Nursing Research and Practice

Dissemination and Implementation Research: Intersection between Nursing Science and Health Care Delivery

Guest Editors: Deborah Vincent, Marie Hastings-Tolsma, and Kathleen R. Stevens

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Editorial Board

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Editorial

Dissemination and Implementation Research: Intersection between Nursing Science and Health Care Delivery

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Dissemination is the targeted distribution of information and intervention materials to spread knowledge and evidence-based interventions to a larger audience (NIH, 2011). Implementation is the use of strategies to promote the systematic uptake of evidence-based practices into routine practice and healthcare policy to improve the quality and effectiveness of health services (IOM, 2012). The dissemination and implementation (D&I) lexicon includes many terms like translational research, knowledge translation, knowledge exchange, improvement science, and technology transfer. Dissemination and implementation researchers and practitioners must carefully consider strategies for translating evidence into practice to optimize health care delivery. D&I science focuses on translating knowledge into practice by facilitating stakeholder access to findings using a variety of strategies and designs that include pragmatic trials, evidence-based quality improvement, health technology assessment, systematic reviews, randomized clinical trials, and comparative effectiveness research. This collection of articles begins with broad-level perspectives such as priorities, collaboration, and IRB regulations and moves to specific examples of D&I research.

Given the tremendous possibilities for D&I research, where should a nation or organization focus its resources? The manuscript by K. Stevens and J. Ovretveit addresses developing national improvement priorities for D&I research to guide researchers and funders. Results of this study suggest that, at least for the United States, the most important and urgent needs include care coordination, implementation of evidence-based practice, improving structure and clinical processes, and developing a culture of quality and safety. These types of research studies require transdisciplinary teams and an infrastructure that supports academic-practice partnerships. The article by F. Puga, K. Stevens, and D. Patel identifies best practices in developing a healthcare improvement research network that integrates various theories, methods, and perspectives of each discipline into a cohesive unit able to focus on complex research issues and topics. A companion article by D. Patel, K. Stevens, and F. Puga identifies variation in institutional review board approval process for D&I studies especially when these studies focus on quality improvement initiatives across multiple sites.

Two manuscripts describe specific efforts to implement evidence-based practices. The manuscript by S. Daniels et al., describes the efforts of one Veterans Administration hospital to implement screening for dysphagia in patients who presented to the emergency department with symptoms of stroke. Multidisciplinary team cooperation and organizational support were major facilitators of this quality improvement study, while lack of adequate training perceived lack of time was seen as barriers to implementation. The manuscript by A. Wallace et al. describes the process and framework used to integrate diabetes self-management support into routine diabetes care provided in four community health clinics.

The final manuscript by Y. Ogbolu et al. assessed the level of nurse compliance with evidence-based guidelines

for preventing mother-to-child transmission of HIV in a resource-limited country. Although making up the greatest portion of the health care workface in most countries, educational and scope of practice barriers often hinder their effectiveness in improving health outcomes.

By compiling these papers, we hope to enrich our readers with respect to the need for and variety of D&I studies. We also hope to stimulate thought for future studies to enhance the translation of evidence into practice and to improve health outcomes for populations.

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Research Article

Improvement Research Priorities: USA Survey and Expert Consensus

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The purpose of this study was to identify stakeholder views about national priorities for improvement science and build agreement for action in a national improvement and implementation research network in the USA. This was accomplished using three stages of identification and consensus. (1) Topics were identified through a multipronged environmental scan of the literature and initiatives. (2) Based on this scan, a survey was developed, and stakeholders ($n = 2,777$) were invited to rate the resulting 33-topic, 9-category list, via an online survey. Data from 560 respondents (20% response) were analyzed. (3) An expert panel used survey results to further refine the research priorities through a Rand Delphi process. Priorities identified were within four categories: care coordination and transitions, high-performing clinical systems and microsystems improvement approaches, implementation of evidence-based improvements and best practices, and culture of quality and safety. The priorities identified were adopted by the improvement science research network as the research agenda to guide strategy. The process and conclusions may be of value to quality improvement research funding agencies, governments, and research units seeking to concentrate their resources on improvement topics where research is capable of yielding timely and actionable answers as well as contributing to the knowledge base for improvement.

1. Introduction

Improvement science is an emerging multidiscipline which overlaps with other fields such as implementation science and conventional medical research as noted by Wensing and others [1]. Experts point out that the evidence base for the science spans controlled trials of interventions with patients, providers, and organizations, to small scale rapid cycle testing of improvement changes by local project teams [2]. A healthy debate in the literature focuses on the type and strength of evidence which might form the scientific basis and whether the aim should be to build a knowledge domain with characteristics distinct from other sciences [3–5].

Largely separate to these debates, healthcare organizations and governments globally are implementing different ideas and interventions which hold promise for improving quality, safety, and performance [6]. Research of different types can contribute to more effective choice and implementation of improvements, but resources are limited, and expertise in this field is scarce. There is a case for concentrating research resources on investigating targeted problems and potential solutions. If researchers and funders were to concentrate efforts and resources, then which topics and improvement strategies should be the focus and which criteria should be used to set priorities? Should choices be made on the likelihood of the question being answerable by current methods? How much weighting should be given to the likely practical value of the findings for action and how much should be given to developing methods, measures, and theories?

This project aimed to identify national priorities for improvement science and create an agenda to focus and guide researchers and funders. One motive for this work was a felt need by a USA national improvement research network to create a strategy for improvement research and a

Table 1: Three-stage process for establishing consensus on research priorities.

Stage 1 Topic identification	Stage 2 Stakeholder survey	Stage 3 Priority consensus
Topics identified through broad environmental scans of healthcare literature, regulatory and accreditation criteria, innovation challenges, national campaigns, and discussions with leaders	Survey instrument was developed and refined as follows: (i) paper-based survey data collection (n = 320; 62% response rate); (ii) content and clarity review (n = 12); (iii) online survey pilot and telephone debrief (n = 5) Online survey data were collected from stakeholders (n = 2,777; 20% response rate)	Consensus formed by Expert Panel (Delphi process) (n = 14) (i) Expert panel completed online survey prior to meeting (ii) Criteria for prioritization established at in-person meeting (iii) Discussions and multiple iterations occurred during in-person meeting Consensus declared by professional facilitator and group
Result Topics were incorporated into survey instrument	*Result* Stakeholder survey data provided foundation for consensus formation	*Result* Priority research agenda finalized and disseminated

consensus about priorities. Founders of this network emphasized collaboration between researchers in different centers and services so as to maximize the use and value of improvement research [7, 8]. The leaders took the view that consensus-based research priorities would serve as a common rallying point for improvement scientists and clinical leaders to collaborate around common research goals.

2. Materials and Methods

The three-stage approach used to identify improvement topics and develop consensus about priorities is outlined in Table 1 and included (1) environmental scan to identify improvement topics, (2) development, refinement, and administration of a stakeholder survey, and (3) consensus development by an expert panel. Further details of methods are available in the resource document available from the authors, which also provides guidance to others seeking to use a similar process.

2.1. Environmental Scan to Identify Topics. A review identified improvement topics from healthcare literature. In addition, topics were identified from guidance and requirements issued in regulatory and accreditation criteria (e.g., The Joint Commission goals) [9]. Additional improvement topics were identified from challenges identified in improvement innovations (e.g., AHRQ Health Care Innovations Exchange) [10], national improvement campaigns (e.g., IHI 100 K Lives Campaign) [11], and discussions with improvement leaders.

2.2. Survey Development, Refinement, and Administration. A stakeholder survey about improvement research priorities was developed through several steps. First, a list of 33 topics identified from the environmental scan were used in an initial paper-based survey and administered to healthcare professionals attending a quality improvement conference event (n = 320, response rate = 62%). Descriptive statistics of these responses showed that all of the 33 topics were rated as "highly important" (on a 0–10 point scale). Respondents also suggested additional topics, all of which were logically grouped within the existing categories. The revised survey organized the 33 topics into 9 categories with a 1–6 point rating scale.

Highlights of Survey to Set Research Priorities for Improvement Science

Categories and Improvement Strategies

(1) Process improvement in clinical care

- (a) Evidence-based practice in clinical care
- (b) Integration of best practices into clinical routines
- (c) Checklists and other care improvement tools
- (d) Process improvement techniques and tools (e.g., plan-do-study-act, root cause analysis, and Six Sigma)

(2) Systems and microsystems

- (a) Workplace environment and quality improvement
- (b) Climates for change and learning organizations
- (c) Innovation for improvement
- (d) Adoption of best practices (hardwiring change)
- (e) High-reliability organization concepts in acute care settings

(3) Patient safety

- (a) Culture of patient safety (e.g., shared willingness to report and learn from errors, open communication, leadership support)
- (b) Prevention of targeted patient safety incidents (e.g., falls, medication errors)

(4) Patient-centered care

- (a) Patient and family activation and engagement
- (b) Patient-centered care and patient advocacy

(5) Care coordination

  (a) Handoffs and transitions *within* the hospital
  (b) Handoffs and transitions *across* healthcare settings

(6) Quality indicators (e.g., performance and outcome measures)

  (a) Quality indicator sets (e.g., *National Database of Nursing Quality Indicators*)
  (b) Reliable metrics for measuring improvement
  (c) Reports to the public on quality and safety (transparency)
  (d) Feedback and dashboards to guide performance
  (e) Baseline and follow-up measures to assess impact of improvement
  (f) Measurement of total system processes

(7) Policy, regulation, and recognition programs

  (a) Impact of healthcare policy issues (e.g., public reporting, pay for performance)
  (b) Economic impact of improvement processes
  (c) Programs of excellence impact on patient outcomes (e.g., Magnet Recognition)
  (d) Economic impact of healthcare regulations on costs and outcomes

(8) Workforce preparation and competencies

  (a) New competencies for quality improvement and patient safety
  (b) Redesign of clinical roles (e.g., clinical nurse leaders)
  (c) Appropriate staffing levels
  (d) Frontline provider engagement in quality and safety (e.g., Transforming Care at the Bedside)
  (e) Team performance and interprofessional communication (e.g., standardized team training)
  (f) Disruptive behavior management

(9) Technology

  (a) Technology applications in clinical care (e.g., electronic decision support tools, smart pumps)
  (b) Integration of technology applications into clinical care.

Over the next four months, 12 quality experts from an improvement research network advisory board contributed to content review and refining and clarifying wording. An online survey was piloted with five additional experts in healthcare improvement. The respondents were subsequently debriefed via telephone to assess clarity of the online survey and offer changes. This led to a revision of the 1–6-point scale to the 1–4-scale used in the subsequent survey of healthcare professionals as stakeholders. The final survey is available as online Supplementary Material at http://dx.doi.org/10.1155/2013/695729.

The aim was to survey a range of stakeholders with interest in quality improvement research, including researchers, academics, clinicians, administrators, health service personnel, and others. Because no single sampling frame exists for this group, to achieve representation from multiple disciplines and settings, the target sample for the survey was compiled from several lists. These lists included purchased lists from professional societies (e.g., healthcare executive associations, health scientist groups), a commercial list of multiple disciplines focused on improvement, and an internal improvement practice-and-research list which had been built over 10 years from a variety of sources. While those included in the sampling frame were selected through a variety of approaches, because of their affiliations, they were deemed to share a common interest in evidence-based quality improvement, delivery improvement, and patient safety. Characteristics of the final sampling frame were reviewed to assure that it included directors and health professionals associated with scientific groups, clinical leaders, evidence-based practice leaders, and clinical directors, managers, and administrators; the list also included persons associated with excellence recognition programs (e.g., Malcolm Baldrige Quality Award and Magnet hospital recognition), individuals involved in the Agency for Healthcare Research and Quality (AHRQ) Health Care Innovations Exchange (a database of tested healthcare innovations implemented in the US and Canada) [10], leaders on healthcare research society boards, editors of quality and patient safety journals, academic deans and faculty, and others attending conferences on interprofessional evidence-based quality improvement.

The online stakeholder survey was administered following the Dillman method [12]. This involved a prenotification email three days before the survey; survey invitation email and survey link; then, email reminders at 7 days and 14 days after survey initiation.

Methods used to analyze results included analysis of respondent characteristics (Table 2, in the "results" section below); "home" institutions; and ratings of topic importance. Topics rated as "very important" formed the basis of the next phase of consensus development.

2.3. Consensus Development of an Improvement Research Agenda. A Delphi method, as advanced by Rand, was used to develop consensus about research priorities [13], using an expert panel. The panel was made up of 14 experts representing clinical, academic, science, and management roles in the USA and one international expert. Two months prior to an in-person meeting, the panel completed the stakeholder survey described previously. Results of the panel's survey and of the stakeholder survey were discussed and processed by the group during the one-day, professionally facilitated meeting. The meeting involved five steps.

Step 1. Panel members were presented: (1) top ten priorities identified by the stakeholder survey and (2) premeeting priorities selected by the panel on the same survey.

Table 2: Stakeholder survey respondent characteristics (n = 560).

Characteristic Position(s) held*	Number (%)	Percent
Researcher/scientist	254	46
Academic faculty member	227	41
Administrator	132	24
Clinical educator	102	18
Consultant	71	13
Frontline clinician	71	13
Midlevel manager	31	6
Supervisor/coordinator	24	4
Unit manager	7	1
Other	72	13
Total (missing)* *Respondents were allowed to select all applicable	NA	NA
Years of career experience as a health professional		
More than 20 years	350	63
16–20 years	61	11
11–15 years	64	12
6–10 years	34	6
1–5 years	39	7
Less than 1 year	5	1
Total (missing)	553 (7)	100 (1)
Highest level of education		
Doctorate degree	235	47
Master's degree	151	30
Medical doctorate degree	78	16
Bachelor's degree	23	5
Other	11	2
Total (missing)	498 (62)	100 (11)

Step 2. Panel members discussed their opinions on the importance of various improvement topics. Members developed a list of criteria for assessing the importance of research topics, described in the Results section.

Step 3. Members casted a second vote by completing a slightly modified version of the stakeholder survey and ranked their "top three" improvement strategies. Project analysts compiled these results, identifying the topics the panel had identified as most important.

Step 4. The facilitator reported results from the second vote and facilitated further discussion. The highest priority topics were identified using two criteria: number of panel members ranking the item as "top three" and number of panel members rating the item as "very important."

Step 5. The panel debated not only the top research priorities but also the best way to categorize them. Panel members reviewed the top priorities identified in Step 4 and derived a list of four research priorities.

3. Results and Discussion

3.1. Analysis of Respondents. Email invitations to complete the internet survey were sent to 2,777 stakeholders; 560 completed the survey (20% response rate). Demographic characteristics (Table 2) reflected that respondents were 46% researchers, 34% clinical administrators or managers, and 13% frontline clinicians. Eighty-four percent had over 11 years of experience and 96% held an advanced degree. Forty-five percent were university-based professors. Of those responding, 85% were nurses and 16% held medical doctorates. Based on desired target sample characteristics, respondents represented the intended target sample. The preponderance held advanced degrees in experienced careers and were in leadership positions. For the scientific sector, key stakeholder researchers (46%) and university professors (45%) were well represented. Clinical administrators and managers (total 47%) were also well represented. The multidisciplinary makeup of the respondents (RNs = 84%; MDs = 16%) roughly aligned with national proportions (RNs = 79% [14]; MDs = 21% [15]).

Table 3: Frequency (%) with which survey scale descriptors were used to rate 33 improvement topics (by 560 respondents).

Survey scale descriptor	Mean %	Median %	Min–max % (range)
Very important	51	48	28–74 (46)
Important	36	36	21–46 (25)
Somewhat important	12	12	2–27 (25)
Not important	1	1	0–5 (5)
COMBINED (important and very important)	87	87	68–98 (30)

Table 4: Top ten improvement topics ranked by frequency of "very important" rating ($n = 560$).

Improvement topic (ranked highest to lowest)	N (%) rating "very important"
Handoffs and transitions across healthcare settings	414 (74)
Integration of best practices into clinical routines	408 (73)
Culture of patient safety	386 (69)
Evidence-based practice in clinical care	381 (68)
Prevention of targeted patient safety incidents	381 (68)
Reliable metrics for measuring improvement	364 (65)
Adoption of best practices	336 (60)
Integration of technology applications into clinical care	325 (58)
Baseline and follow-up measures to assess impact of improvement	325 (58)
Handoffs and transitions within the hospital	319 (57)

3.2. Analysis of Responses. Survey results showed that quality improvement initiatives were strongly supported at respondents' home institutions. Of the respondents, 92% percent agreed that their institutions' healthcare professionals are expected to improve processes and systems of care; 88% noted that the actions of leaders show that patient safety and quality improvement are top priorities; 84% agreed that clinicians engage in quality improvement and patient safety strategies in their daily work; and 77% agreed that clinical staff feels free to suggest changes and new programs.

3.2.1. Highest Rated Topics and Variations in Topic Ratings. Respondents rated 87% of the 33 topics as "very important" or "important." Table 3 displays the summary of use of each scale descriptor. Few topics were rated "somewhat important" (12%) or "not important" (1%).

Table 4 presents the ten topics most frequently rated as "very important." Topics least frequently rated as "very important" fell into two categories: (1) policy, regulation, and recognition programs and (2) workforce preparation and competencies.

There were variations in respondent ratings of the 33 topics in the 9 categories. For example, a large majority of respondents rated two of the four topics in the category "process improvement in clinical care" as highly important: "evidence-based practice in clinical care" (68%) and "integration of best practices into clinical routines" (73%). By contrast, fewer respondents rated the other two topics in this category as highly important: "checklists and other tools" (44%) and "process improvement techniques and tools" (35%). Additionally, in the "patient-centered care" category, about half of the respondents rated both of the two topics as "very important." In the "patient safety" category, more than two-thirds considered the two topics to be "very important." This contrasted with ratings of the four topics in the "policy, regulation, and recognition programs" category; these ratings ranged from 39% to 49%.

3.2.2. Variations in Ratings by Respondent Characteristics. Two respondent subgroupings, "researcher/scientists" (46%) and "nonresearchers" (54%), showed similarity in selection of the top ten improvement topics. Eight topics were in the top ten for both groups. Career experience subgroups (5 or fewer years; 6–15 years; 16–20 years; more than 20 years) showed similarity in only five topics ranked in the top ten.

The analysis also showed differences in the top ten topics rated across education level. Five topics were in the top ten for all groups. Notably, respondents with more experience and higher education were more likely to rate as "very important" items in the workforce preparation and competencies categories.

Forty-three percent of respondents suggested a total of 515 additional topics not listed in the original survey. These additional topics focused on specific populations (such as elderly), different care settings, and specific design strategies. All were conceptually grouped into the nine categories in the survey.

3.2.3. Consensus Prioritization Results. Criteria formulated in Step 3 for deciding priority topics were as follows: potential impact on patient health and safety; quick payoff; cost effectiveness; presence of data gap (i.e., critical need for evidence-based information); practice community's priorities and concerns; fundability; simplicity; likelihood of success/failure;

diversity of focus; greatest areas of uncertainty; current issues within practice environments; and likelihood of clinician engagement.

In this phase, experts used two criteria to identify the highest priority improvement topics: (1) the number of panel members ranking the item in the "top three" and (2) the number of panel members rating the item as "very important." Both approaches pointed to the same top two priorities: "integration of best practices into clinical routines" (survey item number 2) and "frontline provider engagement in quality and safety" (survey item number 29). Other items rated as "very important" by the majority of panel included "handoffs and transitions within the hospital and across healthcare settings;" "workplace environment and quality improvement;" "climates for change and learning organizations;" and "prevention of targeted patient safety incidents."

During Step 5, each member reviewed the top priority topics identified in Step 4 and derived a list of three or four research priorities. During this process, the panel noted the difficulty of comparing such diverse topics as coordination of transitions in care, effectiveness, and efficiency of various methods and models for best practices, evidence-based practices for outcome improvement, and improved organizational environments. They noted that quality and safety require efforts on multiple fronts. Discussion then focused on separating the overlapping areas and differentiating distinct subject categories from the prioritized subjects. This resulted in members recommending four priority research topics: care coordination and transitions, approaches to improvement used by high-performing clinical systems and microsystems, evidence-based quality improvement and best practices, and culture of quality and safety. To provide further detail and add meaning to each category, priority topics and examples of strategies and research issue were developed for each category. Table 5 presents the resulting improvement research agenda.

4. Discussion

This study produced the first national stakeholder-informed research agenda for the study of improvement and implementation strategies. The consensus priorities highlight the most important and urgent needs in improving knowledge as identified by clinical and academic scholars, leaders, and change agents in acute healthcare settings. The expert panel approach was successful in building on stakeholder survey results to further define and prioritize a research agenda that reflected consensus. Final priorities were crafted into a statement which the experts considered would be understood by those they represented and thus could be effectively communicated to the larger group of stakeholders.

This research agenda reflects knowledge needs in general areas of improvement; a more specific research agenda would provide clear guidance for scientists and clinicians in the field. Challenges in creating such an agenda arise from several sources. First, the fields of improvement and implementation science are new and, as such, lack common terminology. At the same time, other related fields such as translational science and knowledge translation can also share many scientific priorities and overlaps in the goal of quality healthcare. The improvement research agenda provides a starting point for building interchange with knowledge domains, common frameworks, and scientific capacity across these fields. This method could be used by other groups both to identify priorities and develop commitment to a research agenda in new fields. The consensus topics will be of interest to those working in overlapping and related fields, including "translational science," "implementation research," "healthcare innovation," and "service delivery research."

Any survey and consensus process reflect characteristics of the participants and the methods used. This study resulted in national, interprofessional consensus across those who took part in the various stages of the process of providing and interpreting information. Because improvement stakeholders are not a homogeneous group and are from many disciplines and traditions, the sampling frame was created from multiple sources. It likely included some that did not represent the target population; this may have affected our response rate. The large sampling frame did result in a sizeable number of respondents from academic and clinical settings (almost equally distributed), multiple professions, and a range of experience and education. Because only a few demographic variables were collected from the respondents, it is not possible to provide a detailed profile of the respondents.

A source of bias in this study arises from the early and evolving state of improvement science. Because concepts of improvement that were used in this work are not yet well defined in this emerging field, usage and meaning of terms are not precise. Terms such as "patient centered care" and "microsystems" may be defined in different ways. This lack of common terminology presented obstacles to accurate communication in the surveys used and, to a lesser extent, in the in-person interactions across multiple disciplines.

This study produced research priorities reflecting not only the rapidly emerging field of improvement science but also the perspectives of stakeholders who are new partners in improving care and patient safety. Perspectives of university-based researchers and clinical practitioners and managers regarding research priorities are affected by the incentives and core activities in each setting. This study did not detect wide disparities between these two groups; rather, it provided some indications that the perspectives of research/scientists and nonresearch/scientists were similar in their top ten priority topics. This could be due to the approach used to identify the study sample. Efforts to identify quality improvement stakeholders, whether researchers or clinicians, resulted in inviting respondents from both groups that already shared a common focus. In addition, as the consensus moved to the expert panel, the improvement science focus was further sharpened.

