not related to the study protocol.
• Possible: The event follows a reasonable temporal sequence associated with participating in the study and/or is consistent with events related to the study protocol but is possibly related to factors such as the participant's clinical state.
• Probable: The event follows a reasonable temporal sequence associated with participating in the study and/or is consistent with events related to the study protocol and cannot be reasonably explained by factors such as the participant's clinical state.

The severity of an adverse event in both groups is defined as a qualitative assessment of the degree or intensity of an adverse event as determined by the principal investigator as follows:

• Mild: No impact (in any way) on the participant.
• Moderate: Impacts on the participant but is not life-threatening or incapacitating.
• Severe: Fatal, life threatening, permanently disabling; severely incapacitating; requires/prolongs inpatient hospitalization.

All adverse events will simultaneously be reported to institutional officials. The report will summarize the facts of the case, including the date and a description of the participant; whether the event is related to the study's protocols; the steps that have been taken to address the issue; whether the event provides emerging knowledge about the risks of the study that should be conveyed to participants; and whether the consent form should be revised.

As this is a minimal-risk study, we do not plan on having a data safety monitoring board review. The UMMH MIH program is a fully licensed program that meets clinical standards of care; it is supervised by the Massachusetts Department of Public Health and its medical director submits clinical data to them quarterly for quality and safety review. The program also has an internal quality improvement/assurance protocol for all completed visits. The program is accustomed to providing peri-acute care, particularly to patients with COPD.

The frequency of data review for this study is summarized in the following table:

Data Type:	**Frequency of Review:**
Participant recruitment (adherence to protocol on inclusion & exclusion criteria)	The PI will directly observe recruitment for the first five cases, then will observe random cases bi-monthly once the study is established.
Data collection methods	The PI will directly observe data collection on the first five cases, then will observe random cases bi-monthly once the study is established.

Integrity of data storage procedures	The PI will directly monitor data storage the first five cases, and then will review all data monthly once the study is established.

The PI will report all new information required by the IRB within 5 business days including: Information that indicates a new or increased risk, or a new safety issue, a protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm or any of the other required reporting parameters.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*
NA

16. RISKS TO SUBJECTS*
The main risks to participants are:

- Delays in definitive emergency care
- Loss of confidentiality or privacy given that their contact information and PHI will be collected
- Psychological distress from participating in the survey or qualitative interview

1) **Delays in definitive emergency care**
    a. The mobile integrated health service provided as part of this study is licensed under the purview of the state Department of Public Health and is considered a standard of care. It is an already active program and is utilized by patients daily under the supervision of Dr. O'Connor, who is the medical director of the program, to provide peri-acute care. To mitigate any risk of patients' delaying emergency care by inappropriately requesting an MIH visit, patients and clinicians will be extensively educated about the purpose of the MIH program and its capabilities and limitations. They will be counseled in symptoms and conditions necessitating immediate use of the 911 system instead of the MIH hotline. A copy of the licensure letter provided by the Massachusetts Department of Public Health is included with this application.
    b. The MIH team is also extremely well positioned to transition care into the traditional 911 care pathway should a participating patient be determined to be experiencing a medical emergency. The dispatch and ambulance services that support the MIH program are the same services that perform emergency transportation in the geographical catchment area where the study will be performed; therefore, their communications are integrated, and the nature of the care being performed can be transferred at any time.
    c. The MIH care pathway has several safeguards to transition care into an emergency response if needed. If a community paramedic is dispatched to the patient's home and the paramedic or the consulting physician feels that the patient is experiencing an emergency, he/she may contact the program's dispatch and activate the 911 pathway. If this happens, a transporting vehicle will be immediately dispatched to the patient's home. The community paramedics are all

experienced professionals with years of work functioning in an urban 911 system and will render care until the transporting vehicle arrives.

d. All community paramedics will be equipped with a full cadre of advanced life support level medications and supplies. The MIH program will only function in the geographical zone where the community paramedics belong to the same organization as the 911 responding service and no other organization's involvement is anticipated.
e. If the patient has any questions or clinical concerns during any research or clinical visit, there will always be both a physician on call for the research study as well as a clinical physician on call for the mobile integrated health program who can be contacted for additional real-time support.

