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Linda L. Costa
University of Maryland - Baltimore

Kathleen L. Bobay
Loyola University Chicago

Ronda G. Hughes
University of South Carolina

Sarah J. Bahr
Marquette University

Danielle M. Siclovan
Froedtert Hospital

See next page for additional authors

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Using the Consolidated Framework for Implementation Research to Evaluate Clinical Trials: An Example from Multisite Nursing Research

Linda L. Costa
University of Maryland School of Nursing, Organizational Systems and Adult Health, Baltimore, MD
Kathleen Bobay
School of Health Sciences and Public Health, Professor, Marcella Niehoff School of Nursing, Loyola University, Chicago, IL
Ronda Hughes
Center for Nursing Leadership, Director, Executive Doctorate of Nursing Practice, Associate Professor, University of South Carolina College of Nursing, Columbia, SC
Sarah J. Bahr
Marquette University College of Nursing, Milwaukee, WI
Danielle Siclovan
Risk Management, Froedtert and The Medical College of Wisconsin, Milwaukee, WI

Susan Nuccio
Marquette University College of Nursing, Milwaukee, WI
Marianne Weiss
Marquette University College of Nursing, Milwaukee, WI

Abstract

Background

The Consolidated Framework for Implementation Research (CFIR) is a comprehensive guide for determining the factors that affect successful implementation of complex interventions embedded in real-time clinical practice.

Purpose

The study aim was to understand implementation constructs in a multi-site translational research study on readiness for hospital discharge that distinguished study sites with low versus high implementation fidelity.

Methods

In this descriptive study, site Principal Investigator interviews (from 8 highest and 8 lowest fidelity sites) were framed with questions from 20 relevant CFIR constructs. Analysis used CFIR rules and rating scale (+2 to −2 per site) and memos created in NVivo 11.

Findings

From a bimodal distribution of differences (1.5 and 5), 7 constructs distinguished high and low fidelity sites with ≥5-point difference.

Discussion

CFIR provided a determinant framework for identifying elements of a study site's context that impact implementation fidelity and clinical research outcomes.

Keywords

Implementation science, fidelity, translational research

Introduction

Multisite research studies provide the opportunity for health systems to collaborate to better understand the impact of interventions across larger populations than within any one organization. Multiple organizations working together can aggregate research data to more rigorously assess the effect of the intervention on improving patient outcomes. These studies also provide an opportunity to explore the organizational contexts of the implementing sites, providing a window into the underpinnings that make some organizations successful with complex interventions while others fail to implement even core components of the research. The impact of the intervention on patient outcomes is influenced by myriad human, sociocultural, and organization factors referred to as context (Alexander & Herald, 2012). Variations in organization structure, mission, resources, and staff support

can facilitate or impede the delivery of new evidence-based practices. Knowledge about organizational context can aid researchers in developing implementation strategies that facilitate success. Key issues that need to be explored in evaluating context include readiness for change, the fit of complex multicomponent interventions, and fidelity to the intervention (Alexander & Herald, 2012).

The Readiness Evaluation and Discharge Interventions (READI) study was an international, cluster-randomized, multi-site clinical trial that involved translation of prior evidence about nurse assessment and patient self-report of readiness for hospital discharge through integration into day-of-discharge nursing practices (Weiss et al., 2019). Clinical nurses assigned to the implementation units in 33 Magnet hospitals (1 implementation and 1 control unit per hospital, 31 US hospitals, 2 Saudi Arabia hospitals) were trained in the evidence on readiness for discharge assessment and study protocol procedures. Three sequential discharge readiness assessment protocols were required for the study in a year-long intervention. During Protocol 1, the discharging nurse assessed the patient for readiness; in Protocol 2, the patient completed a self-assessment of discharge readiness and then the discharging nurse completed a parallel assessment informed by the patient's responses and all other information about the patient known to the nurse; in Protocol 3, the discharging nurse was informed of a cut-off score for low readiness and was instructed to initiate actions to prevent readmission for all low scores. In all protocols, the nurses used their professional judgment to determine appropriate actions in response to their discharge readiness assessments. The study goal was to implement the READI protocols with all eligible patients on the implementation units to influence post discharge utilization. Previously published results for the READI study noted that the use of READI protocol 2 was associated with readmission reduction of nearly 2 percentage points in intent-to-treat analysis from high-readmission units (≥11.3%) with a stronger effect (3 percentage points) for patients actually treated-per- protocol (Weiss et al., 2019).

Fidelity to the intervention was a concern during this study. Measuring the extent that the protocol was implemented as planned (fidelity) is an important component of protocol delivery and study outcomes. Identifying contextual elements of the research environment that affect fidelity produces a clearer picture of influencers on study outcomes (Hasson, 2010). For the READI study, standardized education for sites was provided through an internet platform with web conferencing and downloadable PowerPoint presentations. Each READI nurse researcher (n = 4) was responsible for a site visit to an assigned hospital (eight or nine hospitals per researcher). The visit purpose was to meet the site Principal Investigator (PI) and study team, participating clinical staff, nurse leaders, and Chief Nurse Officers (CNOs). In addition, because of the large deidentified dataset that each hospital was required to extract from their electronic health records, a meeting with information technology (IT) personnel was included during site visits when possible. During site visits, contextual variations were noted including site PI experience, leadership support, frontline nurse engagement, electronic health records implementation, and patient acuity.

