

ANCC RESEARCH COUNCIL 

# MULTI-SITE RESEARCH PLAYBOOK



A PRACTICAL GUIDE TO SUPPORT MULTI-SITE  
RESEARCH STUDIES FOR GREATER IMPACT

EDITED BY MEG JOHANTGEN, PhD, RN



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# FOREWORD

## FROM THE ANCC RESEARCH COUNCIL

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Rigorous, high-quality nursing research creates an evidence base that advances nursing practice, shapes health policy, and contributes to improving nurse, patient, and system outcomes. Yet, too often, nurse researchers conduct studies that are narrow in scope, underpowered, or lack elements such as a comparison group, thereby limiting generalizability of results and application in practice. Multi-site studies offer the opportunity to increase the rigor of research and the generalizability of findings.

Multi-site studies leverage the power of Magnet® and other research-engaged nursing organizations to conduct research across multiple units and settings. Options for research designs are expanded with larger and more diverse samples. These studies require more planning and coordination, yet also provide opportunities to increase staff engagement in the research process, grow research capacity within and among organizations, and address research questions that cannot be effectively evaluated through a single-site study.

The American Nurses Credentialing Center (ANCC), in collaboration with the ANCC Research Council, has facilitated multi-site research studies since 2010 as a strategy to increase research capacity within organizations and to help organizations credentialed through the Magnet Recognition Program® meet criterion requirements. Lessons learned from these multi-site studies have been collated into this practical research playbook, creating a road map for nurse researchers at all levels and across all types of settings.

The target audiences for this playbook are hospital and health system researchers from organizations where nurses practice, nurse administrators who lead research-engaged health care organizations, and nurse researchers from academia who partner with these entities to conduct practice-relevant nursing research. The playbook is not intended to be a comprehensive textbook for multi-site studies, but rather a practical guidebook. The hope is that readers are inspired by the contents to consider opportunities to develop multi-site studies when appropriate to their research questions.

# INTRODUCTION

This *ANCC Multi-site Research Playbook* is intended to serve as a resource for nurses

desiring to design and lead multi-site research studies, particularly more novice researchers. Most often, nurses are educated and gain experience in the design of studies that are narrow in scope and conducted in single sites. In the clinical practice setting, nurses with research-focused doctorates frequently conduct research either as the sole researcher or with a small supporting team. Nurses with practice-focused doctorates may focus on evidence-based practice or quality improvement in a single institution. This playbook should be useful for both groups as they assume their roles as clinical

partners in interprofessional research. The creation of scholarly work across disciplines can promote common languages and frameworks – and better explain shared clinical problems.

The playbook is organized in five parts as outlined in the table below. Embedded throughout this practical research playbook are tools and examples of strategies that have been effective in conducting multi-site studies. **Appendices** provide additional resources. Multi-site studies are a mechanism to engage in collaborative science with a broader research team to answer important nursing care questions and generate findings that are impactful both locally and across multiple settings.

## PART I CONTEMPLATING MULTI-SITE RESEARCH

**Chapter 1** provides definitions and context for multi-site studies within nursing.

**Chapter 2** highlights issues to consider when contemplating a multi-site study including the return on investment (ROI).

## PART II ALIGNING PURPOSE AND RESEARCH QUESTIONS

**Chapter 3** reinforces the similarities and differences among quality improvement (QI), evidence-based practice (EBP), and research.

**Chapter 4** highlights the importance of positioning multi-site research to be translated within a translational research framework.

## PART III PLANNING MULTI-SITE RESEARCH STUDIES

**Chapter 5** discusses the importance of engaging stakeholders.

**Chapter 6** discusses issues in developing research protocols.

**Chapter 7** addresses the crucial issues to consider when compiling a research team and how to operationalize communication among individuals involved in the study.

## PART IV CONDUCTING A MULTI-SITE RESEARCH STUDY

**Chapter 8** outlines ethical responsibilities for principal investigators.

**Chapter 9** addresses important procedural issues including engaging staff, optimizing efficiency, and monitoring fidelity.

**Chapter 10** discusses data management and security concerns.

## PART V IMPLEMENTATION EVALUATION AND DISSEMINATION

**Chapter 11** offers suggestions for implementation evaluation.

**Chapter 12** presents strategies for dissemination.

# CONTENTS

<b>PART I</b>	<b>CONTEMPLATING MULTI-SITE RESEARCH</b>	<b>1</b>
CHAPTER 1	Nursing and multi-site research	2
CHAPTER 2	Assessing Return on Investment (ROI)	5
<b>PART II</b>	<b>ALIGNING PURPOSE AND RESEARCH QUESTIONS</b>	<b>8</b>
CHAPTER 3	QI, EBP, and Research	9
CHAPTER 4	Positioning multi-site research to be translated	12
<b>PART III</b>	<b>PLANNING MULTI-SITE RESEARCH STUDIES</b>	<b>14</b>
CHAPTER 5	Engaging stakeholders	15
CHAPTER 6	Developing the research protocol	18
CHAPTER 7	Team selection and operations	21
<b>PART IV</b>	<b>CONDUCTING A MULTI-SITE RESEARCH STUDY</b>	<b>30</b>
CHAPTER 8	Ethical responsibilities for principal investigators	31
CHAPTER 9	Procedural considerations	32
CHAPTER 10	Data management and security	37
<b>PART V</b>	<b>IMPLEMENTATION EVALUATION AND DISSEMINATION</b>	<b>39</b>
CHAPTER 11	Implementation evaluation	40
CHAPTER 12	Dissemination	42
<b>APPENDICES</b>		<b>47</b>
APPENDIX A	References	48
APPENDIX B	Summary of selected articles examining facilitators and challenges to conducting multi-site clinical research	49
APPENDIX C	Summaries of ANCC-commissioned multi-site studies	56
APPENDIX D	Examples of study summaries for stakeholders from ANCC’s multi-site READI study	60

In preparing to develop a multi-site research project, it is crucial to consider the rationale as well as challenges to be anticipated. Part I provides an overview of multi-site research from the context of nursing and the importance of considering the effort that is required. [Chapter 1](#) provides some historical context and definitions, while [Chapter 2](#) considers investments and returns.

# PART I CONTEMPLATING MULTI-SITE RESEARCH

## CHAPTER 1

# Nursing and multi-site research

### What are multi-site studies?

The most common type of multi-site research familiar to many of us is the large, externally funded clinical trial. These studies are often conducted at more than one site to recruit and retain enough diverse participants to provide valid answers to research questions. The same research procedures (i.e., same protocol) are conducted in two or more sites. From a human subject's research perspective, Institutional Review Boards (IRB) consider studies to be "multi-site" when there is collaboration with sites external to the organization that approves the research. The focus of this playbook is on multi-site research that is more broadly defined as research involving several centers in a single study. This research may involve several units in a system (e.g., different ICUs), multiple hospitals, or multiple clinics.

### Why conduct a multi-site study?

Multi-site studies allow for a more sophisticated and higher impact project than any of the participants could do alone. One of the most common reasons to use a multi-site approach is to put the research team in a better position to say that its findings apply to more than just the patients and/or nurses at one particular site. A multi-site approach will increase generalizability of findings to the "real" world and provide a diverse and inclusive experience. Another motivation for a multi-site study may be when a particular problem is uncommon. Having multiple sites (and recruiting nurses or patients within them) increases the likelihood that a critical mass of instances of the phenomenon will be identified. Sometimes, multi-site studies are proposed for political or organizational purposes — involving a group of clinicians/leaders, units, clinics, and/or organizations can help build or sustain a network of connections.

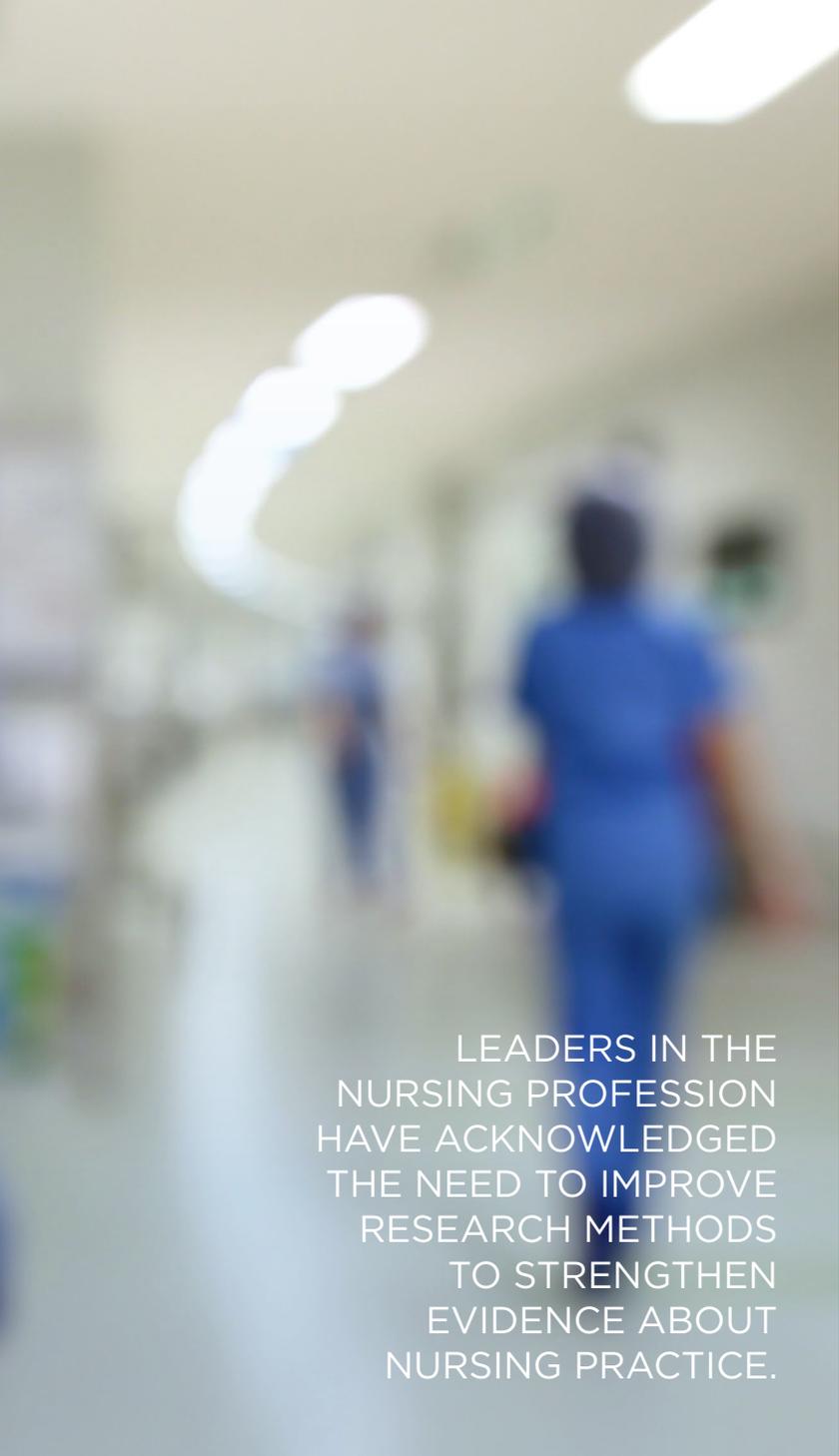


MULTI-SITE STUDIES ALLOW FOR A MORE SOPHISTICATED AND HIGHER IMPACT PROJECT THAN ANY OF THE PARTICIPANTS COULD DO ALONE.

TABLE 1.1

## COMPARISON OF CHARACTERISTICS OF SINGLE-SITE VS. MULTI-SITE STUDIES

	▼ SINGLE-SITE	▼ MULTI-SITE
<b>DESCRIPTION</b>	A single nursing unit, clinic, or other organizational unit	Multiple nursing units, clinics, or other organizational units from more than one facility
<b>AIMS</b>	<p>Understand the unique characteristics of a specific patient population</p> <p>Evaluate a new nursing procedure/protocol/innovative practice</p> <p>Evaluate patient outcomes of current care practices</p> <p>Improve implementation and outcomes of a new care practice</p>	<p>Explain patient and care delivery factors that affect patient outcomes across a range of patients and/or settings</p> <p>Test a new nursing protocol/innovation across multiple patient care settings</p>
<b>IMPACT</b>	Local	Broad
<b>RESEARCH DESIGNS</b>	Often limited to descriptive, before/after comparisons, or qualitative research with local transferability	<p>Nested comparisons within and among units and patients</p> <p>Experimental comparative effectiveness/implementation designs</p> <p>Qualitative/mixed methods research</p> <p>Implementation science methods</p>
<b>TEAM SIZE</b>	Small, usually single PI	Larger, single, or multiple PIs, with site coordinators (aka site PIs)
<b>RESEARCH TEAM</b>	PI, organization nurse researcher, local/unit nurses, interdisciplinary expertise as appropriate, and data/statistics support	<p>Study PI, nurse researcher with methodology expertise, site PIs, local/unit nurses, interdisciplinary team, and data/statistics support</p> <p>Note: a study coordinating center may be used</p>
<b>GENERALIZABILITY</b>	Limited to local context (i.e., single nursing unit, clinic, or other organizational unit)	<p>Broader context for generalizing</p> <p>Able to study implementation factors associated with differences in findings within and between sites</p>



LEADERS IN THE  
NURSING PROFESSION  
HAVE ACKNOWLEDGED  
THE NEED TO IMPROVE  
RESEARCH METHODS  
TO STRENGTHEN  
EVIDENCE ABOUT  
NURSING PRACTICE.

## Multi-site nursing research – lessons learned

Leaders in the nursing profession have acknowledged the need to improve research methods to strengthen evidence about nursing practice. Highly powered studies, better measures, more sophisticated analyses, and interdisciplinary or interprofessional teams enhance the likelihood of reaching valid conclusions. Launched in 2005, the Robert Wood Johnson Foundation's Interdisciplinary Nursing Quality Research Initiative (INQRI) funded 40 interdisciplinary teams to conduct rigorous studies. Essential was the need for an interdisciplinary focus, better measures, and evaluating impact. Many of these research teams conducted their studies at multiple sites, with some having an emphasis on implementation. One of these researchers, Linda Flynn, summarized lessons learned ranging from needing time to develop trust and collaboration across research sites, the importance of central coordination and control from the principal investigator (PI), anticipation of a longer IRB approval process, and the imperative of clear protocols and timelines (Flynn, 2009).

Several articles have described the lessons learned by nurse researchers in conducting multi-site clinical studies. Pediatric nurse researchers (Bossert et al., 2002) highlight issues and challenges when organizing multi-site studies based on a study of pain in children with leukemia in three children's hospitals. In oncology, challenges in a multi-site study of hazardous drug exposure of nurses across 12 sites were highlighted, noting that studying workers rather than patients has unique demands (Freise, 2017). Articles related to the experiences conducting multi-site studies are summarized in [Appendix B](#).

**ANCC multi-site research.** In 2010, recognizing the challenges in funding multi-site studies, ANCC developed a “pay-to-participate” model that facilitated research across multiple Magnet hospitals (Hickey et al., 2014). ANCC commissioned three studies with scientific accountability under the control of independent nurse-led research teams. Lessons learned from those studies provided the impetus for this playbook. [Appendix C](#) summarizes the studies and where they were published.

**Single-site vs. multi-site research.** Multi-site studies are different than single-site studies in design, method, and analysis. The complexity of conducting multi-site studies lies in the diversity of nurses and patients involved in the research and the management of the study protocol and team across sites with differing practices and environments. [Table 1.1](#) summarizes some of these differences.

## CHAPTER 2

# Assessing Return on Investment (ROI)

The value proposition for multi-site studies lies in the human and monetary costs of investing in a multi-site research project relative to the benefits and impact of such studies. ROI can include enhanced reputation of either an organization, individual, or team; improved patient outcomes; decreased costs of care; and dissemination of evidence. Investment can include financing, time, commitment, staff involvement, education of participants and staff, coordination, implementation, monitoring for fidelity, data collection, data analysis, and evaluation and development of presentations and publications. More specific examples are listed below.

