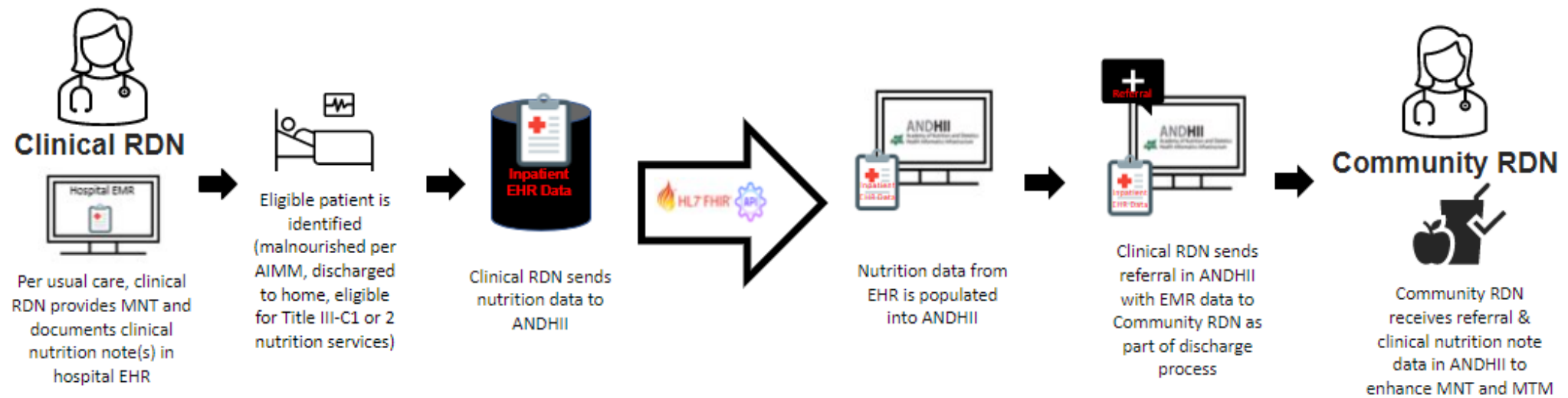


CONNECT Study

ESSENTIAL CONNECTIONS: HOW IMPROVED REFERRALS
FROM HOSPITAL TO COMMUNITY MEAL PROVISION CAN
IMPACT MALNUTRITION OUTCOMES IN OLDER ADULTS

Background

The purpose of this research is to test a new referral process that will allow continuity of nutrition care for malnutrition treatment across settings and determine if it improves food security and quality of life in patients 60 years and older who are eligible for Title III C1 or Title III C2 meal provision services.



Objectives & Outcomes

OBJECTIVE 1:

- To test the feasibility of a patient identification, cross-referral, data reporting and communication (including data transfer) process from an acute care hospital to a community meal provision organization.
 - Outcome measures: Program Sustainability Assessment Tool, barriers and facilitators to implementation

OBJECTIVE 2:

- To increase the rate of patients older than 60 years of age with malnutrition receiving care (MNT, MTM) in the community setting.
 - Outcome measures: change in percent receiving MNT/Nutrition care and meals from the meal provision Title III-C1 and C2 funded organization

OBJECTIVE 3:

- To improve food security, determinants of malnutrition, and quality of life in persons older than 60 years of age discharged home from the hospital and have a diagnosis of malnutrition
 - Outcome measures: food security risk, quality of life (CASP-19), risk of malnutrition (MST), malnutrition (AAIM)

Multi-site Design

RESEARCH SITES

- 8 research pairs -- 1 hospital and 1 community center will function as a pair.
- Pairs will collect data for 5 periods. Each period will last 7 months long.

ENROLLMENT GOALS

- Researchers in the clinical setting will enroll **~7 patients per month** (28 patients per period), totaling 140 patients over the entire study.
- Over the 5 periods and across 8 site pairs, the total enrollment target is 1,120 patients.

STUDY SUBJECTS

- Eligible subjects for this study are adults 60 years and older with AAIM malnutrition diagnosis.
- There is an emphasis on recruiting sites who serve individuals who are Black, Latino, Indigenous and Native Americans and individuals living in rural areas of the country.

Multi-site Design – Study Periods

Pairs will collect data for **5 periods**. Each period will last 7 months long.