READI researchers used site PI interview as an implementation evaluation method to capture descriptive information on the variations in structures and processes used by the site PIs and their site study teams to implement the READI study. The purpose of the PI interview was to describe contextual factors in the implementation of the READI study associated with high and low fidelity to the intervention protocols. Qualitative approaches such as interviews with key informants used in

conjunction with quantitative methods provide an enhanced understanding of why evidence-based practices are successfully implemented in one setting and not as successfully in another (Albright, Gechter, & Kempe, 2013). Interviewing site PIs as key informants provided qualitative data to enhance understanding of implementation fidelity rates.

Methods

Design

The study was designed as a descriptive comparison of implementation experiences at hospitals participating in the READI study, focusing on the contextual factors that distinguished sites with high fidelity (HF) versus low fidelity (LF) to the READI protocol. Sites submitted monthly patient tracking logs of eligible patients and intervention completion to the central study team. Fidelity rates were calculated based on the number of patients with completed READI protocols divided by the number of eligible patients on each implementation unit. To explore differences in implementation context between HF and LF sites, we selected the 8 sites with the highest fidelity and the 8 sites with the lowest fidelity (upper and lower quartiles of 33 participating sites) for inclusion in this study, in order to maximize the opportunity to identify the differences between HF and LF sites. The development of a semistructured guide for site PIs interviews was considered the best method to gain an understanding of site experiences with implementing the study.

Interview Guide Development Process

A determinant implementation evaluation framework, the Consolidated Framework for Implementation Research (CFIR), was selected to develop the site PI interview guide. Determinant frameworks describe domains that have been found to be influential on implementation by identifying barriers and enablers impacting implementation (Nilsen, 2015). The CFIR framework is a synthesis of multiple implementation theories that can be used for planning, formative, or summative evaluation of "what works where and why across multiple contexts" (Damschroder et al., 2009, p. 2). CFIR has been used in a wide variety of settings for studying operational aspects of implementation through the lens of the socioecological dynamics of changes at multiple levels (e.g., clinician, organizational) (Tabak et al. 2012) using qualitative, quantitative and mixed methods (Kirk et al., 2015). Health care settings have been the most common settings for use of the CFIR framework with research objectives focused on gaining an understanding of practitioners' experiences in innovation implementation (Kirk et al., 2015). Innovations included health care delivery and process re-design, health promotion and disease management (Hill et al. 2018; Kirk et al., 2015). CFIR was selected as the guiding framework for this post-implementation evaluation due to its direct applicability to health care settings, its structure that guides evaluation of implementation factors across organizational layers within the setting, and the availability of detailed interview questions that can be customized for the study.

The CFIR has 39 constructs organized across five domains: intervention characteristics, outer setting, inner setting, individual characteristics, and process. Damschroder and Lowery (2013) recommended researchers should select relevant domains and constructs for a particular study. CFIR questions related to all constructs were downloaded from the website, www.cfirguide.org. Four READI study investigators each separately identified their perceptions of relevant constructs and questions. Potential interview questions were revised based on construct definitions and specific components

applicable to the READI study. Investigators then met in a face-to-face meeting to develop the final questions using a consensus approach. During this 8-hour meeting, final constructs were identified that were thought relevant to understanding study implementation. A total of 20 of the 39 CFIR constructs from 4 of the 5 CFIR domains were included in the interview guide: (a) In the *intervention characteristics* domain, we measured 6 constructs including intervention source, relative advantage, adaptability, complexity, design and packaging, and cost. (b) In the *outer setting* domain, we measured the needs and resources of the patient population served by the organization, including patient responses to being asked about discharge readiness. (c) The *inner setting* domain includes features of structural, political, and cultural contexts. The inner setting for the READI study was the implementation unit. The construct "structural factors" included changes in leadership during the READI study and unit study team membership and effectiveness. The construct "networks and communication" queried the meeting methods and frequency among study teams. Within the construct "implementation climate," relevant subconstructs included relative priority of the study within the organization's scope of work, organizational incentives and rewards, and the learning climate. Within the construct "readiness for implementation," relevant subconstructs included leadership engagement (site PI, CNO, nonnurse leaders) and access to knowledge and information. (d) The domain *characteristics of individuals* was not included because the intervention was at the unit level. (e) The effect of individuals within the implementation units was thought to be captured in the *implementation process* domain, which included four important leadership subconstructs (opinion leaders, formally appointed implementation leaders, champions, and key stakeholders). The final two constructs "executing" and "reflecting and evaluating" encouraged the site PI to reflect on implementation and consider how the organization will measure success of the READI study. CFIR construct definitions can be found at https://cfirguide.org/constructs/.

To finalize the interview guide format for logic in the flow of the interview conversation, questions were then grouped under eight topics including: Site PI role, READI decision process, READI effect on unit operations, reactions to READI, local study team, study implementation, clinical staff engagement, and life after READI.