**Return** in multi-site nursing research varies but can include the following elements:

**Improved patient outcomes and cost of care.** The likelihood of improved patient outcomes is estimated in the research proposal and tested in data analyses. Costs are not routinely estimated but should be considered when the cost of intervention is high. For example, a cost-effective estimate may conclude that the allocation of nursing staff time to implement a new nurse assessment within the research study will be recouped only if non-reimbursable readmissions are averted.

**Direct benefits to the nursing division.** These may include meeting Magnet® or clinical advancement criteria, quantifying the value of nurses to organizational outcomes, participating in a ‘big science’ project of national scope and significance, and/or exposing staff to research conduct and a research network.

**Nurse engagement in research.** Engaging nurses not only as study team members but also within the study design (i.e., collecting data on the relationship between nursing practices and patient outcomes) has important benefits. Through their participation in the research, nurses see evidence of their impact, incorporate innovative practices within their standard repertoire, and continue to use the new protocol after the study ends. This fosters direct translation of evidence to practice. Nurses take pride in their practice and develop a sense of the importance of future engagement in research (Bobay et al., 2021).

**An enhanced doctoral nursing pipeline.** Increasing nursing skills and capacity to engage in research may result in more nurses pursuing further doctoral education. As the nursing profession is critically challenged by a lack of nurses prepared with research-based doctoral degrees, engaging and mentoring nurses in conducting meaningful research studies is one strategy to grow the doctoral nursing pipeline. Multi-site studies can provide exciting new opportunities and mentorship to encourage greater inclusivity and build research capacity for nurse researchers and clinical nurses of diverse backgrounds.

**Greater nursing knowledge and practice.**

Participating in multi-site research will encourage nurses to stay current and translate research into practice. Participation can also support career advancement, academic progression goals, and succession planning.

**Improved partnerships and collaboration.** New nursing and interprofessional partnerships within and across organizations can bring immediate and lasting benefits and recognition to all participating individuals and units.

**Heightened reputation for nursing knowledge excellence.** Participating in multi-site research builds the organization’s reputation for excellence in nursing knowledge development through dissemination of research findings and research-driven practice change. A downstream benefit is that engaged nurses generate new research-related questions that shape nursing knowledge in a focal area of particular interest/importance to practice.

**Transferability of interventions to other nursing units.** Research findings from studies conducted on some units within a single hospital or multiple units across more than one hospital may be transferable to other units. For example, a study in four critical care units may produce results that suggest broader application to other units, with or without modifications.

**Stronger grant applications.** Experience in conducting multi-site research can better position researchers and organizations to submit strong, competitive grant applications.



PARTICIPATING IN MULTI-SITE RESEARCH  
BUILDS THE ORGANIZATION’S  
REPUTATION FOR EXCELLENCE IN  
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THROUGH DISSEMINATION OF RESEARCH  
FINDINGS AND RESEARCH-DRIVEN  
PRACTICE CHANGE.



**Investments** in multi-site nursing research vary but often include the following elements:

**Study leadership.** As the motivational and operational leader of the study, the PI will require dedicated time to generate support, engage a scientific team of advisers, identify operational team members, lead the team through all phases of the study, manage data collection, analyze data, and prepare dissemination materials.

**Team members.** Some members may need assigned/released time from other duties, or their time may be allocated within their current assigned hours.

**Departmental support.** Other departments may need to allocate time or resources for the study. This can include review of the study for awareness, assessing how it might impact services, providing comments, and communicating to others in the department. In addition, some departments may have fees for services rendered. For example, information technology (IT) services may need to construct data files and databases, as well as allocate server space over time.

**IRB protocol development.** Depending on the complexity and human subject review procedures, assistance with protocol development may be needed and charges for review may be assessed.

**Study materials.** Supplies and equipment needed to implement the research may include materials for data collection and record keeping, building electronic data collection procedures, equipment for measuring and recording outcomes, and software for analyses and data visualization.

**Training.** Both training materials and training time for nurse/team participants must be considered. Training may be implemented in different ways such as lecture, guidebook, or video modules. Mandatory training of study personnel may need to be paid for through research funds, administrative funds, or unit budget. All study personnel who conduct research activities will also require human subjects training.

**Dissemination.** While preparation of manuscripts and presentations may be part of the study team's dedicated time, additional costs can include conference fees, travel, poster preparation, and journal publication fees.



# PART II

# ALIGNING PURPOSE AND RESEARCH QUESTIONS

As the nurse researcher and team develop a multi-site research protocol, it is crucial that there be an alignment of purpose, research questions, and study design. [Chapter 3](#) is a brief discussion of quality improvement (QI), evidence-based practice (EBP), and research to provide context for the focus on research. The qualities of good research questions are considered. [Chapter 4](#) emphasizes the importance of situating multi-site studies within a translational research framework.

## CHAPTER 3

# QI, EBP, and Research



While there is increasing clarity regarding the differences among QI, EBP, and research, their methods and activities often overlap yet are distinct (Shirey et al., 2011). Indeed, a model of the continuum of clinical scholarship has been proposed to acknowledge the interdependence among the activities (Carter et al., 2017). And it should be noted that local IRBs determine the need for human subject review, and interpretations can vary. To help investigators determine which type of study is proposed and if human subject review is required, the Office of Human Research Protection (OHRP), which regulates human subject research, has developed these [FAQs](#).

Clinical problems generate the need for research. The purpose and kind of clinical questions that lead to QI projects, EBP, or research are different. [Table 3.1](#) illustrates clinical questions that lead to research questions for each type of inquiry. The problems and questions that are best answered with multi-site research are ones that affect nurses and their patients in multiple care contexts. When clinical problems are studied in different care contexts, we learn about how the setting affects how the study procedures are implemented in practice and the similarities and differences in outcomes among nurses and patients.

TABLE 3.1

## COMPARISON OF SIMILARITIES AND DIFFERENCES AMONG QI, EBP, AND RESEARCH

STUDY TYPE	▼ QUALITY IMPROVEMENT	▼ EVIDENCE-BASED PRACTICE	▼ RESEARCH
<b>PURPOSE</b>	To monitor and evaluate quality and appropriateness of systems and processes of care with intention to improve care and outcomes.	To use the best clinical evidence in making patient care decisions typically from research, patient preferences, and clinician expertise. EBP <i>translates</i> knowledge into practice.	To discover new, generalizable knowledge for practice, and uncover factors associated with improved care practices and patient outcomes. <b>Translational research (TR)</b> focuses on implementation of innovations, their effectiveness in care, and the factors that impact the effectiveness.
<b>EXAMPLE: CLINICAL QUESTIONS LEADING TO STUDY TYPE</b>	<p>What percentage of our patients have fall risk assessment done per protocol?</p> <p>Do all of our patients with identified fall risk have a care plan in place?</p>	<p>What are the best interventions to prevent patient falls in patients in inpatient rehabilitation units?</p> <p>Which fall risk prevention tool is most predictive for identifying patients at risk for falls for hospitalized elders?</p>	How can nurses better predict patients at risk for falls?
<b>QUESTIONS FOR STUDY TYPE</b>	<p>Did the percentage of patients with a fall risk assessment done per protocol change/improve from pre-QI project to post-QI project?</p> <p>Do more patients with identified fall risk have a care plan in place following the QI project?</p>	<p>Did patient falls decrease in number and injury rate after implementation of an EBP fall prevention protocol?</p> <p>Did the new EBP fall risk assessment tool improve prediction of elders at risk for falls?</p>	<p>Does the FIM (functional independence measure) scale or any of its subscales better predict fall risk than the current fall risk score? For which patient populations is it a better predictor?</p> <p>Does use of an environmental scan process/checklist result in fewer falls? Is the environmental scan cost effective?</p>
<b>PRODUCT/IMPACT</b>	<p>Change in practice.</p> <p>Improved quality of care.</p>	<p>Validation of a new EBP protocol in the local patient population.</p> <p>Include recent best evidence for practice in the standard of care.</p>	<p>New knowledge in support of EBP, sustained implementation and broad dissemination.</p> <p>Identification of practice setting factors that facilitate or inhibit successful outcomes of implementation.</p>

# The range of QI, EBP, and research questions

**Table 3.1** gives examples of QI, EBP, and research questions about a clinical question: falls. Equally important are questions related to nurses as the population of interest.

### Examples of multi-site studies include:

- A study of the effect of a new protocol for mechanical ventilator extubation could be conducted as a multi-site study in four hospitals within a health care system.
- A study of family caregiver responses to presence during cardiac resuscitation could be conducted in four ICUs (SICU, MICU, CCU, Neuro ICU) across hospitals.
- A study of decision-making about referral for home health care could be studied with patients preparing for discharge from multiple types of units in multiple hospitals.
- A study of nurse responses to well-being support programs could be conducted to examine differences by nurse characteristics and practice setting.

### In deciding on a research question for multi-site research, the project should:

- Have **significance** for nurses and the organizations involved.
- Have potential for high impact on **patient outcomes** (e.g., better outcomes, improved patient experience, and/or reduced costs of care).
- Improve a **high visibility** care practice (e.g., one that is currently or potentially used as a quality metric).
- Be **innovative** with potentially widespread application and benefit (e.g., a previously overlooked or underexplored aspect of patient experience of care that will provide new knowledge as a basis for future novel approaches or redesigns for patient care).
- **Align** with the organization and nursing strategic plans.

### In developing the specific research question, the PICOT components can help (Stone, 2002). They include:

- P = Patient, population, or problem
- I = Intervention or independent variable
- C = Comparison
- O = Outcome or dependent variable
- T = Time period for outcome

For example, taking a question from **Table 3.1**, all components can be added:

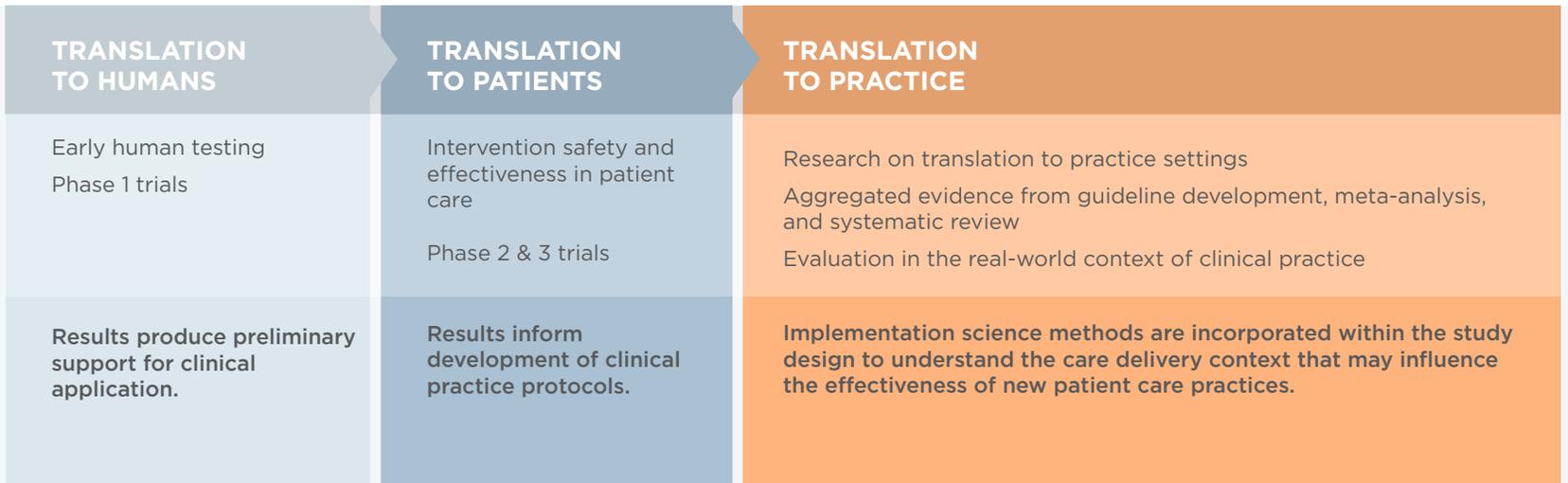
In hospitalized people over 75 (P), does the FIM scale (I) versus current fall risk score (C) better predict fall risk (O) within the hospital stay (T)?

Another clarification that should be noted is the difference between EBP and translational research. While EBP is the actual application of evidence in practice, translational research is the study of the implementation — the intervention, factors, and contextual variables that affect knowledge uptake and use (Titler, 2018).

## CHAPTER 4

# Positioning multi-site research to be translated

Multi-site research should be set with a clear understanding of how it can be translated (Weiss et al., 2018). As noted by the NIH Center for Advancing Translational Sciences, the translational science spectrum has stages “along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public.” This continuum is increasingly recognized as not linear or unidirectional.



**Most nursing multi-site research studies can be situated within one of three translation phases.**

**Translation to Humans** are the first clinical trials (Phase 1). In nursing, these are often pilot studies of new innovations in care that need initial testing in a small sample to determine feasibility, acceptability, and early evidence of potential positive outcomes. These studies would commonly be single-site or a small number of sites and may be qualitative or quantitative.

**Translation to Patients** phase is when new innovations in patient care are tested to determine if they are safe (Phase 2) and efficacious (Phase 3). These studies are characterized by controlled, rigorous testing and measurement with strict sampling criteria and detailed innovation/intervention/care delivery protocols. In nursing, these studies often use mixed methods and are conducted with a small number of sites in a single facility.

**Translation in Practice** refers to implementation research on the effectiveness of research within the context of practice (Phase 4). These studies involve more widespread testing of an innovation/intervention/care delivery change within the real-world context of the variability of patients and practice settings. The goal is to learn

about effectiveness under the usual conditions of patient care and how the context of care influences implementation, adoption, and effectiveness. These studies simultaneously ask and answer two questions:

- The **effectiveness question**: Is the new innovation/intervention/care delivery process effective compared to prior usual care conditions?
- The **implementation question**: How well was the innovation/intervention/care delivery process implemented and did factors in the implementation affect the effectiveness? Which nurses/units produced better results and why?

To address these questions, different methods, or a combination of methods (“mixed methods”) may be needed. Effectiveness questions often require a quantitative approach and ideally should measure individual outcomes such as an actual change in health status, rather than a proxy measure like length of stay or attitudes. Implementation questions may use quantitative approaches to assess differences across nurses/units but understanding why may be best assessed with qualitative approaches (e.g., interviews, surveys, or focus groups).

# PART III PLANNING MULTI-SITE RESEARCH STUDIES

Conducting research at more than one study site increases the likelihood of impact and generalizability of study findings, but also presents challenges for the research team in planning and operationalizing the study. Planning a study is an iterative and ongoing process, thus these are not sequential steps.

Chapter 5 discusses engaging stakeholders, which often starts prior to study conceptualization. Chapter 6 highlights important issues to consider in developing the protocol for a multi-site study. Chapter 7 provides guidance on selecting and organizing a research team, including budgeting, operations, and communication.

## CHAPTER 5

# Engaging stakeholders

A crucial early step in developing multi-site research is engaging organizational stakeholders. Depending on the proposed research, many different individuals/groups may be considered stakeholders.

Organizational leaders should be engaged early since their support is often key to successful participation. Other stakeholders include those who represent the participants (e.g., the nurses, patients, educators, and data analysts) involved in the study procedures. Recommendations about what will make the procedures clearer, doable, simpler, and not burdensome should be solicited. It's important to listen to these responses. It will increase the likelihood of success with the project.