The picture reported above is representative of perceptions of the informed persons and experts on the importance of quality improvement research in the USA at that point in time. With rapid changes occurring in USA healthcare delivery, perceptions of the respondents may have changed since the survey. Following the network's adoption of the priority statements, they have been continuously monitored

Table 5: National improvement research agenda.

Category	Priority topics	Examples of strategies and research issues
(A) Coordination and transitions of care This category emphasizes strategies for care improvement to care processes in specific clinical conditions. At this time, care coordination and transitions of care are the key clinical focus	(i) Evaluate strategies and methods to assure coordination and continuity of care across transitions in given clinical populations (ii) Test and refine methods of handoffs and other strategies to assure safe, effective, and efficient transitions in given clinical populations	Interprofessional team performance, medication reconciliation, discharge for prevention of early readmission, patient-centered care, and measurement of targeted outcomes
(B) High-performing clinical systems and microsystems approaches to improvement This category emphasizes structure and process in clinical care and healthcare as complex adaptive systems	(i) Determine effectiveness and efficiency of various methods and models for integrating and sustaining best practices in improving care processes and patient outcomes (ii) Investigate strategies to engage frontline providers in improving quality and patient safety (iii) Evaluate strategies for preventing targeted patient safety incidents (iv) Establish reliable quality indicators to measure impact of improvement and isolate nursing care impact on outcomes	Frontline provider engagement, unit-based quality teams, factors related to uptake, adoption, and implementation, sustaining improvements and improvement processes, academic-practice partnership, and informatics solutions
(C) Evidence-based quality improvement and best practice This category emphasizes closing the gap between knowledge and practice through transforming knowledge and designating and implementing best practices	(i) Evaluate strategies and impact of employing evidence-based practice in clinical care for process and outcomes improvement (ii) Determine gaps and bridge gaps between knowledge and practice (iii) Transform evidence for practice through conducting systematic reviews, developing practice guidelines, and integrating practice into clinical decision making (iv) Develop new research methods in evidence-based quality improvement, including comparative effectiveness research and practice-based evidence	Develop and critically appraise clinical practice guidelines, adoption and spread of best practices, customization of best practices, institutional elements in adoption, defining best practice in absence of evidence, consumers in evidence-based practice, and technology-based integration
(D) Learning organizations and culture of quality and safety This category emphasizes human factors and other aspects of a system related to organizational culture and commitment to quality and safety	(i) Investigate strategies for creating organizational environments, processes that support cultures fully linked to maintaining quality, and patient safety in order to maximize patient outcomes (ii) Determine effective approaches to developing organizational climates for change, innovation, and organizational learning	Professional practice environments, protecting strategy from culture, shared decision making and governance, patient-centered models, leadership to instill values and beliefs for culture of patient safety, and organizational design (e.g., omit first-order failures)

and annually reviewed by the international steering group of the improvement research network, assuring continued alignment with contemporary needs.

What can improvement leaders and researchers in other countries learn from this process and the findings? First, that there are many different groups with an interest in improvement science and related fields. These priorities provide a sound reference point for initial discussions across improvement, implementation, health delivery, and translational sciences. Second, that identifying and communicating with all who have an interest in and can contribute to improvement science and research may be more difficult than expected because of the lack of clear constructs and classifications. This can make building consensus about priorities difficult to achieve, but doing so also helps build scientific communities and networks. Thirdly, differences in views about appropriate research methods and approaches may emerge from fields that traditionally use randomized control trials and differently used terms across groups.

This research agenda can prompt a reframing of the current quality improvement research paradigm to include collaborative, rigorous studies of strategies across academic-practice partnerships. Articulation of top priorities can help to develop common terminology with which to advance discussion between academic and clinical partners about

the kinds of studies needed to improve care and patient safety.

This initial formulation of research priorities highlights several remaining challenges. The first is to design rigorous scientific investigations of specific quality improvement initiatives that can be adopted in healthcare. The expert panel considered how to articulate research priorities that would be broad enough to encompass critical areas of research, yet sufficiently specific to guide the identification of actual research topics. Ultimately, the panel defined four general areas for research, provided descriptions, and suggested examples but stopped short of detailing actionable research questions or hypotheses. Toward this end, four multisite network demonstration projects are currently underway as described by the research network [16].

A second challenge is availability of scientists who are prepared to test quality improvement interventions. As education bodies address this challenge (e.g., American Association of Colleges of Nursing and American Association of Medical Colleges), there is also the need to innovate in research methods and designs to be more responsive to practical and scientific criticisms of some improvement research.

A final challenge is the lack of a universally accepted vocabulary to ensure clear communication about improvement concepts. While the improvement research agenda is general, it does provide a basis for classifying improvement strategies to be tested.

The process described and the resulting priority statements have led to decisions about resource investment as research projects were selected, developed, and conducted in the last 18 months addressing Priorities B-Microsystems and Priority D-Learning Organizations and Culture of Safety. The next 18 months will further address Priority B and D as well as additional research projects addressing Priority A-Care Transitions, and Priority C-Evidence-Based Best Practice is discussed further on the research network website (http://www.isrn.net/) [16].

5. Conclusions

The priorities identified were adopted by the improvement science research network to guide their strategy. The process and conclusions may be of value to quality improvement research funding agencies, governmental units, and research units seeking to concentrate their resources on topics where research is capable of yielding timely, actionable answers.

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Research Article

Translating Research into Practice in Low-Resource Countries: Progress in Prevention of Maternal to Child Transmission of HIV in Nigeria

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Background. Research related to prevention of maternal to child transmission (PMTCT) of HIV is dynamic and rapidly changing and has provided evidence-based interventions and policies for practitioners. However, it is uncertain that research and policy guidelines are adequately being disseminated and implemented in resource-constrained countries with the largest burden PMTCT. This study examined current PMTCT practices in 27 public health facilities in Nigeria. *Methods.* A cross-sectional survey of 231 practicing nurses was conducted. Current PMTCT care practices were evaluated and compared to WHO and national PMTCT policy guidelines. Linear mixed models evaluated the association between PMTCT care practices and training in PMTCT. *Results.* Most nurses (80%) applied practices involving newborn prophylaxis; yet significant gaps in maternal intrapartum treatment and infant feeding practices were identified. PMTCT training explained 25% of the variance in the application of PMTCT care practices. *Conclusion.* Key PMTCT practices are not being adequately translated from research into practice. Researchers, policymakers, and clinicians could apply the study findings to address significant knowledge translation gaps in PMTCT. Strategies derived from an implementation science perspective are suggested as a means to improve the translation of PMTCT research into practice in Sub-Saharan African medical facilities.

1. Background

Each year, an estimated 350,000 infants, mostly in low-resource countries, acquire human immunodeficiency virus infection from their mothers [1, 2]. Resource-limited countries in Sub-Saharan Africa continue to bear the greatest burden of maternal to child transmission and account for the highest number of new pediatric human immunodeficiency virus (HIV) infections globally. Nigeria alone is responsible for 30% of the global burden of maternal to child transmission of HIV and has joined a group of 22 countries as part of a global initiative to reduce the number of new pediatric HIV infections [3]. Prevention of maternal to child transmission (PMTCT) has become a key public health priority in Nigeria, a country faced with 56,681 annual HIV-positive births and more than 210,000 women living with HIV [2, 4]. In high-resource countries, successful implementation of evidence-based interventions from research has resulted in a reduction of perinatal HIV infections to 2% or less [5, 6]. If evidence from current international studies is translated successfully from research into practice in resource-limited countries, the burden of maternal to child transmission of HIV may be reduced. Global and national guidelines have been developed using this international evidence; yet there has been limited research examining whether or not this evidence has been applied within clinical practice settings in resource-limited countries. Enabling the translation of evidence-based practice from research to frontline nursing is a critical element of a systems approach to reducing maternal to child transmission of HIV.

Registered nurses make up more than 60% of the healthcare workforce in Sub-Saharan Africa [7, 8] and serve as the backbone of the healthcare system, according to the World Health Organization (WHO) [9]. In many African countries, including Nigeria, nurses are dually certified as midwives, which places them in a position to prevent maternal to child transmission of HIV. Given this dual role, nurse/midwife and nurse are used interchangeably throughout the paper. This critically important role extends from preconception to prenatal, perinatal, postnatal, gynecologic, and family planning. The specific nursing practices aimed at eliminating maternal to child transmission of HIV across phases of the childbearing period are outlined in Table 1.

Task shifting of HIV care and treatment responsibilities from physicians to nurses has resulted in an expansion of the nurse's role as the primary medical care provider for mothers with HIV and AIDS in many resource-limited regions of the world [10–12]. When task-shifting practices are well implemented, nurses and midwives in rural, hard-to-reach communities are empowered to provide appropriate, integrated, patient-centered PMTCT services. Research has demonstrated that lay health workers, including traditional birth attendants (TBAs), directly providing health services to mothers and children depend on nurse/midwives as their most common source of information related to PMTCT of HIV [13]. Given that 60% of women in Nigeria continue to be delivered by lay workers who rely on governmental nurses/midwives for their knowledge related to PMTCT, it is important that the nurses/midwives offer the best advice. In view of the current global agenda for an AIDS-free generation, it is essential that frontline maternal, newborn, child health (MNCH) nurses in resource-limited settings have the knowledge and ability to utilize the best evidence-based practices in PMTCT.

Despite nursing's important role, research has not adequately examined whether evidence-based knowledge is being translated into the practice settings of nurses in resource-limited settings, like Nigeria. The purpose of the present study is to examine the translation of evidence-based practices related to PMTCT in maternal, newborn, child health nurse/midwives ($n = 231$) in 27 public health facilities in Nigeria. The paper begins with a review of studies that examine HIV knowledge and practice among nurses in developing countries. Next, the methods and results of the study are presented, followed by a discussion of study implications related to the challenges nurses face in the translation of evidence-based practices in perinatal HIV prevention in resource-limited settings. The conclusion applies an implementation science perspective to formulate recommendations that could enhance the translation of PMTCT research to nursing practice.

1.1. Review of the Literature. An extensive literature review resulted in a limited number of articles directly related to the translation of PMTCT evidence-based practices among nurses. The literature review was subsequently expanded to include studies examining the HIV/AIDS knowledge and practice of other types of MNCH providers in developing countries. Multiple studies in Sub-Saharan Africa have indicated gaps in nursing knowledge associated with minimal access to training in HIV/AIDS care [14, 15]. Research on nurses has identified specific gaps in knowledge, including the inability to identify high-risk groups, describe symptoms, interpret diagnostic tests, and utilize universal precautions. Studies on nursing populations have also reported decreased confidence in their knowledge of HIV, inadequate understanding of appropriate infant feeding practices, and limited skills in HIV counseling and assessment of medication adherence [14]. Clinical experience, frequency of care, and greater levels of training have been shown to be associated with significant improvements in knowledge of HIV/AIDS care among nurses [15]. Research studies specifically examining PMTCT knowledge in nurses are quite limited. A recent Nigerian study examined PMTCT practice in traditional birth attendants (TBAs) and found that the overwhelming majority (91%) lacked basic knowledge related to HIV/AIDS [13]. TBAs reported performing unsafe PMTCT care practices, which limited their ability to prevent HIV in mothers, reduce transmission to newborns, and safely protect themselves from HIV. Nurses may assist in the reduction of unsafe practices related to PMTCT by providing TBAs with reliable information. The marked scarcity of studies on translation of PMTCT knowledge into the practice setting indicates the need for further research in this area.

2. Methods

2.1. Design. The study employed a cross-sectional survey design of maternal, newborn, child health nurses across 27 public healthcare institutions in Nigeria.

2.2. Theoretical Framework. The diffusions of innovation theory [16, 17] was used as the conceptual framework for this paper. This model has been used extensively to examine the transfer of evidence-based knowledge from research to policy and practice. The model identifies five core components that determine whether a new evidence-based practice is adopted and subsequently diffused into practice. First, *relative advantage* must be present; that is, key practitioners must perceive the new evidence-based practice as an improvement to the current practice. The second component is *compatibility*, which considers whether the new practice works well with existing practices, past experiences, and the needs of the potential end users. *Complexity* is the third component, which considers whether the practice is relatively simple and well defined. The newly developed practice must also demonstrate the fourth component, *trialability*, meaning opportunities must be offered for the practice to be tested or trialed in the clinical setting. Finally, *observability* allows nurses to see the evidence-based practice demonstrated by key clinical leaders within their particular clinical setting.

2.3. Sample. The sample was drawn from a sample frame of 140 public health facilities supported by the Institute of Human Virology, Nigeria (IHV-N), a major Presidential

Table 1: The role of nursing in preventing maternal to child transmission of HIV.

Preconception	Providing education on safe sex practices, HIV testing, counseling, and treatment
Prenatal	HIV testing and counseling; maternal treatment with antiretroviral (ARV) medication if HIV positive; coordinating care and support for adherence, disclosure, and other psychosocial needs; and assistance in navigating a fragmented healthcare system for PMTCT services
Perinatal	Safe delivery practices; intrapartum antiretroviral treatment (ART); immediate neonatal care
Postnatal	Counseling related to informed infant feeding options; continued ART to HIV-positive mothers; and prophylaxis to exposed newborns
Gynecological/family planning	Continued support, treatment, and counseling during the postnatal period related to safe sexual practices and family planning

Emergency Program for AIDS Relief (PEPFAR) implementing partner in Nigeria. Through grants administered by the Center for Disease Control and Prevention in Nigeria, IHV-N provides technical support to the government of Nigeria for HIV/AIDS prevention, diagnosis, treatment, and care and support services at approximately 140 health facilities. These facilities include teaching and general hospitals as well as community-based primary health centers within the six geopolitical zones of Nigeria. A convenience sample of public health facilities across all three tiers of the healthcare system (primary, secondary, and tertiary) was selected and twenty-seven facilities agreed to participate. Facilities were chosen based on government ownership and their geographic location in the northern, southeastern, and south-southern regions of Nigeria. All MNCH nurses at each of the participating facilities were invited to complete the anonymous, self-administered survey, and 231 nurses completed it. Nurses were clustered within facilities, and the response rate was greater than 95% at each facility. Nurses not actively employed in the care of pregnant women or newborns were excluded.

2.4. Data Collection. Nigerian nurses from University of Maryland and our collaborating nurses at the Institute of Human Virology in Nigeria both provided face validity and expert validity by reviewing and piloting the nurse survey prior to implementation. Healthcare providers in Nigeria speak English as their official language; thus, language translation of the self-administered survey documents was not necessary. Data collection occurred over 6 weeks from March to May 2010. The survey consisted of the following sections: demographics; knowledge questions related to PMTCT; and a nursing care practices scale related to direct PMTCT nursing care. The surveys were implemented in 27 healthcare facilities across 10 of the 36 states in Nigeria. All maternal, newborn, child health nurses on duty on the day of the in-person administrative interview were invited to participate, and the response rate was 95 percent or greater for each site.

2.5. Measures

2.5.1. PMTCT Practice Scale. The PMTCT practice scale consists of 12 items related to nursing practices associated with the prevention of maternal to child transmission. Translation was explored with a series of survey questions, which are aligned with the WHO and Nigerian Federal Ministry of Health (FMOH) guidelines on PMTCT. The items were dichotomous (yes/no), and the scale included evidence-based practices related to postexposure prophylaxis for newborns, newborn feeding practices, maternal prenatal laboratory testing and screening, maternal treatment during delivery, and availability of protective equipment for universal precautions. Cronbach's alpha for the PMTCT practice scale was 0.621, consistent with other HIV knowledge scales [17].

2.6. Ethical Considerations. The appropriate ethics committees and health authorities approved the study. The Institutional Review Board of the University of Maryland Baltimore and the Institute of Human Virology Nigeria (IHV-N) Institutional Review Board both approved the study.

2.7. Data Analysis. Data were analyzed using SPSS Version 19. Exploratory analysis was used to detect potential outliers and data collection errors. Standard descriptive statistics (mean, standard deviation, and frequency) were used to describe all key variables. During the data collection phase, each nurse survey was coded to indicate the facility in which the nurse respondent practiced. During data cleaning, eight surveys were noted to have >80% missing data and were deleted from the analysis. The remaining surveys ($n = 223$) had less than 10% missing data for all variables and served as the final sample for analyses. Practice-related knowledge in prevention of maternal to child transmission of HIV and the proportion of nurses participating in training were analyzed. Differences in characteristics in groups of nurses receiving PMTCT training were examined using t-test or chi-square test. Student's t-test was used to examine mean differences in age, nursing experience, and PMTCT knowledge scores. Chi-square or Fischer's exact test (for those with fewer than five in a group) analysis was applied for bivariate analysis of categorical variables, nursing education, professional rank, and unit. Finally, multilevel modeling approaches, that is, bivariate and multivariable linear mixed models, were used to account for clustering of nurses within facilities.

3. Results

3.1. Sample Characteristics. As depicted in Table 3, nearly half (43%) of the 223 participating nurses had received training in PMTCT. Nurses who received training were significantly older, mean age 43 years (SD 8.1) compared to nontrained, mean age = 39 (SD 8.8); $t = -3.3$, $P = 0.001$. While intercultural differences between and within the major tribes (Hausa, Ibo, and Yoruba) and geographic regions in Nigeria do exist, respect and privilege for older adults (including nurses) is a culturally bounded practice, which may result in older nurses having more opportunities for training [18, 19]. The nurses were highly experienced, with an average of 16.5 years in nursing and within maternal, newborn, child health nursing, specifically, a mean of 8.7 years. Most nurse participants were diploma-prepared nurses (>90%), and although the group size was small, nurses with a BS or MS degree reported not receiving PMTCT training. Currently 75% of practicing RNs in Nigeria are certificate and diploma holders [20]. All respondents were MNCH nurses and were employed in various specialty units, including 34% in labor and delivery, followed by 17% in the special baby care units, 14.3% in antenatal care/prenatal care clinics, and 14.2% in pediatric units. The largest number of nurses in the study who received PMTCT training were maternity (labor and delivery) nurses, and the smallest proportion of nurses receiving PMTCT training were postpartum nurses. These differences by specialty unit were significant (Fisher's exact test, $P = 0.007$).

3.2. Bivariate Analysis of Training in PMTCT with Demographic Variables. Earlier studies examining HIV knowledge and practice in nurses have demonstrated significant relationships between practical knowledge and nursing experience, professional rank, nursing education, level of care (primary, secondary, and tertiary), and specialty unit type. PMTCT training was significantly associated with age, nursing experience, and specialty unit; however, no significant associations were noted with professional rank, nurse educational level, and facility level of care (primary, secondary, and tertiary). See Table 3.

3.3. PMTCT Care Practice Scores. In this group of nurses, the PMTCT care practice scores had a mean of 8.3 (SD 2.6) and ranged from 0–12, with higher scores associated with increased application of PMTCT practices. As illustrated in Table 4, on average, the PMTCT care practice scale scores were higher for nurses who received training in PMTCT, with a mean of $M = 8.7$ (SD 2.0) compared to those without training, with a mean of 7.9 (SD 2.5). The bivariate linear mixed model showed that the PMTCT care practice scores of the group of trained nurses were significantly higher than those of the nontrained group. The care practice scores were highest for nurses working in maternity/labor and delivery and special care baby units (SCBU), with means of 8.4 and 8.6, respectively. The scores were lowest for nurses working in primary health care settings, mean = 7.1 (SD 1.5). These differences by specialty unit were not statistically significant when analyzed in the bivariate linear mixed model (with ANOVA, Wald $\chi^2 = 10.40$, $P = 0.109$).

3.4. Facility Level Variations in Nurse's Knowledge of PMTCT. Nigeria's health system is comprised of three levels: primary, secondary, and tertiary. HIV care was initially centralized in tertiary settings; however, the National Strategic Plan for 2010–2015, developed by the Nigerian National Agency for the Control of AIDS [21], identified decentralization of HIV services, including PMTCT, into the primary settings, as the core strategic approach to improving HIV-related outcomes. Due to this phased rollout approach, nurses in primary and secondary settings had not benefited from observability of evidence-based practice related to PMTCT. Therefore, the data were segregated by level of care (primary, secondary, and tertiary), and the sample was further analyzed based on nurse training in PMTCT for group comparisons. The nurses with the highest PMTCT care practice scores were in tertiary centers (accounting for 59% of the scores that were greater than 10). These univariate trends were not significant with bivariate analysis, Fischer's exact tests $P > 0.05$, indicating no significant difference in PMTCT knowledge by the facility's level of care.

On average, the mean PMTCT care practice scores for nurses employed in primary health care settings were lower, with mean = 7.7 (SD 1.9), than for secondary settings, mean = 8.0 (SD 2.8), or tertiary settings, mean = 8.1 (SD 2.5). These differences by level of care were not significant (Wald $\chi^2 = 0.22$, $P = 0.896$). Due to their increased experience in HIV care, nurses in tertiary centers were expected to have increased knowledge related to maternal intrapartum treatment. However, when nurses were stratified by the facility's level of care, 37% of tertiary nurses incorrectly responded that they would not provide maternal intrapartum treatment, compared to 25% of primary care nurses and 21% of secondary care nurses. See Table 4.

3.5. PMTCT Knowledge Gaps: Individual Item Analysis. Most nurses were able to correctly access maternal HIV laboratory reports, wear gloves, and provide newborns with ART prophylaxis, and many indicated that they would treat mothers with ART during the intrapartum period. It is notable that very few nurses (2.3%) reported being completely unsure about how to treat HIV-positive mothers and their exposed newborns. Most nurses, 91% of trained nurses and 77% of nurses not exposed to PMTCT training, reported correctly that they would provide ART prophylaxis to HIV-exposed newborns. On the other hand, several appropriate evidence-based practices were not reported as being implemented in the clinical setting. Most nurses incorrectly reported they would not bath HIV-exposed infants after birth, recommend breastfeeding to HIV-exposed infants, or wear gowns with every patient. Only 11.8% of nurses who received training in PMTCT reported that they would bath the infant after birth compared to 8.4% of nurses who did not receive training. Most nurses in this study (85.5%), regardless of exposure to PMTCT training, incorrectly reported that they would not recommend breastfeeding by HIV-positive mothers.

A significant number of nurses, 27%, incorrectly responded they would not provide antiretrovirals to mothers during the intrapartum period. This gap persisted even for the nurses who received PMTCT training and those in tertiary centers. When asked about universal infection prevention practices in newborns and mothers, 23% of maternal child health nurses reported that they did not wear gloves, and 62% did not wear gowns. Gaps in practices related to universal precautions and lack of utilization of gloves and gowns may increase the risk of contraction of HIV and compromise the safety of mother, newborns, and nurses.