Data Collection

Institutional Review Board approval was obtained from the IRB of record for the READI study, Marquette University. The University of Maryland provided nonhuman subject determination for this secondary data analysis. Online consent to participate in the interview was obtained from the site PIs. All site PIs agreed to participate in an interview. Interviews were conducted via Go-to-Meeting between March 2016 and January 2017. Each interview had two study team members, one who conducted the interview and another who recorded verbatim comments and summary notes during the interview. The audio portion of the interviews were recorded to be used as needed to clarify respondent comments. The investigators did not conduct interviews with PIs from their assigned sites. Interviews ranged in length from 45 minutes to 1 hour

Data Analysis

Completed interviews guides were formatted and entered in NVivo 11. Deidentified sites were randomly assigned among three READI nurse researchers, two raters per site. A codebook with definitions of CFIR constructs was used to define each construct. From the interviews, memos

representing the notes and verbatim comments made by respondents during the interviews were created in NVivo 11. Several constructs used more than one question to uncover site experience related to the construct. The comments from these multiple questions were treated as a group to create a rating score for the construct. Guided by recommendations from Damschroder and Lowery (2013), the READI investigators evaluated constructs based on CFIR Rating Rules for: valence (+/-/X/0) and strength (1, 2). The valence rating was determined by the influence the coded data had on the implementation process, i.e. contextual factors that facilitate (+) or hinder (-) implementation. If comments regarding constructs were mixed and could not be classified as positive or negative a mixed (X) rating can be used. If comments were neutral, or had no bearing on implementation, a (0) rating was applied. The strength component of a rating (1 to 2) is determined by factors including strength of language and use of concrete examples. Scoring + 2 indicates the construct had a strong positive influence on implementation. Scoring + 1 means the construct had a weak to moderate influence. Negative scoring of -2 indicates strong negative influence and -1 indicates weak to moderate negative influence (www.cfirguide.org).

We used a consensus approach where researchers met via web conference to review rating variances. The third researcher who had not rated the site facilitated consensus discussions. We had no difficulty reaching consensus nor comparing constructs across cases. We created a rating score for each site's ratings for the 20 individual constructs. The score was the sum of the 2-rater scores for each of the sites: there was a summed score for the low (n = 8) and high (n = 8) fidelity sites. The possible range of summed construct rating scores was from −16 to +16. After completing the scoring, we found a bimodal distribution of difference scores between HF and LF with modes at 1.5 and 5.0. Therefore, we considered a difference ≥ 5 points as indicating a construct distinguishing HF and LF sites.

Findings

Mean fidelity for the READI study was 70.8% and the median fidelity across all sites was 76% (Weiss et al., 2019); however, there was wide variation among sites. Fidelity rates for the 8 LF sites ranged from 29% to 60%. Fidelity rates for the 8 HF sites ranged from 92% to 99%. Study sites had the following characteristics: LF sites included 1 academic medical center and 7 community hospitals; HF sites included 4 academic medical centers and 4 community hospitals. Hospital bed size was 180 to 650 for LF sites and 220 to more than 1500 for HF sites. LF study units had 21 to 48 beds and HF units had 24 to 36 beds; LF units included 6 medical (for telemetry/mixed acuity cardiac, general medicine, pulmonary, stroke, diabetes patients), 1 surgical, and 1 mixed medical surgical units and HF sites included 4 medical (telemetry/ mixed acuity cardiac, general medicine, pulmonary) units; 24 to 95 nurses were trained in the READI intervention protocols in LF units and 27 to 63 nurses in HF units, Unit readmission rates at baseline ranged from 2% to 16% for LF units and 9 to 17% for HF units. Compared to LF sites, HF sites had a lower proportion of site PIs with doctoral degrees (25% vs 50%), more PIs with at least 6 years in their current role (67% vs 33%), and similar prior experience as a PI (62%).

Of the 20 CFIR constructs embedded in the site PI interview, the differences in rating scores for LF versus HF sites was ≥ 5 points for seven of the constructs. Figure 1 illustrates these seven constructs, all of which were in the intervention characteristics domain and the inner setting domain. Distinguishing constructs included: Adaptability and complexity in the intervention characteristics domain, and structural characteristics (study team), relative priority, organizational incentives and rewards (site PI

and staff), leadership engagement (Chief Nurse Officer), and access to knowledge and information (READI team and training information) in the inner setting domain. Most scores for the 7 distinguishing constructs were in the positive range, except for complexity and relative priority of the study where LF sites scored in the negative range and for adaptability, HF sites scores were negative. Figure 1 plots the construct summed scores distinguishing high and low fidelity sites.

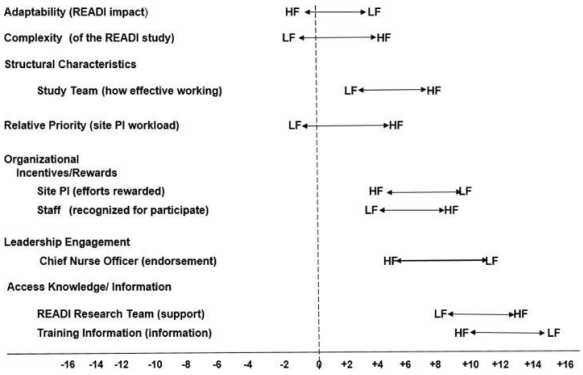

Figure 1. Summed constructs distinguishing high [HF] (*n* = 8) and low fidelity [LF] (*n* = 8) Sites by ≥ 5points*
*Each construct rated +2 to -2 per site then summed across the 8 high versus 8 low fidelity sites.