Considering that stakeholders are diverse and in more than one site, strategies for implementing the engagement should be detailed. The following are recommended:

### 5.1 Identify potential stakeholders and strategies for engagement

Stakeholders should be viewed broadly, recognizing that individuals can represent multiple perspectives in research. The **Patient-Centered Outcomes Research**

**Institute (PCORI)** advances patient-centered, stakeholder-engaged research with meaningful involvement of diverse stakeholders throughout the research process. PCORI resources include recommendations for building teams and teaching modules regarding engagement of stakeholders in different phases of research.

Listing potential stakeholders, titles, contact information and who will be accountable to connect with them is an early planning step. Protocol development is an iterative process and stakeholders will likely be contacted at successive stages of the research. New stakeholders may be added or deleted. Prior to meeting with stakeholders, multi-site researchers must prepare. **Table 5.1** provides an example of stakeholders and examples of important considerations for each.

Based on feedback from stakeholders, the scientific team can continue to develop and refine the study protocol. There may be differences across sites. For example, sites may have some differences in who must approve research, where data collection boxes are located, or who gets consent from participants. Ownership of the data should also be determined early (see **Chapter 10**).

TABLE 5.1

## POTENTIAL STAKEHOLDERS AND ENGAGEMENT CONSIDERATIONS IN NURSING MULTI-SITE STUDIES

STAKEHOLDER	▼ ENGAGEMENT STRATEGIES	STAKEHOLDER	▼ ENGAGEMENT STRATEGIES
<b>PARTICIPANTS</b>	Participants should be consulted and be part of the planning stages. If patients are involved, the importance of incorporating their perspectives has been increasingly recognized. Likewise, if nurses are the participants, they can provide important inputs into the design and research procedures, as well as make findings more relevant and useful. If nurses are participants, explain consent and ethics procedures, distinguishing their role as subjects versus care providers.	<b>NURSES</b>	When nurses participate in the research activities (e.g., completing logs) but are not research subjects, concerns about added workload should be considered. Discuss what involvement may be expected, the education and skills training that might be needed, and an estimate of time commitment. Offer opportunities to nurses for mentoring and for engaging a broad and diverse population of nurses and other nursing support staff to engage in the study.
<b>ORGANIZATION LEADERS</b>	Learn what is important to leaders and the organization, their values and priorities, leaders' span of control, and potential or actual aligned or competing initiatives of leaders and organization. This will help in developing a business case with a timeline for what the research will involve. Researchers must also be able to convince leaders that the project team can complete the project on time and on budget.	<b>NURSING PROFESSIONAL DEVELOPMENT/ EDUCATION DEPARTMENT</b>	An important aspect of study planning is the education of nursing staff to engage them in the conduct of the research, how they will participate, the rationale for the study, and the specific study protocol. The education/ training plan should be developed in conjunction with professional development/education specialists who can assist with the use of learning management platforms for dissemination of structured education and documentation of completion.
<b>CNO, NURSE DIRECTORS, NURSE MANAGERS</b>	As with organization leaders, learn what is important to the CNO and other nurse leaders, and what initiatives are currently underway. Discuss what involvement may be expected of them and/or their staff, including an estimate of time commitment and expected timeline.	<b>DIRECTOR OF IT/NURSING INFORMATICS SUPPORT</b>	Clearly identify what data will need to be collected and data management services required, provide clear data specifications, identify skills needed, and estimate cost of needed data collection and data management. Other issues need to be assessed including data access, use, storage, and dissemination, which may need to be coordinated with other organizations. Nursing informatics can assist with requirements that could impact nursing workflow. Encourage use and linking of existing electronic data where possible. Engage support and assistance with big data analysis.
<b>INTERPROFESSIONAL TEAM/KEY PROVIDERS (PHYSICIANS, ADVANCED PRACTICE PROVIDERS, PHARMACY, ETC.)</b>	Consider how research will impact clinical practice and medical education. Be specific about expected involvement, time commitment, and timeline. If no involvement is expected, this may be a courtesy meeting to inform these team members about potential research.	<b>LEGAL AND MARKETING DEPARTMENTS</b>	Organizations participating may have procedures that should be considered such as use of organizational logos, publicizing the study, and planning for dissemination. It may be necessary to seek approval for use of organizational data, ensuring data protection. Advise on the perspective of information dissemination and permission to share findings no matter what the outcomes may reflect.
		<b>OTHER RESEARCHERS, INCLUDING ACADEMIC AND COMMUNITY PARTNERS</b>	For organizational researchers and academic partners, discuss opportunities for them and/or their staff, and estimate the time commitment. Consider incentives to attract researchers from academic partners. Incentives might include developing research skills, access to clinical populations, expanded opportunities for student learning, and exposure to the practical realities of current health care for improved relevance.

## 5.2 Prepare materials to support stakeholder engagement

Different materials will be needed depending on the stakeholder group, but all should be prepared with consistency of terminology and information in mind. Marketing experts may be engaged to help in content and professional presentation.

### Examples of materials include:

- Written summaries for stakeholder meetings
- Scripts for an “elevator speech”
- Presentation slides
- Suggestions for language in written announcements in newsletters, emails, etc.

Engagement of marketing and graphic design experts to develop a project logo and compelling research descriptions is also recommended. Logos can help signify the research study and be used on all communications and study materials. [Figure 5.1](#) illustrates the logo developed for the ANCC-commissioned multi-site study Improving Heart Failure Outcomes (IHO).



Organizational leaders may need a shorter summary that focuses on resources required and benefits to the organization. Leaders of units where the study takes place may need detailed explanations of what is expected, of whom, and over what time frame. Researchers who are responsible within organizations often want details about study conceptualization, research design, methods, and proposed analyses. [Appendix D](#) includes a few examples from the ANCC-commissioned READI study.

## CHAPTER 6

# Developing the research protocol

When planning for any study, the development of the protocol is an iterative process. Early drafts are often compiled by a few team members and gradually engage others as needed. In the early drafts, the study conceptualization identifying gaps and proposed research design often includes a list of specific study aims. As the protocol takes shape, the expertise of team members is used to revise and clarify ideas and develop procedures. A large part of the protocol reflects the research methods and data analysis. The goal of this chapter is to highlight important points to consider in creating designs for studies that can be scaled to include multiple sites with a range of similar and unique considerations for conducting the research project. Research and statistical references cover these and other topics in more detail.

## 6.1 Choosing the best research design

Research methods and design issues are very important to settle before attempting to secure financial support for a project (i.e., to convince funders inside or outside your organization that your project is likely to be completed and that it will generate useful information on a scale that matches the requested investment). Even if your team self-funds the project, attention to these considerations is vital to make sure members get the satisfaction and benefits of their investment of time in the project — completed data collection, analysis, and dissemination of meaningful results.

Research design choices, which must align with research questions and study purposes, can be influenced by practicalities of conducting research in real-world settings and the perspectives, preferences, and skills of research team members. Most of these choices are made in the planning phase of a study. While the broad outline of a research design can be simple (e.g., cluster randomized trial, pre-post, etc.), there are almost always aspects of the design (e.g., sample, measures, analyses) that can greatly restrict the usefulness of the study results. Thus, even if the team includes experienced researchers who have taken courses in research and been involved in studies that deal with similar topics and/or use similar methods, consultation with research and/or statistical experts is always vital when planning any study. It is even more crucial when resources and effort are being invested across units and/or facilities on a larger scale in a multi-site study.

## 6.2 Defining a sample and sampling strategy

It is vital to make careful decisions about how many units or settings will be studied, over what time, and how many patients, nurses, or events will have measures. Determining the optimal sample size to detect statistical significance of hypothesis testing is fundamental. Consultation with a statistician is vital as the multi-site design elements must be considered in the power analyses.

The research team then must specify the details. Will all subjects meeting specific criteria be included (or recruited) for the study? Or will a random subset of subjects be considered? Convenience or voluntary samples may be used. It is particularly important that the sampling plan reflect the goals of the study and the purposes of using multiple sites (neither too many or too few sites and observations be gathered), that it considers available resources (especially that it not be too ambitious or complex for the time of staff), and that a consistent and parallel approach be used across all sites. For example, the type of units or clinics should be very similar and imbalances in sites should be monitored and kept to a minimum when

comparisons across sites are planned as part of the study design. If the study includes a translation-to-practice phase, a diversity of patients and units will be needed to conduct sub-analyses by type/ characteristics of patients or units.

### 6.3 Determining and standardizing measures

Determining the source of the data to be amassed for the study is a critical feature of study planning. In the current era of electronic health data systems, electronic extraction of data should in general replace reviewing the record and re-recording data elements needed for the research. That said, as is the case in all research, consistency, and completeness of data collection is vital. But, in multi-site studies there is the additional twist that consistency and completeness of data collection must be ensured across different teams and settings. Information about patients may be recorded in different ways in the electronic or paper health record. Different terminology may be used in different settings. Developing specifications for what data are extracted from the electronic record and in what format should be accomplished with IT specialists at each site.

In many studies, data will need to be collected directly from patients and/or care providers. Whenever data are collected directly from research participants using measurement tools (e.g., a tape measure, administering a questionnaire), there is always the potential for differences in the use of tools that can lead to measures with inconsistent meaning or even invalid or missing data. It is vital to work carefully to identify and reconcile possible differences in definitions or practices across sites early. Pilot testing of the data collection protocol is recommended and can be well worth the time invested.

### 6.4 Specifying data analyses

Exactly how data will be handled and analyzed should be decided up front with an understanding that problems and/or opportunities may arise that will need to be dealt with once data are in hand. It is very easy to put off the question of what analysis methods will be used, including making a sweeping statement that descriptive statistics will be used to pursue descriptive research goals. However, the choice of samples, measurement tools, and intervention and data collection protocols are intimately tied to the analytic approaches that are possible and the research questions that can be addressed using those analyses.

Issues of how data will be managed and by whom are particularly crucial and thus are addressed in Chapter 10. It is strongly advised that data collection, management, and analysis be planned from the outset of a study. Even though studies, especially smaller ones, may go forward and receive ethics approval and even begin data collection before the analysis plan is fully clarified, it is useful to draft table shells that reflect the anticipated analyses.

**Several analytical issues are of particular relevance in multi-site studies. They include:**

**Determining unit of analysis.** It is important to clarify what the unit or units of analysis will be for the study, particularly in the case of a multi-site study, because sites represent a potential unit of analysis. The subjects and units of analysis can be similar or slightly different from each other. For instance, the subjects of study (the people or objects under study and from whom data are being obtained) can be patients, nurses, units/clinics — or a combination. The units of analysis in the various calculations or comparisons (or other analyses) can be the same for all the research questions and analyses, or they can be different for different research questions. For instance, while data may be collected by nurses about patients, the goal may be to understand something about overall rates of pressure injuries for all the patients cared for on particular units. The unit of analysis is the nursing unit, rather than the risks for individual patients of experiencing an injury (in the latter case, the unit of analysis would be the individual patient).

**Accounting for nested structure and measures.** In choosing the analytic approach for multi-site data, there is often a multi-level structure underlying the data (i.e., the observations are not completely independent of each other). For example, multiple observations may be made within patients over time, patients may be nested within units, or units are nested within hospitals.

Failure to consider the multi-level structure of data may lead to inappropriate analyses that result in incorrect conclusions about the effect or non-effect of an intervention or the ability of a variable to predict an outcome.

Likewise, in many multi-site studies, variables and outcomes may exist at different levels in the data structure. For instance, each patient in a study may have an individual outcome measured once or may have an outcome measured at multiple points over the course of participation. Each patient might be exposed to different unit-level conditions (that are common to all patients and nurses for the life of the data collection) or may experience different conditions on the same units at different points of time (from one day or one month to another). While not all multi-site studies will rise to this level of complexity in terms of levels and time frames, if there is even the potential to become this involved, statistical consultation is definitely needed to plan a data collection and analysis approach that could potentially handle these intricacies.

**Using specialized statistical techniques.** Different statistical approaches may be appropriate depending on the types of variables and levels of measurement (nominal through ratio). Most introductory and intermediate-level statistics courses focus on analysis of continuous variables (for instance, blood pressure, questionnaire total scores, etc.). However, in clinical research there are many instances where some or all variables are dichotomous (e.g., an outcome is present or is not present) or have multiple levels (e.g., the stage of pressure ulcer). Likewise, most of the

techniques taught in foundational statistics courses deal primarily with simple comparisons, perhaps comparisons between two and five groups or before versus after an event, with a limited number of time points. In clinical research, there may be potentially complex exposure structures (e.g., an intervention might be staggered, or different variants of the intervention may be tested in different sites). There may also be suboptimal fidelity (e.g., adherence) to the protocol, which occurs in unit-level interventions when some patients are inadvertently omitted from the intervention protocol or protocol procedures drift. Analytical approaches are available to deal with each of these circumstances, some more easily and widely implemented than others, but assistance of statistical experts with knowledge of these specialized approaches is often needed.

**Analyzing variation across study sites.** In addition to the unit of analysis and nested nature of data, the site-to-site variation in characteristics of the organizations or organizational units should be considered. Is site-to-site variation something the research team wants to study or is it primarily a potential confounder or source of bias in understanding the results? It will probably be worthwhile to explore site-to-site variations on a preliminary basis before proceeding with the main study analyses, keeping in mind that some site-to-site differences will be expected based on chance alone and the characteristics or nature of various settings. For most multi-site studies, the findings that will be of primary interest to most audiences will involve analyses of the entire sample, but the possibility of biases must be examined and perhaps taken into account in the statistical analyses.

The operation of outside variables (other than the main ones under study) or aspects of a study design that can lead to erroneous conclusions can be handled in one of three ways. They can be eliminated using consistent procedures and/or inclusion and exclusion criteria, they can be measured and presented for the consideration of readers, or they can be included in the analyses.

## CHAPTER 7

# Team selection and operations

During the protocol development process, many of the feasibility and operational challenges are revealed. These include developing the right study team, planning for operations and communications, and securing administrative and IRB approvals.

### 7.1 Assembling a qualified study team

While study teams may seem to develop organically, deliberate planning is necessary. If external funding is anticipated, funders want to know that the team is strong, with appropriate disciplines represented, and with the expertise to conduct and complete the project. Even with internal funding and perhaps a limited budget, each team member should have a specific scope of responsibility and contribute meaningfully to the project. This requirement should be specified clearly and negotiated with each team member.

Multi-site studies may be further complicated by inclusion of site PIs and individuals who expect to be included on the study team. Defining a scientific study team and an operations study team is one approach to address contributors' roles and expectations.

**The study team should include:**

**Experienced PI (or a novice PI with support from an experienced PI).** Skills needed to move a complex study team and process include:

- Knowledge and skills in designing and conducting research
- Position in the organization with sufficient connection to facilitate engaging the necessary supports and resources (e.g., physician support/collaboration, IRB, IT services)

- Experience in managing teams
- Strong communication and organizational skills
- Adequate time given other commitments and constraints to prepare and conduct the study
- A passion for research and the selected topic

**Research team(s).** The PI may or may not be a content expert in the field of the study. Experts will be needed related to the clinical content, as well as specific aspects of the methodology (e.g., qualitative methods, implementation science). Depending on the size and scope of the study, the research team may be operationalized in multiple teams, for example a scientific team, a consultative/advisor team, and a study operations team. When building a research team, the PI should consider a broad range of stakeholders who represent the target population of interest and/or can provide unique perspectives on the study protocol or variables of interest, regardless of whether they may be experts in research. In particular, including researchers who have backgrounds, knowledge, and experiences relevant to the populations of interest in the study will generate more insightful research.

**Clinicians/clinical leaders.** Individuals who can facilitate operationalization/implementation of the study protocol are assets for a study team. Clinicians who know current practice patterns and can help integrate the study protocol into the practice setting will help the team to plan for fidelity and completeness of implementation of the study protocol. Clinical leaders can help to identify and negotiate logistical challenges to study operations in the planning phases of the study.

**Statistician.** A statistician with knowledge of multi-site study design and analyses should be engaged early in the study design. Assuring adequate sample size to adequately test hypotheses is fundamental and statisticians generally have the expertise to conduct such power analyses.