Protections against the specific risks identified above include the following:

- **Loss of Privacy/Confidentiality**
  - All data will be managed securely as noted above. We view this risk to be minimal. All data and personal information about subjects from both the observational cohort and the qualitative arm will be managed securely and accessible only by authorized members of the study team. All identifiers will be disposed of as soon as appropriate (see section 26).

- **Psychological Distress**
  - The informed consent process will discuss the potential risk that participating in discussions related to health and emergency care might cause distressing rumination about overall health and aging. We will inform all subjects verbally and in writing that they may decline to answer any question asked and may stop participating in the interviews at any time. We view this risk as minimal.
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17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

Patients who participate in the program may experience improved outcomes related to their COPD from the enhanced healthcare access provided by the PEACE program.

18. VULNERABLE POPULATIONS*

Employees of site

No employees at the site will be purposely recruited but may be included incidentally.

Children

Children will not be included in this study.

Prisoners

Prisoners will not be included in the study.

Adults Unable to Consent

Adults unable to consent will not be included in this study

Pregnant Women

Pregnant women will be excluded from enrolling as patient participants.

Pregnant women may be included as clinician participants. This part of the study is minimal risk and presents no intervention that will impact or pose additional risk to their pregnancy. No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.

19. MULTI-SITE RESEARCH*
NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*
Individual results from surveys and interviews will be shared with subjects upon their request.. Completed deliverables such as manuscripts, whitepapers, and posters may be shared with subjects at their request.

22. SETTING

- ***Enrollment & Informed Consent:*** Patients will be located in the community; study team will be located in private offices at the University Campus in the departments of medicine and emergency medicine

- ***Data Abstraction:*** Private offices at the University Campus in the departments of family medicine and emergency medicine

- ***Interviews:*** Subjects will be located in the community or in private offices at the university campus; the study team will be located in private offices at the University Campus in the departments of medicine and emergency medicine

- ***Follow-up data collection:*** Private offices at the University Campus in the departments of medicine and emergency medicine

- **Data analyses and manuscript writing** will occur in private offices at the University Campus in the departments of medicine and emergency medicine

23. RESOURCES AVAILABLE

Study Staff: All Study Staff members are up to date on CITI certification and are aware that this training must be renewed every three years. They will conduct this research in accordance with the current, IRB-approved protocol.

- ***Study Investigators:***
  - → ***Principle Investigator (PI):*** The PI is a board-certified Emergency Medicine physician with experience in human subjects research.
    - ***Responsibilities:*** The PI will be responsible for overseeing the entire study including, but not limited to (1) dissemination of the research protocol to all Study Staff; (2) recruitment; (3) enrollment; (4) data collection; (5) data analysis; and (6) dissemination of results. The PI will ensure all Study Staff are adequately trained and monitor their progress to ensure they are following the protocol.
  - → ***Co-Investigators (Co-Is):*** The Co-Is are physicians from the departments of Emergency Medicine and Medicine
    - ***Responsibilities:*** The Co-Is will assist the PI with all aspects of the study including, but not limited to: (1) recruitment; (2) enrollment; (3) administering questionnaires; (4) interpretation of results; and (5) preparation of the resulting manuscripts.
- ***Additional Study Staff Roles:***
  - → ***Research Assistants (RA):*** The RA will have basic training in research methods and human subjects' research, as well as a bachelor's degree in a human science field or equivalent.
    - ***Responsibilities:*** They will be trained by the PI and co-investigators to complete most aspects of the study including, but not limited to: (1) explaining the study to eligible individuals; (2) obtaining informed consent; (3) how to conduct a chart review; (4) data handling; and (5) administering questionnaires.

24. LOCAL RECRUITMENT METHODS

Feasibility*:* We have completed similar studies in the target population and were able to recruit 100 participants in one year.[26] Therefore we feel that the small number of patients anticipated for inclusion in this pilot study will be minimal.

Procedures: We have created a one-page basic *solicitation* to provide to prospective subjects that outlines the study details in an easy-to-read format.

- Study staff will identify potentially eligible individuals through EHRs with assistance from the Research Informatics Care. As described above, the RIC will securely provide the team with a list of patients who are potentially eligible for the study based on their age, city of residence, diagnosis of COPD, and participation in the Wellinks program.
  - → If the individual seems eligible based on the above information, the study staff will query other portions of the EMR (medical history, healthcare utilization patterns etc.) to verify EMR-based eligibility.
  - → If the individual still appears eligible, the study team will send the patient a MyChart message soliciting participation in the study. The message will include

PI contact information for questions and prompt interested patients to fill out an online screener indicating interest.