Several constructs had modest (>1 but <5 point) differences between LF and HF sites. These constructs included intervention characteristics: (a) design quality and packaging - both LF and HF rated as positive with customizable PowerPoints and webinars helpful, though rated with higher positive scores in LF sites; and (b) intervention costs - rated positive in both LF and HF sites; however, several site had "no impact" ratings (0). In LF sites, costs were often not tracked; however, time for staff training was allocated in the unit budget. For HF sites, costs were cited by PIs as part of doing research. In the outer setting domain, patient response to being asked about discharge readiness was positive in both LF and HF sites although higher for LF sites. In the inner setting, scores for engagement of non-nurse leaders were positive for both HF and LF sites but lower for LF, with comments indicating limited communication with non-nurse leaders because the study involved one unit in the hospital. In the process domain, four categories of leadership had high positive scores for both LF and HF sites, including opinion leaders (individuals in the organization have influence on attitudes of their colleagues); formally appointed implementation leaders (either the site PI or research coordinator); champions (individuals who dedicate themselves to driving the intervention); and key stakeholders (individuals in the organization directly impacted by the intervention)

Six constructs were scored ≤1-point difference between LF and HF sites. In the intervention characteristics domain, both HF and LF sites had high positive scores for the externally developed READI study supported by a nationally recognized accrediting body (American Nurses Credentialing Center). The inner setting constructs included: (a) structural characteristics, specifically changes in leadership during the READI study (b) networks and communication, (c) learning climate, and (d) leadership (site PI) engagement. Inner setting scores were positive for these constructs in both LF and HF sites; however, structural/leadership changes had the lowest scores, suggesting that leadership changes may have interfered with the effectiveness of leadership as a facilitator of study implementation.

Table 1 has construct scores and examples of case memos for LF and HF sites.

Table 1. CFIR Constructs and Interview Questions, Rating Scores, and Example Case Memos

CFIR constructs	**READI Study Interview Questions**	**Rating Scores‡ LF Sites/HF Sites**	**Example Case Memos – Low Fidelity (LF) Sites**	**Example Case Memos – High Fidelity (HF) Sites**
I. INTERVENTION CHARACTERISTICS DOMAIN				
1.Intervention source	What are the main factors influencing to participate in READI?	+11.5 /+10.5	Application to Magnet was the driving force. The study had a ready-made protocol and design. +2	PI requested the organization to support the project. Benefits include improving length of stay (LOS) and potential gaps in care. +2
2.Relative advantage	Has the discharge process on the unit changed since the READI study? How is the READI study similar or conflicting with other discharge programs? Are there nondischarge initiatives or activities related to hospital policies, practices, priorities that could impact the study?	−0.5 /+3.0	Prior to the study, we did not have an overarching discharge program on this unit. Many of our issues with discharge have to do with timing of discharge. Focus is on timeliness…nurses calling physicians to get orders for patients they were told are leaving. −1	There is a major push for progression of care and LOS. Partnering for excellence and rounding going on throughout the study. The staff know LOS very well; they speak to the MDs about it. +2
3.Adaptability	What new discharge initiatives or activities are or have happened that might impact on the READI results? Is the READI study conflicting with any programs?	+4.5/−0.5*	Transition team had developed a checklist and a robust discharge phone call. The checklist has been going on during the study and the phone call was always there but was adjusted a little bit. All seemed to work well together. +1.5	Phase 3 of the study there were new consults/wound care and may have extended the hospitalization or delayed discharge. There was a big push to move patients. -1.5

4.Complexity	How easy or complex is the READI study for you as a PI to coordinate? Which parts are easier, which are most difficult?	−1.0/+4.5*	The data collection looked basic. We had the survey and filled it out. As the progression of the study continued, the data retrieval was the complex part of it. The IRB was just a tedious process. Hard wiring the nurses to fill out the papers was difficult. We spent a lot of time on the front end for the IT people to cooperate. It was a political and organizational challenge. −2X	Easy to coordinate. Resources on website and contact with READI researcher was most helpful. +2
5.Design Quality and Packaging	Have you found the study website helpful? Which materials on the website were most helpful? Was the website effective to support the materials needed for implementation? Was the logistics planning worksheet helpful?	+7.5/+6.0	The customizable training Power Points were great and the recorded webinars. Logistic worksheets were helpful for how the study worked but thinking back we would have liked a more detailed follow up. +2	Data was helpful straight forward, could get resources, user friendly. It was helpful especially for the staff. +2
6.Cost	Are you tracking costs of the implementation? How and what are you tracking?	+5.5/+2	Training for the first phase, we were able to allocate the staff time. Second and third phase were shorter so done on their time. +1.5	No, it is in our job description to do research. 0
II. OUTER SETTING DOMAIN				
7.Patient Needs and Resources	How are the patients responding to being asked about discharge readiness? What if any feedback have you gotten from patients regarding their experiences? What impact to date do you think	+12.5/+8	Very few refused. The only issue that came up was that if patients only had an hour before leaving and were given paperwork then they tended to not fill it out.	Patients did not mind. Most filled it out. Patient experience (similar to HCAHPS) has improved almost 20%. Study resulted in increased education for