**Information technologist.** If data are to be drawn from hospital information systems/electronic health records, including IT personnel early in the process will facilitate identification of data sources and availability of specific data elements. Likewise, managing data from multiple sites may require database development and data management skills and an understanding of information systems and how they relate to each other.

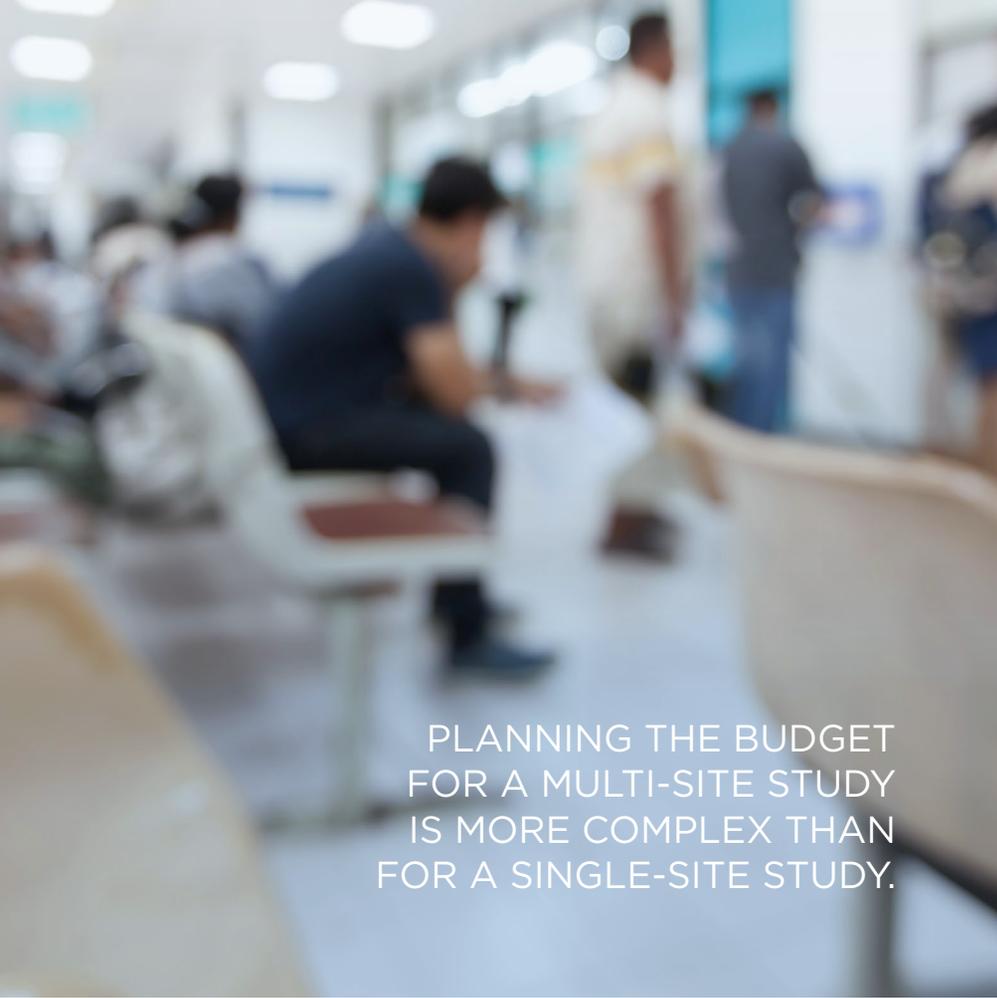
**Regulatory specialist.** Complex clinical studies may also include a regulatory specialist (perhaps for a smaller percentage) to help facilitate human subject application development and to complete reports for research activities from initial submission through study closure. In multi-site studies where site-specific regulatory requirements must be considered, having an accountable person with the expertise and knowledge of regulations can expedite approvals.

**Site PI.** Most multi-site study teams include a site PI for each location. A designated nurse researcher may assume the site PI role. Likewise, each unit within a facility may have a unit lead if the study is a single organization with multiple internal sites.

**Project manager.** Depending on the complexity and number of study sites, a full- or part-time project manager is desirable to support the study operations. This position is best filled with a well-directed research assistant or an individual with clinical research management experience.

Multi-site studies also provide opportunities for others to participate in the research process although all may not be designated members of the research team. Academic-practice partnerships are common in multi-site studies and should be mutually beneficial to both. Academic partners (faculty and students) bring methodological expertise while practitioners (e.g., nurses, physicians, social workers) bring practical and context-specific expertise that can help the flow of the study and facilitate access to patient populations. Such collaborations co-produce evidence and should promote generalizability as well as translation and dissemination. Many academic faculty need access to study populations and opportunities to be current in practice. They can apply their research expertise to clinical problems and mentor others. Clinical staff participation in multi-site studies helps them see the value of research and how it relates to EBP. It also provides an avenue for nurses to advance their clinical practice and explore pathways to continue their education, and may have an impact on growing the pool of doctorally-prepared nurses in the future.

Nursing students at every level can benefit from participation in multi-site studies. Students in baccalaureate programs may gain a clearer understanding of the rigor involved in, and hence the value of, the creation of sound scientific evidence. Participation in research activities may include involvement in planning meetings, data collection, and dissemination. Students in master's programs may also help with comprehensive literature reviews, identification of valid and reliable instruments, and assistance in IRB application materials. Practice-focused doctoral students can be mentored in assessing the evidence, designing studies, collecting data, and dissemination. Research-focused doctoral students also can be mentored in these areas as well as complex designs and conducting advanced statistical analyses. However, it should be noted that some of these activities may require inclusion of students as members of the research team as per human subject protection regulations. All participating students should complete appropriate human subject training.



PLANNING THE BUDGET FOR A MULTI-SITE STUDY IS MORE COMPLEX THAN FOR A SINGLE-SITE STUDY.

## 7.2 Budgeting within funding constraints

Planning the budget for a multi-site study is more complex than for a single-site study. Considering options for funding will depend on whether the study will be multi-site across organizations, multi-site within a single health care system, or multi-site (unit) in a single hospital. It will also depend on whether the study will be funded through external grants, internal through foundation grants, internal through health care organizations, or some combination of research support funds. Internal support through operational funds will need to be negotiated early in the research planning during the process of obtaining organizational support. Existing positions and nursing staff resources will be part of decisions about return on investment of the study and about feasibility. Budget and operational constraints may result in modifications to the research design.

**Figure 7.1** illustrates potential areas to consider in developing a budget for a multi-site study. Salary support for team members may be a large proportion of the budget and often must include fringe benefits. In-kind funding (i.e., non-monetary) should also be considered. These expenditures may include salary support for some team members (e.g., hospital nurse researcher), services (e.g., hosting the learning platform), and resources (e.g., tablets for data collection). Some in-kind contributions may be a pre-requisite for participation, such as salary support for site PI, ability to make copies, or data extraction from the electronic health record.

FIGURE 7.1

## GENERAL BUDGET PLANNING TEMPLATE FOR NURSING MULTI-SITE STUDY

### FUNDING SOURCE

A=External grant  
 B=Internal funds/grant  
 C=Hospital/unit operations  
 D=Education department  
 E=Included in current position  
 F=Other (specify)

### HOW PROVIDED

1. In-kind  
 2. Fund transfer  
 3. Billed to multi-site PI

BUDGET ITEM	BUDGET \$	FUNDING SOURCE	HOW PROVIDED
<b>MULTI-SITE INVESTIGATIVE TEAM</b>			
PI			
Co-investigators			
Statistical support/statistician			
Project coordinator			
Other support persons			
Consultants			
<b>SITE TEAM (HOSPITAL/UNIT/CLINIC)</b>			
Site PI (Coordinator)			
Site research team members			
Nursing staff time			
Nurse education time			
<b>RESOURCES</b>			
Payments to patient participants			
IT support for programming and data extraction			
Development of study database (e.g., REDCap)			
Website development			
Computer hardware (e.g., iPads, mobile phones)			
Computer software development			
Development/printing of educational materials for site PI, team members, and nurses participating			
Development/printing of recruitment materials			
Development/printing of study materials, including consents, questionnaires, data forms, etc. (may be electronic)			
Lab analysis fees			
Travel – multi-site team			
Travel – site team			
Dissemination – conferences, journal fees for publication			

## 7.3 Developing an operations management plan

A multi-site study has a more complex organizational structure than a single-site study. There can be tiered approaches to manage the study operations. The following four management groups are provided as an illustrative approach.

**Scientific team.** A management team that is responsible for the scientific integrity of the overall study is common. It oversees the decisions about study design, choice of measures, ethical considerations, and operations plans for the conduct of data collection. Depending on the nature of the study, the scientific team or a separate Data Safety Monitoring Board should review data and preliminary results as they become available. The multi-site scientific team is also responsible for analysis and interpretation of data and dissemination of findings. Individual members of the team may be assigned to specific functions such as liaison with specific sites for oversight and assistance or to production of dissemination materials. Members often include the PI, the site PIs, co-investigators, statistician, and relevant consultants. Project administrators and research assistants may also be included.

**Multi-site advisory board.** An advisory board of high-level representation from participating sites is useful in planning for approvals at each site and for engaging resources as needed for the study. The advisory board should be engaged early to assure that the research plan addresses a meaningful research question for which answers will impact practice. The advisory board can also provide insights into logistic plans and the best mechanisms for dissemination and implementation of findings. Members may include the study PI, selected co-investigators, chief nurse executives of participating organizations or directors of participating units, and diverse patient/family representation as appropriate.

**Operations team.** An operations team is responsible for the study operations, including helping to organize site teams, train site participants, data collection and management, and making recommendations for protocol revisions. In addition to administrative support (e.g., project director/manager or operations manager), members often include the site PIs, selected co-investigators as appropriate, IT/database management, and site representatives as needed.

**Site team.** Each site needs a leadership team for planning and monitoring the logistical plan for the study. The frequency of its meetings will depend on the stage of the study. Following planning for study operations, the site team is responsible for staff training about the study and data collection procedures. During the study, the site team is responsible for monitoring fidelity to the study protocol, encouragement of nursing staff in study participation, problem resolution as needed, and celebrations of study success. The team is also responsible for dissemination of findings and leadership in determining how the results should be implemented or sustained. Members may include the site PI, nurse researcher, other key site leaders (hospital or unit level depending on the study), nurse educator/trainers, nursing staff representation, and information technologists.

It is important to explicitly define the members of each team and the role(s) of each member for clarity of study operations. Documents required to achieve and support regulatory compliance in human subjects research may also require clarity of team member roles (e.g., delegation log). **Table 7.2** illustrates a matrix showing scientific/research team roles juxtaposed with site roles for a hypothetical multi-site study involving multiple hospitals and data collection by clinical nurses during patient care, and an extraction of electronic data by hospital IT.

TABLE 7.2

## SAMPLE RESPONSIBILITY MATRIX BETWEEN SITE TEAM MEMBERS AND SCIENTIFIC TEAM IN NURSING MULTI-SITE STUDIES

SITE TEAM MEMBER	▼ RESPONSIBILITY	▼ SCIENTIFIC TEAM OVERSIGHT
<b>CNO</b>	Advance/submit organization agreements Unit selection Identify champions Approve budget Initial and ongoing communication and feedback within the organization Align with organization's mission and strategic priorities Set expectations for site's participation in the study	Review agreements Verify and document unit selection and champions
<b>SITE COORDINATOR</b>	Site-specific planning Initial and ongoing communication with CNO and research team Liaison with IRB to determine and execute mechanism of approval Assure IRB/ethics training for all research team members Liaison with IT to secure data extraction Conduct staff training	Conduct operation team meetings, compiling specific issues and strategies to address (e.g., IRB, data extraction) Submit local IRB approvals to Coordinating Center IRB Develop and oversee documentation of required training
<b>NURSING STAFF</b>	Complete training Implement protocols (e.g., collect data, secure data, and quality check per protocol)	Develop study training materials Make sure training is documented
<b>IT TECHNOLOGIST</b>	Data extraction, management and transmission	Identify data specifications Check data quality, compile and report results

## 7.4 Developing a communication plan

Communication is a key factor in the success of a multi-site study. Utilizing a web portal is a recommended approach to organizing study-related materials that can be easily accessed by the research team. This may be done in various web platforms including a website builder, Learning Management Software, or Project Management Software. Document management and version control are essential. Ideally, the web portal should also be able to deliver training and host online meetings.

### Common documents included in a web portal include:

- Project overview
- Study team members and bios
- Study protocol
  - ▶ recruitment materials
  - ▶ instruments
  - ▶ procedures
  - ▶ FAQs to document questions and recommendations

### Depending on the software capabilities and design, other areas of a web portal can include:

- Calendars
- Video conferencing links
- Training materials
- Project management status
- Archived meeting minutes
- Presentations/publications

Maintaining documentation of meetings, decisions, timeline, and changes is essential and often the major focus of a project manager.

### Project management documentation may include:

**GANTT chart/timeline.** Whether via a simple timeline or project management software, notations of revisions and completion of tasks should be documented, with dates and individual responsibility. Since study sites may be at different stages of data collection, each site may have separate timelines.

**Decision notes.** Whether from an external body, operational meeting, or PI, all changes to study protocol must be documented and communicated to team members. This requires documentation of all decisions — dates, by whom, recommended change, who is responsible, and date completed. Protocol and consent form changes require submission of an amendment to the IRB.

**Regulatory records.** All documents related to human subject review and approvals should be maintained — and are often required — in a regulatory binder. This includes all communications with IRB including initial approvals, amendments, protocol deviations, and quality review reports.

**Fidelity tracking.** In multi-site studies, it is crucial to seek and document regular updates as to progress on major elements of protocol including training, recruitment, data collection, and challenges faced at each site. This is useful for overall project management, interim progress reports, and troubleshooting common problems.

Developing a specific and consistent plan for frequency of meetings and communication approach will assure effective communication with all members of the study team. **Table 7.3** illustrates how standard meetings may be set for a hypothetical multi-site study.

TABLE 7.3

EXAMPLE OF STANDING MEETINGS TO SUPPORT MULTI-SITE RESEARCH STUDY COMMUNICATION

	MULTI-SITE SCIENTIFIC TEAM ▼	SITE LEAD/ OPERATIONS TEAM ▼	SITE TEAMS ▼	ADVISORY BOARD ▼	NURSING LEADERSHIP ▼	NURSING STAFF ▼
<b>REGULAR MEETINGS/ CHECK-INS</b>	Monthly 1st Wednesdays	Q2 weeks Monday	Q3 weeks Tuesday	As needed, beginning and end of study	Quarterly	Monthly
<b>COMMUNICATIONS APPROACH</b>	Face-to-face via in-person or video	Video webinars Website Discussion boards	Video webinars Website Discussion boards	Video conference	FAQs Website Progress boards	FAQs Website Progress boards Newsletter Email blasts



## 7.5 Securing administrative and IRB approvals

Administrative approvals are likely required before starting a multi-site study. As noted above in stakeholder engagement and developing research teams, these discussions start early and are usually secured before a proposal is funded. Support letters that state approval to conduct the research with qualifications of specific unit and organizational contributions are needed. When contracts need to be developed and executed across multiple organizations, legal departments should be consulted early and the expected processes and timelines should be determined.

**Formal administrative approval.** In many organizations, formal administrative approval to conduct the study is required before IRB approval; in other organizations the IRB approval comes first. Early contact with the IRB will facilitate understanding of the need for, and order of, IRB and administrative approvals to conduct the research. Several IRB-related issues are discussed below.

**Approval of activities preparatory to research.** IRB approval may not be required for activities preparatory to research. Often this relates to accessing data to determine the number of available patients to be used in sample size determination. Consultation with the IRB will provide guidance as to what is required to conduct activities prior to research.