There will be **8 Site Pairs** and they will be randomized to a sequence

The **Sequence** outlines which site pairs will be completing ‘usual care’ or the ‘intervention’

Sequence	Site Pairs	Period 1	Period 2	Period 3	Period 4	Period 5
1	1	Usual Care	Intervention	Intervention	Intervention	Intervention
	2	Usual Care	Intervention	Intervention	Intervention	Intervention
2	3	Usual Care	Usual Care	Intervention	Intervention	Intervention
	4	Usual Care	Usual Care	Intervention	Intervention	Intervention
3	5	Usual Care	Usual Care	Usual Care	Intervention	Intervention
	6	Usual Care	Usual Care	Usual Care	Intervention	Intervention
4	7	Usual Care	Usual Care	Usual Care	Usual Care	Intervention
	8	Usual Care	Usual Care	Usual Care	Usual Care	Intervention

Multi-site Design – Timeline

Year 1 PLANNING	Year 2 DATA COLLECTION	Year 3 DATA COLLECTION	Year 4 DATA COLLECTION	Year 5 DISSEMINATION
<ul style="list-style-type: none"> ➤ Study protocol development ➤ Identify participating research sites ➤ Research Approval ➤ Study Training and preparation 	<p>Period 1: All site pairings provide usual care</p>	<p>Period 2 & 3: First site pairing start referral interventions during either period 2 or 3</p>	<p>Periods 4 & 5: Remainder of site pairing start referral interventions during either period 4 or 5</p>	<p>Data cleaning Data analysis Writing articles, presenting at conferences, and other dissemination activities</p>

Study Team Members – funding and tasks

	Research RDN	Clinical RDNs	Community RDN (usual care periods)*	Community RDN (intervention periods)*
Estimated Time Commitment	~20 hours/week	2-4 hours/week during first few months of each period	~4-5 hours/week	~8-10 hours/week
Grant Support	Funding to support position for ~20hr/week for 4 years	\$5,000 stipend distributed in increments when site meets study milestones	Funding to support position for ~10 hr/week for 4 years	Funding to support position for ~10 hr/week for 4 years
Tasks	<ul style="list-style-type: none"> • Screening patient for study eligibility • Informed consent process • Data collection & entry into Survey Monkey • Data & regulatory management • Scheduling outpatient follow-up visits • Administrative communication 	<ul style="list-style-type: none"> • Notify the Research RDN of potentially eligible patients for screening • Assess for AAIM diagnosis while completing their usual nutrition care • Some data entry into ANDHI, only during intervention periods • Some administrative communication & regulatory tasks 	<ul style="list-style-type: none"> • Schedule study visits with participants • Conduct endline data collection in patient's home or congregate meal site • Data entry in SurveyMonkey 	<ul style="list-style-type: none"> • Administrative communication with participants • Conduct nutrition care visits in patient's home or congregate meal site (3 visits per patient) • Data entry in ANDHII and SurveyMonkey

*Research RDN may complete Community RDN tasks depending on site needs

Site Eligibility Criteria

Clinical Site	Community Site
Use EPIC as your Electronic Health Record	A meal provision service that provides Title III-C1 or Title III-C2 nutrition services (i.e., receive some amount of funding from AAA to provide these services)
Meet the study's technical requirements to allow for transfer of data to ANDHII from EHR	

Clinical and Community Sites
Complete data use agreement and site agreement with the Academy
Agree to 5-year time commitment
Rely on the IRB of Record (WCG IRB)
Agree to a key contact staff person of the organization that will facilitate practical execution of study and provide facility wide baseline data

Site Responsibilities – Study Approval

STUDY APPROVAL

Approval from an IRB, if present at your organization. Alternatively, approval from your administration via a Letter of Support

ACADEMY SITE AGREEMENT

An agreement outlining research relationship between your facility and the Academy

DATA USE AGREEMENT

An agreement between your facility and Academy and between the hospital and community site to allow PHI to be shared between institutions

IT COLLABORATION AGREEMENT

Written verification that the IT department and/or EPIC Health Informatics Management team will allow and assist with development of data transfer functionality for your site, if needed