	the READI study is having care processes and patient outcomes?		Needed to get to them earlier in the four-hour window. +1.5	patients and more patient involvement. Nurses are now considering the entire nursing care process for areas to improve. +2
III. INNER SETTING DOMAIN				
8.Structural characteristics	*Changes in leadership* Have there been changes to hospital leadership (CNO), unit leadership, or the site PI since the start of the READI study? How did any of these changes impact the study implementation?	+2.5/+2.0	PI retired and position was not replaced. Assistant manager position removed. −1	CNO changed into a COO role. The new CNO was not involved. Nursing Informatics person retired. The new Senior Director was the previous unit director and that helped the study quite a bit. -1.5
	Study team What is the composition/structure of the study team at your hospitals (is it just you? How effectively is the team working?	+4.0/+9.0*	At first, the team was site PI, educator, data and quality people but ended up with only educator (new site PI). −1	Site PI, CNO and Nursing research council chair, nurse manager, nurse lead, and educator. Watched training webinars together. +1.5
9. Networks and Communication	How often does your study team meet formally and informally?	+10.5/+10.5	Met regularly at the start of each phase of the study. After the beginning of each phase, held “just in time” meetings. The group was functional, and the study leaders were physically located nearby so it was helpful. Consistency of team members helped. +2	Regularly scheduled meetings lead to better communication. Monthly reports to various groups. Also discussed at implementation staff meetings. Everyone facilitated. +2
Implementation Climate: 10.Relative priority	How has being site PI for the READI study affected your personal workload?	−1.0/+5.5*	It increased, that is why I needed an extra person to help. It did not occur to me at the time all the other time commitments. It was	It has increased the workload. It was never thought of as a bad thing, but I had to go to the unit every day and more than previously. It was also an

			overwhelming as part of my workload to add the READI study. -2	opportunity to participate in a research study on that unit +1
11.Organizational incentives and rewards	*Site PI* To what extent are your efforts as site PI being recognized by leadership in your organization? What are the benefits to you, in terms of recognition within your organization, of being a site PI?	+10.5/+4.5*	Magnet resubmission is due at the end of the year, so leadership is very aware. The transition team (two hospital systems merged) are aware and include information in the forum. +2	Seen as any other task that she is responsible for planning. No extra benefit. -1
	Unit staff How are staff being incentivized to participate in the READI study? How are staff being rewarded for participation in the READI study?	+3.5/+8.5*	Staff not being incentivized. Positive feedback to keep momentum going. Fidelity graph. +1	Staff like new things, being part of big research. Certificates for each education session for performance appraisal reviews. +2
12.Learning climate	What was the level of receptively of the implementation unit to the READI study?	+7/+7.5	In order to get the nurses to see the impact of what they were doing, when their compliance was high the patient satisfaction was high, so their efforts were paying off. +1.5	Reinforced that they were going to see the results, that this was an international study. I talked with the champions, that this was part of their clinical ladder. +2
Readiness for Implementation 13.Leadership engagement	*Site PI* What critical attributes do you see as necessary for a site PI in the READI study?	+11/+11	Basic understanding of research Understanding of implementation processes, IRB processes, and how to obtain reports The ability to collaborate, mentor, and reorganize work. Prioritize, teach and mentor, have big picture, enthusiasm. +2	Commitment to the study, no matter what you have on your plate, I have many units as an educator and CNS. Organizational skills and collaboration skills, communication. Established relationship with the staff, important to have a strong link rather than having someone coming from the outside. +2

	Chief Nursing Officer Has your CNO made visible his/her endorsement of the READI study? If so, how.	+10/+5*	Leadership meetings always have an update added on. CNO constantly following up with PI, manager, and staff. +2	Higher leadership is in a flux, interim CNO aware but not a lot. Previous CNO handed us the ball. -1
	Non-nurse leaders What is the level of awareness of the READI study among non-nursing leaders in the organization?	+3.0/+6.0	We are pretty nursing focused, but I would say it really does not touch ancillary workers. Informatics has a good understanding. Hospitalists are semi-aware. +1	We talked about it with the medical directors; their knowledge at the local level is present. This is a large organization; it is hard to communicate throughout the organization. We are waiting for the results to take the next steps. +1
14.Access to knowledge and information	*READI team* Have you received sufficient information and support from the research team?	+8.5/+13.5*	Would have liked more detail and a timelier response. A grid or table would have been more helpful because the requirements would have been more delineated. -1	Had good support, liked the webinars, never had any problems, whatever questions we had they were answered. Most important to have the face to face contact. +2
	Training information How effective were the training webinars and the training materials for clinical staff education about the READI protocol?	+15.0/+9.5*	The webinar made me slow down and really hear everything. I think this really helped me. Training times gave us enough time to prepare and if we needed more information, we could always go back to material. +2	PowerPoint slides for each phase helpful. Phase 1 and planning webinars were the most helpful. Phase 2&3 not as much new info but helpful to know we were on right track. +1.5
V. Process Domain				
Engaging 15.Opinion leaders	What are influential individuals on the implementation unit saying about READI? Who are the influencers (position)?	+13/+12.5	Mainly positive comments. Case Manager-often asking "any data yet?" and has been engaged RNs will ask if there is anything they need to be	The unit leadership sent weekly quality reports and included the study as to how it was going. I see the unit several times