**Type of IRB approval.** The type of study, type of data collected, identification of human subjects, and patient risk will determine the type of study — exempt, expedited, or full review. Some studies may be considered “non-human subjects” research. Most often these are QI or EBP studies. However, the local IRB should make the determination of “non-human subjects” research. Obtaining proper IRB approval is not only needed for the research process; reference to it will be needed for future scientific dissemination.

**Single versus multiple IRBs.** While NIH funding has set the expectation that some multi-site studies that use the same protocol use a single IRB, this practice is slowly penetrating all multi-site studies. A single IRB is the approach for multi-site studies conducted within a health care system if the system may review and approve for all units within the system. Otherwise, approval may be required from each organization. Negotiating multiple IRBs can be a challenge. Three approaches are common:

1. Coordinating IRB to which all organizations/system hospitals belong provides a single IRB approval for the study.
2. IRB of the PI serves as the IRB of record for the study, with other IRBs (if they agree) deferring (ceding) oversight by the IRB of record through an Institutional Authorization Agreement.
3. Each participating site receives separate IRB approvals.

# PART IV CONDUCTING A MULTI-SITE RESEARCH STUDY

Even with good planning, additional challenges are anticipated in multi-site studies. [Chapter 8](#) reviews the ethical responsibilities of the PI throughout the study. [Chapter 9](#) addresses various research-related procedures that are particularly challenging. Data management and security issues are discussed in [Chapter 10](#).

## CHAPTER 8

# Ethical responsibilities for principal investigators

The study PI has primary oversight of the full multi-site study, including scientific rigor, human subject protections, communication among the research team, and adherence to protocol and regulation for all study-related procedures. Furthermore, the study PI is responsible for knowledge of, and compliance with, any organizational, university, state or federal regulation that may apply to the study. While some responsibilities can be delegated, the study PI is ultimately responsible.

To ensure **ethical compliance**, the following responsibilities are outlined by the Office for Human Research Protections (OHRP):

- Obtaining and documenting informed consent
- IRB approval prior to any modifications to protocol or informed consent
- Ensuring IRB review and approval of progress reports and continuing review
- Reporting to IRB any unanticipated risks
- Retaining certain study-related materials for at least three years after study completion
- Ensuring 24-hour coverage for all hours when study interventions and data collection are carried out

Depending on the requirement of the IRB or the conducting site, regulatory review may also include developing a regulatory binder (may be electronic) demonstrating compliance with the regulations and protocol. Items may include:

- Protocol and amendments
- IRB approvals and compliance
- Informed consent documents
- Investigator qualifications documents
- Delegation of authority
- Screening and enrollment log
- Clinical site monitoring visits log
- Data safety monitoring documents

In multi-site studies, consideration should also be given to which documents are maintained and how they are protected at each site. While it may seem that site PIs serve the same functions as a study PI in relation to the specific site, delegated responsibilities must be documented.

## CHAPTER 9

# Procedural considerations

### 9.1 Providing education and training

Education related to the purpose and value of the study and the underlying science leading to the study should be supported by consistent materials as described in Chapter 5. Participant training is related to the study procedures and may be tailored based on an individual's roles. Multi-site studies require substantial advance planning for education and training of study personnel. In a train-the-trainer model, education and training are accomplished in two phases. First, the site PIs and study educators are trained in the study protocol as well as other aspects of the study including:

- The underlying science
- The study design
- The study protocol for intervention (if applicable), data collection, risk protection
- Logistical plans
- Data management procedures

Second, once the site PIs and/or site educators are trained in the study protocol, they become responsible for educating the appropriate staff at their respective sites.

A variety of methods can be used for training. In many cases, multiple methods may be used to assure that education/training reaches all appropriate participants. These may include:

- In-person presentation, either in groups or individual training
- Webinar, presented live and/or recorded
- Voiced video slide presentation that can be accessed at any time
- Printed materials

Documenting training is also required and is more difficult in multi-site studies using multiple methods. Often, the site PI is responsible for the process. Creating a list of nurse or other staff members who require education/training is a first step. Then, attendance can be recorded by physical attendance or by attestation. Posting the webinar/presentation on the learning management system has been used successfully to deliver training and record attendance. Depending on the length of the study and the responsibilities expected of nurses, a mechanism may be needed to train new hires or to train float nurses.

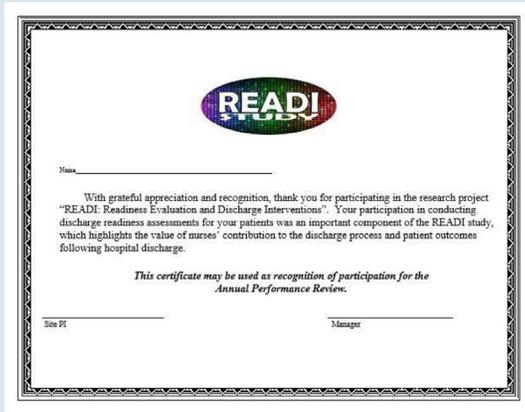
Training may require a specific line item on the budget. This may include resources needed for development of education/training materials, support for distribution, and staff time required to attend training. In some instances, the operational department/unit where the study is taking place absorbs the training costs for its employees.

### 9.2 Engaging and maintaining staff support

While the research team is involved in many of the processes in a multi-site study, staff who participate in the study at the sites may have intermittent engagement. Staff engagement is initiated during the decision to participate and during education and training, but it is important to maintain and boost engagement over the course of the study. [Figure 9.1](#) shows one way to do this.

FIGURE 9.1

## READI ANCC MULTI-SITE STUDY APPRECIATION CERTIFICATE



Other successful strategies include:

- Kick-off party
- Celebrations of progress
- Visibility of the study on the unit through posters, etc. (as long as this visibility does not compromise an intervention)
- Recognition of the study by organizational leaders
- Recognition of highest enrolling study units
- Individual recognition for participating nurses (if permitted by IRB)
- Documentation of participation in employee file for use in annual review and promotion
- Celebration event when study activities have been completed
- Sharing study results with participating units

## 9.3 Optimizing efficiency and decreasing burden

Multi-site studies are by nature complex, involving multiple types of patients, nursing units, and/or hospitals. For study planning and operations, the burden on individuals at study sites must be considered. This includes research staff, clinical staff, and patients.

For clinical nurses involved in the study, whether as recruiters, interventionists, data collectors, or study monitors, how they conduct their role while caring for patients is a key factor to achieve consistency in study procedures and acquire complete data. Thus, it is crucial to consider how study procedures will be integrated into the usual care process. Since care processes vary across sites, it is important to engage site PIs and staff nurses in defining study procedures.

Likewise, it is important to select data collection surveys and tools that are simple to use. Data collection at a time of a usual care process will facilitate operational procedures. Building integration of the study into usual care process by reviewing the logistics of intervention and data collection (i.e., who, what, where, when, and how) with informants in the practice setting will create smooth, non-burdensome study processes.

Whenever possible, existing administrative data should be used rather than collecting data directly from patients and nurses. If possible, add fields to existing screens or as new tabs or screens. Some EHR and HR systems are nimble enough to allow this, but getting approval and making such changes often takes considerable time. In some cases, altered screens can be made available only to the study unit or can be hidden from view for non-participating parts of the organization.

For data not routinely collected electronically, consider collecting it directly from patients or from clinicians using electronic entry portals. A portal can be created in the point-of-care computer system to allow clinicians or research assistants to enter data directly at the bedside. For patient data collection, an electronic approach — rather than paper — should be used, when possible. Data can be collected from patients on a device that links directly to a cloud-based research database (e.g., REDCap, Qualtrics) for later downloading by the research team.

## 9.4 Monitoring treatment and/or data collection protocol fidelity

In multi-site studies, it is particularly important to plan for and assess treatment fidelity — the extent to which treatments are delivered as intended. Taking this into account contributes to the validity of the findings and allows researchers to examine how treatment fidelity contributes to study outcomes. The fidelity workgroup within the Behavior Change Consortium (BCC) developed guidelines to comprehensively evaluate treatment fidelity in behavior change research (Bellg et al., 2004). Aspects of treatment fidelity were defined in regard to study design, training of interventionists, delivery and receipt of the intervention, and enactment of the intervention in real-life settings. Illustrations from behavior change studies provide useful examples of approaches to consider (Resnick et al., 2005).

Planning should include mechanisms to evaluate the aspects of fidelity, as relevant to the study design. For example, monitoring of the protocol implementation can be done through observation of random trainings, counts of enrollments and data collected, and review of the quality of the data. During the study, treatment fidelity should be tracked at regular intervals so corrective actions can be taken as needed. For example, gaps in training of study staff and participating nurses may be identified and unexpected logistical barriers may be encountered. Monitoring may identify issues with protocol that lead to beneficial changes. In studies with long data collection periods, it is particularly important to maintain monitoring as study fatigue may diminish study enrollments and fidelity to the protocol.

## 9.5 Assessing local adaption and maintaining control

Aligned with treatment fidelity is the importance of acknowledging and measuring local adaption. Every clinical unit has its own operational uniqueness that may require different adaptations, and unit ownership may be a key factor in successful implementation. The multi-site team should review the logistical plan for each unit to determine which study components must remain the same in all sites and which are amenable to local adaptations. Importantly, data should be collected, and variables considered, in the analysis that describes this unit-level uniqueness.

Logistics planning is a key factor in the success of any study, and especially in multi-site studies. It is important to think through all logistics to assure that the implementation of the innovation/ intervention/care delivery redesign and the collection of study data run smoothly and efficiently. Tools/worksheets that facilitate consistency across sites can be helpful and improve the fidelity of the study. **Figure 9.2** is an example of a logistics planning document that provides site coordinators with tasks and key considerations in implementing the protocol.

FIGURE 9.2

## SAMPLE SITE LOGISTICS PLANNING DOCUMENT FROM ANCC'S MULTI-SITE READI STUDY

Hospital unit name		
TASK	▼ KEY CONSIDERATIONS	▼ DECISIONS/PLANS
1. Decide on a starting date for phase 1.	Start date should be on the 1st of a month between February and April [YEAR] and not later than June [YEAR].	
2. Set training dates for phase 1.	Training dates should be two weeks prior to the start date. Identify timelines within your hospital for approval and loading of training materials to learning platform.	
3. Develop a flow diagram to describe the process of distribution of study forms, data collection, and the retrieval of forms after data collection.	Attach flow diagram to this logistics planning form.	
a. Identify how the study forms will be made available to clinical nurses on the day of discharge.	How will the nurse access the form? Will it be placed in an on-unit chart? Who will put it there? Where in the chart? Will study forms need to be completed for all patients being discharged (including home and non-skilled assisted living facilities)? Will the study form be embedded in the EHR? How easy will access be? How will nurses know they need to do the assessment?	
b. What triggers/reminders will be used to assure that nurses complete the required data on EVERY patient?	Consider: <ul style="list-style-type: none"> <li>• Unit signage</li> <li>• Reminders in patient room</li> <li>• Reminders in patient record</li> <li>• Triggers in EHR</li> </ul>	
c. How will the completion of the study data forms be integrated into workflow so that it is completed during the discharge process, not after the patient has left?	What care process or documentation process will the study data forms be linked to that will assure timely completion? Are there alerts that can be created?	
d. Where will nurses put the form after completion?	Will there be a central form collection box? Will unit secretaries retrieve the forms from patient charts? What will happen to forms that end up in the medical records department?	
e. What processes will be in place to quality-check data collection completion?	Daily reconciliation of eligibility and implementation fidelity (# of discharges/# eligible/# completed). Who will do this reconciliation? Where will the log be kept?	

CONTINUED ON NEXT PAGE

FIGURE 9.2

## SAMPLE SITE LOGISTICS PLANNING DOCUMENT FROM ANCC’S MULTI-SITE READI STUDY

CONTINUED FROM PREVIOUS PAGE

Hospital unit name

TASK	▼ KEY CONSIDERATIONS	▼ DECISIONS/PLANS
4. Nurse IDs	<p>Each nurse needs a unique five-item nurse ID for the research, such as:</p> <ul style="list-style-type: none"> <li>a. Last four digits of employee number and first letter of last name</li> <li>b. Last four digits of cell phone and first initial of first name</li> <li>c. Mother’s birthday and month plus a 0 [DDMMO]</li> </ul> <p>Method must be the same for all nurses on the unit.</p>	
5. Floats	Who will orient float nurses to protocol and data collection?	
6. Site PI oversight	Oversight is essential throughout the research and should be planned so accountability is clear.	
a. Engaging staff in the research	<p>What will you do to engage staff on the implementation unit? How will you let them know how critical their role is to the success of the study? Leadership enthusiasm and commitment are important and need to be visible early and often. How will you make staff aware of this commitment and support? Leadership from within is also important. How will you engage staff champions and what specifically will they do? The control unit is an important part of the study but there is no on-unit activity, and we want to make sure they are not contaminated with information about the study. How will you handle presenting the study to the control unit and other units in the hospital during the initial study roll-out?</p>	
b. Maintaining adherence to the protocol over time	Who will monitor adherence to the flow diagram? How often? Who will be the back-up for days off/vacation, etc.? How will you make the protocol adherence visible to staff throughout the study, e.g., monthly chart posted on unit?	
c. Maintaining momentum for the study	How will you sustain energy for completion of study protocol/forms in the face of multiple ongoing changes faced by staff nurses?	
d. New hires	Who will have responsibility for training new hires? When will training occur?	
e. Study log	Complete Excel Study Log of completed study data forms. Once completed forms are retrieved, enter patients into Excel Study Log spreadsheet.	
f. Scan Readiness for Hospital Discharge Scale (RHDS) forms	After forms are entered in Study Log, scan to a pdf file to keep at your site. The original (de-identified) forms will be mailed to the research team.	

## CHAPTER 10

# Data management and security

Managing study data is particularly challenging across multiple sites, with considerations for collection ease and accuracy of data. Fundamental decisions relate to how to collect data including software to be used, electronic or paper collection, who has access to the data, how the data will be secured and stored, who will manage data, how data will be shared across sites, and how long data will be retained. Organizations may have data governance policies that address any or all issues about the use and reuse of data. Data-related details often need to be sorted out before ethics approval is obtained (and careful consideration of privacy and data security issues is often required by IRBs). Data inconsistencies can contribute to unexpected dropping of sites, elimination of individual data points, or the need to declare a study's data as too contaminated to analyze or disseminate at all. Therefore, costs involved, the need for training together with data entry and verification, and the ongoing need to monitor data quality can never be neglected.

If data are requested from an EHR or other hospital information system, it is essential to provide clear specifications and definitions for the data to be collected. While many facilities collect the same or similar clinical data, the format (structure) in the information systems may vary. If collecting data on paper forms, the same forms should be used at each site.

Creating a spreadsheet of data elements and their definitions needed for the study will help IT specialists determine:

- What data are available
- In what format (structured or unstructured)
- From what sources
- Whether the data can be extracted, queried electronically, or manually retrieved
- How much effort IT services should budget to meet the data needs of the study

**Figure 10.1** illustrates an example of data specification for a multi-site study. To protect confidentiality and integrity of the data, once the data are collected, they must be stored securely per IRB requirements. This often includes:

- Storage in locked facilities or password-protected technology
- Copying of paper records and data files and storage in separate secure files
- Restricting access to the data to a small number of trained study team members
- Development of a data transfer plan to move data from the data collection site to a central repository through secure uploads
- Assuring secure HIPAA-compliant cloud-based web storage
- Defined data retention policies

A clear understanding needs to be established regarding who owns which portions of the data. The scientific interests of the collaborative group (study teams at all sites) to disseminate results of the study should be the primary consideration, when an individual team considers analyzing or presenting its own site's data. Aggregated results from all sites should be disseminated first, with individual site analyses centrally planned and coordinated across all the teams. It is particularly damaging to the credibility of a study if a single site goes forward with an analysis of its own data that reaches a different conclusion than the multi-site version. Given the nature of analyses (and of statistics and statistical power), different results from the same data are more common than might be expected. Often, challenges like this may be mitigated through a data use agreement and an agreed upon dissemination plan. An agreement about when and under what circumstances a site can use its data in isolation needs to be clearly stated and embedded in the site contract to join a study.