→ Once subjects have completed the online screener, the study team will contact them via phone to discuss the study, answer any further questions, and proceed with study activities.

→ We will inform patients during this initial phone conversation that consent forms and surveys will be sent via email which is not a secure form of communication and receive permission to email them links or QR codes to access the REDCap consent form/survey. If patients do not want to receive links/QR codes to study instruments via email, we will offer patients the option of receiving them via snail mail.

→ Patients will be given the option of reviewing and signing the consent form independently or doing it while on a teleconference with a member of the study team so that the consent can be reviewed in real-time.

→ A $(50) gift card will be given to each participant after they complete baseline intake forms, and then again after each interview during the study. To be eligible to receive the research stipend - the subject's name, address, phone number, and type of phone (mobile, landline) will be collected by the study team and provided to the UMass Chan business office to procure the payment. Once this information is provided to the business office – this identifying information will be destroyed by the PI.

→

- Documents
  - STUDY00002240_PEACE_HIPAA Waiver of Authorization
  - STUDY00002240_SCREENER_12.4.2024_V1
  - STUDY00002240_PEACE_DeclinedIneligibleLog
  - STUDY00002240_SOLICITATIONMESSAGEPATIENTSUBJECT

Destruction of Identifiers:

- ***Declined or Ineligible:*** Any participants who decline will be noted on the *Declined/Ineligible Log*. No identifiers are maintained on this log.
- ***Agree to Participate:*** Following the enrollment and intake visit, identifiers from the *Screening Log* will be transferred to the *Master Code* and de-identified demographic information will be transferred to the appropriate Redcap Database.

Professional Subjects:

- The study team will identify and subsequently email each subject (e.g. clinician, administrator) using a standardized email script to describe the study.
- Potential subjects will be identified and contacted individually. The invitation will include a description of the project and a summary of the topics to be covered in the interview.
- Only publicly available contact information (i.e., email address) will be used to contact clinicians

- After initiating the recruitment email or phone call, the team will make a single follow-up attempt for non-responders.
- Interested participants will be invited to self-schedule interview in an online scheduling portal
- Once the interview has been scheduled, the study team will proceed with informed consent as per section 30.
- A $(50) gift card will be given to each participant after they complete each of their interviews and surveys. To be eligible to receive the research stipend - the subject's name, address, phone number, and type of phone (mobile, landline) will be collected by the study team and provided to the UMass Chan business office to procure the payment. Once this information is provided to the business office – this identifying information will be destroyed by the PI.
- Documents*:*
  - » STUDY00002240_PEACE_CONSENTEMAILCLINICIANSUBJECTS_12.4.2024_V1
  - » STUDY00002240_PEACE_DeclinedIneligibleLogClinician_12.6.2024_v1

25. LOCAL NUMBER OF SUBJECTS

We expect up to 25 patient participants will be enrolled in the intervention, plus up to 11 clinician participants will be enrolled to participate in usability/acceptability ratings and the qualitative evaluation.

26. CONFIDENTIALITY

Because the National Institute of Health (NIH) is funding this research, this study will automatically have a Certificate of Confidentiality. The Certificate protects the study team from being forced to release information that may identify participants as part of a court, legislative, administrative, or other proceeding.

Procedures to Secure the Data:

- Participants will be assigned a unique Study ID# and most data related to a given participant will use this ID *(see table below)*.
- We may quote participant comments in presentations and publications; however, any direct quotations will be carefully reviewed to ensure that they do not include any potentially identifiable content.
- UMMS/UMMMC computers are password-protected and encrypted.
- Data will be stored in REDCap