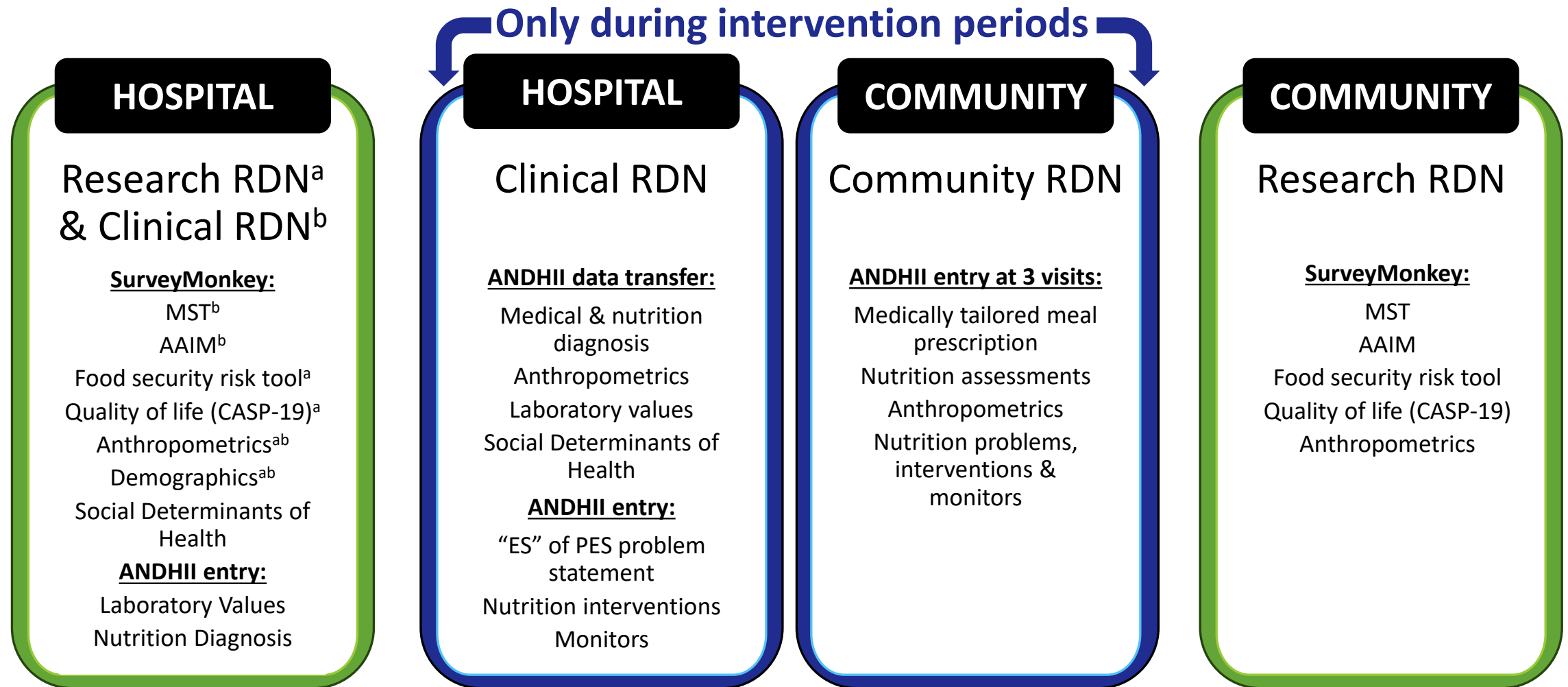
Site Responsibilities – Study Training

All participating researchers at the research sites will complete in-depth virtual trainings and receive support to ensure they are competent and confident in executing the study procedures and following research ethics policies.

The study trainings will be approved for Continuing Education Units and there may be an opportunity to complete additional CPE through independent learning/ mentorship.

We anticipate trainings to take 12-15 hours

Patient Data Collection



^b MST, AAIM, anthropometrics, and demographics will be abstracted from the medical record if assessed and documented by the Clinical RDN as part of usual care. If they need to be collected for the study, then the research RDN will interview & assess the patient to complete data collection.

Year 1 Timeline

Now – February, 2024 = IRB, IRB trainings (CITI), site agreements, Research RDN, hiring/onboarding RDN for community care, IT development

February – March, 2024 = Asynchronous + zoom call trainings

April, 2024 = Study start-up & Preparation

May, 2024 = Initiation of data collection, completion of one-time surveys