FIGURE 10.1

**SAMPLE SITE LOGISTICS PLANNING DOCUMENT FROM ANCC’S MULTI-SITE READI STUDY**

▼ VARIABLE NAME	▼ VARIABLE LABEL	▼ DEFINITION	▼ FORMAT	▼ CODE
<b>LINKING</b>				
MRECNUMB	Medical record number	Medical record number assigned by hospital	6 digits	After matching, use hospital-defined conversion to create de-identified
DCUNIT	Discharge unit	Hospital unit patient discharged from	20 characters	Text name of unit
<b>ADMISSION</b>				
ADMINCLAS	Admission classification	How hospital is classified	1 digit	1=Inpatient 2=Observation 3=Outpatient in bed 4=Short stay
ADMINTYPE	Admission type	Type of hospital admission	1 digit	1=Emergency 2=Urgent 3=Elective 5=Trauma 9=Info not available
<b>PATIENT CHARACTERISTICS</b>				
GENDER	Gender	Gender of patient in medical record	1 digit	1=Male 2=Female 3=Unknown
MARITALS	Marital status	Marital status of patient	1 digit	0=Not married 1=Married 3=Unknown
AGE				
<b>DISCHARGE INFORMATION</b>				
HOSP30D	Prior hospitalization within 30 days	Was there an inpatient discharge date within past 30 days?	1 digit	0=No 1=Yes
TOT_LOS	LOS	Total number of days from admission to the hospital through day of discharge	3 digits	Count day of admission, do not count day of discharge
DRG				
<b>READMISSION/ED UTILIZATION</b>				
READMIT30	Number of readmissions within 30 days	Total number of hospitalizations within 30 days after discharge from this hospital stay	2 digits	Count inpatient readmissions
READMDAYS				

While much goes into planning any study, the importance of a complete evaluation and effective dissemination cannot be overemphasized. The scientific team should specify the approach to implementation evaluation and consider how findings will be disseminated during the planning stages. Part V presents an overview of frameworks that can help in defining the implementation plan in [Chapter 11](#) and discusses considerations for dissemination in multi-site studies in [Chapter 12](#).

# PART V IMPLEMENTATION EVALUATION AND DISSEMINATION

## CHAPTER 11

# Implementation evaluation

While the focus of studies is determining the effect of the intervention on outcomes (as reflected in research questions or study aims), evaluating the implementation facilitates the understanding of how and why the intervention had (or did not have) those outcomes. Studying implementation can help in drawing valid conclusions, provide lessons learned, and inform future research. In multi-site studies evaluating implementation is particularly important since these “real-world” settings have inherent variation that may influence outcomes.

Implementation evaluation frameworks are useful when developing a plan for data collection and procedures to be used in answering implementation questions. Such frameworks can help structure analyses and contribute to a meaningful discussion of study findings. Three such frameworks are described below to assist with this implementation evaluation process. Note that each has some similar constructs.

### 11.1 Process-evaluation

The process-evaluation framework (Saunders et al., 2005) examines key aspects of the implementation process and the context within which the study took place that may contribute to the study results, confidence in the study findings, and generalizability. These key aspects are summarized in [Table 11.1](#) with example metrics.

TABLE 11.1

KEY ASPECTS OF IMPLEMENTATION PROCESS (SAUNDERS ET AL., 2005)

IMPLEMENTATION EVALUATION COMPONENTS	ASPECTS MEASURED	EXAMPLE MEASURES
FIDELITY	Extent to which the innovation was implemented as planned	Nurse adherence to study protocol (all components completed on time)
COMPLETENESS	Dose of the intervention delivered	Mean number of components completed per patient
DOSE	Dose of the intervention received by the patient	% of patients receiving the intervention
SATISFACTION	Participant satisfaction and burden	Patient satisfaction with the intervention Patient perceived burden of the intervention
REACH	Participation rate (penetration of the intervention), barriers to participation	% of eligible patients who participated Refusal rate, loss to follow-up rate % of eligible nurses who delivered the intervention Patient- and/or nurse-reported barriers/reasons for non-participation
RECRUITMENT	Recruitment and retention	% of contacted who agreed to participate % who agreed to participate who completed the study Loss to follow-up rate
CONTEXT	Organization and unit factors	Descriptors of implementation and control settings Changes occurring during the implementation period on study units (implementation and control units)

TABLE 11.2

## CFIR CONSTRUCTS (DAMSCHRODER ET AL., 2009)

CONSTRUCT	EXAMPLE DOMAINS TO BE ASSESSED
INTERVENTION CHARACTERISTICS	Key stakeholders' perceptions of the intervention design, significance, complexity, and other relevant characteristics
INNER SETTING	Characteristics of the work unit(s) where the intervention occurred in terms of structure, culture, priorities, readiness, and resources
OUTER SETTING	External factors inside and outside the organization including policies, pressure, and networks
INDIVIDUAL CHARACTERISTICS	Characteristics of individuals participating in the intervention
PROCESS	Implementation processes in executing the intervention such as planning, leadership, engagement, etc.

TABLE 11.3

## RE-AIM CONSTRUCTS AND MEASUREMENT EXAMPLES (GLASGOW ET AL., 1999)

CONSTRUCT		EXAMPLE MEASURES
REACH	R	Participation: number, proportion, and representativeness of target participants
EFFECTIVENESS	E	Outcomes
ADOPTION	A	Participation by those who deliver the intervention: number, proportion, individual characteristics; individual and setting representativeness
IMPLEMENTATION	I	Fidelity to the process/protocol
MAINTENANCE	M	Extent to which the intervention becomes part of routine operational practices (sustained > six months)

## 11.2 Consolidated framework for implementation research

The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009) can be used for formative or summative evaluation research involving the introduction of an intervention, innovation, or new program. Five key constructs, summarized in [Table 11.2](#), are used to formulate the implementation plan with attention to the aspects of the intervention and the environment within which the intervention will be introduced. Similarly, these same constructs form the basis for evaluating the successes and challenges with the implementation process. Interviews with key stakeholders are the primary means of evaluation. The CFIR offers a [detailed guide](#) for designing interviews to address the five construct domains, each with several subconstructs.

## 11.3 RE-AIM

RE-AIM (Glasgow et al., 1999) is an evaluation framework that focuses on essential program elements that can influence effective implementation and sustainable adoption. The five constructs are summarized in [Table 11.3](#) with example measures for each construct.

While there is overlap with other implementation frameworks, RE-AIM is often used to frame implementation planning. The Maintenance construct adds the dimension of sustainability to implementation planning and evaluation. The [RE-AIM website](#) provides examples of how it has been used and updated.

# CHAPTER 12

## Dissemination

### 12.1 Take a broad view of dissemination

Deficiencies in the dissemination of research-based knowledge into routine clinical practice have been increasingly recognized over the past few decades. This phenomenon has led to funders asking for specifications of dissemination plans that go beyond traditional journal publications. Research dissemination has been defined as “a planned process that involves consideration of target audience and the settings in which research findings are to be received, and, where appropriate, communicating and interacting with wider policy and health service audiences in ways that will facilitate research updates in decision-making processes and practice” (Wilson et al., 2010). A major role of the PI in any study is to disseminate findings that contribute to the development of new knowledge.

Dissemination activities should focus on communicating findings and lessons learned from the study to broad general audiences to broaden the professional practice knowledge base and to local audiences at each participating site for local impact of site-specific findings. Engaging professional writing assistance to develop and refine manuscripts for publication, and communication/marketing experts to assist in professional and social media communication plans, will facilitate timely dissemination of research findings.

### 12.2 Developing a dissemination plan

A dissemination plan refers to a roadmap that guides the sharing of outcomes associated with a research study or project. This roadmap should be started during the development of the protocol. The dissemination plan strategically shapes the communication of outcomes with key stakeholders and relevant target audiences to achieve an important objective. The dissemination strategy is generally based on an understanding of the stakeholders and their information needs and preferences.

**A dissemination plan incorporates five important elements: why, what, to whom, how, and when:**

- **Why** refers to the purpose of the dissemination and guides selection of the dissemination strategy, which could be to raise awareness, inform, engage an audience, or promote products.
- **What** identifies the message to be disseminated and may be captured in the title of an activity or work product.
- **To Whom** identifies the target audience that will receive the specified message.
- **How** involves the method to be used for sharing the message and could include a presentation, publication, or other activity.
- **When** refers to the timing of the message and ideally includes a timeline along with identification of the responsible person to lead the effort.

In a multi-site study, the target audience for dissemination efforts includes those individuals, groups, or entities that would most benefit from the new knowledge. For the ANCC studies, findings influenced nursing practice and organizational processes, but they also had wider applicability to other disciplines and organizations. The specific target audience for any dissemination effort must be identified early so that information can be shaped and tailored to this particular audience. A well-crafted message is a call to action and prompts the target audience to do something meaningful with the presented information.

## 12.3 Approaches to dissemination

Within a broader context of dissemination, there are many types. Traditional publications and presentations remain important and collaboration and co-authorship are encouraged. The study PI should provide guidance on how authorship will be handled in the study, including criteria for authorship, order of authors, use of acknowledgements, and how site-specific publications relate to publications for the whole study. Decisions about authorship should be determined in the early stages of manuscript development. Author inclusion and order of authorship should be discussed, and decisions should be transparent. Many journals provide guidance on authorship. The International Committee of Medical Journal Editors (ICMJE) identifies **four criteria for authorship**:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

In addition to traditional publications and presentations, press releases, executive summaries, newsletters, and social media should be considered. These forms of dissemination help to amplify and customize a message that may have begun with the release of a published scientific paper or delivery of a professional presentation. They can be used alone or in combination to strategically communicate layered and repeated messages to target audiences. Before selecting a venue, consider the intended audiences and purposes of dissemination.





**Publications.** Publications and presentations are geared mostly to professional audiences in each discipline. Careful thought should be given to journal selection including the target audience, the restrictions on number of pages or word count, the review turnaround time, and how often journals are published.

**Presentations.** Likewise, presentations at professional meetings can be valuable to share findings and recommendations, network with other researchers, and stimulate future research. However, the audience is often limited, even when abstracts are published.

**Press releases.** A press release is an official statement delivered to the media to convey newsworthy information. When a study starts, a press release may announce the study. When a study ends, findings may be released with implications. A marketing department staff member often prepares press releases after interviewing the PI. If a study involves multiple organizations, the marketing departments should coordinate with each other.

**Executive summaries.** An executive summary is a brief report that rapidly captures the essence of a longer report without the reader having to sort through an entire document. While an abstract or overview of research is common in academic circles, in business environments the more in-depth executive summary is the preferred condensed version of a full document. This is what organizational leaders are often looking for. An executive summary is approximately 5 to 10% of the length of the full report. It begins with a summary, is written in a similar order as the full report, and ends with a conclusion and recommendations.

**Newsletters.** A newsletter is a printed or electronic report that contains various news elements including past or future happenings of an organization, activities or stories about its members or subscribers, or informational content pertinent to its readership. Newsletters are usually circulated on a regular basis as serial publications. They vary in length and content, but usually follow a standard organization-specific format.

**Social media.** Social media refers to interactive web-based technologies that allow for displaying and exchanging information. Social media allows researchers to personally share just-in-time information and images using a variety of platforms that include Twitter, Facebook, LinkedIn, Instagram, YouTube, and blogs. Use of social media needs to be consistent with organizational policies. Furthermore, each social media has its unique guidelines in terms of the amount of information that can be shared. For example, the text content of a Tweet using Twitter is 280 characters, whereas the ideal number of characters for a LinkedIn status update is 50 to 100 characters. Lastly, most social media platforms have built-in data analytic tools to track hits to the site and thus use this information as a measure of information uptake.

A sample dissemination template that incorporates the five key elements is illustrated in **Figure 12.1**. The study PI and project manager should populate the various components of the template and direct the dissemination effort. Updating should be done at regular meetings as the project evolves and dissemination becomes clearer.

TABLE 12.1

## EXAMPLE OF A DISSEMINATION PLAN TEMPLATE

### WHY

#### DISSEMINATION STRATEGY

WHAT TITLE OF WORK PRODUCT	HOW			TO WHOM TARGET AUDIENCE	WHEN TIMELINE Start/end member	RESPONSIBILITY Lead team member
	ACTIVITY Presentation Publication Other	VENUE Conference Journal Other	LEVEL L=local R=regional N=national I=international			

#### The take-home points related to dissemination are:

- Dissemination refers to the act or process of distributing information to enhance learning, advance a body of knowledge, and/or address societal needs.
- Everyone who takes part in a research study or other scholarly project has a duty to share the findings of that study.
- A target audience for dissemination is identified for purposes of shaping and tailoring a specific message.
- Dissemination may be achieved through publication, presentations, and other forms such as, but not limited to, press releases, executive summaries, newsletters, and use of social media.
- A dissemination plan refers to a roadmap that guides the sharing of outcomes associated with a research study or project.
- The dissemination plan includes five important elements that address why, what, to whom, how, and when information is shared.
- A dissemination plan template helps to capture these five important elements.
- Beyond dissemination, it is important that information be used to create change that advances education, practice, research, and policy.

## 12.4 Beyond dissemination

Research utilization is a broad older term that goes beyond just dissemination to include the process of synthesizing, disseminating, and using research-generated evidence to facilitate change in existing practice. New knowledge derived as a product or output of the research process is shared through dissemination strategies. Beyond dissemination, knowledge is then utilized in new ways and incorporated into policies and guidelines (uptake) in evidence-based practice to ultimately benefit society and achieve broader impact. Studies of this process and the effect on outcomes is often the focus of practice doctorate projects.

Assessment and continued monitoring of uptake may identify further problems and knowledge gaps that need to be addressed with new research studies. The use of such cycles of knowledge generation to knowledge translation are needed in nursing to address crucial quality problems and to strengthen evidence about nursing practice.