			doing differently. The manager is involved and tells the PI the nurses like the study. PI walking around unit. +2	every week and elicited feedback. +2
16. Formally appointed Implement-ation leaders	How did you become site PI for the READI study?	+12/+9.5	I received an email from [study sponsor] announcing the study, I took it to my counterpart to see if any of the sister hospitals would be interested, we were the only ones that could do it; took to the IRB and it was accepted. +2	I was approached by the nurse research director about the possibility of joining the study. It originated with the CNO. It was much needed. I have always had an interest in research. +2
17. Champions	Did you identify unit champions on the implementation units? How did you determine who would be unit champions? When during the implementation planning process did you engage the champions? What has been the role of unit champions?	+11.5/+10	Unit champions were identified for their leadership qualities displayed at council meetings and other shared governance venues. They were responsible, showed interest, and appreciation for the importance of the study. +2	We looked at their level of interest with research… We tried to mix it up with new staff and others who were on the unit about 10 years. And we asked for volunteers, if not they were selected. +2
18. Key stakeholders	How are you communicating with nursing staff about progress of the READI study? What materials/modes/venues do you use?	+12.5/+14	Progress was shared at unit meetings and through postings in the back/break rooms. The data were also shared at research council and shared in newsletters to reach the broader staff levels. +2	Regularly attended unit meetings, nursing research newsletters, staff RN talked about experience, staff nurse presentation/poster +2
19.Executing	How active is unit leadership in encouraging participation in the READI study? How active are staff	+8/+11	It has been an expectation. The focus is on improving patient care and it is a way to get nurses on board.	Unit leader encouraged staff to participate. The clinical leads with supervision of the director were giving the

	in encouraging each other to participate?		Sometimes an extra thing to do, but part of patient care. +1	encouragement. These were the interim leaders. They never let it be on the back seat. +2
20.Reflecting and evaluating	How will your organization determine if the study is successful? What is the metric of success?	+12/+12.5	We are in the process of reinstituting the assessment. I didn't want to end it because it was the right thing to do. But the longer we didn't do the assessment the lower the [satisfaction] scores were from the patients. They decided to adopt the patient piece as most valuable and felt that was the piece that was missing from our practice. So we created it electronically. Now the night shift would begin the assessment; the day shift would complete and wrap it up. +2	We will wait for results of the study, but more important to us is whether the staff felt it was important to them. We want to know if they gained new knowledge. I think it is important to know their perception and find out if they think it improved patient care. +2

X - Denotes mixed comments within the rating.

∗Constructs distinguishing high and low fidelity sites by **≥ 5.**

‡Rating scores calculated by summing the 2-rater scores for LF and HF sites; maximum score is 16.

Discussion

The CFIR was valuable for identifying distinguishing constructs when comparing the intervention implementation in LF and HF sites. The high overall level of fidelity achieved in this study demonstrated the commitment of the nurses from the study units given the size and scope of what nurses were asked to do along with the many competing demands of patient care over a long study period. However, since fidelity variance was evident across sites, the opportunity to study site characteristics within the lowest and highest quartiles of fidelity can inform future multisite research of facilitators and barriers within intervention implementation that can affect study fidelity.

Seven constructs were considered to distinguish LF versus HF sites. In the intervention characteristics domain, complexity and adaptability were the distinguishing constructs. Intervention complexity has been found to influence implementation fidelity (Hanson, 2010). In LF sites, site PIs identified barriers including the daily requirements for documenting protocol completion rates and data retrieval from complex hospital information systems as burdensome. In comparison, site PIs in HF sites found teamwork and taking responsibility for understanding data sources part of their role, which facilitated discussions with IT staff about variables needed from administrative and financial databases. We learned that a clearer understanding of the scope of research components (assessments and interventions) and data requirements, particularly for electronic data, was needed for sites to determine readiness to implement the study protocol. The difference in adaptability scores was primarily affected by two sites, one HF and one LF. In the LF site, the composition of the patient population changed from inpatient to primarily observation patients during the study period, significantly increasing discharged patient volume. For the HF site, several initiatives were in process to achieve early discharge. When Protocol 3 that required an action for low readiness scores was implemented, it created a delayed discharge for some patients.