3.6. Multilevel Modeling to Account for Clustering of Nurses. Finally, multilevel modeling analysis was performed to evaluate the influence of these nurse and facility characteristics on PMTCT care practices. Under the null model, the intraclass correlation (ICC) was 0.17 (95% CI: 0.044, 0.30) [22]. The random intercept model was appropriate to account for clustering of nurses within the participating facilities. The final model of PMTCT care practices scores was also controlled for nurses' age, years of experience, and level of care (primary, secondary, and tertiary). As summarized in Table 5, age, experience, and level of care were not significant predictors of PMTCT knowledge scores. However, training in prevention of maternal to child transmission was a significant predictor of PMTCT care practices ($b = 0.7$, 95% CI: 0.07, 1.3; $P = 0.03$). On average, nurses who received training had scores 0.7 higher than those without training.

4. Discussion

Research evidence related to caring for HIV-infected mothers and HIV-exposed newborns is rapidly evolving (WHO, 2010). Significant progress has been made over the last decade in the global scale-up of prevention of maternal to child transmission of HIV in developing countries; yet very little is known about the actual translation of this knowledge into nursing practice. The current study addresses several important concerns: first, HIV-infected women and their infants deserve the best possible nursing and medical care to break the cycle of the HIV epidemic; second, nurses need to be provided with the knowledge, skills, and attitudes that can help them provide the basic provisional services. Even though nurses are foundational to the healthcare system in Nigeria, their capacity is weakened by lack of sufficient access to the education, practical experiences, and coaching support needed to implement evidence-based practices. The current study identified specific gaps in key PMTCT practices related to maternal intrapartum treatment and breastfeeding in the context of HIV. By contrast, areas where nurses have demonstrated strong knowledge and application of PMTCT practices have also been identified, specifically, their knowledge related to providing antiretroviral treatment (ART) for newborns after delivery. A particular strength of the current study is that all participating facilities maintain a strong ongoing relationship with the Institute of Human Virology-Nigeria (IHV-N), which continues to provide support and training in HIV/AIDS and PMTCT treatment and care.

This study also has some limitations. It utilizes a cross-sectional design, which reflects data collected at only one point in time. In addition, the data in this study were collected while some facilities were in the midst of decentralizing HIV care from tertiary to primary and secondary sites, which may have subsequently altered the level of training available at sites where HIV/AIDS care was previously limited. Furthermore, PMTCT translation was examined in MNCH nurses who were employed in public, government-owned hospitals, and the findings should not be generalized to nurses in the entire Nigerian healthcare system, which has a significant private sector. More generally, the challenge associated with examining the translation of PMTCT knowledge into practice in resource-limited countries is exacerbated by the limited research performed in this area to date.

4.1. Translation and Theory. The diffusions of innovation theory [18, 19] and its five determinants of adoption of new evidence-based practices (i.e., relative advantage, compatibility, complexity, trialability, and observability) are applicable to the study results. (See Table 2.) Access to antiretrovirals at all sites, due to the organizational relationships with a donor organization, is a relative advantage and it was expected that it would affect the provision of antiretrovirals in the clinical setting. For newborn prophylaxis, this proposition was supported; however, despite access to maternal antiretrovirals, nurses reported not providing intrapartum ARVs to mothers. Due to the centralization of HIV care in tertiary centers in Nigeria, the lack of observability (not having the opportunity to see the performance in their institutions) may have outweighed the benefit of relative advantage. Nurses in primary and secondary care had limited or no opportunities to observe the practice of caring for HIV mothers. Under the centralized model, once pregnant women were identified as HIV positive, they were referred to a tertiary setting. Currently HIV and PMTCT care and treatment are being decentralized into primary settings; based on the findings in this study, increased training in PMTCT is needed in order for nurses in these settings to perform the appropriate nursing practices to prevent maternal to child transmission of HIV. Nurses working in primary and secondary settings had lower mean PMTCT practice scores than nurses working in tertiary settings; trained nurses had higher mean scores than did nontrained nurses. Surprisingly, nurses in tertiary centers also lacked application of knowledge related to maternal intrapartum care and additional training and may benefit from continued education and training. The failure of nurses to treat mothers with antiretrovirals during delivery is a significant gap in practice that warrants further investigation.

Gaps in practice were also noted with nursing practice related to breastfeeding in the context of HIV. The relative advantage and complexity associated with HIV-positive mothers providing breast milk to their infants were evident in the study. Participating nurses seemed to be bound to the idea that avoidance of breast milk is best and continue to perform duties based on old evidence, indicating a lack of relative advantage. The new evidence (recommending breastfeeding) is not perceived as better than the idea that

Table 2: PMTCT practice items related to determinants of adoption.

Determinants of adoption	Definition	Related PMTCT practice category	Hypothesized outcomes
Relative advantage	The new practice is perceived as better than the one that preceded it	Newborn antiretroviral (ARV) treatment	Adoption of the practice related to newborn ARV treatment is expected to be positive due to presence of ARVs at all sites due to relationship with donor agency
		Breastfeeding	Earlier recommendation was the avoidance of breastfeeding. The expectation of the study is that the recommendation to breastfeed is not perceived to be better than avoiding breastfeeding. Adoption is not expected
Compatibility	The practice works well with existing practices and structures	Maternal and newborn ARV treatment	Adoption is expected due to availability of ARVs at all sites
		Universal precautions	Adoption of the practice is not expected due to research evidence of limited material resources, including gowns and gloves
Complexity	The practice is simple and well defined	Breastfeeding	Multiple changes in recommendations over the last decade, varying from avoiding breastfeeding to providing breastfeeding. Adoption is not expected
Trialability and observability	The practice is offered in the clinical setting and nurses have opportunities to observe the practice being delivered in their institution	Maternal intrapartum treatment	Due to centralization of HIV treatment in tertiary settings, nurses in primary and secondary settings had no opportunities to trial or observe care of HIV-positive pregnant women. Adoption of the practice is not expected to be implemented in primary and secondary sites

came before it (avoiding breastfeeding). Secondly, due to the rapid increase in research and change in information on PMTCT, the new evidence related to breastfeeding is complex and appears to be constantly changing. Evidence-based practices related to breastfeeding in the context of HIV have fluctuated greatly over the last decade, thereby muddling practical knowledge and intensifying complexity in the diffusion of research to practice. During the emergent response to the HIV epidemic, the strategy was to avoid breast milk feeding, where possible, in all HIV-exposed newborns [23]. Yet, the social and economic disparities and variations in cultural practices in resource-limited countries made this approach increasingly challenging. Later studies in resource-limited countries demonstrated that the reductions in HIV transmission from replacement feedings were often offset by increases in mortality due to respiratory and diarrheal illness [24]. By 2001, the WHO recognized the increases in mortality and morbidity unrelated to HIV among HIV-exposed infants and [25] introduced the acceptable, feasible, affordable, sustainable, and safe (AFASS) criteria. Each mother was expected, with appropriate counseling support (often delivered by frontline nurses), to use the AFASS criteria in making the decision of whether to use breast milk or replacement milk. More recently, infant feeding guidelines from WHO initiated in 2010 [1] did not use the AFASS language and shifted the decision making away from nurses, counselors, and mothers onto national health authorities, who are expected to provide leadership and guidance by deciding, promoting, and supporting appropriate feeding practices for their country and context.

Frontline nurses have been noted in earlier research to provide "strong advice" rather than counseling on infant feeding decisions in the context of HIV, and therefore may have a direct impact on infant feeding choice at time of discharge [14]. Most nurses in this study would not recommend breast milk and preferred to offer replacement feedings, despite evidence that cost and culture may limit the family's ability to provide replacement formula. This may be grounded in an ethical dilemma related to the evidence-based knowledge that continued infant exposure through breastfeeding still carries an HIV transmission risk between 5–20% [26]. This gap in advocacy for breastfeeding may account for the nearly 72% of women that are HIV positive who decide to use formula/replacement feeding at time of discharge from a Nigerian health facility [3, 27]. However, longitudinal studies have demonstrated that most newborn infants (71%) that were formula fed at time of hospital discharge subsequently switched and were exclusively breastfed at 1 month and 6 months [27]. Switching from replacement formula to breast milk results in exposure to mixed feeding, defined as the combination of replacement milk and breast milk. In recent Nigerian studies, HIV-exposed infants that received mixed feeding were nearly six times more likely than infants that received exclusive formula feeding to acquire HIV [27]. Multiple studies have demonstrated that mixed feeding exposure is associated with a higher risk of transmission of HIV

Table 3: Nurse demographic characteristics by PMTCT training, $N = 223$[a].

MNCH nurse characteristics	PMTCT training $N = 93$ (43%)	No PMTCT training $N = 123$ (57%)	P value[†]
	M (SD)	M (SD)	
Age (years)	43 (8.1)	39.1 (8.8)	0.001
RN experience (years)	18.3 (8.6)	15.2 (8.8)	0.01
Professional rank	N (%)	N (%)	0.764
Staff nurse, direct care	68 (43)	89 (57)	
Staff nurse, direct & indirect[b]	14 (48)	15 (52)	
Nurse matron	10 (38)	16 (61)	
Nursing education			1.0
Diploma prepared	90 (43)	118 (57)	
BSN or MSc	3 (38)	5 (62)	
MNCH specialty (assigned unit)			0.007[‡]
Maternity (labor and delivery)	37 (52)	34 (48)	
Special care baby unit//neonatal ICU	10 (25)	29 (74)	
Antenatal clinic	19 (61)	12 (39)	
Primary healthcare	4 (44)	5 (56)	
Pediatric unit	10 (33)	20 (66)	
Rotating MNCH nurses	9 (45)	11 (55)	
Postpartum	2 (14)	12 (86)	
Facility/level of care			0.067
Primary	5 (31)	11 (69)	
Secondary	44 (52)	40 (48)	
Tertiary	43 (37)	72 (62)	

[a]N varies due to missing data; [b]nurses had additional administrative duties; [†]t-test or chi-square test was used; [‡]Fisher's exact test was used.

compared to exclusive breastfeeding or exclusive replacement formula [3, 27, 28]. This evidence needs to be translated into clinical practice, and nurses need to take practical steps to prevent new pediatric infections due to maternal to child transmission through breast milk.

Facilitating changes in practice can begin with educating frontline workers about the evidence-based knowledge. This information can be utilized to support such actions as (1) advocating for exclusive breastfeeding, if possible; (2) supporting families' decisions to exclusively use formula feed; and (3) alerting families to the increased risk of acquiring HIV associated with mixed feeding. If nurses are presented with an adequate and continuous flow of research evidence and information, long-standing practices can be changed and gaps in practice can be resolved. Given that training in PMTCT increases knowledge and application of PMTCT practice, nurse training and education are needed to investigate and address this serious gap between knowledge and practice related to breastfeeding of infants exposed to HIV. Nurse education at the preservice level (embedded into their basic nursing education) can advance knowledge of new nurses entering practice, while in-service training (practice-related educational updates) is urgently needed for nurses who are already in clinical practice. Upscaling of nurse education in general to the bachelor's, master's, and doctoral level may improve the dissemination and implementation of research into practice. Although there is currently momentum to advance nursing education to the bachelor's level in Nigeria, in 2009 75% of practicing RNs in Nigeria were certificate or diploma prepared [20].

Discussing the gaps in translation of evidence-based practices in PMTCT using the diffusions of innovation theory provided a basic framework for clearly articulating the challenges around adoption of the practices. Future studies examining the translation of evidence-based practices should also expand on this process by collecting specific, objective data related to nurse perceptions of relative advantage, compatibility, complexity, trialability, and observability. Additionally, using the theoretical framework further assisted in the development of strategic recommendations for improved translation of PMTCT research to practice.

4.2. Strategic Recommendations for Improved Translation. The findings in this study could be used to strengthen nurses' ability to provide evidence-based care for HIV-infected mothers and newborns. With the growing emphasis on the translation of research from policy to practice, strategic approaches grounded in implementation science theories and frameworks are needed to increase translation and the rate of adoption for evidence-based practices in PMTCT. Researchers, policymakers, and clinicians should work together to support expedited translation of evidence

Table 4: PMTCT care practice scores by training, level of care, and specialty unit.

	Mean (SD)	Wald χ^2 (df)	P value
Training		7.21 (1)	0.007
Not trained in PMTCT	7.9 (2.5)		
Trained in PMTCT	8.7 (2.0)		
Level of care		0.22 (2)	0.896
Primary	7.7 (1.9)		
Secondary	8.0 (2.8)		
Tertiary	8.1 (2.5)		
Specialty unit		10.4 (6)	0.109
Antenatal clinic	8.3 (2.8)		
Maternity (L&D)	8.4 (2.7)		
Special care baby unit (SCBU)/neonatal ICU	8.6 (2.2)		
Pediatric unit	7.3 (2.7)		
Rotating MNCH nurses	7.6 (2.2)		
PHC setting	7.1 (1.5)		
Postpartum	7.2 (2.9)		

The b (95% CI) and P value were estimated from the bivariate linear mixed models of PMTCT knowledge score on each predictor separately. A random intercept of facility was included in each model to account for clustering of nurses within facilities.

Table 5: Association between PMTCT training and PMTCT care practice using a linear mixed model.

	b (95% CI)[†]	P value
Age (years)	−0.003 (−0.08, 0.08)	0.095
RN experience (years)	0.01 (−0.07, 0.09)	0.805
PMTCT training (yes versus no)	0.7 (0.07, 1.3)	0.03
Type of facility		
Secondary versus primary	0.6 (−0.8, 2.0)	0.4
Tertiary versus primary	0.4 (−1.0, 1.7)	0.619

[†]Linear mixed model adjusted for age, experiences, and type of facility and with a random intercept of hospital to account for clustering of nurses within each hospital.

into real clinical practice. Nurses, in particular, have an important role in providing both practical and scientific insight into the development and implementation of strategies that support translation in both global and national practice settings.

In order to translate research successfully into practice, nurses must first understand why these gaps in translation of evidence into practice remain even in the midst of this surge of research and policy-based guidelines in PMTCT. Secondly, nurses must determine what practical measures can be utilized to address this gap in an era in which research, policy, and practice in PMTCT are rapidly changing. It has been argued that failures to translate evidence into practice remain, in part due to tradition-driven health practitioners, including nurses, who prefer to continue to practice with outdated knowledge as well as researchers and policymakers that believe simply publishing the evidence will result in practical use [29]. Importantly, to a certain extent, PMTCT research has been translated into policy and expert guidelines, as evidenced in both national policies and global policies from the WHO for PMTCT. However, if nurses are to fully realize the application of these evidence-based practices in the clinical setting, additional strategic efforts are needed to ensure that healthcare professionals on the frontline are able to apply the knowledge in practice and have continuing access to new knowledge.

One practical strategic approach is the development of implementation teams that focus on quality, integration, alignment, problem solving, and sustainability of new research knowledge as it enters practice (National Implementation Research Network, 2011). Development of hospital-based implementation teams that are closely aligned with the Ministry of Health (MOH) may increase organizational capacity to update nurses and other healthcare workers regularly on changes in research, policy, and practice. These teams would also provide the structure to support organizational capacity to sustain PMTCT interventions strategically. The interdisciplinary team could be responsible for training nurses on PMTCT practices, continuing to engage them through coaching as well as by modeling the evidence-based interventions in clinical practice, and assisting in the development of feedback mechanisms that address barriers to care. The team could also engage in the complementary process of "exnovation," which targets false beliefs and outdated practices [29]. This would ensure that in addition to the translation of the new best practices, outdated nursing practices, such as those associated with PMTCT care in Nigeria, would be removed from nursing practice [29]. The team would support connectivity between the Nigerian Federal Ministry of Health (and other key stakeholders) and healthcare facilities to ensure that the best and current evidence-based practices related to PMTCT reach frontline workers. This strategy has the potential to ensure that the national message developed by the Nigerian FMOH on infant feeding practices in the context of HIV reaches and is implemented in "real" practice settings. Furthermore, regular monitoring and evaluation of PMTCT programs for accuracy and consistency by ministries of health and other key stakeholders from nongovernmental organizations, the Nursing and Midwifery Council, nursing schools, and other regulatory bodies could also ensure a system of accountability related to the translation of knowledge into practice. This strategy would ensure that researchers, policymakers, and frontline practitioners work in a complementary way to transfer new knowledge into practice efficiently. These combined efforts serve to advance translation of knowledge to action and improve patient outcomes.

5. Conclusion

This study provides insight into the translation of evidence-based knowledge related to PMTCT into practice. Nurses demonstrated that some evidence-based interventions related to PMTCT are translating from research and policy

into clinical settings; yet significant gaps in key practices remain. The PMTCT knowledge and application gap was found to be ameliorated with training. Innovative strategic interventions to link research, policy, and practice that are grounded in implementation science theory may support efficient translation of PMTCT and nursing research. Ministries of health, program administrators, clinical leaders, and policymakers could apply the evidence and recommendations to improve the content of training programs and to develop novel approaches to ensure translation of research into practice.

Abbreviations

AFASS: Acceptable, feasible, affordable, sustainable, and safe feeding criteria
ART: Antiretroviral treatment
ARV: Antiretroviral
ARVs: Antiretrovirals
EBP: Evidence-based practices
FMOH: Nigerian Federal Ministry of Health
ICU: Intensive care unit
IHV-N: Institute of Human Virology Nigeria
MCH: Maternal child health
MOH: Ministry of Health
MNCH: Maternal, newborn, child health
MTCT: Maternal to child transmission
PMTCT: Prevention of mother to child transmission
RN: Registered nurses
SCBU: Special care baby unit
TBA: Traditional birth attendant.

Authors' Contribution

Yolanda Ogbolu is the corresponding author of this paper, which is a report of her dissertation. The conceptualization, implementation, data collection, data analysis, and reporting of the data in this paper are her contributions. Emilia Iwu is the Nigerian implementing partner at IHV-N and was responsible for overall coordination of research activities in Nigeria. She was directly involved in the editing of this paper and provided expert scientific knowledge on HIV care and treatment. Shijun Zhu served as the statistician for the multilevel modeling analyses and reviewed overall data analysis. Jeffrey V. Johnson was involved in the conceptualization of the study and editing of the final paper.

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Research Article

Variations in Institutional Review Board Approval in the Implementation of an Improvement Research Study

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The purpose of this paper is to report the variance in institutional review board (IRB) reviews as part of the implementation of a multisite, quality improvement study through the Improvement Science Research Network (ISRN) and recommend strategies successful in procuring timely IRB approval. Using correspondence documents as data sources, the level of review was identified and time to submission, time to approval, and time to study start were analyzed. Thirteen of the 14 IRBs conducted independent reviews of the project. Twelve IRBs approved the study through expedited review while two IRBs reviewed the project at a full board meeting. Lastly, 11 of the 14 sites required documented consent. The greatest delay in approval was seen early on in the IRB process with site PIs averaging 45.1 ± 31.8 days to submit the study to the IRB. IRB approvals were relatively quick with an average of 14 ± 5.7 days to approval. The delay in study submission may be attributed to a lack of clear definitions and differing interpretations of the regulations that challenge researchers.

1. Introduction

With the push to increase the quantity, quality, and generalizability of improvement research [1–3], networks such as the Improvement Science Research Network (ISRN) provide an opportunity to conduct rigorous multisite studies; however, the inconsistency of review for improvement research brings challenges to both academic- and hospital- based IRBs. A formidable barrier to carrying out multisite improvement research is the IRB review process itself. Completion of the IRB application is a necessary yet time-consuming process [4]. The ISRN has developed a streamlined approach to facilitate IRB submissions at the local site through the use of the protocol implementation kit (PIK).

Quality improvement in the healthcare industry has gone through a major change. With the landmark report from the Institute of Medicine indicating the need to transform the healthcare system [2], quality improvement research must go beyond the single site, single investigator mindset. Using the implementation science framework focusing on participatory implementation process [5], many clinicians are working alongside their academic partners engaging in quality improvement activities to improve healthcare processes and patient outcomes. With the need to disseminate best practices, publication of quality improvement activities is warranted; however, many journals and publishers will not publish original data if the project was not approved by an accredited institutional review board. IRB review and federal agency oversight are increasing in importance as QI initiatives must rise to the level of research in order to facilitate dissemination and implementation of effective improvement strategies.

Title 45, part 46 of the Code of Federal Regulation (CFR) defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [6]." Alternatively, quality improvement (QI) is defined as a systematic, data-guided activity designed to bring about immediate, positive changes in the delivery of healthcare in particular settings [7] or a process by which individuals work together to improve systems and processes with the intention to improve outcomes [8]. The Office for Human Research Protection (OHRP), the federal office governing IRBs, provides leadership in the protection of the rights, welfare, and wellbeing of participants involved in research conducted or supported by the US Department of Health and Human Services (DHHS) [9]. Therefore, as the governing office for IRBs, DHHS

charges each IRB to assure, both in advance and by periodic review, that risk to human subjects is minimal and the welfare and rights of human subjects are protected [9].

Quality improvement may be successful within a single unit or hospital; however, the limiting factor with single site quality improvement projects is that it may not yield generalizable knowledge that can be implemented into clinical settings [1, 3]. Therefore, to address the issue of generalizability, the Improvement Science Research Network (ISRN) was created [9, 10]. The ISRN was created through the National Institutes of Health funding in 2009 as a national research infrastructure to advance improvement research. The ISRN is made up of nearly 200 academicians and clinicians from across the country, a cyberinfrastructure supporting virtual collaboration, and a research coordinating center. The mission of the network is to advance the scientific foundation for quality improvement, safety, and efficiency through transdisciplinary research addressing healthcare systems, patient-centeredness, and integration of evidence into practice [7]. In addressing its mission, the ISRN's infrastructure is tailored to conduct multisite improvement research to produce generalizable knowledge.

Previous publications have documented variations of IRB review for research networks engaged in multisite clinical trials [4, 11–15]. A large, high profile study to reduce central line-associated bloodstream infection (CLABSI) in the state of Michigan may have initiated the debate of whether a project is a QI initiative or a research study involving human subjects [16]. This study aimed to improve culture within the hospital and implement evidence-based practice to prevent CLABSI. This study was reviewed by the John Hopkins IRB and was considered exempted from further review. After the study report was published, OHRP indicated that Hopkins and the participating hospitals should have obtained full IRB approval with patient consent prior to initiating this study. This action by OHRP greatly changed the way quality improvement is viewed. The purpose of this report is to provide an ad hoc, descriptive review of the process required to obtain IRB approvals for the implementation of a multisite, quality improvement study.

1.1. Objectives of the Multisite Study. Small troubles, adaptive responses (STAR-2): frontline nurse engagement in quality improvement (PIs: Kathleen R. Stevens, RN, EdD and Robert Ferrer, MD, MPH) was a multisite, cross-sectional, multivariate research study aimed to describe the type and frequency of operational failures (or workarounds) detected by frontline nurses on their clinical units [17]. To complete this project, ISRN PIs partnered with 14 hospitals from across the country. Each site, led by a site PI, engaged nurses from three medical-surgical units to self-report operational failures encountered in routine care, in real time, using an index sized "Pocket Card" for 10 shifts over 20 days. Subsequently, frontline engagement, work environment, and quality improvement outcomes data were collected using an integrally designed survey packet. In total, 716 nurses participated from the 41 units involved in this study. This study start was staggered and broken into three waves. Wave 1 consisted of 2 hospitals, while waves 2 and 3 consisted of 6 hospitals each.