# APPENDICES



## APPENDIX A

# References

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## APPENDIX B

# Summary of Selected Articles

APPENDIX B1

### ARTICLES ABOUT FACILITATOR AND CHALLENGES TO CONDUCTING MULTI-SITE CLINICAL RESEARCH: THE ANCC MULTI-SITE RESEARCH EXPERIENCE

▼ REFERENCE	▼ FACILITATORS	▼ CHALLENGES
<p>Haugen M, Skeens M, Hancock D, Ureda T, Arthur M, Hockenberry M. Implementing a pediatric oncology nursing multi-site trial. <i>J Spec Pediatr Nurs.</i> 2020 Jul;25(3):e12293. doi: 10.1111/jspn.12293. Epub 2020 May 17. <a href="https://doi.org/10.1111/jspn.12293">https://doi.org/10.1111/jspn.12293</a></p>	Nursing/leadership/medical support including nurse educators and researchers	IRB processes
	Commitment of nursing staff	Consent process
	Current state lack of practice guideline	Timing of the intervention for nurses and patients
	Intervention useful for inpatient and outpatient	Nursing time for the study
	Availability of nurses to identify eligible patients	Balancing study work with patient care priorities
	Clear delineation of study roles	New skills development related to consenting and intervention
		Changing the culture-related usual care discharge practices
<p>Patton L, Montgomery K, Coyne K, Slaven A, Arthur M, Hockenberry M. Promoting Direct Care Nurse Engagement in Research in Magnet® Hospitals: The Parent Education Discharge Support Strategies Experience. <i>J Nurs Adm.</i> 2020 May;50(5):287-292. doi: 10.1097/NNA.0000000000000885. <a href="https://pubmed.ncbi.nlm.nih.gov/32317570/">https://pubmed.ncbi.nlm.nih.gov/32317570/</a></p>	Engaging leaders and stakeholders	Study promotion and dissemination
	Clarity about the study from the outset	IRB processes: use central IRB when participating hospitals allow; multi-site team should serve as resource to sites in preparation for site IRB reviews
	Involving nurses as study personnel	
	Educational mentorship of site PI	Nursing time: use concise intervention materials; division of labor as possible for consenting, intervention, data collection, regulatory maintenance
	Study personnel training	Authorship and presentation: predetermined guidelines
	Communication with study personnel and stakeholders at individual sites	

## ARTICLES ABOUT FACILITATOR AND CHALLENGES TO CONDUCTING MULTI-SITE CLINICAL RESEARCH: THE ANCC MULTI-SITE RESEARCH EXPERIENCE

### ▼ REFERENCE

Bobay KL, Conway-Phillips R, Hughes RG, Costa L, Bahr SJ, Siclovan D, Nuccio S, Weiss M. Clinical nurses' perspectives on discharge practice changes from participating in a translational research study. *J Nurs Manag.* 2020 Oct 6. doi: 10.1111/jonm.13171. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/33025695/>

Costa LL, Bobay K, Hughes R, Bahr SJ, Siclovan D, Nuccio S, Weiss M. Using the consolidated framework for implementation research to evaluate clinical trials: An example from multi-site nursing research. *Nurs Outlook.* 2020 Aug 25;S0029-6554(20)30247-5. doi: 10.1016/j.outlook.2020.07.005. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/32859426/>

Weiss M, Yakusheva O. Challenges in Conducting a Multi-site Cluster-Randomized Pragmatic Clinical Trial to Test the Effectiveness of a Discharge Readiness Assessment Protocol. *SAGE Research Methods Cases: Medicine and Health.* 2020. <https://methods.sagepub.com/case/multisite-cluster-random-pragmatic-discharge-readiness-assessment-protocol?fromsearch=true>

### ▼ FACILITATORS

Perceived value of participation in nursing research

Visibility of the outcome of practice change to the participating nurses

Integration of research data collection with workflow and EHR documentation

Decision to participate based on potential for high local impact, and relative priority of the topic for the site

How well the study team worked together

Rewards/recognition from the organization for PI and staff

Leadership engagement

Access to information (support from the study team, training info)

Multidisciplinary research team

Coordinated and regular communication within research team, and with site leads, and clinical nursing staff

Preparation and conversation directly with site IRBs — provide site leads with IRB talking points to facilitate process

Web-based study platform for study documents and training materials

Preparation of training materials centrally with local customization

Encrypted study database for site to directly load their study data

Detailed specification of data to be extracted from health information systems

### ▼ CHALLENGES

Integrating new practices into routine workflow — additional work and burden

Engaging the whole nursing unit

Variation in use of standardized/structured study practice protocols

Complexity of the study

Leadership changes

Recruitment and engagement across multiple sites

Sustaining data collection and study protocol fidelity over a long data collection period

Variation in site PI experience with research

IRB approvals — options may include site review or site deferral to central IRB through an institutional authorization agreement

Organizational changes/turnover of leadership and IT systems during the study

Complexity and skill of site analysts in extracting data from health information systems according to study specifications

Complexity of analysis may require additional time and statistical support

## ARTICLES ABOUT FACILITATOR AND CHALLENGES TO CONDUCTING MULTI-SITE CLINICAL RESEARCH: THE ANCC MULTI-SITE RESEARCH EXPERIENCE

### ▼ REFERENCE

Johantgen M, Newhouse R. Participating in a multihospital study to promote adoption of heart failure guidelines: lessons for nurse leaders. *J Nurs Adm.* 2013 Dec;43(12):660-6. doi: 10.1097/NNA.000000000000008. <https://pubmed.ncbi.nlm.nih.gov/24232240/>

### ▼ FACILITATORS

- Adopting (adapting) knowledge use (evidence/intervention/study protocol) to local context
- Assessing barriers to knowledge use
- Select, tailor and implement interventions
- Monitoring knowledge use
- Evaluate outcomes (health, practitioner, system)
- Sustain knowledge use

### ▼ CHALLENGES

## ADDITIONAL ARTICLES ON FACILITATORS AND CHALLENGES IN CONDUCTING MULTI-SITE CLINICAL RESEARCH

### ▼ REFERENCE

Aitken, L.M., Pelter, M.M., Carlson, B., Marshall, A.P., Cross, R., McKinley, S., & Dracup, K. (2008). Effective strategies for implementing a multicenter international clinical trial. *Journal of Nursing Scholarship*, 40(2), 101-108.

### ▼ FACILITATORS

- Effective project coordination
- Multidimensional communication (written and verbal, guidelines for email communications)
- Flexible recruitment and retention strategies
- Delivery of the intervention [intervention fidelity (training, monitoring delivery)]
- Structured data management approaches (structured data entry, systematic checks, monthly review of data)

### ▼ CHALLENGES

- Ethics (multiple IRBs, modifications to IRB and privacy rules during the study) and budgetary requirements across political and legislative boundaries
- Retention of subjects over a multi-month study
- Data uploading from remote sites

## ADDITIONAL ARTICLES ON FACILITATORS AND CHALLENGES IN CONDUCTING MULTI-SITE CLINICAL RESEARCH

### ▼ REFERENCE

Cooley, M.E., Sarna, L., Brown, J. K., Williams, R.D., Chernecky, C., Padilla, G.,Danao, L.L. (2003). Challenges of recruitment and retention in multi-site clinical research. *Cancer Nursing*, 26(5), 376-386.

### ▼ FACILITATORS

- Recruitment: 1) passive (letters to MDs, posters, announcements to community groups, media ads and PSAs), 2) active (direct contact with participants), 3) attend groups
- Convenience
- Flexibility in scheduling
- Rest periods
- Reminders
- Maintain communication throughout study
- Reimbursement for time and effort
- Research assistants from surrounding communities
- Staff consistency
- Staff review forms to assure participants understand study risk/benefits and procedures
- Collaborate with community agencies
- Use of multimedia campaign

### ▼ CHALLENGES

- Attrition (death, severity of illness)
- Refusals (health limitations, lack of interest, inconvenience)
- Physical vulnerability
- Distrust of research
- Low literacy
- Community-based care

Flynn L. (2009). The benefits and challenges of multi-site studies: lessons learned. *AACN advanced critical care*, 20(4), 388-391. <https://pubmed.ncbi.nlm.nih.gov/19893380/>

- Collaboration – nurture trust and collaboration with time and effort
- Study epicenter - a central location for study leadership
- On-site liaison
- Clear protocols and timelines
- Translation to practice built into study design

- Interfacility politics and interpersonal conflicts
- Clarity of decision regarding leadership and responsibilities across sites
- Integrity of study data – uniformity of definitions and data collection across sites (adherence to study protocol)
- Consensus on dissemination of findings, authorship, and contributions

## ADDITIONAL ARTICLES ON FACILITATORS AND CHALLENGES IN CONDUCTING MULTI-SITE CLINICAL RESEARCH

### ▼ REFERENCE

### ▼ FACILITATORS

### ▼ CHALLENGES

<p>Friese, C. R., Mendelsohn-Victor, K., Ginex, P., McMahon, C. M., Fauer, A. J., &amp; McCullagh, M. C. (2017). Lessons Learned From a Practice-Based, Multi-site Intervention Study With Nurse Participants. <i>Journal of nursing scholarship: an official publication of Sigma Theta Tau International Honor Society of Nursing</i>, 49(2), 194–201. <a href="https://doi.org/10.1111/jnu.12279">https://doi.org/10.1111/jnu.12279</a></p>	<p>Web-based study platform with centrally prepared documents, and nurse registration/consent for nurse study participants</p>	<p>Variation in human subjects protection policies may delay IRB approvals</p>
	<p>Scheduled web conferences</p>	<p>IRB determinations: IRBS have less experience with studies where employees are the participants and nurse outcomes are measured – these may qualify for determination on “non-human subjects” (See criteria offered by Friese et al. )</p> <p>Grants and contracts budgeting: there may be changes over the course of the study that require renegotiation and flexibility</p> <p>IT variation</p>
	<p>On-site study coordinator and site-based study champions</p>	
	<p>Site visits by the multi-site principal investigator</p>	
	<p>Senior leadership engagement during proposal preparation and periodically throughout the study</p>	
<p>Minnick, A., Kleinpell, R.M., Micek, W., &amp; Dudley, D. (1996). The management of a multi-site study, <i>Journal of Professional Nursing</i>, 12(1), 7-15, <a href="https://doi.org/10.1016/S8755-7223(96)80069-X">https://doi.org/10.1016/S8755-7223(96)80069-X</a></p>	<p>General study design — use of a business perspective: quality of product (research data) management of production function and product storage</p>	<p>Distance</p>
	<p>Public relations: with administrators at participating sites, prepared information for general media communications</p>	<p>Lack of familiarity with site specifics</p>
	<p>Data quality assurance — availability of supplies for data collection, training of personnel for data collection, simulation, refreshers</p>	<p>Human errors in study production: lack of timely availability of data collection materials, ordering of supplies, etc.</p>
	<p>Data management: machine readable form, weekly data submission from sites, timely review of data</p>	<p>Communication between data collectors, site PIs and study PI</p>
	<p>Human resources; project coordinator, co-investigators, site leads, on-site data collectors, project secretary, personnel policies, morale</p>	
<p>Mitchell, T. &amp; Jones, S. (2004). Leading and coordinating a multi-nurse researcher project. <i>Nurse Researcher</i>, 12(2), 42-55.</p>	<p>Project preparation, coordination, and leadership</p>	
	<p>Ethical approvals and funding</p>	
	<p>Support systems — communication with internal and external stakeholders</p>	
	<p>Education and training</p>	
	<p>Managing data analysis</p>	
	<p>Anticipating day-to-day problems</p>	

## ADDITIONAL ARTICLES ON FACILITATORS AND CHALLENGES IN CONDUCTING MULTI-SITE CLINICAL RESEARCH

▼ REFERENCE	▼ FACILITATORS	▼ CHALLENGES
<p>Oermann, M.H., Hallmark, B.F., Haus, C., Kardong-Edgren, S.E., McColgan, J.K., &amp; Rogers, N. (2012). Conducting multi-site research studies in nursing education: brief practice of CPR skills as an exemplar. <i>Journal of Nursing Education</i>, 51(1), 23-28.</p>	Structure of the team (PI, project director, statistician, site PIs, support/administrative staff, technical support personnel)	Failure to consult a statistician early in the study planning process
	Training of site coordinators (additional on-site hands-on preparation)	Ethical review (multiple IRBs vs deferral to the lead site)
	Communication and team building (traditional face-to-face/ website, frequent and immediate feedback)	Scheduling in long studies
	Recruitment and retention (direct benefits to participants, incentives)	Protocol errors
	Technical aspects of the intervention (dedicated space, security)	
	Data collection, management, and quality (study ID/ passwords), statistical review of incoming data	
	Dissemination (use of CONSORT criteria, inclusion of study team members in writing for publication)	
<p>Smith, L., Tan, A., Stephens, JD., Hibler, D., &amp; Duffy, SA. (2019). Overcoming challenges in multi-site trials. <i>Nursing Research</i>, 68(3), 227-236. doi: 10.1097/ NNR.0000000000000324</p>	Use of epicenter/coordinating center	Site selection (accrual rates, geographic location, incentive for site PI participation, qualified and cooperative site personnel, site-specific communication needs)
	Hiring/managing staff (program director, the right research personnel at each study site, use of site staff vs hire research personnel)	Fidelity monitoring (fidelity assessments)
	Fidelity (standardized training, accommodate site-specific needs for learning models/platforms, booster sessions)	Statistical analysis (power, homogeneous [efficacy] vs heterogeneous [effectiveness], site differences, clustering, subgroup differences)
	Authorship (manuscript/authorship decision should be made at the outset of study)	IRB approval (single vs multiple site IRBs)
		Authorship (group authorship credits, clinical partners may not have the time or expertise for writing articles, complexity of writing process with a large group of co-authors)

## ADDITIONAL ARTICLES ON FACILITATORS AND CHALLENGES IN CONDUCTING MULTI-SITE CLINICAL RESEARCH

### ▼ REFERENCE

Vessey, J. A., Broome, M. E., & Carlson, K. (2003). Conduct of multi-site clinical studies by professional organizations. *Journal for Specialists in Pediatric Nursing*, 8(1), 13-21.  
<https://onlinelibrary.wiley.com/doi/10.1111/j.1744-6155.2003.tb00179.x>

### ▼ FACILITATORS

Shared and sustained vision for the study's potential for contribution and opportunity to create an implementation model for the topic of interest

Well-defined structure and clear communication (face-to-face interaction and internet support; tracking communication)

Adequate resources (communication needs, travel, data management, personnel skill mix, site-specific contribution of resources)

Establishing protocols for data ownership (who owns and who has access to data, data storage and time frame, restrictions on data sharing and use of data)

Formal dissemination plan (drafted at study onset, authorship and publication guidelines, guidelines for informing sites, organization and sponsors of findings, press releases, manuscript generation and clearance)

### ▼ CHALLENGES

Improving research review (selection of primary IRB, sites without IRBs/letters of agreement)

Confidentiality (data transfer policies and procedures)

Logistical complexity

Sampling (proactive planning for inadequate sampling)

Instrumentation (instrument clarity, brevity and costs for instrument, format of forms and costs of data entry, coding and scanning errors)

Research design and data collection (pilot testing, lack of data consistency, detailed protocol for data tracking)

Data management and analysis (records of data cleaning decisions and procedures, copies of data, access to data files)

## APPENDIX C

# Summaries of ANCC-commissioned multi-site studies

These studies were commissioned by ANCC following a competitive application process. Participating hospitals paid a fee to participate. The results, analysis, conclusions, and recommendations of the study, authors, and/or researchers are independent of ANCC and do not necessarily reflect the views of ANCC.

### Improving Heart Failure Outcomes

#### PI

Robin Newhouse, PhD, RN,  
NEA-BC, FAAN  
Associate Professor, University  
of Maryland School of Nursing

#### STUDY DATES

2010-2013

**Research Problem.** Heart failure (HF) affects 5.7 million people with a cost in the US of \$37 billion annually. High hospital readmission rates within 30 days (27%) contribute to this high cost. The standard of hospital care for HF patients includes education prior to discharge, but the effectiveness of education by nurses is unknown. Standardized education, focused on the patients' identified needs, results in better self-management at home and fewer preventable readmissions.

**Aims.** To test a nursing intervention with a direct effect on improved patient outcomes. The specific aims were to: 1) Conduct a quasi-experimental study to evaluate the effect of standardized education on HF patient and readmissions; 2) Identify hospital and nursing characteristics that are associated with improvements in HF patient care; and 3) Evaluate the cost effectiveness of nursing interventions to improve HF patient care.

**Design.** A quasi-experimental study was conducted in 40 hospitals with ANCC Magnet Recognition®, including 587 patients. Nurses were the vehicle of the intervention, which included standardized patient education, assuring patient appointment is made prior to discharge, and targeting instructions for self-care.

**Results.** Patient heart failure knowledge increased from admission to discharge. Heart failure self-care (maintenance, management, and confidence) also increased from admission to 7-days post discharge. However, neither was associated with readmission within 30 days. Patients who have more depressive symptoms were more likely to be readmitted.

**Conclusions.** While IHO did not influence readmission, standardized interventions and teaching for HF patients in the study hospitals has the potential to influence patient self-care and readmission. Secondary benefits of participation in the multi-site study by hospitals included incorporating aspects of the IHO protocol into routine care practices, increased staff nurse exposure to nurse-led research, and improved capacity to engage in future research.