In the inner setting domain, five constructs distinguished LF and HF sites: structural characteristics, relative priority, organizational incentives/rewards, leadership engagement, and access to knowledge/information. Structural characteristics evaluated the social complexity of the study, evident in how many people and roles were involved with READI implementation. Study teams on HF units had diverse membership including managers, clinical nurses, case managers, and often nursing informatics or an IT representative/liaison. LF sites tended to have fewer team members to start and lost members over time. Relative priority, the perception of the importance of implementation within the organization, was evident in the site PI's priority within their workload and their personal capacity. This was a strongly distinguishing construct with a negative score in LF sites. The READI team specified that an additional 0.2 FTE would be required for the study. However, the personal capacity of site PIs to introduce a complex study was not built into the estimated qualifications or workload and could have affected implementation fidelity. The construct incentives and rewards, with positive scores, was a facilitator for this study; however, for LF organizations, the recognition for the site PI was scored higher than for staff. This could reflect a reward for managing the READI study which was viewed as complex. The HF sites used broader team membership overall to implement the study and this translated to recognizing and rewarding all staff who participated, including celebrations as the study progressed through three phases. The site PIs at HF sites often reported that leading research was part of their role responsibilities within their organizations.

Leadership engagement of the CNO was a important factor in sites' readiness for implementation. LF sites had higher positive scores than HF sites, largely due to CNO turnover in HF sites. The CNO made a 3-year financial commitment at the beginning of READI study to fund the organization's enrollment in this pay-to-participate study (Hickey, Koithan, Unruh, & Lundmark, 2014). All participating sites were Magnet hospitals, and LF sites more frequently indicated the importance of participating in the study to meet the New Knowledge component of the requirements for Magnet redesignation from American Nurses Credentialing Center (which can be found at https://www.nursingworld.org/organizational-programs/magnet/magnet-model/rom).

For the construct access to knowledge and information, both HF and LF sites reported positive scores. HF site PIs reported greater support from the READI research team than LF sites which reported greater satisfaction with the training materials and methods. Face-to-face and individual contact with the research team was valued by all sites, as were the train-the-trainer webinars and customizable PowerPoint training materials for trainings for each phase of the study. Accessing hospital databases for data retrieval was particularly challenging. Several site PIs had limited knowledge of data found in hospital databases and how to identify and access the appropriate IT department staff to obtain data. During site visits, it was evident some sites would have benefited from extra support in setting up data collection tables, identifying where to find required electronic variables, and interacting with the IRB. Site PIs from HF organizations contacted the READI study team often to clarify and problem solve particularly related to data acquisition, whereas LF site PIs found accessing website information helpful. While the electronic data acquisition process should not have affected on-unit fidelity in applying the READI intervention, the differences between the experiences of site PIs at HF and LF sites may have contributed to their overall pattern of performance of study tasks.

Table 2 presents the constructs distinguishing LF and HF sites with barriers encountered and recommended strategies identified by the READI research team to mitigate them. Some of these barriers and solutions have also been identified in other reports of multisite study implementation. For example, in a multi-site implementation of an intervention to improve hazardous drug exposure prevention, Friese et al., (2017) identified infrastructure for nursing-led research and IT changes as challenges in multi-site study management. Successful strategies included web conference, site-based champions, site visits by the investigator, and central preparation of study documents. In a multisite implementation study of a nurse-led Parent Educational Discharge Support Strategies intervention for children newly diagnosed with cancer (Patton, Montgomery, Coyne, Arthur, & Hockenberry, 2020), barriers to multisite research included study dissemination and promotion, hospital leadership engagement and communication, education and mentoring, nursing time for study activities, and study team coordination with local sites. Successful strategies included informational calls with site leadership and regular progress reports, frequent scheduled communication with sites, engaging site PIs in providing guidance for operational issues, and concise intervention materials that could easily integrate into routine workflow. The challenges and strategies for the READI study were remarkably similar to these example studies.

Table 2. Distinguishing Constructs from Analysis of High and Low Fidelity Sites: Potential Barriers and Recommendations

	Potential Barriers	**Recommended Strategies (Best Practices)**

I.INTERVENTION CHARACTERISTICS		
Adaptability	• Decrease in unit fidelity over the course of the study • Change in unit's patient population during the study. • Conflict in priorities for the study vs. other hospital specific initiatives to address hospital discharge • The study protocols may have prolonged hospital stay	• Use unit champions to determine sources of decreased fidelity and facilitate greater fidelity as needed. Explore options for timing of study procedures and how protocol can be integrated with usual care practices • Determine if new patient populations qualify for the study • Interdisciplinary teams can facilitate communication across initiatives focused on the same outcome. • Locally, use intentional communication strategies to get protocol information into the hands of clinical leaders to reduce the impact of conflicting messages and keep the focus on the patient for best care practice.
Complexity	• Daily data collection was difficult for a single individual to oversee. • Unfamiliarity with hospital databases caused a stressful situation for site PIs	• The level of FTE support should be determined by each site. Pre-study estimates may not considered applicable across all sites as resources are variable in amount and flexibility. • Recognize that many PIs will need assistance in identifying and connecting with IT resources in their organization and many are unfamiliar with data language, structure, and configuration. • Include IT specialist on the study team. • Initiate early joint training with site PIs and IT specialist.
III. INNER SETTING		
Structural characteristics Study team	• Limited roles included in teams • Infrequent team meetings as study progressed	• Identify key team roles for the study based on the intervention. Engage leadership and practicing nurses in co-managing the project. • Identify how much time is needed at the beginning and negotiate time with senior leaders. • Set up regular meetings less frequently as study progresses however maintain face-to-face meeting to keep team intact and informed.
Relative priority	• Multiple obligations for site PIs in addition to READI.	• Link READI to high priority organizational initiatives such as maintaining Magnet