2. Methods

2.1. Protocol Fidelity. To assure that scientific rigor and protocol fidelity were maintained, the ISRN Coordinating Center, housed in the Academic Center for Evidence-Based Practice at UTHSCSA, coordinated this project. To facilitate fidelity of the project, a protocol implementation kit (PIK) specific to the STAR-2 study was provided to each site PI. The PIK included standardized materials to implement this project uniformly across each site. The PIK included the standardized protocol, marketing/advertising materials, IRB templates to facilitate the IRB submission process, step-by-step data collection processes, data entry guidelines, and tips to interpret results (see Puga et al.'s article on pages XX-XX for more detail) [18]. The UTHSCSA IRB approved this study prior to sending materials to each site.

2.2. IRB Approvals. This study was approved through expedited review by the University of Texas Health Science Center at San Antonio (UTHSCSA) Institutional Review Board (IRB) with verbal consent. Using materials from the initial approval as a template, the ISRN Coordinating Center developed a standardized protocol, IRB application, consent form, and other IRB materials for each site to facilitate IRB applications. These documents were sent along with the PIK to each site principal investigator for use in preparation of local IRB submissions. Each site was also requested to ask their local IRB to sign an investigator agreement to allow the UTHSCSA IRB and its Federalwide Assurance (FWA) to have oversight of the research site to speed up the implementation of the STAR-2 study. The ISRN Coordinating Center assisted each site PI in preparing for IRB submission and addressing any queries their IRB may have. If modifications to the protocol or consent form were required, standard operating procedures at the Coordinating Center stipulate that changes be implemented for the individual site only and not implemented at the other sites. Upon receiving local IRB approval, the site PI was asked to provide the ISRN Coordinating Center with the IRB approval letter prior to initiating study related procedures. Figure 1 depicts the schematic for IRB approval process for the ISRN.

2.3. Data Collection on IRB Variation. Using the IRB application, correspondence, and approval letters as data, we identified the level of review conducted (exempt, expedited, or full board) and noted any changes that were made in the final approved documents relative to the standardized protocol and consent form. We calculated time to submission from the date the materials were received by the hospital to the date the IRB submission was made, time to approval from the date of IRB submission to IRB approval, and time to study start from the date IRB approval was recieved to the date the study began.

2.4. Analysis. An ad hoc review of IRB application materials and correspondences was conducted. Where materials were unclear, the coordinating center contacted the site PI and/or local IRB for clarification. Statistical analysis is descriptive and presented as mean ± standard deviation.

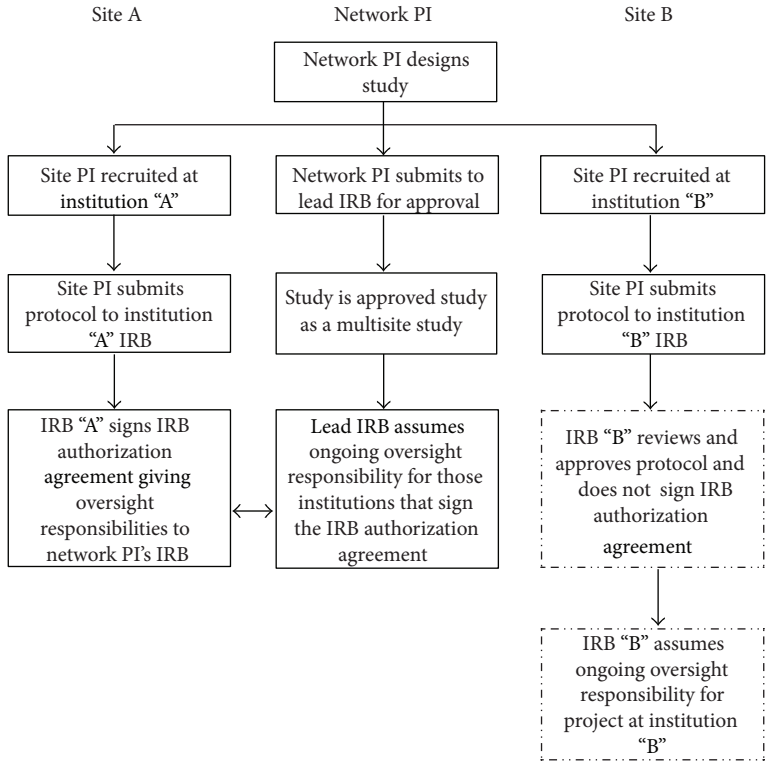

Figure 1: Overview of the multi-site research approval process.

3. Results

3.1. Type of Review. Each of the 14 sites received IRB approval from their IRB of record without revisions to the protocol, consent form, or resubmissions. All but one of the study sites conducted an independent review of the standardized protocol. The IRB of the study site that did not pursue independent review accepted the UTHSCSA IRB approval and signed an investigator agreement to fall under the UTHSCSA FWA. Of the fourteen hospitals that were engaged in this study, 4 used IRBs affiliated with local universities while the remaining 10 used IRBs located within their hospital or hospital system.

Twelve of the 14 (86%) study sites obtained IRB approval through an expedited process, with the remaining two study sites having the study go to full board review. Each of the expedited approvals were approved under 45 CRF 46.110(b)(1) category 7 [6]. Two of the sites that underwent expedited review had concerns about the database security. Standard procedures and accessibility guidelines were provided to these IRBs by the ISRN Coordinating Center and the study was ultimately approved. Twelve of the 14 IRBs required that consent be documented in the form of a consent form while 2 hospitals only required verbal consent. Table 1 describes the type of IRB used, type of review conducted, and whether documented consent was required.

3.2. Approval Timelines. The STAR-2 multisite study was implemented in three waves with two study sites in wave 1 and 6 study sites each in waves 2 and 3, respectively. Study materials were sent to all study sites on the same calendar date regardless of the study start date and study sites were asked to complete the IRB process as soon as possible to prevent delays in study startup. Table 2 provides data on the approval timelines for time to submission, time to approval, and time to study start. On average, the 14 study sites submitted the project to their IRB 45.1 ± 31.8 days after receiving the study related documents, received approval 14.3 ± 5.7 days after submission, and started the study 29.9 ± 10.1 days after receiving IRB approval. There was no significant difference in approval times between academic-based IRBs and hospital-based IRBs.

4. Discussion

The purpose of this paper was to document variation in IRB review in the implementation of the STAR-2 multisite study conducted and coordinated by the ISRN. With 14 study site IRBs engaged in this study plus the UTHSCSA IRB of the ISRN Coordinating Center, there is a possibility that variations in review processes and time to approval would directly impact the study timeline. However, based on the results of this report, there were many similarities between IRBs with regard to the level of review and time to approval. We attribute this to the nature of the STAR-2 study and provision of the PIKs provided to each site PI to facilitate the submission of their IRB applications. Furthermore, support and interactions from the ISRN Coordinating Center along with the Network PIs (Stevens and Ferrer) assisted in guiding the site PIs in the IRB process and working with individual

Table 1: IRB Review type and requirement for documented consent.

Wave	Hospital	IRB type	Review type	Documented consent
1	A	Academic	Expedited	No
1	B	Academic	Expedited	Yes
2	C	Hospital	Expedited	Yes
2	D	Academic	Expedited	Yes
2	E	Hospital	Full Board	Yes
2	F	Hospital	Expedited	Yes
2	G	Hospital	Expedited	No
2	H	Hospital	Expedited	Yes
3	I	Hospital	Expedited	Yes
3	J	Hospital	Full Board	Yes
3	L	Hospital	Expedited	Yes
3	K	Hospital	Expedited	Yes
3	M	Academic	Expedited	Yes
3	N	Hospital	Expedited	Yes

Table 2: Study start-up times (in business days).

	Days to submission	Days to approval	Days to study start
All hospitals	45.1 ± 31.8	14 ± 5.7	29.9 ± 10.1
Academic IRB	24.0 ± 22.0	16.3 ± 10.6	22.75 ± 10.2
Hospital-based IRB	54.1 ± 32.2	13.7 ± 2.8	32.7 ± 9.1

IRB process and addressing questions regarding IRB issues. Each PIK consisted of templates for IRB applications, consent forms, data collection tools, recruitment and marketing materials, and information to be presented to hospital executives to gain buy-in. These templates were based on the initial submission made by the ISRN Coordinating Center to the UTHSCSA IRB. By providing an IRB template, the site PIs and research associates simply had to modify certain components of the application specific to their IRB and were able to submit the IRB application as soon as 2 days after receiving the PIK.

The largest variance in the study timeline was seen between the three waves of the study. As indicated in Section 2, the STAR-2 study was implemented through three separate waves to allow for adequate oversight and assistance by the ISRN Coordinating Center. Two hospitals participated in the first wave, 6 in wave two, and the final 6 in wave three. Two of the hospitals (hospital H and hospital N) had to adjust their start-up time based on competing demands and arising priorities (e.g., local credentialing visits by Joint Commission and various other organizations). This accounted for the delays in their time to submission. However, once submitted, these two hospitals received IRB approval and started the study within one standard deviation of the average approval time. Eliminating these two sites as outliers, average time to submission was 33 days.

Looking at each of the academic IRBs individually, there was variation in the IRB's composition and structure. Hospital A's IRB of record chose to sign an investigator agreement falling under the regulatory oversight to the UTHSCSA IRB. Hospital B's IRB of record was a part of the faculty senate consisting of an IRB chair, 7 scientific reviewers, and one public reviewer. Hospital D and hospital M's IRB of record come from large universities with standing administrative review processes in place, including expedited/exempt review panels specific for each of the major schools in the program. Hospital M's IRB goes as far as having an online checklist to determine if the research projects require IRB approval. To facilitate a quick approval from each of the study sites at the onset of the STAR-2 study, each site was encouraged to sign investigator agreements to fall under the federalwide assurance of the parent IRB at the UTHSCSA. Though strongly encouraged, this agreement was done only by one hospital that participated in this study. The extremely low number of investigator agreements perhaps is due to oversight pressures felt by local IRBs to govern and regulate studies conducted at their respective institutions and an increase in regulatory actions [19]. In a multisite research study for the ISRN, the site PI is considered a partner on the investigative team and given the rights and responsibilities directed by DHHS.

The level of review conducted and the time for this review by the local IRB were a concern for the ISRN Coordinating Center going into the implementation of this study. For example, if all 14 study site IRBs conducted full board reviews of the project, the study timeline for the entire project would be greatly affected and potentially delay study start up at these hospitals. More specifically, engaging employees of the hospital brings into account sensitivities in job performance and job security; however, because the focus of the study is centered on operational processes and system failures, review boards considered this minimal risk to the study participant as indicated by the number of expedited approvals. Additionally, the structure and process of documenting operational failures and system context were done so in an anonymous fashion, ensuring confidentiality for the protection of participants against risk and harm.

An important consideration made by the review boards was the role supervisors would play in consenting staff they oversaw. The ISRN and the site PIs collaborated on ways to reduce undue influence by supervisors during the consent process. Working with the site PIs and their local IRB, a decision was made requiring supervisors not be involved in the consenting process. If consenting was to be done during a regular staff meeting, then the supervisor was asked to step out of the meeting. If the consenting was to be done individually, as time permitted, then research staff would be the ones consenting study participants. This was explicitly written into the protocol implementation kit as well as discussed in detail during the protocol training/study initiation meeting.

There are several limitations to this study. First, this is a descriptive study of 14 hospital IRBs evaluating one study and thus the results of this study may not be generalizable. Secondly, this report presents data based on a single QI study and may not represent how these IRBs would review other

types of projects (i.e., drug trials involving patients, observational studies involving staff and patients, etc.). Though limitations to this study exist, this report presents important review of how 14 IRBs review a single study. Furthermore, the multisite study presented in this report was a minimal risk study of nurses self-reporting system operational failures with no interactions with patients. However, the operational failures have direct impact to patient safety and patient care. Therefore, no matter the level of risk involved in improvement science studies, there is a direct impact to patient safety and any delay in approving improvement science studies because of variance in IRB review directly impacts patient care.

In summary, steps and strategies implemented by the ISRN are believed to have helped each of the 14 study sites in successfully achieving timely IRB approvals. Using template IRB documents provided by the Network, each site was given responses to each question on the IRB application reducing the turnaround time for submission. Furthermore, each PIK sent to the site PI included a sample consent form and HIPAA document which eliminated the need for the site PI to develop consent forms of their own, greatly reducing the burden on the site PIs. By providing these templates and documents through the study PIK, each site PI simply needed to transcribe the provided information into their site specific IRB application forms. As indicated earlier, each of the documents in the PIK were reviewed by the UTHSCSA IRB. It can be concluded that providing these previously approved documents as templates, site-specific IRB reviews were able to be completed in a shorter amount of time, resulting in quicker study startup.

5. Conclusion

Improvement initiatives have increased dramatically since the IOM report, "To err is human: building a safer health system," was published [20]. Implementation of improvement research is continuously evolving with new methodologies, new topics of study, and expansion from single site to multisite research. This progress will raise the scientific rigor of these improvement initiatives and will facilitate spread and uptake of effective improvement strategies. Furthermore, with this evolution, challenges have arisen for regulatory agencies, IRBs, and researchers to keep up to date on the interpretation of the regulatory guidances as part of the improvement research initiative. In this report of the ISRN's STAR-2 study, IRB review was conducted in a seemingly streamlined and timely way. However, multiple publications have documented variations of IRB review for research networks, similar to the ISRN, engaged in multisite improvement projects [4, 11–13]. Solutions must be found to facilitate timely and accurate approvals as not to delay the innovation that comes out of quality improvement research. Continued dialogue between improvement researchers and review board chairs is needed for this to happen. By working with a national organization such as the ISRN and the resources it provides, variations in IRB approvals can be limited as evident by the results of this study. However, continued investigation on methods to streamline the implementation of improvement research is warranted.

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Research Article

From Intervention to Innovation: Applying a Formal Implementation Strategy in Community Primary Care

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Objective. To describe a comprehensive strategy for implementing an effective diabetes self-management support intervention incorporating goal-setting and followup support in community health clinics (CHCs) serving vulnerable patients. *Methods*. The Replicating Effective Programs (REP) framework was applied to develop an intervention strategy. In order to create a strategy consistent with the REP framework, four CHCs engaged in an iterative process involving key-informant interviews with clinic staff, ongoing involvement of clinic staff facilitating translational efforts, feedback from national experts, and an instructional designer. *Results*. Moving through the REP process resulted in an implementation strategy that aims to facilitate commitment, communication, and change at the clinic level, as well as means of providing interactive, time-limited education about patient behavior change and support to health care providers. *Conclusion*. The REP offered a useful framework for providing guidance toward the development of a strategy to implement a diabetes self-management intervention in CHCs serving medically underserved and underrepresented patient populations.

1. Introduction

Effective patient self-management has been demonstrated to prevent adverse clinical outcomes from diabetes [1, 2]. While research has examined factors that influence patient receptivity and use of self-management skills, there has been less attention to the delivery of diabetes education and support in primary care settings, where most patients receive this counseling [3–5]. In fact, the quality of diabetes self-management support delivered in primary care falls short of that demonstrated to improve outcomes. Delivering even basic diabetes education is challenging to busy primary health clinics, much less providing ongoing support which addresses the many factors influencing patients' ability to make significant lifestyle changes and integrate complex tasks into their daily lives such as problem-solving, collaboration, psychosocial issues, and behavior change skills [3, 4, 6].

Collaborative goal-setting between health care providers and patients has been proposed as a strategy for providing diabetes-related self-management support in busy primary care settings [7, 8]. Because research suggests that goal-setting increases patients' self-efficacy and motivation to continue developing and maintaining self-management behaviors [9–11], goal-setting is now a common strategy in the more comprehensive Diabetes Self-Management Education curricula reimbursed by the Centers for Medicare and Medicaid Services [6, 12, 13], is an element of quality improvement efforts in primary care, and has been proposed as a measure of clinical quality [14]. However, goal-setting and followup support activities are seldom reported in primary care [8, 15], suggesting that finding cost-effective, feasible means of addressing gaps in goal-setting and followup "indicate [sic] an important area for quality improvement and diabetes self-management research" [15, page 2660].

Table 1: Parties involved in development process.

Professional role	Study role	Those involved
University-Based Research Team	Study facilitation, data collection, and analysis	1 PhD RN 1 DNP 1 Medical Anthropologist 1 DrPH
Clinic-Based Research Coordinators	Study facilitation, ongoing input regarding implementation package	1 MD 1 RN 2 Health Educators
Clinic Staff Members	In-depth interview data regarding diabetes counseling in context of CHCs	2 ARNPS 1 PA 1 PharmD 1 RD 1 MPH-Quality Director
National Experts	Feedback on developing implementation package and revisions	2 MDs 1 ARNP 1 Health Services Researcher
Instructional Designer	Iterative development of training materials and process	1 MLS—University Technology Staff Member

The relative effectiveness of various delivery models for delivering diabetes self-management support (e.g., group education and individual counseling) [16–19] suggests that any number of strategies for delivering diabetes-related goal-setting and followup may be successfully tailored to the resources of individual primary care settings. However, research from implementation science suggests that numerous factors varying between individuals and organizations influence clinicians'/organizations' decisions to adopt and implement clinical interventions. These include a number of characteristics of the intervention itself such as the legitimacy of the intervention source, strength and quality of the evidence, relative advantage versus alternative solutions, adaptability, trialability, complexity, design quality and packaging, and costs [20]. Because of this, it has been argued that the gap between generation of effective interventions and widespread, sustained use in clinical practice can be addressed by strategies that consider how interventions themselves can be adapted to meet the needs of patient populations, structures, personnel, and financial incentives of individual clinic sites while also maintaining the fidelity, or consistent delivery of components necessary for an intervention to be effective [21, 22].

Since little is known about how best to integrate diabetes-related self-management support into the routine diabetes care provided in community (versus academic) health clinics, much less those serving vulnerable (underserved and underrepresented) populations, this study tested the usefulness of the Replicating Effective Programs (REP) framework to develop a strategy for improving diabetes self-management support, particularly goal-setting and followup support, delivered to vulnerable patient populations in community primary care settings.

2. Methods

This study capitalized on academic-community-based partnerships between the Iowa Center for Clinical and Translational Science, The Iowa Primary Care Association (IPCA), and four geographically diverse federally qualified community health clinics (CHCs) located across the state of Iowa. In response to preliminary survey results documenting the need for simple strategies for providing diabetes-related self-management support in the four CHCs, the development team, which consisted of a university-based research team and four clinic staff members acting as research coordinators in each of the CHCs, engaged in a participatory process in order to develop a strategy for incorporating goal-setting and followup support in community primary care settings serving vulnerable patient populations. The process involved continuous discourse within the development team, in-depth interviews with six clinic staff members working in two of the CHCs, feedback from local stakeholders and national experts, and development of materials with an instructional design professional (Table 1). The study was approved by the Community-Based Research Institutional Review Board of The University of Iowa.

2.1. Study Framework. The Replicating Effective Programs (REP) model, developed in 1996 by the Centers for Disease Control and Prevention (CDC) to implement HIV-AIDS behavioral and treatment programs in community-based settings, is an empirical framework combining strategies to maximize both intervention fidelity, or consistent delivery of components necessary for an intervention to be effective, and flexibility, or the ability for individual settings to adapt the intervention to their needs [21]. The REP strategy has been successfully applied to other implementation efforts including violence, substance abuse, and delinquency prevention programs as well as packaging interventions for depression care [23], suggesting its applicability beyond its initial targeted prevention efforts. Because the goal of the REP framework is to ensure successful adaptation and implementation of interventions into nonacademic, community-based settings, we believed it was particularly well-suited for

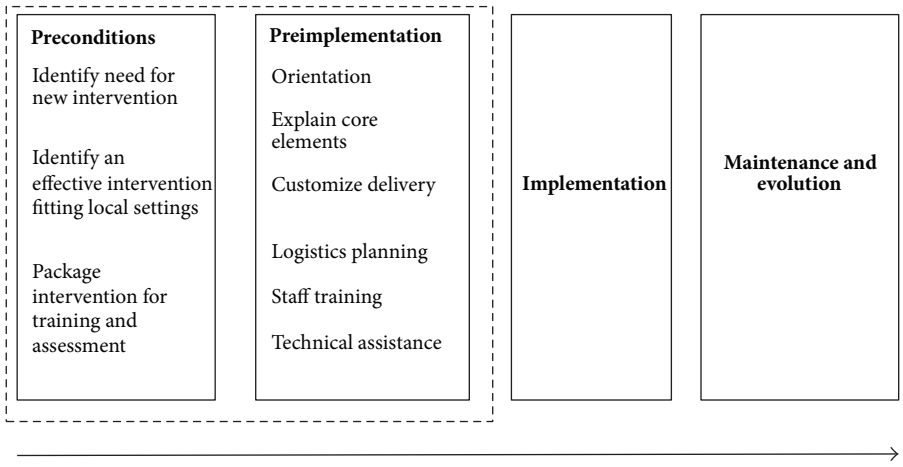

Figure 1: REP framework as used to plan for diabetes self-management support.

efforts aiming to implement diabetes-related goal-setting and followup support in CHCs.

The REP model describes four key phases for researchers to consider while attempting to implement a program in nonacademic community settings: preconditions, preimplementation, implementation, and maintenance and evolution. Satisfying preconditions entails establishing the need for an intervention, identifying an intervention that addresses the needs of settings (e.g., clinics) as well as the targeted population (e.g., patients), and identifying barriers to implementation. After the needs of the setting and population have been identified, the REP model suggests implementers develop a strategy to assist sites as they attempt to use the intervention including (1) clear identification of the intervention's core elements (or factors that should not be changed in order for it to be effective) as well as elements that may help appropriately tailor the intervention to the context of individual sites (e.g., the skill sets of available staff and technological resources) and (2) an implementation package that, in everyday language, provides concrete information and resources to clinic sites about how to implement the intervention (e.g., setup procedures, underlying theory, and scripts). The next phase, preimplementation, begins with soliciting input from a community working group about the implementation strategy, which should also include training and technical assistance for clinic sites. The implementation strategy is then tested for clarity and functionality. Based on the feedback of the community working group and experiences of the preliminary test, the implementation strategy is refined and finalized for full implementation (Figure 1). This study focused on satisfying the preconditions and preimplementation phases of the REP in order to develop a strategy for implementing diabetes self-management support focused on providing goal setting and followup support, in primary care settings serving vulnerable populations.