#### PUBLICATIONS

- Johantgen M, Newhouse R. Participating in a multihospital study to promote adoption of heart failure guidelines: lessons for nurse leaders. *J Nurs Adm.* 2013 Dec;43(12):660-6. doi: 10.1097/NNA.0000000000000008. <https://pubmed.ncbi.nlm.nih.gov/24232240/>
- Liu W, Johantgen M, Newhouse R. Psychometric Testing of the Smoking Cessation Counseling Scale Among Magnet® Hospital Nurses. *West J Nurs Res.* 2018 Apr;40(4):562-581. doi:10.1177/0193945917698689. Epub 2017 Apr 3. <https://doi.org/10.1111/j.1547-5069.2011.01420.x> [Free via PubMed]
- Liu W, Johantgen M, Newhouse R. Shared Vision Among Acute Care Magnet® Hospital Nurses: Ordinal Confirmatory Factor Analysis. *West J Nurs Res.* 2017 Feb;39(2):305-318. doi: 10.1177/0193945916651835 Epub 2016 Jul 9. <https://pubmed.ncbi.nlm.nih.gov/27256344/> [Free article at PubMed]
- Newhouse R, Byon HD, Storkman Wolf E, Johantgen M. Multi-site Studies Demonstrate Positive Relationship Between Practice Environments and Smoking Cessation Counseling Evidence-Based Practices. *Worldviews Evid Based Nurs.* 2018 Jun;15(3):217-224. doi: 10.1111/wvn.12277. Epub 2018 Mar 12. <https://doi.org/10.1111/wvn.12277>

## READI (Readiness Evaluation and Discharge Interventions): Implementation as a Standard Nursing Practice for Hospital Discharge

### PI

Marianne Weiss, DNSc, RN  
Professor, Marquette University College of Nursing

### STUDY DATES

2014-2017

**Research Problem.** Preparation of patients for discharge is a primary function of hospital-based nursing care and readiness for discharge is an important outcome of hospital care. Inadequacies in discharge preparation have been well-documented and linked to difficulty with self-management after hospital discharge and with increased likelihood of emergency department (ED) use and readmission. Prior studies by the research team have led to recommendations for implementation of discharge readiness assessment as a standard nursing practice for hospital discharge.

**Aims.** To test the impact of unit-based implementation of discharge readiness assessment on readmission and ED use within 30 days post-discharge. Three protocols, each adding a component to discharge readiness assessment, will be used to introduce, in sequence: (1) discharge readiness assessment by the discharging nurse; (2) discharge readiness assessment

by the discharging nurse informed by prior patient self-report of discharge readiness; and (3) patient-informed nurse assessment, with the addition of an instruction to the discharging nurse to initiate and document nursing action(s) for patients with low readiness. Nurse and patient versions of the 8-item short form of the Readiness for Hospital Discharge Scale (RHDS) will be used for discharge readiness assessment.

**Design.** The study will use a prospective, parallel cohort, stepped intervention design with four study steps (baseline and the three intervention steps) and two study conditions (implementation units and usual care control units). Participants included 33 Magnet designated hospitals: 31 in the United States and two in Saudi Arabia. Each hospital provided two medical surgical nursing units that the multi-site research team randomly assigned to intervention and control units. Over 1,500 nurses were trained in the study protocol. The patient sample was 144,868.

**Results.** None of the READI protocols reduced the primary outcome of return to hospital in intent-to-treat analysis of the full sample. In exploratory subgroup analysis, when patient self-assessments were combined with readiness assessment by nurses (READI2), readmissions were reduced by 1.79 percentage points (95% CI, -3.20 to -0.40 percentage points;  $p = .009$ ) on high-readmission units. With nurse assessment alone and on low-readmission units, results were mixed.

**Conclusions.** Implemented in a broad range of hospitals and patients, the READI interventions were not effective in reducing return to hospital. However, adding a structured discharge readiness assessment that incorporates the patient's own perspective to usual discharge care practices holds promise for mitigating high rates of return to the hospital following discharge.

## PUBLICATIONS

Bahr SJ, Bang J, Yakusheva O, Bobay KL, Krejci J, Costa L, Hughes RG, Hamilton M, Siclovan DM, Weiss ME. Nurse Continuity at Discharge and Return to Hospital. *Nurs Res.* 2020 May/ Jun;69(3):186-196. doi: 10.1097/NNR.0000000000000417. <https://pubmed.ncbi.nlm.nih.gov/31934945/>

Bobay K, Bahr SJ, Weiss ME, Hughes R, Costa L. Models of Discharge Care in Magnet® Hospitals. *J Nurs Adm.* 2015 Oct;45(10):485-91. doi: 10.1097/NNA.0000000000000239. <https://pubmed.ncbi.nlm.nih.gov/26425972/>

Bobay KL, Conway-Phillips R, Hughes RG, Costa L, Bahr SJ, Siclovan D, Nuccio S, Weiss M. Clinical nurses' perspectives on discharge practice changes from participating in a translational research study. *J Nurs Manag.* 2020 Oct 6. doi: 10.1111/jonm.13171. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/33025695/>

Costa LL, Bobay K, Hughes R, Bahr SJ, Siclovan D, Nuccio S, Weiss M. Using the consolidated framework for implementation research to evaluate clinical trials: An example from multi-site nursing research. *Nurs Outlook.* 2020 Aug 25:S0029-6554(20)30247-5. doi: 10.1016/j.outlook.2020.07.005. Online ahead of print. <https://pubmed.ncbi.nlm.nih.gov/32859426/>

Weiss ME, Bobay KL, Bahr S, Costa L, Hughes R, Holland, DE (2015). A model for hospital discharge preparation: from case management to care transition. *Journal of Nursing Administration*, 45(12), 606-614. Doi: 10.1097/NNA.0000000000000273 <https://pubmed.ncbi.nlm.nih.gov/26502068/>

Weiss M, Yakusheva O. Challenges in Conducting a Multi-site Cluster-Randomized Pragmatic Clinical Trial to Test the Effectiveness of a Discharge Readiness Assessment Protocol. *SAGE Research Methods Cases: Medicine and Health.* 2020. <https://methods.sagepub.com/case/multisite-cluster-random-pragmatic-discharge-readiness-assessment-protocol?fromsearch=true>

Weiss ME, Yakusheva O, Bobay KL, Costa L, Hughes RG, Nuccio S, Hamilton M, Bahr S, Siclovan D, Bang J; READI Site Investigators. Effect of Implementing Discharge Readiness Assessment in Adult Medical-Surgical Units on 30-Day Return to Hospital: The READI Randomized Clinical Trial. *JAMA Netw Open.* 2019 Jan 4;2(1):e187387. doi: 10.1001/jamanetworkopen.2018.7387. <https://pubmed.ncbi.nlm.nih.gov/30681712/> [Free at PubMed]

Yakusheva O, Weiss ME, Bobay KL, Costa L, Hughes RG, Hamilton M, Bang J, Buerhaus PI. Individual Nurse Productivity in Preparing Patients for Discharge Is Associated With Patient Likelihood of 30-Day Return to Hospital. *Med Care.* 2019 Sep;57(9):688-694. doi: 10.1097/MLR.0000000000001170. <https://pubmed.ncbi.nlm.nih.gov/31335757/> [Free at PubMed]

## Nurse-led Parent-Education Discharge Support Strategies for Children Newly Diagnosed with Cancer (PEDSS)

### PI

Marilyn Hockenberry, PhD, RN, PNP-BC, FAAN  
Professor, Duke University SON

### STUDY DATES

2017-2020

### PUBLICATIONS

Haugen M, Skeens M, Hancock D, Ureda T, Arthur M, Hockenberry M. Implementing a pediatric oncology nursing multi-site trial. *J Spec Pediatr Nurs*. 2020 Jul;25(3):e12293. doi: 10.1111/jspn.12293. Epub 2020 May 17. <https://pubmed.ncbi.nlm.nih.gov/32419299/>

Patton L, Montgomery K, Coyne K, Slaven A, Arthur M, Hockenberry M. Promoting Direct Care Nurse Engagement in Research in Magnet Hospitals: The Parent Education Discharge Support Strategies Experience. *J Nurs Adm*. 2020 May;50(5):287-292. doi: 10.1097/NNA.0000000000000885. <https://pubmed.ncbi.nlm.nih.gov/32317570/>

Hockenberry M, Haugen M, Slaven A, Skeens M, Patton L, Montgomery K, ... Arthur M (2021). Pediatric Education Discharge Support Strategies for Newly Diagnosed Children With Cancer. *Cancer Nursing*. <https://doi.org/10.1097/NCC.0000000000000947>

**Research Problem.** Educating children newly diagnosed with cancer and their families regarding self/parent-management of common symptoms is a primary component of nursing practice and has the potential to affect illness-related experiences and health outcomes. However, parents often report difficulty with the complexity of information received during the initial hospitalization. Furthermore, there is a lack of standardized education across institutions with educational practices for newly diagnosed pediatric oncology patients and their parents.

**Aims.** The study evaluated the effectiveness and feasibility of two parent education discharge support strategies for parents of children newly diagnosed with cancer: the PEDSS Symptom Management or the PEDSS Support for Parents and Caregivers. The aims were: 1) To explore the effects of PEDSS on childhood cancer symptoms and parents' perceptions of their ability to care for their child with a new cancer diagnosis; 2) To determine if PEDSS decreases unplanned utilization of health care services and preventable toxicity; and 3) To examine the feasibility and fidelity of implementing PEDSS at the initial hospital discharge.

**Design.** A cluster randomized clinical trial design assigned 16 Magnet-designated sites to one of the two types of education support strategies. Education intervention strategies were developed into two separate worksheets and used by nurses to deliver concise and consistent information to parents of children newly diagnosed with cancer. A total of 283 children's parents were enrolled. Outcome measures evaluated at baseline, one, and two months after diagnosis include symptom experiences (pain, fatigue, sleep, nausea, appetite), parent perceptions of care, unplanned service utilization, and feasibility and fidelity evaluation of the worksheets.

**Results.** Participants included 283 newly diagnosed children and their parents. Children in the symptom management group had greater decrease in pain with greater nausea and appetite disturbances experienced by older children in both groups. Greater satisfaction with the intervention was reported by the symptom management group.

**Conclusions.** Evidence supports the importance of standardized discharge education focusing on concrete knowledge related to symptom management. Since nurses assume much of the responsibility for this education, nurses across institutions could implement and sustain such an intervention.

## GENERIC ANCC MULTI-SITE READI STUDY SUMMARY

### APPENDIX D

# Examples of study summaries for stakeholders from ANCC's multi-site READI study

#### READI STUDY

##### (Readiness Evaluation And Discharge Interventions): Implementation as a Standard Nursing Practice for Hospital Discharge

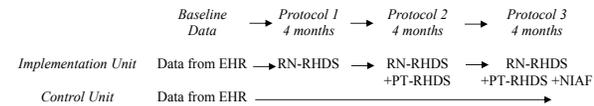
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**Why is it important to study the nurse's role in hospital discharge?** Reducing readmission and ED utilization rates is central to health care improvement and reform efforts. With Medicare readmission rates approaching 20% and financial penalties for high 30 day readmission rates, novel approaches to engaging hospital nurses in readmission reduction efforts are needed to improve quality, affordable care. Problems with hospital discharge are well documented. Most readmissions within 30 days are viewed as preventable and failures of discharge preparation. Discharge preparation is a primary function of hospital nurses (RNs). Readiness for discharge is an outcome metric of the hospitalization phase of care and has a risk indicator for readmission. Yet discharge readiness assessment is not a standard of nursing practice for hospital discharge.

**What is the purpose of the study?** The aim is to evaluate the impact on outcomes and costs of implementing discharge readiness assessment as a standard practice on nursing units. We will sequentially evaluate 3 implementation protocols to determine the best approach for achieving improvements in readmission and ED use post-discharge.

#### How will the study be conducted?

Using a prospective, parallel cohort, stepped intervention study design, we will implement, in sequence, 3 discharge readiness assessment protocols and compare readmission/ED use results to a paired control unit.  
**Protocol 1:** 8- item Readiness for Hospital Discharge Scale – RN form (RN-RHDS) administered on the day of Discharge by the discharging nurse.  
**Protocol 2:** Protocol 1 with the addition of 8 item PT-RHDS completed by the patient and reviewed by the discharging nurse  
**Protocol 3:** Protocol 2 with the addition of a Nurse Initiated Action Form (NIAF) to document actions taken in response to discharge readiness assessment. Action required for RHDS scores <7.



#### Study Sample:

- Implementation and control units.** Hospitals will identify 2 units of the same type (medical, surgical, or medical-surgical). The implementation and control units will be randomly selected.
- Patients:** Adult medical surgical patients who are discharged home without hospice care. Sample will include all eligible patients.
- Nurses:** All RNs on implementation units.

#### Data collection:

- Implementation Units:** Discharge readiness assessment using RHDS will be conducted by the discharging nurse on the day of discharge. Patient characteristics and readmission/ED use will be extracted from electronic records.
- Control units:** There is no on-unit data collections. Patient characteristics and readmission/ED use will be extracted from electronic records.

#### Study Team Role and Visibility

The study team will work with site coordinators at each site to plan for study implementation including IRB approval, data collection logistics, staff training, and electronic data acquisition. A research team member will be assigned as a direct liaison and will be on site during study start-up. Communication throughout the study will occur via video-assisted webconferencing. Site specific and total study results will be provided to each site.

#### For more information about this study, contact:

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Visit our study website at <http://www.marquette.edu/nursing/readi-index.shtml>

## ANCC MULTI-SITE READI STUDY SUMMARY FOR SITE LEADERS

\_\_\_\_\_ Hospital \_\_ and \_\_ units are participating in the

**READI STUDY**  
**(Readiness Evaluation And Discharge Interventions):**  
**A Multisite Study of Implementation of Discharge Readiness Assessment**  
**as a Standard Nursing Practice for Hospital Discharge**

*National Multi-Site Research Team: Nursing and health services researchers from Marquette University, University of Maryland, and University of Michigan*

**Site Principal Investigator:** **Add name, title and contact information**

**Why is it important to study the nurse's role in hospital discharge?** Reducing readmission and ED utilization rates is central to health care improvement and reform efforts. With Medicare readmission rates approaching 20% and financial penalties for high 30 day readmission rates, novel approaches to engaging hospital nurses in readmission reduction efforts are needed to improve quality, affordable care. Problems with hospital discharge are well documented. Most readmissions within 30 days are viewed as preventable and failures of discharge preparation. Discharge preparation is a primary function of hospital nurses (RNs). Readiness for discharge is an outcome metric of the hospitalization phase of care and has a risk indicator for readmission. Yet discharge readiness assessment is not a standard of nursing practice for hospital discharge.

**What is the purpose of the study?** The aim is to evaluate the impact on outcomes and costs of implementing discharge readiness assessment as a standard practice on nursing units. We will sequentially evaluate 3 variations of discharge readiness assessment implementation protocols to determine the best approach for achieving improvements in readmission and ED use post-discharge.

**How will the study be conducted?** Nurses on \_\_\_\_\_ unit will conduct a short discharge readiness assessment for all patients being discharged to home. Nurses will also determine patients' perceptions of discharge readiness to inform their assessment. \_\_\_\_\_ unit will serve as the control unit. Outcome data will be extracted from electronic hospital information systems.

**Study Sample:**

- A. **Patients:** All adult medical surgical patients who are discharged home from \_\_\_\_\_ and \_\_\_\_\_ units. Only patients on \_\_\_\_\_ unit will have a discharge readiness assessment by the discharging nurse.
- B. **Nurses:** All RNs on \_\_\_\_\_ unit.

**How long will the study be conducted:** The on-unit data collection portion of the study will last 13 months beginning in \_\_\_\_\_, 2015.

**For more information about this study, contact:**

Visit the study website at <http://www.marquette.edu/nursing/readi-index.shtml>

**NOTE TO MEDICAL RECORDS DEPARTMENT:** If study forms are inadvertently sent to medical records, please call \_\_\_\_\_ at \_\_\_\_\_ or send the forms to \_\_\_\_\_ mailcode \_\_\_\_\_.