	• Non-nurse leaders may not be informed of study and importance to organization.	status. • Integrate the study into organizational strategic plan. • Highlight components of READI that may address gaps in existing clinical programs and initiatives.
Organizational incentives and rewards		
Site PI	• Recognition of the workload of the site PI may not be evident due to wide span of responsibility in the organization.	• Actively communicate project data to senior administrators. Share difficulties in enrolling eligible patients due to staff time constraints with workload.
Clinical nurses	• Clinical staff turnover rate could affect study integrity. Additional work at discharge could be viewed as negative due to added time.	• Recognize staff and share unit data frequently during study. Include in staff meetings: highlight success stories, track progress
Leadership engagement (CNO)	• Executive leaders may not be aware of study commitments, financially and clinically. • Leaders may not provide material support for the study if new to the organization	• Present a business case for additional allocation of staff time for training and orientation of new staff. • PI and team members keep CNO apprised of study needs and successes. Maintain two-way communication.
Access to knowledge and information		
READI team	• Site PI turnover in several institutions	• Provide face-to-face conferencing for new PIs. Consider additional site visits if difficulty in meeting study requirements.
Training information	• Information available on the website. Some found it difficult to navigate the files	• Provide a roadmap for the site showing beginning and phase's related files. • Planned face-to-face videoconferencing for review and practice accessing documents and files.

The remaining 13 of the 20 CFIR constructs were not substantially different for LF and HF sites. Overall, the highest positive scores were obtained for the following constructs: intervention source; design quality and packaging; patient needs and resources; leadership engagement; engaging opinion leaders, formally appointed implementation leaders, champions, and key stakeholders; and reflecting/evaluating study results. These scores point to the common elements of the implementation that were rated as successfully contributing to implementation success. Research has identified leadership at all levels of the organization including nurse executives, managers and champions has a

strong positive influence on positive work environments (Boamah, Laschinger, Wong, & Clarke, 2018; Miech, et al. 2018; Pearson, 2020).

A few concepts were rated by both HF and LF sites as low positive or negative, suggesting areas for attention for study implementation and for planning future multi-site studies: complexity, relative priority and changes in leadership. Leadership changes at all levels in the organization occurred in many institutions during the READI study. Changes in leadership not only of senior managers but also middle managers (service line chiefs) and direct supervisors can aid or hinder implementation (Weiner et al., 2012).

The CFIR guidance on questions for each domain supported the development of the site PI interview guide for analysis of construct impact ratings. Implementation research occurs in real world settings distinguished by complexity and context (Landsverk, et al. 2012). We used the CFIR-based interview guide to help translate what we were told by key informants into evidence of implementation facilitators and barriers. We learned valuable information about each construct's impact on study fidelity. Analyzing 20 constructs using a valence and strength score allowed us to review each construct to see if there was uneven influence across sites. Although the CFIR with 5 domains and many constructs appears complex, using the tools for interview development based on the domains and constructs, the rating rules, and the literature reports of researchers' experience with CFIR provided on the website (www.cfirguide.org) created a path to follow.

Limitations

There are several limitations to the study. We interviewed site PIs as key informants. Therefore, their experiences constructed our understanding of the implementation processes. In aggregating their experiences, we reduced the individual unique experiences of our sites to quantitatively distinguish between the highest and lowest fidelity sites. We did not include the range of implementation experiences of sites with average study fidelity. The CFIR includes a total of 39 constructs. Nineteen constructs were not included due to limited relevance to the READI study but perhaps could have provided further insight; we constructed the interview guide to access key concepts and to respect the time burden to respondents in completing the interview. The READI questions were developed based on the construct definition as interpreted by the study team.

The interview and analysis were conducted by the nurse researchers who developed and managed the study. While we excluded ourselves from interviewing or conducting primary reviews of the interview responses of sites for which we each provided direct oversight and assistance during the study, our biases may have influenced interpretation of the findings particularly when disagreements occurred between primary reviewers.

Recommendations for Future Research

In planning future multisite studies, explication of implementation context will facilitate successful implementation of intervention protocols. While not applied for study planning or formative evaluation in the READI study, this framework would be valuable for designing proactive and corrective strategies to promote study fidelity. Strongly distinguishing constructs, complexity and relative priority in the organization work had negative scores in the LF sites. These constructs should be explored in depth before introducing new research to an organization system.

The CFIR was useful as a guide for summative evaluation of implementation of the READI study. In multi-site studies, adaptation of the intervention to the local operational context while assuring that the core elements of the intervention protocol are the same across sites is essential for successful implementation and outcome measurement. Site leadership, communication among team members and the research team, organizational incentives and rewards were influential for site PIs and unit staff. Access to knowledge and information about the study and engaging leaders in several roles promoted HF. Study complexity, relative priority, and changes in leadership were associated with low fidelity. Connecting READI study fidelity data with analysis of context from site PI interviews increased the breadth of our understanding of individual site strengths and challenges in doing research in health systems.

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