3. Results

During the fall of 2010, researchers at The University of Iowa partnered with clinicians serving as research coordinators in each of the four clinics (one physician, one nurse, and two health educators) to begin planning for an intervention to address the needs related to diabetes self-management support in the CHCs. Guided by the REP framework, this process involved weekly telephone calls and development of a research study incorporating (1) the recruitment of clinic staff to participate in key-informant interviews focusing on identifying specific needs and barriers related to diabetes-related self-management support, including goal setting and follow-up, in the clinic settings; (2) the drafting of a strategy, responsive to the needs of clinicians and staff, to overcome barriers to diabetes-related self-management support; (3) the solicitation of input from national content experts related to the implementation strategy; (4) the refinement of the strategy with the assistance of an instructional design professional.

3.1. Satisfying Preconditions: Data Gathering and Planning

3.1.1. Identify Need for New Intervention. In 2006, The University of Iowa researchers partnered with the Iowa Primary Care Association (IPCA) and CHCs across the state to identify needs that might be addressed through academic-clinic research partnerships. Among the topics identified as problematic by primary care leadership was the quality of care being provided to patients with diabetes. To further assess this issue, quality improvement surveys were distributed to both patients and health care providers and revealed a high level of diabetes burden in these clinics, variability in the nature of diabetes-related self-management support provided by clinicians, and a lack of self-management support perceived by patients. Results of these surveys, as well as input from the IPCA, clinic leadership, and research coordinators, suggested that the four CHCs would be well-served by an intervention aiming to improve the consistency and quality of diabetes self-management support given to patients.

3.1.2. Identify an Effective Intervention Fitting Local Settings. Informed with the aforementioned survey results,

the university-based research team examined interventions aiming to facilitate diabetes self-management support in primary care settings. Because of its reliance on a simple strategy for establishing goal-setting and followup support, the university-based research team believed that the previously developed *Living with Diabetes* patient materials [24] and associated intervention [25, 26] would fit the needs of the four clinic settings. The Living with Diabetes (LWD) intervention consisted of low literacy patient materials coupled with a goal-setting session and two followup calls by research assistants. Both the guide and intervention were developed through a participatory process with diabetes patients and providers and were seen as responsive to the need for a simple, adaptable strategy for use in primary care. Because the materials were developed with vulnerable patient populations and focused on providing information to those with limited literacy skills in both English and Spanish, the intervention appeared well-suited for use in CHCs. An evaluation of LWD showed that the intervention resulted in successful development of goals by patients, increased self-efficacy, self-care behaviors, diabetes-related knowledge, and reductions in diabetes-related distress [25, 26]. Because the intervention involved approximately 10 minutes of patient contact per session and sessions were successfully conducted by nonclinician research associates, the research team believed it might be readily adapted to the needs of different CHC settings. The patient materials and associated information is available through the American College of Physicians Foundation (see http://www.acpfoundation.org/materials-and-guides/patient-guides/guide-products/living-with-diabetes.html).

In order to ensure that the objective of the LWD intervention met the needs of the CHCs, the university-based research team presented the intervention and associated materials to the clinic research coordinators, CHC medical directors, and IPCA medical director and staff. This process was accomplished through in-person, telephone, and email conversations as well as during in-person presentations during which the tenets of the intervention and potential logistics were discussed. The research coordinators and IPCA representatives responded enthusiastically to the potential intervention, believing it would help address the needs of their colleagues and provide a good resource for both English and Spanish speaking patients.

3.1.3. Package Intervention for Training and Assessment. Between April and May 2011, six in-depth interviews were conducted with clinic staff members (2 ARNPS, 1 PA, 1 PharmD, 1 RD, and 1 MPH-Quality Director) to begin developing a strategy for implementing the LWD and in the four participating CHCs. During these hour-long interviews, participants were asked about their practice and that of their colleagues related to diabetes self-management education, including the barriers and facilitators, materials and methods they use, and their feelings about the approach of the *Living with Diabetes* guide and goal-setting strategy [24]. These interviews suggested (1) that clinicians do not use particular behavioral counseling strategies to facilitate goal-setting, (2) a belief that successfully communicating the nature of diabetes and its risks to patients is sufficient for patients to make behavior changes, and (3) that goal-setting has been a priority in the past but has not been maintained due to support staff turnover or completing duties for support staff assigned with the task. When asked about means of implementing the counseling into their practice settings, participants liked the idea of goal-setting but strongly believed that primary care providers had to play a major role in establishing and following up on patient goals rather than handing off responsibility for doing so to support staff. They all reported that the clinics were in the midst of implementing use of electronic health records (EHRs), so that incorporating goal-setting might be seen as an overwhelming task by their colleagues. However, they also reported that, unlike paper-based systems that were not sustainable, EHRs could help facilitate tracking of patient goals and follow-up. Finally, related to the training of healthcare providers in the use of the proposed LWD intervention, participants reported that the training would have to be engaging, time-limited, and presented in a way that would facilitate commitment. Participants believed that the use of goal-setting in the past was met with variable enthusiasm and foresaw that making it clear that the intervention addressed their challenges rather than adding to them would be helpful in getting providers to participate. They reported that previous interventions were influenced by those charged with implementation and believed having an esteemed colleague presenting the intervention during a group meeting of primary care providers would be most effective at winning support.

Following the REP framework and based on the key informant interview findings, the opinions of the academic and community-based research team (i.e., the development team) and expert opinion (e.g., nationally recognized diabetes education, practice change, and implementation experts), an implementation package was created for community sites. The development of this package is described in the following section.

3.2. Satisfying Preimplementation: Drafting the Implementation Package. The REP preimplementation activities include orienting settings to the intervention, explaining core elements, customizing delivery, logistics planning, staff training, and ongoing technical assistance. The core research team decided to incorporate these activities into a participatory process of developing the implementation package. The implementation package includes content to be used by a program champion—a clinician-colleague charged with the role of facilitating use of the intervention—and training materials to be used by clinicians and support staff engaged in diabetes care. The content also includes setup procedure, underlying theory and logic flow, scripts, and options for adapting the delivery of intervention core elements to local organizations in a way that does not compromise core elements, or means of ensuring intervention fidelity. Because of the desire to develop a package appropriate for larger scale dissemination efforts and because clinicians communicated the need for time limited and interactive elements, the university-based

Table 2: Elements of implementation package.

Content	Audience	Format	Purpose
Materials with clear, evidence-based steps for implementing the *Living with Diabetes* intervention	Clinical Leader, or "Program Champion"	Web-based instruction, planning checklist	Assist program champion with change process
Introduction to the *Living with Diabetes* intervention, including purpose, counseling steps, and patient materials	Clinicians and staff involved in both direct and indirect diabetes care	Web-based videos and instruction to be shared to colleagues by clinical leader during a group meeting	Facilitate buy-in
Training regarding the use of the *Living with Diabetes* intervention	Clinicians and support staff	Interactive web-based instruction	Build counseling skills in an engaging, time-limited format
Patient instruction regarding diabetes self-management	Patients with diabetes	Hardcopy of *Living with Diabetes* patient education booklet	Reinforce messages given during clinical visits in a way that is accessible to diabetes patients with limited literacy
Means of contacting the *Living with Diabetes* research team	Program Champions	Routine prompting via email, collection of lessons learned	Provide ongoing support and troubleshooting by content experts

research team (after confirming the availability of the technological capacity in the CHCs) embarked on a process of organizing, tailoring, and developing content that is primarily web-based, including informative videos, checklists, interactive tutorials, and means of facilitating ongoing contact and support by the university-based researchers (Table 2).

3.2.1. Orientation. The first element to be addressed by the implementation package is to orient sites to the tenets of the intervention. A number of means of accomplishing this task were discussed. However, because clinic staff members reported a need to facilitate commitment through a group presentation, the university-based research team decided to develop a voiceover presentation which highlighted (1) that the intervention was developed by an interdisciplinary team of clinician-researchers to address the frustrations of clinicians and patients around diabetes management; (2) the basic tenets of the intervention; (3) how it might be adapted to different clinic resources. Because clinician interviews communicated the potential of clinic sites to feel overwhelmed by changes introduced by the introduction of EHRs, the development team felt it particularly important to incorporate content strongly communicating that the intent of the intervention is to *assist* clinicians in their practice, particularly with their quality improvement efforts, rather than simply providing one more thing to do. The resulting product is a hybrid video-slide show introduction that is intended to be used by program champions during a group presentation to their colleagues. In addition, content about how to resolve possible technical difficulties that could be encountered when attempting to screen the presentation is included in the program champion materials.

3.2.2. Explain Core Elements. The second element to be addressed by the implementation package is to provide an explanation of the intervention's core elements, or those key to its effectiveness. Although the LWD intervention was intended to be adapted to the needs of individual settings, the research team concluded that its core elements included (1) an initial in-person goal-setting session for which the hardcopy *Living with Diabetes* guide reinforces and provides information for patients to take home and (2) two followup support sessions. Followup support may be provided in-person or *via* telephone [25–27].

Because clinic staff members believed that supporting education and counseling by primary care providers was a key barrier to overcome but felt strongly that diabetes self-management support is most meaningful to patients if delivered by primary care providers and reinforced by other members of the health care team, the team focused on developing intervention trainings targeting primary care clinicians. However, the team also kept a broader audience in mind to facilitate use by other staff members should the clinic believe that others (e.g., nurses and health educators) should be involved with the patient goal-setting and followup process. The result is a module called Guiding Principles that is used to begin (and is used as a reference during) interactive trainings instructing those involved in diabetes care in how to engage patients in goal-setting and in the use of the hardcopy *Living with Diabetes* patient booklet.

3.2.3. Customize Delivery. According to the REP process, customizing delivery of an intervention involves tailoring it to the needs of specific patient populations and clinic settings. Because the LWD materials and goal-setting process were developed and tested in academic settings serving vulnerable patient populations, both the academic research team and clinic-based coordinators felt it was well suited for both English-and Spanish-speaking patients served by the CHCs. Further, because the goal-setting process is meant to facilitate the creation of personal goals with the help of care providers, the team felt the intervention was responsive to patients' desire for interventions customized to their personal needs as well as to the needs of primary care clinicians who have

communicated a high level of frustration with behavior change counseling [24, 27] but—as reported by the clinic staff members during interviews—are without a formal strategy with which to engage and support patients.

3.2.4. Logistics Planning. A key element of the REP process is attempting to maintain an intervention's effectiveness upon dissemination to a new setting by preserving key elements of its success while allowing for adaptation to the context (e.g., staff, resources, competing priorities, and patient population) of specific clinic settings. Therefore, content in how the LWD intervention might be adapted to CHC settings in a way that maintains elements key to its effectiveness was developed for those taking on the role of program champion. The content includes (1) how an initial goal-setting session might be conducted and (2) how followup contact by primary care provider and/or clinic support staff might be accomplished during routine care for patients with diabetes. However, after feedback of national experts and stakeholders, the university-based research team recognized that the logistics of implementing the intervention also involves the fine art of facilitating organizational change. Therefore, the team sought additional resources to support program champions in the complex task of planning and implementing the intervention within their clinic settings.

Because of its public availability and comprehensive steps for program champions to consider when implementing an intervention in a new setting, the university-based research team decided to adapt the implementation tools put forth by the TeamStepps program, which is a collective effort between the Agency of Healthcare Research and Quality and the Department of Defense to improve patient safety (see http://teamstepps.ahrq.gov/about-2cl_3.htm). The TeamStepps materials outline steps for planning and implementing a patient safety program, including sections on conducting a needs assessment, planning, training, and implementing. Details regarding planning for change, gaining leadership commitment, communicating a plan, final preparation, training, and implementation were believed most germane to this phase of the REP framework and to implementing the LWP in the CHCs. Details for each of these steps were made specific for the goal-setting intervention and patient materials and described in (1) an in-depth online presentation and (2) a checklist, both of which are intended for program champions.

Program Champion Checklist:

(1) Plan for Change

Completion Date

(i) Map current information, processes, and available resources for diabetes self-management support in your clinic.

(ii) Identify methods of tracking patient goals in your clinic.

(a) In an EMR, other tracking systems and/or.

(b) Designating one person to followup on patient goals.

(iii) Identify teamwork deficiencies around diabetes self-management support.

(a) Are there additional support needs related to functioning as a team?

(b) Are there areas where *communication* between team members needs to improve before patients' behavioral goals can be tracked?

(iv) Define the goal of your intervention as Program Champion.

(a) State in one sentence what will be achieved, who will be involved (whose behavior will change), and when and where the change will occur.

(b) *For example*, all primary care clinicians will begin using the Living with Diabetes counseling strategy and materials with diabetes patients, and tracking behavioral goals in a new EMR field, beginning on February 1st.

(v) Identify a team goal related to the using the Living with Diabetes Program.

(a) Some examples of process goals.

(a.1) 80% of patients with diabetes have a behavioral goal .

(a.2) Of patients who have received the materials, 75% have received a phone call within 1 month about the goal.

(a.3) 90% of patients with diabetes given the materials.

(a.4) Action plans/goals set and/or progress recorded for 75% of diabetes patients seen during March.

(b) Some examples of clinical outcome goals.

(b.1) Reduction in A1Cs.

(b.2) Improvements in patient satisfaction.

(vi) Develop an implementation plan.

(a) Identify what groups will be invited to do the online clinician training.

(b) When and how will the program be introduced to the clinic (i.e., during a group meeting)?

(c) Determine how long clinicians and staff will be given to complete training and, after they are introduced to the training, when the patient materials can start being used?

(2) Gain Leadership Commitment

Completion Date

(i) Inform leaders of all facets of the plan.

(a) How will clinical processes be used to implement the Living with Diabetes counseling strategy?

(b) How will patient's goals be tracked?

(c) How the Living with Diabetes Program be introduced to the clinic?

(c.1) Who will be involved?

(c.2) How they will be trained?

(3) Communicate the Plan

Completion Date

(i) Communicate the goals of the Living with Diabetes Program during a group Meeting.

(a) Make use of the online introduction provided by the research team.

(ii) Present the detailed plan for using the Living with Diabetes Program.

(a) Describe the detailed plan for using the patient materials during routine care, including concrete details of.

(a.1) Where the materials will be located.

(a.2) Who is involved.

(a.3) What EMR fields (if any) are used for tracking patient's action plans.

(b) Details of the online training modules outlining how to use the materials and set behavioral goals with patients.

(b.1) Make use of the interactive tutorial.

(c) Communicate a start date.

(iii) Supply the following.

(a) Hardcopies of the patient materials.

(b) Concrete examples of what needs to be done to track goals.

(b.1) *For example*, if using clinical information systems, screen shots of new fields added or how to use existing fields are extremely helpful.

(iv) Clearly identify where colleagues should go if they are having difficulty using the online training, patient materials, or tracking patient action plans.

(v) Elicit any final feedback.

(4) Final Preparation

Completion Date. Based on any additional input, refine the implementation plan regarding use of the patient materials, counseling strategy, followup of patient action plans, and training

(5) Training

Completion Date

(i) Send email invitations to targeted clinicians and staff directing them to the online training, including a reminder of.

(a) Where materials are located.

(b) How goals are tracked.

(c) Concrete deadlines for completing the training.

(6) Implementation

Completion Date. Begin using the Living with Diabetes patient materials and tracking action plans!

3.2.5. Staff Training. The next step in the implementation package as suggested by the REP framework is the development of the staff training or, in this case, the training of clinicians and associated staff in how to couple the *Living with Diabetes* patient guide with a goal-setting process with patients. Based on the need for short, relevant, and engaging trainings to fit into a hectic workday, the instructional designer developed an interactive, web-based tutorial based on the clinical experiences of (1) the clinician-researchers who developed the *Living with Diabetes* materials and intervention; (2) the research assistants who conducted the original intervention study using the *Living with Diabetes* patient guide [26]; (3) the research coordinators working in the CHC sites. The module, which is also informed by the intrinsic motivation model advanced by Malone and Lepper [28], interactively demonstrates how to work with low-literacy patients, common barriers to a successful goal-setting session (e.g., patients setting behavior change goals that are too large to fit into their lifestyle), and challenges clinician assumptions by using informal assessment techniques (e.g., feedback for incorrect choices). Through this simulation, clinicians practice preferred intervention strategies and, more importantly, work past common barriers to support behavior change in patients. The interactive tutorial also simulates a role-playing exercise that could be practiced during an on-site workshop. Moving through the modules takes approximately 20 minutes but, because of its interactive nature, the time required for training is highly variable and can be completed at once or incrementally. The interactivity of the tutorial also enables the development team to track clinician use of training materials and collect feedback from clinicians, with permission from the clinician, to help the team improve the web-based curriculum in future iterations.

3.2.6. Technical Assistance. According to the REP framework, the final step in the preimplementation phase is to develop means of providing ongoing assistance to clinic sites regarding the use of the intervention. This process should be proactive, in which sites are contacted routinely and prompted for questions and concerns. For next steps related to this particular study, during the implementation phase, program champions in the four clinics involved in the development process will be routinely contacted for questions, concerns,

and lessons learned. In broader dissemination efforts, this process could be facilitated by having those who use the online resources disclose their name, contact information, and the dates during which they intend to begin using the intervention. In addition, while not proactive, the web-based resources display the core research team's email contact at all times. All correspondence occurring through this channel will be tracked by the research team, with the goal being a response within 48 hours.

Finally, while not a part of the definition of technical assistance as intended by the REP framework, two additional forms of needed support were identified and content was developed as a result of piloting the program champion and clinician-staff tutorials. This content relates to the possible technical problems that might be encountered while using the online resources and steps to address these should they arise and is readily accessible on the program champion and clinician-staff training websites.

4. Discussion

The REP offered a useful framework for providing guidance toward the development of a strategy to successfully implement a diabetes self-management support intervention incorporating goal-setting and followup support in CHCs. Using the REP to guide the development process called attention to several barriers and facilitators of implementation that may not have otherwise been explicitly addressed. That said, the process of engaging a diverse stakeholder group and soliciting in-depth opinions of clinic staff members not only added detail to the framework, but also uncovered additional areas in need of significant attention, particularly related to facilitating practice changes by program champions.

An example of an area that might not have been emphasized without the REP framework, but one for which additional content was uncovered by the iterative development process, was the need to provide ongoing technical assistance on the web-based technology to clinic sites. According to the REP framework, technical assistance is expert support related to use of the intervention itself. To this end, a great deal of thought was put into prompting the program champions as well as tracking questions and suggestions as we move into the next REP phase of formally implementing the goal-setting and followup support intervention in clinic settings. However, an additional element of technical assistance was uncovered by the development team and stakeholders as they tested the web-based content and, at varying degrees, encountered difficulties using the technology. As a result, content providing instruction to both program champions and those using the tutorial about how to address potential technological issues was developed.

As anticipated, interviews with clinic staff uncovered a number of areas that had to be addressed during training. First and foremost, the training needed to deliver key content in a way that was readily accessible, engaging, and time-limited. However, we were unclear whether this content should target primary care clinicians or support staff. Results of interviews with clinic staff strongly suggested the need to target primary care providers themselves, with support staff taking a secondary role in the goal-setting and followup provided to patients. However, less obvious was the amount of effort that would have to be dedicated to support those who are largely charged with the role of implementing the intervention, or the program champions. While the REP process itself is meant to facilitate commitment from a number of stakeholders, it is less explicit about means of accomplishing this at the clinic level, where the program champion is attempting to influence change. Finding methods of accomplishing the work of an intervention within busy primary care clinics is a primary challenge of any implementation effort, but interviews with clinic staff also supported a growing body of research documenting that gaining the support of those carrying out the intervention is a significant, if not the most significant, element in successfully implementing practice changes [29]. It appeared to the development team that the TeamStepps curriculum, if adapted to the particulars of the intervention, would add adequate structure to the training and support of program champions.

Interviews with clinic staff revealed that any implementation effort in primary care is done in the extremely hectic milieu of busy practice settings. In the case of this intervention, two factors appear to work in favor of the diabetes goal-setting intervention (1) that goal-setting is seen as a measure of clinical quality for a number of payers and accrediting bodies and (2) that, while implementation of electronic medical records is currently burdensome to clinic settings, they will likely provide means of implementing and sustaining goal-setting in the CHCs. However, this speaks to the importance of steps outlined in the preconditions phase of the REP framework that help ensure that a given intervention addresses the needs of a population and that well-informed stakeholders (i.e., clinicians) believe it can be implemented.

There are numerous areas by which the process of developing the implementation strategy might be improved. The development process would have benefitted greatly from additional information regarding how to best support the role of program champion. This might have been accomplished by asking additional questions of the clinic staff members who were interviewed, or by recruiting additional participants who have been charged to making practice changes in the past. While we attempted to address this omission by incorporating and adapting content from the TeamStepps program, which is based on extensive work conducted by AHRQ and the DOD, we are yet unclear whether this element will fully address the needs of the program champions as they attempt to implement this intervention. Those examining the development process will also notice that the voice of patients is absent. While we believed that the formative work conducted during the LWD intervention itself adequately captured the opinions of patients [24], the clinic staff who were interviewed communicated that patients are likely to respond best to primary care providers emphasizing the creation of goals. Because feasibility testing of the original LWD intervention used nonclinician research assistants for the counseling process, it is unclear how patients may respond to primary care clinicians using the intervention materials and process. We will better understand whether (and how) our

efforts successfully support program champions and target the appropriate clinic personnel following the testing of the implementation process.

5. Conclusion

Increasing recognition of the translational gap between efficacious interventions and their widespread adaptation and use in routine clinical practice has led researchers to more systematically examine the contextual and organizational factors likely to influence implementation. In this study, we used the REP framework to guide the development of a strategy to implement a diabetes self-management intervention in community health center primary care settings. Our findings, reported here in relation to the first two REP phases of preconditions and preimplementation, demonstrate the benefit of relying on a structured approach to guide this process. Researchers considering the use of REP or other such frameworks may also consider the need to maintain flexibility as variations in contextual factors will likely influence both the approach and decisions about resource allocation. Lastly, as the evolving field of implementation science matures, it will be important for researchers to report their experiences as a way to further refine both overall protocols and specific strategies to enhance translational efforts.

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Research Article

Dissemination and Implementation Research Funded by the US National Institutes of Health, 2005–2012

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Dissemination and implementation (D&I) research is a growing area of science focused on overcoming the science-practice gap by targeting the distribution of information and adoption of interventions to public health and clinical practice settings. This study examined D&I research projects funded under specific program announcements by the US National Institutes of Health (NIH) from 2005 to 2012. The authors described the projects' D&I strategies, funding by NIH Institute, focus, characteristics of the principal investigators (PIs) and their organizations, and other aspects of study design and setting. Results showed 46 R01s, 6 R03s, and 24 R21s funded totaling $79.2 million. The top funders were the National Cancer Institute and the National Institute of Mental Health, together providing 61% of funding. The majority of PIs were affiliated with Schools of Medicine or large, nonprofit research organizations and think tanks. Only 4% of projects were to PIs with appointments at Schools of Nursing, with 7% of the funding. The most commonly funded projects across all of the studies focused on cancer control and screening, substance abuse prevention and treatment, and mental health services. Typically implemented in community and organizational settings, D&I research provides an excellent opportunity for team science, including nurse scientists and interdisciplinary collaborators.