INVESTIGATOR STUDY PLAN - REQUIRED

Document	***Coding***	***Access***	***Storage***	***Destruction***
Declined Ineligible Logs *- De-identified demographic information will be recorded on this document*	- Will not contain any of the 18 HIPAA identifiers	- Authorized Study Staff & Support Personnel	- Securely stored on a password-protected UMMMC/UMMS computer	- Will be archived once results have been published
Email Script/Solicitations-Patients	- *Identifiable information; Will contain potential participants' name and email address	- Authorized Study Staff	- Securely stored on a password-protected UMMMC/UMMS	- Contact information will be deleted for each participant once data collection is complete.
Email Script/Solicitations-Clinicians	- *Identifiable information; Will contain potential participants' name and email address	- Authorized Study Staff	- Securely stored on a password-protected UMMMC/UMMS	- Contact information will be deleted for each participant once data collection is complete.
Master Codes for Patient Subjects *- Identifiers will be transferred to the Master Code; All other information will be entered into RedCap under a random ID*	- *Identifiable information; The only place that identifying information will be linked with Study ID#	- Authorized Study Staff	- Securely stored on a password-protected UMMMC/UMMS	- Name, date of birth, and contact information will be deleted for each participant once data collection is complete.
Master Code for-Clinician Participants *- Contact information will be collected from participants using Redcap (Contact Info) and then transferred to the Master Code*	- *Identifiable information	- Authorized Study Staff	- N/A	- Contact information will be transferred to the *Master Code* following completion of the enrollment and intake visit and the Redcap form will be destroyed
Consent *- Written documentation*	- *Identifiable information	- Authorized Study Staff	- Securely stored in the PI's locked office	- Forms will be retained for 6 years following completion of this research
Transcribed Interviews	No Identifiers	Authorized Study Staff	- Securely stored on a password-	1) Transcriptions will be archived once results have been published

			protected UMMMC/UMMS	
ALL Data Collection Sheets *Collected using the Redcap form*	Study ID# only	Authorized Study Staff	Directly entered by the RA or subject into Recap	REDCap database will be archived once results have been published
Interview Guide	No Identifiers	Authorized Study Staff	Written in advance by study staff	1) Interview guide will be archived once results have been published
HIPAA Waiver of Authorization	No Identifiers	Authorized Study Staff	Written in advance by study staff	1) HIPAA Waiver of authorization will be archived once results have been published

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

Procedures to Protect Subjects:

- To make subjects feel at ease, Study Staff will clearly explain the function of the PEACE program and the additional steps entailed by the research study. Patients will be notified explicitly that they may participate in the home visits as part of the clinical protocol without participating in the research study.
- Participants will be informed that they can skip any question in the questionnaires or interviews that they feel uncomfortable answering.
- Study Staff will remind participants that their participation is voluntary and withdrawal of participation at any time will not involve any penalty or loss of benefits to which they are otherwise entitled.
- Participants will be given contact information for Study Staff should they have any questions or concerns at any time or if they wish to withdraw from the study.
- Participants will be offered copies of all signed forms *(Consent* and *HIPAA Authorization)* and given contact information for Study Staff should they have any questions or concerns at any time, or if they wish to withdraw from the study.
- Study Staff members directly involved with recruiting and consenting participants will not be involved in their clinical care.
- The collection of sensitive information will be limited to the information that is necessary to conduct this research.

Protected Health Information:

- A HIPAA Waiver of Authorization has been obtained to allow Study Staff to identify eligible participants for recruitment (see Section 24).
- Following consent, a signed HIPAA Authorization will be obtained to access and record additional information from the participant's EMR. This information will be limited to information directly related to the study.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

No funds have been set aside for research-related injury.

29. ECONOMIC BURDEN TO SUBJECTS

There are no anticipated costs for which participants will be responsible because of participation in this research.

The Mobile Integrated Health (MIH) program is currently grant-funded because most insurance providers do not reimburse for it. Thus, while it is a clinical standard of care and licensed under state OEMS protocols, patients will not be billed for UMMH MIH services during research home visits.

30. CONSENT PROCESS

Study Staff Education: Only Study Staff with prior approval who have reviewed **HRP-090 Informed Consent** will be obtaining consent.

Patient Subjects:

Consent Process:

- We will be obtaining informed consent.
- All consent will be collected electronically via the Redcap application. Patients will be able to review, sign, and date consent electronically
- Subjects will be invited to independently read and sign the consent form or sign in with teleconferencing support from a member of the study team to review the consent document.
- All of the potential risks, reasoning, and goals of this research will be explained to each individual prior to obtaining consent. They will be informed that enrollment is voluntary and declining to participate will not affect their treatment. Ample time will be given to answer any questions, and they will be informed that they may opt out of this voluntary study at any point.
- -An electronic or printed copy of the consent will be provided to patients after the electronic signature, depending on the subject's preference.
    - The electronic consent document/process allows subjects to proceed forward or backward or pause for review later if they choose.
    - Several measures are present to ensure that subjects have access to all of the consent-related materials, including hyperlinks or other external documents.
    - These measures include active guidance from the study team while reviewing the consent form to point out salient sections and key language, and access to paper copies of all relevant documents that patients may need to make their decision about participation. Patients will be allowed to read a paper copy of the consent before signing electronically if they prefer.

Clinician Cohort:

This study entails minimal risk for clinician subjects. Specifically, it will not cause harm or discomfort that is greater than those ordinarily encountered in daily life or routine medical practice. This intervention does not impact participants' care, decisions about their care, or future access to care and therefore a waiver will not adversely affect the rights and welfare of the subjects. A Fact Sheet will be provided to subjects explaining the study and its potential (minimal) risks

All of the potential risks, reasoning, and goals of this research will be explained to each individual prior to obtaining consent. They will be informed that enrollment is voluntary and that declining to participate will not affect their treatment. Ample time will be given to answer any questions, and they will be informed that they may opt out of this voluntary study at any point.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

Study Staff Education: Only appropriately trained Study Staff with prior approval who have been trained on best practices in Documentation of Informed Consent and are familiar with HRP-091 SOP: Written Documentation of Consent will be obtaining consent during this study. The PI will train all co-investigators and research assistants on obtaining informed consent prior to initiating study activities. Additionally, there will be a detailed study manual for the project which will obtain HRP-091 for quick reference when needed for this study.

Documentation of Consent: Informed consent will be documented in writing for patient subjects. Written consent will not be obtained for provider subjects as the study activities for this cohort entail less than minimal risk and do not entail any activities that would normally require written consent outside of the research setting. We request a waiver of written consent for clinician subjects.

32. DRUGS OR DEVICES

NA

REFERENCES

1. Li H, Liang H, Wei L, Shi D, Su X, Li F, Zhang J, Wang Z. Health inequality in the global burden of chronic obstructive pulmonary disease: Findings from the global burden of disease study 2019. *Int J Chron Obstruct Pulmon Dis*. 2022;17:1695-1702
2. Elden OE, Uleberg O, Lysne M, Haugdahl HS. Community paramedicine: Cost-benefit analysis and safety evaluation in paramedical emergency services in rural areas - a scoping review. *BMJ Open*. 2022;12:e057752
3. Lurie T, Adibhatla S, Betz G, Palmer J, Raffman A, Andhavarapu S, Harris A, Tran QK, Gingold DB. Mobile integrated health-community paramedicine programs' effect on

emergency department visits: An exploratory meta-analysis. *Am J Emerg Med*. 2022;66:1-10