1. Introduction

The existence of a gap between science and practice is universally recognized. Clinical research findings and clinical practice guidelines that have promise to improve health move very slowly from the research setting into clinical practice, and many of these interventions never reach those who could benefit. It is estimated that it takes an average of 17 years to translate 14% of original research into benefit for patients and an average of 9 years for interventions recommended as evidence-based practices to be fully adopted [1, 2].

Dissemination and implementation (D&I) research is a growing area of science focused on overcoming this science-practice gap. Research on dissemination addresses the targeted distribution or spread of information and interventions to specific public health and clinical practice settings. Implementation science is the study of methods to promote the integration of evidence and change practice patterns and health care policy within real-world public health and clinical service settings [3]. Using the language from models depicting the continuum of translational science from bench to practice and health impact, D&I research is often depicted as "T3" and "T4" science [4, 5].

Although the research enterprise has generated a rich supply of evidence-based interventions, programs, and services, knowledge about how to best disseminate and implement these evidence-based practices has not kept pace. Evidence is needed for how these interventions can be "scaled up," what contextual factors and conditions are pivotal to successful adoption, and how to give added attention to issues of external validity, fidelity, and sustainability. D&I nurse researchers and practitioners are important players in advancing the goals of this science to improve patient and system outcomes [6–8].

Evidence does suggest that passive approaches to dissemination, such as the publication of consensus statements in professional journals, mass mailings, and untargeted presentations to heterogeneous groups, are ineffective strategies

to achieve significant uptake and practice change [9, 10]. Targeted and active dissemination strategies, such as hands-on technical assistance, replication guides, point-of-decision prompts, and training workshops with hands-on experience, are more promising [11]. Implementation strategies have been described as either "top down" or "bottom up" and include a range of approaches, such as stakeholder relationship building and communication, continuous quality management, audit and feedback, service delivery practices and training, and local consensus building [12]. These D&I strategies are often directed at multiple levels and in different combinations of levels, including patient, provider, organizational, and policy. Features of organizations (e.g., hospitals, clinics, workplaces, and schools), such as organizational leadership and climate, managerial relations, and absorptive capacity, are increasingly seen as key intervention targets to facilitate D&I efforts [13].

Although D&I research in health is a relatively young science, advances in both the rigor and ambitiousness of studies over the past decade reflect robust growth in the field [14]. Many conceptual frameworks for guiding D&I research, such as the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) model [15], have been developed and are being tested. Common themes in these frameworks include a heavy emphasis on context, fidelity adaptation and quality of implementation, multilevel targets, and engagement of the target population in partnership research [16]. Research is also focused on developing and validating sound measures important for D&I research, such as measures for key organizational-level constructs [13]. In addition, comparative effectiveness studies of competing active D&I strategies are beginning to appear in the literature, including evaluation of cost [17]. Study designs best suited to answer questions in D&I research are also developing, including a focus on mixed-methods designs and system science approaches [18].

Federal funding for D&I research has traditionally been very small, particularly in relation to the funding available for discovery research. Although the portfolio of D&I research at the National Institutes of Health (NIH) is growing, funding for this science remains extremely small compared with the $30 billion each year that the NIH spends on basic and efficacy research [19]. In 2005, a trans-NIH committee (including the National Institute of Nursing Research [NINR]) issued the first of a set of multi-institute program announcements to stimulate research in this area. These program announcements have been continuously reissued over the past 8 years and include the Research Project Grant (R01) and Small Grant (R03 and R21) mechanisms. The purpose of this funding opportunity is to support innovative approaches to identifying, understanding, and overcoming barriers to the adaptation, adoption, and integration of evidence-based interventions and guidelines that previous research has shown to be efficacious and effective, but where uptake to date has been limited or significantly delayed [20].

A total of 76 D&I research projects have been funded by the NIH through these multi-institute program announcements from 2005 to 2012. Research findings from some of these NIH-funded projects have been presented at the NIH Annual Conference on the Science of Dissemination and Implementation and published in the literature. However, no summary of these funded projects examining the body of work in this research portfolio is available.

The purpose of this study was to examine the D&I research projects funded through these program announcements from 2005 to 2012 in terms of describing what has been funded by which NIH Institutes, the dollars invested, characteristics of the principal investigators (PIs) and their organizations, and an assessment of the focus of these projects, the D&I strategies employed, and other aspects of study design and setting. Although the studies funded through these Program Announcements Reviewed (PARs) do not include all the possible D&I-related research projects funded by NIH over this period, this study was confined to these projects because they represent outcomes of a sustained, multi-institute initiative to stimulate development of D&I science. This paper presents a description of these funded projects and suggests opportunities for nurse scientists in D&I research.

2. Methods

To accomplish the aims of this study, the abstracts from all projects funded by the NIH under the multi-institute "Dissemination and Implementation Research in Health" (PAR-06-039, PAR-06-520, PAR-06-521, PAR-07-086, PAR-10-038, PAR-10-039, and PAR-10-040) were accessed through the NIH Research Portfolio Online Reporting Tools (RePORT) [21]. Projects funded under an earlier program announcement specific to mental health (PAR-02-131, "Dissemination and Implementation Research in Mental Health") were excluded from this review. The paper process is outlined in Figure 1.

The narrative abstracts for all 76 projects were independently examined by two reviewers to extract information on the following areas: funding institute, award amount, project topic, and characteristics of the PI and awardee organization. The 46 R01 projects were further independently examined by 3 reviewers for conceptual frameworks, D&I strategies, level of measurement, and study design and setting. In cases of discrepancies in recorded findings, an iterative process of abstract review was used until 100% agreement among the reviewers was reached. The small grant mechanisms (i.e., R03s and R21s) were excluded from the analysis of the R01s in this examination because the smaller projects were mainly needs assessments, small pilots, and instrument development studies and were generally not intervention research.

Summary tables and figures were constructed, using type of funding mechanism (R01, R03, R21) for initial categorization of abstracts. The quantitative results (e.g., frequencies and means) and qualitative results (e.g., project topic and D&I strategy) provided a foundation for drawing conclusions about the funded D&I research and discussing the implications for nursing research.

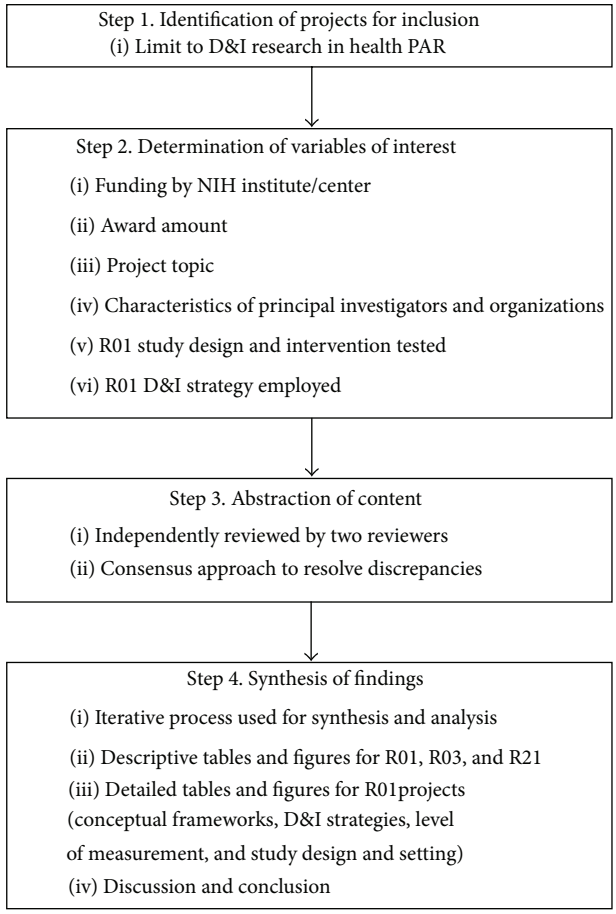


Figure 1: Flowchart for the review process. PAR: Program Announcement Reviewed; D&I: Dissemination and Implementation.

3. Results

3.1. Overview of the Projects. A total of 76 project abstracts were reviewed, representing 46 R01s, six R03s, and 24 R21s funded by the NIH, totaling $79.2 million during the 2005 to 2012 period (Table 1). Nine NIH Institutes and Centers funded these awards, with the National Cancer Institute (NCI) and the National Institute of Mental Health (NIMH) funding 58% of the total number of projects, which accounted for 61% of the total funding. The NINR awarded 6% of the projects: three R01s, one R03, and one R21, totaling $4.9 million. The NIH Fogarty International Center joined the program announcements in 2009 and funded several grants focused on global health. Figure 2 depicts the funding for the R01 awards, again, with the majority of the larger research project grants funded by the NCI and the NIMH.

The majority of PIs for these funded projects were affiliated with Schools of Medicine and large, nonprofit research organizations and think tanks, such as Rand and Kaiser, and these institutions received 58% of the total funding (Table 2). Schools of Public Health accounted for about 18% and 19% of the PI affiliations and the total funding, respectively. Only about 4% of the funded projects were to PIs at Schools of Nursing, making up about 7% of the total funding. The universities and research organizations funded for these projects were more heavily clustered in the West and East coastal states and the East North Central states (Figure 3). The institutions in the West and East coastal states received about two thirds of the total funding for all of the projects.

The topic focus for the 76 projects funded over the past 8 years reflects a broad spectrum of areas, consistent with the missions of the sponsoring NIH Institutes and Centers. The projects included dissemination and implementation of evidence-based health behavior interventions and research-based guidelines, programs, and services for prevention, diagnosis, and clinical management in public health, clinical settings, and the public policy arena. As shown in Figure 4, the most commonly funded projects were cancer control and screening, substance abuse prevention and treatment, and mental health services.

Many of the projects involved scaling up interventions found to be effective in smaller trials or adapting an evidence-based intervention for implementation in a new setting. For example, one R01 project [22] studied the dissemination and implementation of an evidence-based weight-management program for veterans called MOVE! by scaling up this program to reach a broad population of veterans across the Veterans Affairs national network of medical centers and community clinics. Another R01 project [23] examined the impact of adapting and delivering an evidence-based organizational implementation strategy called Availability, Responsiveness, and Continuity (ARC), originally developed in Tennessee, on improving mental health services for youth in community-based agencies in a Midwest community.

3.2. A Focus on the R01 Projects. A more in-depth analysis of the R01 projects was conducted to better understand the intervention projects that move the science beyond the pilot phase. This analysis included an examination of the theories and frameworks, D&I strategies, levels of measurement, and study design and setting.

3.2.1. Theories and Frameworks. Among the 46 R01 projects, the range of orientation to a theory or model varied widely (Table 3). The majority of the R01-funded projects had no mention of a theoretical framework or guiding model (n = 22). Of the frameworks mentioned, the RE-AIM framework for evaluating interventions was most commonly utilized (n = 7), closely followed by Rogers' Diffusion of Innovations model (n = 5) [24]. One study combined Rogers' Diffusion of Innovations model and the RE-AIM framework (n = 1). Nine studies utilized frameworks that had specific relevance for their project, such as grants that proposed the use of behavioral interventions and had a related behavioral model supporting the intervention. For example, a project titled "Dissemination of a Theory-Based Bone Health Program in Online Communities" [25] utilized social cognitive theory in designing an online bone-health intervention targeting adults aged 50 years and older.

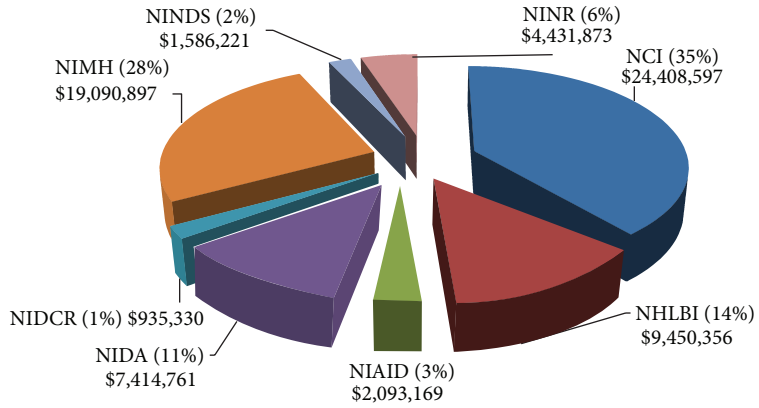


Figure 2: R01 funding by NIH Institutes, 2005–2012.

Table 1: Dissemination and implementation awards by NIH Institute and grant mechanism, 2005–2012 (out-year funding for projects recently awarded is not included).

Institute	Mechanism	Funds, $ (%)	No. of awards (%)	Average award, $	% of total funding
NCI	R01	24,408,597 (91)	19	1,284,663	
	R03	213,000 (1)	2	106,500	
	R21	2,096,157 (8)	6	349,360	
	Totals	26,717,754 (100)	27 (36)		34
NIMH	R01	19,090,897 (89)	11	1,735,536	
	R21	2,353,747 (11)	6	392,291	
	Totals	21,444,644 (100)	17 (22)		27
NIDA	R01	7,414,761 (77)	4	1,853,690	
	R03	177,913 (2)	1	177,913	
	R21	2,041,179 (21)	5	408,236	
	Totals	9,633,853 (100)	10 (13)		12
NHLBI	R01	9,450,356 (100)	5 (7)	1,890,071	12
NIAID	R01	2,093,169 (67)	2	1,046,585	
	R21	1,035,998 (33)	4	259,000	
	Totals	3,129,167 (100)	6 (8)		4
NINR	R01	4,431,873 (89)	3	1,477,291	
	R03	166,404 (3)	1	166,404	
	R21	391,916 (8)	1	391,916	
	Totals	4,990,193 (100)	5 (7)		6
NIDCR	R01	935,330 (46)	1	935,330	
	R21	1,103,698 (54)	2	551,849	
	Totals	2,039,028 (100)	3 (4)		3
NINDS	R01	1,586,221 (100)	1 (1)	1,586,221	2
FIC	R03	221,775 (100)	2 (3)	110,888	0.3
			Total funding		
	R01	69,411,204 (88)	46	1,508,939	
	R03	779,092 (1)	6	129,849	
	R21	9,022,695 (11)	24	375,946	
	Total	79,212,991 (100)	76		100

NCI: National Cancer Institute; NIMH: National Institute of Mental Health; NIDA: National Institute on Drug Abuse; NHLBI: National Heart, Lung, and Blood Institute; NIAID: National Institute of Allergy and Infectious Diseases; NINR: National Institute of Nursing Research; NIDCR: National Institute of Dental and Craniofacial Research; NINDS: National Institute of Neurological Disorders and Stroke; FIC: Fogarty International Center.

Table 2: Projects by PI affiliation, mechanism, and total funding.

PI affiliation	R01	R03	R21	No. of projects (%)	Funds, $ (%)
School of Medicine	21	3	8	32 (42)	29,066,546 (37)
Other research organizations (i.e., Rand, Kaiser, etc.)	7	1	4	12 (16)	17,518,075 (22)
School of Public Health	10	0	4	14 (18)	14,846,637 (19)
School of Nursing	3	0	0	3 (4)	5,869,637 (7)
School of Social Work	2	0	0	2 (3)	4,915,825 (6)
College of Arts and Sciences	2	1	3	6 (8)	3,308,268 (4)
Other university-based organizations	0	1	3	4 (5)	1,385,087 (2)
College of Biomedical Engineering	1	0	0	1 (1)	1,199,218 (2)
School of Dentistry	0	0	2	2 (3)	1,103,698 (1)
Totals	46	6	24	76 (100)	79,212,991 (100)

3.2.2. D&I Strategies. Of the 46 R01 projects, 29 had one D&I strategy and 15 had two D&I strategies, for a total of 59 D&I strategies used (Table 4). In two of the abstracts, the strategies were either unclear or were not stated. Examining the D&I strategies, a majority (78%) of studies utilized active dissemination approaches, whereas 10% used passive dissemination approaches, and the remaining 12% used an evaluative approach (i.e., evaluation of an existing program). Many studies utilized a combination of mixed active, passive, and/or evaluative strategies. The range of active approaches varied; for example, one study adapted patient navigation strategies to Chinese women in Chicago [26] in an intervention that modified tailored patient navigation to improve cancer screening rates in this low-income and underserved population. The dissemination approach proposed in this study incorporated patient navigators as providers of cancer control education and screening in active teaching roles within the Asian immigrant population and was categorized in our study as hands-on technical assistance and training, two active D&I strategies. An example of evaluation of dissemination was demonstrated in a study examining smoking cessation and knowledge integration with people who use tobacco control quitlines [27], in which participant social network analysis was conducted to provide insight about potential dissemination approaches in the future.

3.2.3. Levels of Measurement. These R01 projects used five levels of measurement in evaluating the intervention outcomes: policy level, patient level, provider level, organizational level, and multilevel outcome measures. Multilevel outcome measures involved different combinations of the other four levels, such as a combination of organizational and provider measures or an intervention study that measured both provider and patient outcomes. Multilevel outcome measures were the most common means of evaluation for these R01 projects (47%), whereas the most frequent individual outcome measure was at the organizational level (22%; see Figure 5).

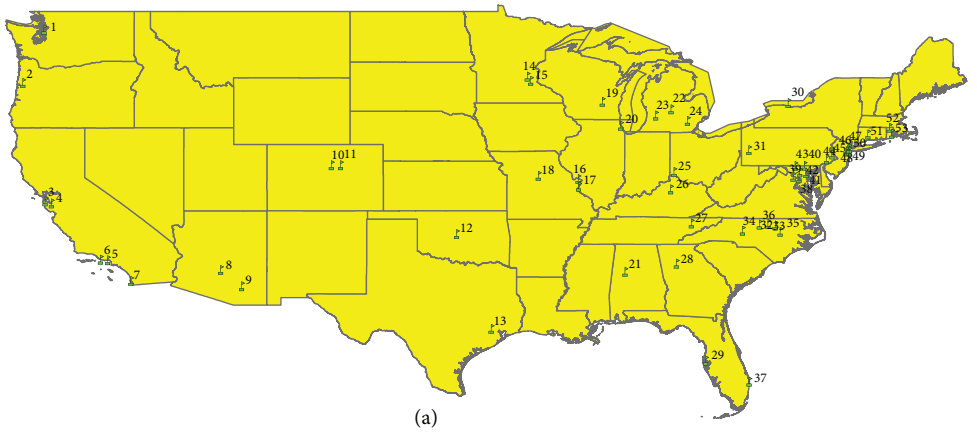
One example of a research study using a multilevel outcomes methodology [28] involved a colorectal screening intervention replicated by a community health services agency for Asian American patients. Intervention outcomes were measured using a combination multilevel evaluation at both the organizational (i.e., the agency) and individual levels by collecting data from individual providers at the intervention community agencies.

An example of program evaluation using a single level of outcome measure [29] involved a 5-year project that examined the transportation, implementation, and sustainability of a computer-assisted cognitive-behavioral treatment (CACBT) for young children's anxiety in elementary schools. In this multisite study, each school provided at least four counselors, social workers, school psychologists, or teachers who could implement the intervention. The outcome of the project was measured in terms of whether or not the school personnel increased the use of the CACBT program and increased identification of elementary school students with distressing anxiety through use of the Behavioral Assessment System for Children, Second Edition, Teacher Rating Scale.

3.2.4. Study Design and Setting. Many of these 46 R01 projects had multiple aims and multiple stages as part of the study intervention. The project designs included randomized controlled trials, quasiexperimental designs, case studies, survey research, community-based participatory approaches, and system science designs, such as social network analysis.

Many projects utilized mixed-methods designs, using quantitative methods to measure outcomes and qualitative methods to describe processes or expand the depth of understanding. For example, one project [30] involved three separate stages, with the first stage using two in-depth case studies of model substance abuse treatment programs serving the substance abuser group in the community. The second stage used a quantitative telephone survey approach to collect data from the directors of all 480 substance abuse treatment programs serving substance abusers in their respective communities. The final stage involved a qualitative approach using in-depth case studies of 12 of these 480 substance abuse treatment programs from the stage-two telephone interviews. As a result, the researchers planned to collect, analyze, and report both quantitative and qualitative data gathered during the three stages of the project [30].

When these R01 projects were grouped by predominant design, 43% of the studies used a quasiexperimental design, and 24% used randomized controlled trials. Together, these two designs accounted for two out of three designs among the



(a)

Map no.	Institute	Total funding, $	% of total funding
1	University of Washington	5,746,703	7.3
2	Oregon State University	1,452,624	1.8
3	University of California San Francisco	2,018,019	2.5
4	Kaiser Foundation Research Institute	2,629,220	3.3
5	University of California Los Angeles	1,142,738	1.4
6	Rand Corporation	5,996,233	7.6
7	University of California San Diego	1,837,714	2.3
8	Arizona State University, Tempe Campus	639,914	0.8
9	University of Arizona	3,118,026	3.9
10	Klein Buendel, Inc.	1,386,185	1.7
11	University of Colorado Denver	2,567,438	3.2
12	University of Oklahoma Hlth Sciences Ctr	1,680,075	2.1
13	University of Texas Hlth Sci Ctr Houston	653,871	0.8
14	Healthpartners Research Foundation	4,154,736	5.2
15	University of Minnesota Twin Cities	63,000	0.1
16	University of Missouri-Columbia	402,298	0.5
17	Saint Louis University	2,466,945	3.1
18	Washington University	1,289,131	1.6
19	University of Wisconsin Madison	2,199,296	2.8
20	Northwestern University at Chicago	602,190	0.8
21	University of Alabama in Tuscaloosa	391,916	0.5
22	Western Michigan University	409,750	0.5
23	Michigan State University	418,337	0.5
24	University of Michigan at Ann Arbor	1,715,510	2.2
25	Children's Hospital Medical Center Cincinnati	371,250	0.5
26	University of Kentucky	3,393,577	4.3
27	University of Tennessee Knoxville	987,766	1.2
28	Morehouse School of Medicine	449,429	0.6
29	University of South Florida	147,000	0.2
30	University of Rochester	718,361	0.9
31	University of Pittsburgh at Pittsburgh	491,400	0.6
32	University of North Carolina Chapel Hill	6,964,288	8.8
33	Davidson College	370,064	0.5
34	Duke University	177,020	0.2
35	Tanglewood Research, Inc.	1,176,751	1.5
36	Wake Forest University Health Sciences	364,553	0.5
37	Florida Atlantic University	880,217	1.1
38	George Washington University	775,677	1
39	American Legacy Foundation	1,740,688	2.2
40	University of Maryland Baltimore	972,500	1.2
41	Johns Hopkins University	2,079,146	2.6
42	Pacific Institute For Res And Evalution	427,262	0.5
43	University of Maryland College Park campus	967,626	1.2
44	University of Pennsylvania	1,236,912	1.6
45	Temple University	818,104	1
46	Weill Medical College of Cornell Univ	5,840,947	7.4

Figure 3: Continued.

Map no.	Institute	Total funding, $	% of total funding
47	Columbia University Health Sciences	419,201	0.5
48	New York University School of Medicine	853,477	1.1
49	Sloan-Kettering Institute for Cancer Res	177,913	0.2
50	Mount Sinai School of Medicine	386,912	0.5
51	Yale University	208,978	0.3
52	Memorial Hospital of Rhode Island	422,848	0.5
53	Brown University	411,255	0.5
	Total funding, $	79,212,991	100

(b)

Figure 3: (a) Geographical distribution of institutions receiving project funding, (b) Legend for Figure 3(a).

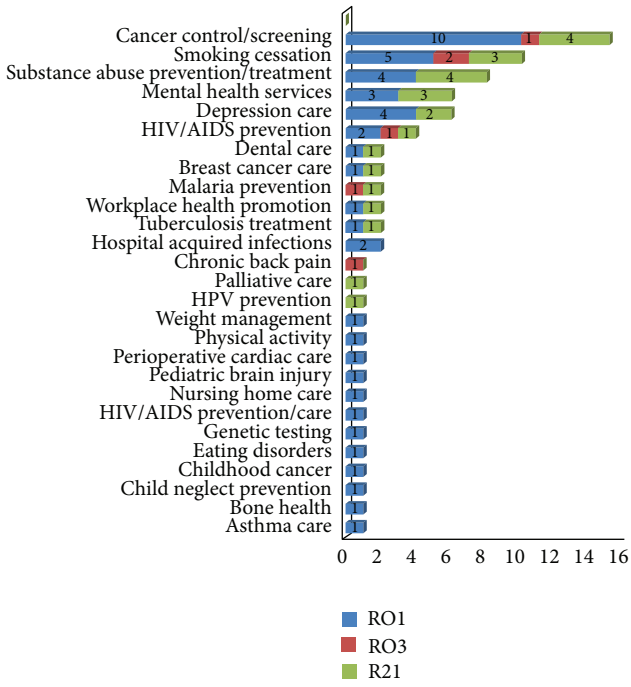


Figure 4: NIH R01, R03, and R21 study topics. HIV/AIDS: human immunodeficiency virus/acquired immunodeficiency syndrome; HPV: human papilloma virus.

R01 studies (Table 5). The project settings were also diverse and included rural and urban primary care and specialty care practices ($n = 14$), state government and international health settings ($n = 8$), community health agencies ($n = 7$), hospitals ($n = 4$), online social networking ($n = 4$), schools ($n = 4$), large health care systems ($n = 2$), churches ($n = 2$), and worksites ($n = 1$). See Table 6 for a list of the 76 abstracts used in the study.

4. Discussion

This review of abstracts was conducted to describe the R01, R03, and R21 projects funded under the NIH program announcements for D&I research from 2005 to 2012. Further analysis was performed for the R01 studies, which were intended to move the science beyond the pilot phase.

Review of these abstracts demonstrated a robust set of projects that reflect a growing and evolving area of science. NCI and NIMH were the major funders for the projects, which is indicative of their long history of working to advance this field. Each of these institutes has designated organizational D&I units and program officers dedicated to broadly stimulating this science. The PIs for these projects represented an array of disciplines, and the topical focus of the projects was equally diverse, illustrating the interdisciplinary nature of the D&I research community. Only a small proportion of PIs for these projects were from Schools of Nursing. Likewise, as illustrated in Figure 3, rural and western states were underrepresented among the funded projects.

When a theory or framework was present, it referred to one that is commonly applied in D&I research in the context of health, particularly the RE-AIM [15] and Diffusion of Innovations [24] models. Other commonly used models included those that supported individually focused behavioral interventions, such as cognitive behavioral theory. Consistent with the literature that demonstrates that active D&I strategies are more effective [12], most of the projects relied on active approaches, such as training and technical assistance.

Assessment of the outcomes and fidelity of the dissemination and implementation of new preventive practices, guidelines, or programs in these projects were most often measured at multiple levels, such as the individual patient, the provider, and the organization. This multimodal approach is characteristic of more recent D&I research and may reflect an evolving use of systems thinking for D&I in terms of understanding how actors and organizations influence each other within a whole [31, 32]. The predominant study designs used in these projects included quasiexperimental and randomized clinical trials. Many of the projects used mixed methods, with a third of them including both quantitative and qualitative components. Mixed methods are particularly useful in generating data from multiple levels and many stakeholders and may be particularly suited to answer the complex questions in D&I research [18, 33].

Many of these funded projects can be considered first-generation D&I research. What areas of knowledge development suggested from these studies and other experts should be promoted to move the field forward in terms of the next generation of D&I research? Developing a standard

Table 3: Theories or models utilized in the R01 abstracts.

Rank (fewest to most)	Theory or model	Frequency (%)
1	Rogers' Diffusion of Innovations + RE-AIM	1 (2)
2	Nonspecific reference to theory or model	2 (4)
3	Rogers' Diffusion of Innovations (alone or in combination with another theory or model)	5 (11)
4	RE-AIM (alone or in combination with another theory or model)	7 (15)
5	Specific theoretical framework or model:	9 (20)
	Cooperation Extension System	1
	Community Readiness Model	1
	Quality Assurance Model	2
	Self-Regulation Theory of Health Behavior	1
	Collaborative Depression Core Model	1
	Cognitive Behavioral Theory	1
	Advanced Recovery Theory	1
	Program Change Model	1
6	No theory or model	22 (48)

Re-Aim: Reach, Effectiveness, Adoption, Implementation, and Maintenance.

Table 4: Passive, active, and evaluative D&I strategies identified.

Strategy/subcategory	No. (%)
Passive	
Publication of information, such as practice guidelines	6 (10)
Active	
Training (train the trainer, certificate training, and staff development workshop)	23 (39)
Hands-on technical assistance	8 (14)
Websites and interpersonal channels (social networking)	5 (8)
Replication guides	3 (5)
Phone calls	4 (7)
Social marketing	2 (3)
Point-of-decision prompts for use	1 (2)
Evaluative	
Evaluation	7 (12)
Total D&I strategies	59 (100)

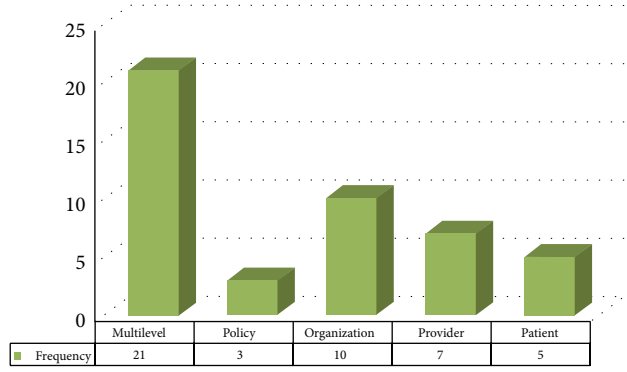


Figure 5: Frequencies for the level of measurement for the evaluation of intervention study outcomes.

and consistent terminology for D&I research is one critical area requiring careful attention [33]. Additional theory development and testing are needed to better understand the relationships among the complex array of factors required for successful dissemination and implementation of health interventions in various settings [34]. Building a more robust set of common measures for D&I research is also a priority [13]. Glasgow and colleagues suggest that alternative study designs beyond the traditional randomized trial that emphasize the importance of external validity and that take advantage of existing social, environmental, and community data should be utilized [19]. A focus on D&I approaches with high-risk populations, including low-income, minority, and low-health literacy groups, and in low-resourced settings is also an imperative [19, 34]. Finally, new interdisciplinary collaborations with diverse partners, including key stakeholders, consumers, and clinicians, will be important to grow the science [19].

4.1. Implications for Nursing Research. D&I science moves beyond the individual as the unit of analysis to focus on groups, systems, the community, and beyond. Nursing research is conducted in all these areas, but D&I research is a way for nurses to influence health and health care on a larger scale. One example is the dissemination of evidence-based practice guidelines throughout a unit, hospital, and health care system. What are the best ways to have these guidelines widely used by nurses and other health care professionals? Which strategies are most cost-effective?

The D&I program announcements clearly present a potential funding opportunity for nurse scientists committed

Table 5: Predominant study designs and methods in the R01 projects.

Rank (most to fewest)	Predominant study design: 46 RO1 projects	Frequency (%)
1	Quasiexperimental designs	20 (43)
2	Randomized controlled trials	11 (24)
3	Systems science (e.g., social network analysis)	10 (22)
4	Case studies	3 (7)
5	Community-based participatory research	1 (2)
6	Unclear study design	1 (2)
	Other categories	
	Studies with more than one design	14 (30)
	Studies using mixed methods (quantitative and qualitative)	14 (30)

to translating evidence-based interventions to improve health (these program announcements were recently reissued on January 9, 2013, under PAR-13-055 (R01), PAR-13-054 (R21), and PAR-13-056 (R03)). Nursing has a rich history of work in research utilization to improve clinical care and promote practice-based inquiry. Nurse scientists are well prepared to lead and participate as members in interdisciplinary teams focused on disseminating and implementing evidence to practice. Symptom management and self-care in chronic disease and end-of-life care are just a few examples where nursing has made significant contributions to the science and should take a leadership role in translating this work to practice [35]. Many nurse researchers are skilled in both quantitative and qualitative designs often used in D&I research. A mixed-methods approach might be especially useful in testing different strategies for implementation across different populations.

There are opportunities to learn more about D&I science and receive assistance and feedback on a proposed grant application. The NIH hosts an annual conference on the science of dissemination and implementation in health, where attendees can hear state-of-the science presentations, learn about research findings in the poster session, network with D&I scientists, and attend a technical assistance workshop led by NIH Program Officers and funded by D&I researchers. Other research training opportunities, such as the annual NIH-sponsored Training Institute on Dissemination and Implementation Research in Health, are also offered periodically to the extramural community. The NIH Office of Behavioral and Social Sciences Research website includes information about these opportunities (http://obssr.od.nih.gov/scientific_areas/translation/dissemination_and_implementation/index.aspx).

Talking to the appropriate NIH Institute Program Officer identified on the PAR as the scientific contact person is also essential in planning an application submission. Considering the fit of an application with the mission of other institutes (e.g., NCI or NIMH), in addition to NINR, is also important. Grant applications for these PARs prior to 2010 were reviewed in Special Emphasis Panels, in which peer reviewers were appointed for each panel on a temporary basis. In 2010, the NIH Center for Scientific Review established a chartered study section to peer review these and other investigator-initiated applications in this science area, called the Dissemination and Implementation Research in Health Study Section (http://public.csr.nih.gov/StudySections/IntegratedReviewGroups/HDMIRG/DIRH/Pages/default.aspx). This website also provides a link to the study section's membership roster. Whereas standing members of this study section are appointed for a specific term, other temporary reviewers are often appointed for a specific review cycle to augment the scientific expertise that may be needed, depending on the pool of applications. Another invaluable opportunity for nurse scientists who have expertise in a specific area of D&I science is to volunteer to serve as a peer reviewer for this study section by sending their curriculum vitae and letter of interest to the Scientific Review Officer assigned to this study section.

4.2. Limitations. The description and analysis in this review were based solely on the funded project abstracts published in the NIH RePORTER under the previously identified program announcements. By their nature, proposal abstracts present a limited amount of information and might not accurately represent the project once completed. Outcomes cannot be identified through review of proposal abstracts; this would require subsequent review of publications based on the funded projects. The level of analysis was limited by having access only to those abstracts publicly available through funding. Consequently, no conclusions can be made based on funded projects compared with all proposals submitted in response to this PAR. No information is publically available regarding the total number of applications submitted. Furthermore, it is not known how representative the funded projects are for any of the descriptors provided in this paper compared with submitted proposals. It is also not known whether different types of applications or specific topics were more or less likely to be funded in relation to the entire pool of applications.

As reported by others [11, 12], this abstract review was hindered by inconsistent terminology for design and strategy and even for what was meant by dissemination or implementation. Although some abstracts provided details of the proposed projects, others omitted relevant content (e.g., model used). Equally evident from this review was the lack of common measures with established validity and reliability, particularly for measuring D&I processes and outcomes. The imperative to develop these common measures as key to the successful advancement of D&I science has been widely advocated [13, 34].

Finally, it should be noted that D&I science has undergone much development since the first general program announcement was released in 2005. It is not known what

Table 6: Abstracts evaluated in the study.

Principal investigator	Project title	Project number	Mechanism	Funding institute	Funding amount*
Aarons, Gregory	Leadership development for evidence-based practice implementation	1R21MH082731-01A1	R21	NIMH	$467,057
Aarons, Gregory et al.	Interagency collaborative teams to scale up evidence-based practice	1R01MH092950-01A1	R01	NIMH	$1,370,657
Allen, Rebecca Sue	Legacy intervention family enactment (LIFE): an effectiveness trial	1R21NR011112-01	R21	NINR	$391,916
Auerbach, Andrew D.	Improving use of perioperative beta-blockers with a multidimensional QI program	1R01HL086473-01	R01	NHLBI	$2,018,019
Berenholtz, Sean M.	A multifaceted intervention to reduce ventilator-associated pneumonia in the ICU	1R01HL105903-01A1	R01	NHLBI	$972,500
Bickell, Nina A.	Implementing cancer treatment measuring and reporting in office and hospital practice	1R21CA132773-01A2	R21	NCI	$419,201
Bogner, Hillary R.	Implementing care for depression and diabetes	1R21MH094940-01A1	R21	NIMH	$240,000
Botvin, Gilbert J.	A collaborative system approach for the diffusion of evidence-based prevention	1R01DA023437-01A1	R01	NIDA	$3,640,886
Bradbury, Angela R.	Communicating genetic test results by telephone: a randomized trial	1R01CA160847-01A1	R01	NCI	$668,104
Brownson, Ross C.	Cancer control dissemination research among state-level policy makers	1R01CA124404-01A1	R01	NCI	$2,466,945
Brownson, Ross C.	Disseminating evidence-based interventions to control cancer	1R01CA160327-01A1	R01	NCI	$517,465
Bruce, Martha L.	Homecare agency-randomized trial of web implementation strategy for depression	1R01MH096441-01A1	R01	NIMH	$386,912
Campbell, Marci K.	Dissemination of a weight-management program among US veterans	1R01CA124400-01	R01	NCI	$2,813,567
Cates, Joan Roberts	Optimizing HPV vaccination: parents, providers, and preteen boys	1R21AI095590-01A1	R21	NIAID	$407,000
Clarke, Jennifer Grace et al.	Methods for understanding sentinel events	1R21DA032739-01	R21	NIDA	$422,848
Cobb, Nathan	Online social networks for dissemination of smoking cessation interventions	1R01CA155369-01A1	R01	NCI	$775,677
Crowley, Rebecca S. et al.	Implementation of automated guideline adherence feedback in Malawi	1R03TW009217-01A1	R03	FIC	$74,775
Dolcini, M. Margaret	Influences on translation of an evidence-based HIV/STI intervention into practice	1R01MH085502-01	R01	NIMH	$1,452,624
Dorsey, Shannon	Improving practice in community-based settings: a randomized trial of supervision	1R01MH095749-01	R01	NIMH	$590,142

Table 6: Continued.

Principal investigator	Project title	Project number	Mechanism	Funding institute	Funding amount*
Dowdy, David Wesley	A user-friendly epidemic-economic model of diagnostic tests for tuberculosis	1R21AI101152-01	R21	NIAID	$243,000
Dunn, Andrea L.	Study of the naturalistic dissemination process of an evidence-based program	1R01HL086448-01	R01	NHLBI	$1,386,185
Epstein, Jeff N.	Disseminating a model intervention to promote improved ADHD care in the community	1R21MH082714-01	R21	NIMH	$371,250
Feldstein, Adrianne C.	Forging implementation of cancer screening reminder systems (FICSRS)	1R21CA124395-01A1	R21	NCI	$357,432
Feldstein, Adrianne C.	Focusing implementation to bring effective reminders: FIBER	1R01CA132709-01	R01	NCI	$2,271,788
Foley, Kristie L.	Implementation and dissemination of tobacco cessation strategies in free clinics	1R21DA024631-01	R21	NIDA	$370,064
Friedland, Gerald H. et al.	Implementing point-of-care CD4 analysis to decentralize HIV care in rural Africa	1R21AI102756-01	R21	NIAID	$208,978
Glisson, Charles A.	Testing an organizational implementation strategy in children's mental health	1R01MH084855-01A1	R01	NIMH	$2,448,880
Hahn, Ellen J.	An intervention for promoting smoke-free policy in rural Kentucky	1R01HL086450-01	R01	NHLBI	$3,393,577
Hannon, Margaret A.	Workplace health promotion	1R21CA136435-01A1	R21	NCI	$303,019
Hannon, Margaret A.	Increasing implementation of evidence-based interventions at low-wage worksites	1R01CA160217-01A1	R01	NCI	$500,557
Hansen, William B.	The impact of adaptation on successful implementation	5R01DA024639-02	R01	NIDA	$1,176,751
Hawkins, Robert P.	Implementing CHESS ehealth breast cancer support in population-based care	1R01CA149005-01A1	R01	NCI	$1,000,078
Hawley, Kristin M.	Increasing the capacity of providers to monitor fidelity to child and family CBT	1R21MH090460-01A1	R21	NIMH	$402,298
Holt, Cheryl L.	Implementation of evidence-based cancer early detection in black churches	1R01CA147313-01A1	R01	NCI	$967,626
Ibrahim, Jennifer K.	Translating science into policy: a survey of state tobacco control plans	1R03CA128644-01A1	R03	NCI	$150,00
Kataoka, Sheryl H.	Implementation strategy for delivering a school-based mental health program	1R21MH082712-01A1	R21	NIMH	$454,805
Kendall, Philip C.	Disseminating evidence-based practice to the schools: CBT for child anxiety	1R01MH086438-01A2	R01	NIMH	$996,912
Krein, Sarah et al.	Implementing evidence to prevent urinary infection and enhance patient safety	1R01NR010700-01	R01	NINR	$1,715,510
Kruk, Margaret E.	Improving maternal and newborn health using the HIV/AIDS program platform in Tanzania	1R01AI093182-01A1	R01	NIAID	$1,499,244

Table 6: Continued.

Principal investigator	Project title	Project number	Mechanism	Funding institute	Funding amount*
Larkey, Linda K. et al.	Navigation from community to clinic to promote population CRC screening in underserved population	1R01CA162393-01A1	R01	NCI	$639,914
Leischow, Scott J.	Knowledge integration in quitlines: networks that improve cessation	1R01CA128638-01A1	R01	NCI	$3,118,026
Lounsbury, David William	Dynamics modeling as a tool for disseminating the PHS tobacco treatment guideline	1R03DA022278-01A1	R03	NIDA	$177,913
Magura, Stephen	Critical review of evidence-based program repositories for behavioral health treatment	1R21DA032151-01	R21	NIDA	$409,750
Mold, James W.	Implementation of asthma guidelines in primary care; comparison of 4 approaches	1R01HL091827-01A2	R01	NHLBI	$1,680,075
Molfenter, Todd David	To test a payer/treatment agency intervention to increase use of buprenorphine	1R01DA030431-01A1	R01	NIDA	$1,199,218
Mullen, Patricia Dolan et al.	Increasing reach and implementation of evidence-based programs for cancer control	1R01CA163526-01	R01	NCI	$653,871
Nahm, Eun-Shim	Dissemination of a theory-based bone health program in online communities	1R01NR011296-01	R01	NINR	$1,836,146
Novins, Douglas K.	Evidence-based practices and substance abuse treatment for Native Americans	1R01DA022239-01A1	R01	NIDA	$1,397,906
Nutting, Paul A.	Practice redesign to improve depression care-PRIDE care	1R01MH069806-01A2	R01	NIMH	$1,169,532
Ouslander, Joseph G. et al.	Implementing interventions to reduce hospitalizations of nursing home residents	1R01NR012936-01A1	R01	NINR	$880,217
Pankratz, Melinda M.	Comparing multiple methods of measuring fidelity of curriculum implementation	1R21DA025588-01	R21	NIDA	$427,262
Picone, Gabriel	Social interactions and malaria preventive behaviors in sub-Saharan Africa	1R03TW009108-01	R03	FIC	$147,000
Powell, Adam A.	Measurement of inappropriate screening tests (MIST)	1R03CA166719-01A1	R03	NCI	$63,000
Prudhomme O'Meara, Wendy	Sustainable financial incentives to improve prescription practices for malaria	1R21AI095979-01A1	R21	NIAID	$177,020
Psoter, Walter J.	Increasing oral cancer screening by dentists: qualitative research on practitioner	1R21DE019766-01A1	R21	NIDCR	$687,073
Reid, Manney Carrington	Implementing a cognitive/exercise therapy for back pain in the community setting	1R03NR010093-01	R03	NINR	$166,404
Rush, William Adams	An innovative approach to disseminate dental research	1R01DE022332-01	R01	NIDCR	$935,330
Sahler, Olle Jane Z.	Online problem-solving skills training for mothers of childhood cancer patients	1R01CA159013-01A1	R01	NCI	$718,361

Table 6: Continued.

Principal investigator	Project title	Project number	Mechanism	Funding institute	Funding amount*
Shelley, Donna R. et al.	Implementing tobacco use treatment guidelines in dental public health clinics	1R01CA162035-01A1	R01	NCI	$700,817
Simon, Melissa Andrea	Adapting patient navigation to promote cancer screening in Chicago's Chinatown	1R01CA163830-01	R01	NCI	$602,190
Smith, Selina A. et al.	Efficacy-to-effectiveness transition of an educational program to increase colorectal cancer screening	1R01CA166785-01	R01	NCI	$449,429
Solberg, Leif I.	Evaluation of a natural experiment to improve statewide depression care in MN	1R01MH080692-01	R01	NIMH	$3,219,406
Spallek, Heiko	Implementing research findings and evidence-based interventions into real-world	1R21DE021494-01	R21	NIDCR	$416,625
Squires, Daniel	Training drug treatment providers to adopt evidence-based practices	1R21DA021150-01A1	R21	NIDA	$411,255
Sutfin, Erin L.	Implementing evidence-based tobacco cessation strategies in campus health clinics	1R21CA161664-01	R21	NCI	$364,553
Tu, Shin-Ping	Cancer control dissemination to Asian Americans	1R01CA124397-01A1	R01	NCI	$987,766
Tu, Shin-Ping	Dissemination through community health centers serving diverse populations	1R21CA136460-01A1	R21	NCI	$317,884
Van Rie, Annelies T. A.	Optimizing the impact of XPERT MTB/RIF on treatment outcomes of drug-resistant TB	1R01AI099026-01	R01	NIAID	$593,925
Vavilala, Monica Shanta	Implementation science to increase use of evidence-based pediatric brain injury	1R01NS072308-01	R01	NINDS	$1,586,221
Weiner, Bryan Jeffrey	Implementing systemic interventions to close the discovery-delivery gap	1R01CA124402-01A1	R01	NCI	$2,815,728
Weiner, Bryan Jeffrey	Increasing colorectal cancer screening rates in community health centers	1R21CA161657-01	R21	NCI	$334,068
Wells, Kenneth B.	Community partners in care	1R01MH078853-01A1	R01	NIMH	$5,996,233
Whitten, Pamela	Implementation of a telepsychiatry program in rural oncology clinics	1R21MH080699-01A2	R21	NIMH	$418,337
Wilfley, Denise Ella et al.	Implementation of evidence-based treatments for on-campus eating disorders	1R01MH095748-01	R01	NIMH	$771,666
Windsor, Richard Anthony	The West Virginia smoking cessation or reduction in pregnancy treatment trial	1R01CA124429-01A1	R01	NCI	$1,740,688
Wyatt, Gail E.	Implementing EBAN II: an evidence-based intervention for serodiscordant couples	1R01MH093230-01A1	R01	NIMH	$687,933

*This funding amount represents awards from 2005–2012. Out-year funding for projects recently awarded is not included.