4. van Vuuren J, Thomas B, Agarwal G, MacDermott S, Kinsman L, O'Meara P, Spelten E. Reshaping healthcare delivery for elderly patients: The role of community paramedicine; a systematic review. *BMC Health Serv Res*. 2021;21:29
5. Sokan O, Stryckman B, Liang Y, Osotimehin S, Gingold DB, Blakeslee WW, Moore MJ, Banas CA, Landi CT, Rodriguez M. Impact of a mobile integrated healthcare and community paramedicine program on improving medication adherence in patients with heart failure and chronic obstructive pulmonary disease after hospital discharge: A pilot study. *Explor Res Clin Soc Pharm*. 2022;8:100201
6. Choi BY, Blumberg C, Williams K. Mobile integrated health care and community paramedicine: An emerging emergency medical services concept. *Ann Emerg Med*. 2016;67:361-366
7. Louras N, Reading Turchioe M, Shafran Topaz L, Ellison M, Abudu-Solo J, Blutinger E, Munjal KG, Daniels B, Masterson Creber RM. Mobile integrated health interventions for older adults: A systematic review. *Innov Aging*. 2023;7:igad017
8. Feldstein AC, Glasgow RE. A practical, robust implementation and sustainability model (prism) for integrating research findings into practice. *Jt Comm J Qual Patient Saf*. 2008;34:228-243
9. Trinkley KE, Kahn MG, Bennett TD, Glasgow RE, Haugen H, Kao DP, Kroehl ME, Lin CT, Malone DC, Matlock DD. Integrating the practical robust implementation and sustainability model with best practices in clinical decision support design: Implementation science approach. *J Med Internet Res*. 2020;22:e19676
10. Shelton RC, Chambers DA, Glasgow RE. An extension of re-aim to enhance sustainability: Addressing dynamic context and promoting health equity over time. *Front Public Health*. 2020;8:134
11. Lyon AR, Pullmann MD, Jacobson J, Osterhage K, Achkar MA, Renn BN, Munson SA, Areán PA. Assessing the usability of complex psychosocial interventions: The intervention usability scale. *Implement Res Pract*. 2021;2
12. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework. *BMC Health Services Research*. 2017;17:88
13. Iheanacho I, Zhang S, King D, Rizzo M, Ismaila AS. Economic burden of chronic obstructive pulmonary disease (copd): A systematic literature review. *Int J Chron Obstruct Pulmon Dis*. 2020;15:439-460
14. Zafari Z, Li S, Eakin MN, Bellanger M, Reed RM. Projecting long-term health and economic burden of copd in the united states. *Chest*. 2021;159:1400-1410
15. Syamlal G KL, Dodd KE, Blackley DJ, Hall NB, Mazurek JM. . Chronic obstructive pulmonary disease mortality by industry and occupation — united states, 2020. 2022:1550–1554
16. Sullivan J, Pravosud V, Mannino DM, Siegel K, Choate R, Sullivan T. National and state estimates of copd morbidity and mortality - united states, 2014-2015. *Chronic Obstr Pulm Dis*. 2018;5:324-333
17. Pasquale MK, Sun SX, Song F, Hartnett HJ, Stemkowski SA. Impact of exacerbations on health care cost and resource utilization in chronic obstructive pulmonary disease patients

with chronic bronchitis from a predominantly medicare population. *Int J Chron Obstruct Pulmon Dis*. 2012;7:757-764
18. Kharbanda S, Anand R. Health-related quality of life in patients with chronic obstructive pulmonary disease: A hospital-based study. *Indian J Med Res*. 2021;153:459-464
19. Nastars DR, Rojas JD, Ottenbacher KJ, Graham JE. Race/ethnicity and 30-day readmission rates in medicare beneficiaries with copd. *Respir Care*. 2019;64:931-936
20. Pleasants RA, Riley IL, Mannino DM. Defining and targeting health disparities in chronic obstructive pulmonary disease. *Int J Chron Obstruct Pulmon Dis*. 2016;11:2475-2496
21. Bashir B, Schneider D, Naglak MC, Churilla TM, Adelsberger M. Evaluation of prediction strategy and care coordination for copd readmissions. *Hosp Pract (1995)*. 2016;44:123-128
22. Korpershoek YJ, Bruins Slot JC, Effing TW, Schuurmans MJ, Trappenburg JC. Self-management behaviors to reduce exacerbation impact in copd patients: A delphi study. *Int J Chron Obstruct Pulmon Dis*. 2017;12:2735-2746
23. Fromer L. Implementing chronic care for copd: Planned visits, care coordination, and patient empowerment for improved outcomes. *Int J Chron Obstruct Pulmon Dis*. 2011;6:605-614
24. Wedzicha JAEC-C, Miravitlles M, Hurst JR, Calverley PM, Albert RK, Anzueto A, Criner GJ, Papi A, Rabe KF, Rigau D, Sliwinski P, Tonia T, Vestbo J, Wilson KC, Krishnan JAAC-C. Management of copd exacerbations: A european respiratory society/american thoracic society guideline. *Eur Respir J*. 2017;49
25. Meeraus WH, DeBarmore BM, Mullerova H, Fahy WA, Benson VS. Terms and definitions used to describe recurrence, treatment failure and recovery of acute exacerbations of copd: A systematic review of observational studies. *Int J Chron Obstruct Pulmon Dis*. 2021;16:3487-3502
26. O'Connor L, Behar S, Tarrant S, Stamegna P, Pretz C, Wang B, Savage B, Scornavacca T, Shirshac J, Wilkie T, Hyder M, Zai A, Toomey S, Mullen M, Fisher K, Tigas E, Wong S, McManus DD, Alper E, Lindenauer PK, Dickson E, Broach J, Kheterpal V, Soni A. Rationale and design of healthy at home for copd: An integrated remote patient monitoring and virtual pulmonary rehabilitation pilot study. *Res Sq*. 2024