NCI: National Cancer Institute; NIMH: National Institute of Mental Health; NIDA: National Institute on Drug Abuse; NHLBI: National Heart, Lung, and Blood Institute; NIAID: National Institute of Allergy and Infectious Diseases; NINR: National Institute of Nursing Research; NIDCR: National Institute of Dental and Craniofacial Research; NINDS: National Institute of Neurological Disorders and Stroke; FIC: Fogarty International Center.

impact this may have had on the number and quality of proposals submitted, especially during the latter part of the time selected for this review.

5. Conclusion

The overall goal of D&I science is to overcome the research-practice gap so that evidence-based health practices yield significant health benefits to all populations and across all health care settings [19]. The purpose of this paper was to enhance understanding of the body of work represented in the projects funded under the NIH dissemination and implementation program announcements over the past 8 years and suggest implications for nurse researchers. The projects in this portfolio demonstrated that D&I research is complex, often multiphase, and requires a collaborative, interdisciplinary approach. These projects make a highly significant contribution to the field, yet much work remains to be done, such as improving methods and measures, to move D&I science forward.

Although many nurse researchers and practitioners are engaged in D&I science, nurse scientists were underrepresented among the PIs for these projects. Nurse scientists are uniquely prepared to contribute to the advancement of D&I research in health. This NIH initiative represents an outstanding potential funding and leadership opportunity for nurse researchers committed to translational research and shortening the science-practice gap.

Conflict of Interests

The authors declare no conflict of interests.

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Research Article

Adopting Best Practices from Team Science in a Healthcare Improvement Research Network: The Impact on Dissemination and Implementation

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Healthcare is a complex adaptive system, and efforts to improve through the implementation of best practice are well served by various interacting disciplines within the system. As a transdisciplinary model is new to clinicians, an infrastructure that creates academic-practice partnerships and builds capacity for scientific collaboration is necessary to test, spread, and implement improvement strategies. This paper describes the adoption of best practices from the science of team science in a healthcare improvement research network and the impact on conducting a large-scale network study. Key components of the research network infrastructure were mapped to a team science framework and evaluated in terms of their effectiveness and impact on a national study of nursing operations. Results from this study revealed an effective integration of the team science principles which facilitated the rapid collection of a large dataset. Implications of this study support a collaborative model for improvement research and stress a need for future research and funding to further evaluate the impact on dissemination and implementation.

1. Introduction

Healthcare has been described as a complex adaptive system (CAS) that involves multiple, interdependent entities and organizational levels [1–3]. Such complexity poses a challenge for transformative change as relationships within a CAS are nonlinear and unpredictable [4, 5]. This challenge is echoed by leaders in the field of quality improvement who have identified shortcomings, such as a lack of rigorous research methods, a failure to study contextual variables, and weak evaluation designs [6–8]. These shortcomings are an indication that the interwoven processes of healthcare delivery are difficult for a single investigator to tease apart. Thus, a collaborative model that integrates multiple perspectives from several disciplines may help advance the field of improvement science and facilitate dissemination and implementation strategies.

Transdisciplinary collaboration is a potentially effective model as it brings together a diverse group of individuals who fully integrate theories, methodologies, and frameworks from their respective fields to work as a cohesive unit on complex issues [9]. This differs from multidisciplinary and interdisciplinary collaboration where multiple individuals work together but remain grounded in their respective ideologies [9–11]. Recently, a few studies have addressed the potential of transdisciplinary collaboration to develop effective interventions in healthcare [12–14]. Despite these efforts, research in healthcare improvement has typically involved a single researcher studying an intervention at a single hospital or clinical unit. This approach is ineffective as the complexity of organizational change and contextual influence can impact the implementation and effectiveness of an intervention [7, 15].

The current consensus in the field of improvement science is that new methodologies are needed to address complex issues associated with healthcare delivery [6, 16]. Specifically, researchers and clinicians need to adopt strategies that redefine relationships and establish new ways of communicating

[6, 16–18]. A transdisciplinary model may be the solution. In fact, implementation science frameworks suggest that transdisciplinary interaction promotes effective and sustainable intervention programs [19].

The shift from a single investigator/single site model to a transdisciplinary investigative team/multisite model calls for unique interactions between clinicians and researchers. Currently, there are few competencies and models for team performance; especially in the context of building transdisciplinary teams for improvement [20]. This paper describes the adoption of a transdisciplinary model in a healthcare improvement research network and the impact of collaboration on the conduct of a national improvement study. The results from this study show promise for enhancing research on improvement and uptake of best practices using transdisciplinary collaboration.

2. Theoretical Framework

The guiding framework to implement and evaluate a transdisciplinary collaborative model in this project was grounded in principles from the science of team science (SciTS). SciTS is a hybrid scientific field that incorporates factors that facilitate and hinder scientific collaboration [21]. This field has generated the evidence to support the claim that transdisciplinary collaboration spurs innovation and accelerates scientific discovery [22–24]. Additionally, SciTS is founded on evidence from human factors engineering and offers guidance on how investigative teams can be effective in studying healthcare improvement.

The SciTS framework for this study was adapted from a previous review of factors contributing to collaborative success [25]. Concepts were adopted by a healthcare research network based on the number of times they were referenced, how often they were used for an evaluation of collaborative work, and their relevance to long-distance collaboration. The four concepts in the framework are as follows: (1) readiness for collaboration, (2) creating a shared mental model, (3) management and planning, and (4) virtual readiness. These concepts are briefly described below.

2.1. Readiness for Collaboration. In order for a collaboration to be successful, scientific teams need to be ready to collaborate on an individual, group, and organizational level [26]. This readiness comes in the form of one's adaptability and flexibility, openness to diverse perspectives, communication skills, conflict resolution, respect for others, institutional support, and availability of reliable technology [27, 28]. Each of these qualities is essential for collaborative processes and group productivity [29].

2.2. Shared Mental Model. A shared mental model is the organized knowledge that people use to interpret, explain, analyze, and predict what is happening around them [30]. A shared mental model helps collaborating researchers to coordinate with teammates, form accurate expectations about tasks, and understand and anticipate each other's actions and needs [31]. Teams make fewer mistakes than individuals, especially when each team member knows his or her responsibilities, as well as the responsibilities of other team members [32]. Organizational researchers have observed that when team members have a shared mental model, it increases the overall team engagement and performance [30].

2.3. Management and Planning. The success of a project is dependent on the way the work is organized and carried out in a scientific team [22]. Structuring and monitoring are necessary to maintain scientific rigor and protocol fidelity especially in multisite studies. Without proper management, the project may not meet its objectives, or results generated from a study may not be reliable due to variations in study implementation and data collection.

2.4. Virtual Readiness. Virtual collaboration requires a high quality, well-functioning technical infrastructure that is designed to fit the nature of the work [22, 27]. Research suggests that user-centered technology, such as access to email, web space for sharing documents, and a centralized databases, is essential features for long distance collaboration [25, 33]. Without a stable technical infrastructure to support virtual collaboration, readiness to collaborate, shared mental models, and management planning are ineffective in multisite, transdisciplinary teams.

3. Methodology

3.1. Design. The main research questions for this study were (1) does an SciTS framework facilitate transdisciplinary collaboration in a healthcare improvement research network? and (2) what impact does a transdisciplinary model have on the conduct of a national, multisite improvement study? Mixed methods were used to collect and analyze data. This project was approved by the University of Texas Health Science Center San Antonio (UTHSCSA) Institutional Review Board (IRB).

3.2. Sample and Setting. The objectives of this project focused on transdisciplinary collaboration within a multisite study conducted by the Improvement Science Research Network (ISRN). The ISRN is a national hospital-based research network comprised of approximately 200 partners from academic and practice settings across the nation that have an interest in studying quality improvement. Demographic information for the ISRN membership at the time of this study is presented in Table 1. The majority of the membership consisted of nurses working in various fields in acute care settings or at academic institutions. Doctorate prepared members represented a variety of fields including nursing research, health services research, public health, translational science, quality improvement, and implementation science.

From the ISRN membership, research partners are invited to join Research Collaboratives for ISRN studies. Each network study is supported by a research infrastructure modeled after practice-based research networks (PBRNs)

Table 1: Demographic breakdown of ISRN membership (total N = 194).

Demographic	Category	N	% of total membership
Institution	Academic	80	41.2%
	Clinical	78	40.2%
	Not reported	36	18.6%
Membership type	Student	13	6.7%
	Professional	182	93.8%
Education	Bachelor	5	2.6%
	Master	33	17.0%
	Doctorate	86	44.3%
	Not reported	70	36.1%
Profession	Nurse	26	13.4%
	Nurse researcher	22	11.3%
	Physician	3	1.5%
	Educator	24	12.4%
	Faculty	74	38.1%
	Other*	34	17.5%
	Not reported	11	5.7%

*For example, program director, manager, executive, and coordinator.

and multisite clinical trials. The research infrastructure supports a Virtual Collaboratory, or center without walls, that allows a team of scientists to work on common problems regardless of location [25, 34]. The cornerstone of this infrastructure is a set of national research priorities that serve as a common rallying point to attract diverse perspectives and integrate paradigms from multiple disciplines in order to study improvement. These priorities were developed through a national stakeholder survey and include transitions of care, high-performing clinical systems and microsystems approaches to improvement, evidence-based quality improvement and best practice, and learning organizations and culture of quality and safety.

ISRN studies are supported through a cyber infrastructure equipped with appropriate communications technology (virtual meeting platforms and teleconference lines), a dedicated web space for sharing information and a central database for data entry. This technology platform is backed with sufficient bandwidth, electronic networking capabilities, and technical support. Adequate capacity for data security, integrity, privacy, rapid retrieval, and long-term archiving are also integrated into the ISRN infrastructure to support data entry and storage.

For this study, data were collected from 14 collaborating hospitals. The average hospital size was 425 beds (range: 120–665) with an average daily census of 74.7% (range: 60%–100%). Each site had at least one principal investigator (PI) and one research coordinator. Both PIs and research coordinators had nursing backgrounds with educational experiences that ranged from Bachelor's to Doctorate levels. Although the collaborative team also consisted of two study PIs (a doctorate-prepared nurse and a physician, both with extensive research backgrounds) and two research scientists (both PhD prepared with backgrounds in psychology and physiology), they were not included in the data collection due to their proximity to the evaluation and interpretation of results.

3.3. Procedure. SciTS principles were used to develop the key ISRN resources to facilitate the conduct of network studies. These resources included training meetings to build readiness and a shared mental model, a protocol implementation kit to facilitate study management, and a robust technical infrastructure to support long distance collaboration. Sites on the investigative team were required to complete capacity building exercises, including a training session on participating in a Research Collaborative. This 2-hour training session consisted of an overview of the ISRN mission and research priorities, a review of the study objectives, an introduction to the protocol, an explanation of data entry procedures, and a presentation of how to work as a collaborative team. Sites were also asked to review recorded ISRN presentations from experts in the fields of team science and virtual collaboration. Concepts from these presentations were discussed during study meetings. Finally, sites were given a resource guidebook on building successful research collaboration. This guidebook synthesized essential qualities for succeeding in research collaboratives for healthcare improvement [35].

To facilitate the study implementation and ensure the protocol fidelity, sites were given a protocol implementation kit (PIK). The PIK was designed with two goals in mind: (1) systematic implementation of the study protocol across multiple sites to yield analyzable/reliable data and valid study outcomes; (2) guidance for site PIs to facilitate the conduct of the study. The PIK provided a structured overview of various topics related to the study including: forming the project team, preparing for IRB submission, establishing project timelines, identifying participating staff members, using data collection materials, submitting data to the ISRN, and understanding results from the study.

Finally, sites were given access to a variety of technical resources, including a shared web space, access to conference lines, and a centralized database. A SharePoint site was developed to allow for the easy exchange of study documents. GoToMeeting (Citrix Systems, Inc.; Santa Barbara, CA) and a teleconferencing line were used for real-time meetings and presentations. Lastly, a centralized database was created and maintained by the UTHSCSA Department of Epidemiology and Biostatistics using the Informatics Data Exchange and Acquisition System (IDEAS), a robust web-based human studies research informatics data management framework.

3.4. Data Collection and Analysis. Variables that best represented measures of collaboration readiness, study management, and the presence of a strong mental model were selected for analysis. These variables included (1) the number of protocol deviations (study management), (2) meeting attendance percentage (shared mental model), (3) number of study timeline adjustments (readiness), and (4) number of questions received from PIs and coordinators regarding

study objectives (study management, shared mental model, and readiness) which were all collected from regulatory documents (e.g., protocol deviation logs), study meeting notes, and email communication.

Additionally, site PIs ($N = 16$) and research coordinators ($N = 14$) were surveyed on ISRN coordinating center services and resources. The survey was designed in Survey Monkey (SurveyMonkey.com, LLC; Palo Alto, CA), and a link to access the survey was emailed to Site PIs and research coordinators. Respondents were asked to rate the importance and quality of ISRN features and services on 6-point Likert scale. Dillman's best practices for internet surveys were adopted for data collection [36]. Results on key resources and services for a collaborative environment are reported. Frequencies and percentages were used to summarize raw data.

4. Results

4.1. Study Document Review. The number of protocol deviations, number of email correspondence, number of timeline adjustments, and meeting attendance percentage is broken down by site in Table 2. On average, collaborating sites reported six protocol deviations. Examples of deviations reported were study instruments turned in after data collection period ended and data collected from unconsented participants. A review of the study notes revealed that a total of ten sites (70%) successfully adhered to study timelines. Study timeline delays were due to late IRB approvals, accreditation visits, or a change in health information technology systems. The average number of email correspondences per site was 55 emails (range: 20–101 emails). The majority of questions from site PIs and coordinators pertained to the conduct of the study, including IRB regulations, participant recruitment, data collection, and data entry. Few questions (<1%) were directed towards the study's goals or the function of the collaboration. Finally, the attendance on conference calls averaged 94% with sites being absent due to scheduling conflicts or unexpected emergencies.

4.2. ISRN Coordinating Center Effectiveness Survey. A survey on the quality and importance of ISRN coordinating center services and resources was sent to a total 30 site PIs and coordinators. A total of 17 responses were received for response rate of 57%. Demographic information from survey participants is presented in Table 3. Each respondent had previous experience participating in studies as a part of a formal investigative team (mean: 6 studies per respondent, Range: 1–20 studies). On average, half of these studies involved professions other than nursing (mean: 3 studies per respondent, range: 0–15 studies). Results from survey items specific to providing a collaborative environment are presented in Table 4. Most services and resources were positively rated in terms of quality, but those related to organizational structure, study objectives, and communication were rated highest by respondents (>90%).

Table 2: Protocol deviations, emails received, and timeline adjustments.

Collaborating sites	Protocol deviations (N)	Emails received (N)	Timeline adjustment	Meeting attendance (%)
Site 1	2	55	Yes	83.3%
Site 2	NA	104	No	100.0%
Site 3	6	42	No	100.0%
Site 4	NA	75	Yes	100.0%
Site 5	1	39	No	100.0%
Site 6	10	32	Yes	100.0%
Site 7	19	78	No	100.0%
Site 8	2	101	No	100.0%
Site 9	NA	43	Yes	100.0%
Site 10	4	32	No	83.3%
Site 11	NA	81	No	100.0%
Site 12	14	33	No	100.0%
Site 13	0	20	Yes	66.7%
Site 14	15	37	No	83.3%

NA: not available.

Table 3: Demographic breakdown of survey respondents (total $N = 17$).

Demographic	Category	N	% of respondents
Education	Bachelor's	1	5.9%
	Master's	5	29.4%
	Doctorate	10	58.8%
	Other	1	5.9%
Current position	Frontline	1	5.9%
	Staff development	2	11.8%
	Faculty—academic institution	4	23.5%
	Research scientist—clinically based	8	47.1%
	Administrator	1	5.9%
	Manager	0	0.0%
	Other	1	5.9%
Career experience	less than 1 year	0	0.0%
	1 to 5 years	0	0.0%
	6 to 10 years	3	17.6%
	11 to 15 years	0	0.0%
	16 to 20 years	1	5.9%
	>20 years	13	76.5%
	Not reported	0	0.0%

5. Discussion

The present study described the adoption of a transdisciplinary collaborative model in a multisite improvement study. Resources developed using best practices from SciTS

Table 4: Summary on the quality of services offered by the ISRN coordinating center.

ISRN coordinating center services and resources	Quality (% responses)			
	Low	Medium	High	Total
Focused on the improvement science as the network mission.	0	0	100	100
Responded quickly and effectively to the site PIs emails and phone calls.	0	6	94	100
Provided clear description of the structure of ISRN (e.g., network PIs; site PIs; network studies).	0	6	94	100
Established Network structure and processes that supported collaboration.	0	19	81	100
Furnished clear call for letters of intent and application for STAR-2 sites.	0	6	94	100
Supported site PIs and collaborators as full partners in the study.	0	13	88	100
Outlined fair guidelines for collaboration (e.g., publication credits).	0	25	75	100
Provided a useful SharePoint site.	7	13	80	100
Engaged sites in an action plan for continuing in ISRN network studies.	13	20	67	100

facilitated the study's conduct as evident by consistent protocol implementation, active engagement, and focused task completion. The impact on productivity could have implications on identifying effective improvement strategies that lead to rapid uptake and spread. Improvement scientists and clinicians in the field need to engage in systems change to support team science and adopt resources, such as research collaborative guidebooks and training modules on SciTS principles, to build capacity for transdisciplinary collaboration.

In the context of collaboration readiness, individuals who demonstrate high levels of readiness are less likely to make mistakes, communicate effectively, and complete objectives in a timely manner [29]. This level of readiness can create a fertile environment for multiple disciplines to come together, blend knowledge, and create a new intellectual space [9]. Both researchers and clinicians must raise their readiness capacity in order to spur transdisciplinary initiatives in the field. The importance of this concept is further validated by the development of standardized evaluations that directly assess readiness in scientific teams, including the National Cancer Institute's Transdisciplinary Research on Energetics and Cancer (TREC) survey and the Collaboration Success Wizard [29, 37].

Additionally, resources are needed to cultivate shared mental models in the field. Currently resources do exist such as national research priorities in improvement science, frameworks for implementation science, and national methodology conferences [6, 15, 38–41]; yet, more is needed to help build transdisciplinary scientific teams for research. For example, experts have called for the establishment of professional organization for improvement and implementation science [42]. Attention has also been called to taxonomy development for an overarching language in hybrid fields [43]. In the present study, the ISRN research priorities and mission were intended to help create a shared mental model that kept research partners engaged in conducting the study. Without a mental model, the observed level of engagement would have decreased and impacted the quality of study outcomes.

The present study also demonstrated the effectiveness of the ISRN research infrastructure, in particular, the management of a multisite study with standardized approaches. A protocol implementation kit was shown to be an effective tool for ensuring protocol fidelity. The use of such a tool helps meet a need in the field for rigorous research and standardized implementation methods [6, 16, 39]. A failure to ensure consistent implementation and protocol fidelity can decrease the reliability of research findings and thus impact translation into multiple clinical settings.

The move from research to clinical practice requires scaling-up quality improvement initiatives to large-scale network studies. Doing so may yield more effective improvement and implementation strategies, improve dissemination of knowledge, and ultimately change policy. An example of transdisciplinary collaboration is in the numbers associated with the ISRN study evaluated for this paper. The dataset consisted of 24,014 data points reported by 716 acute care medical-surgical nurses across 14 hospitals. This represented 2,452 day shifts and 1,447 night shifts. A team-based approach enabled this particular study to capture a representative national sample to enhance the quality of research and raise scientific rigor. Such scale up of an improvement study will hopefully affect spread and generalizability.

A weakness of the present study is that team science concepts were measured indirectly. This is an indication of a need for established evaluation tools for transdisciplinary collaboration in improvement and implementation research. In fact, there is a nonhealthcare specific tool that is designed to identify potential barriers to collaboration and provide recommendations for improvement. The Collaboration Success Wizard (CSW) was developed to evaluate virtual collaborations based on 15 years of evidence that has identified factors that predict collaborative success [25]. An external evaluation of the same ISRN study described in the present paper revealed that the project was well positioned for successful collaboration using the CSW [44].

The present study was also limited in its ability to measure the impact of transdisciplinary collaboration on dissemination and implementation. This is mostly due to

the fact that this type of evaluation requires time. Thus, more research and funding are needed to demonstrate the impact of transdisciplinary research on spread and uptake of evidence-based quality improvement uptake. Given the magnitude of data collected from improvement studies using this approach, it can be inferred that rigors methods and generalizable results may speed uptake and spread; however, data are still needed to justify this claim.

6. Conclusion

This project demonstrated the effectiveness of a transdisciplinary model for academic and clinical scientists that are interested in studying improvement. Indications are that national improvement studies are positively assisted by the guidance gleaned from SciTS. Further research is needed on the causal relationship between team-based research and dissemination and implementation of evidence-based quality improvement. With advances in team research and increased funding opportunities to investigate dissemination, implementation, and improvement strategies in healthcare, the gap between what works and what is actually practiced will narrow to raise the quality of care delivery.

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Research Article

Implementation of Stroke Dysphagia Screening in the Emergency Department

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Early detection of dysphagia is critical in stroke as it improves health care outcomes. Administering a swallowing screening tool (SST) in the emergency department (ED) appears most logical as it is the first point of patient contact. However, feasibility of an ED nurse-administered SST, particularly one involving trial water swallow administration, is unknown. The aims of this pilot study were to (1) implement an SST with a water swallow component in the ED and track nurses' adherence, (2) identify barriers and facilitators to administering the SST through interviews, and (3) develop and implement a process improvement plan to address barriers. Two hundred seventy-eight individuals with stroke symptoms were screened from October 2009 to June 2010. The percentage of patients screened increased from 22.6 in October 2009 to a high of 80.8 in March 2010, followed by a decrease to 61.9% in June (Cochran-Armitage test $z = -5.1042$, $P < 0.0001$). The odds of being screened were 4.0 times higher after implementation compared to two months before implementation. Results suggest that it is feasible for ED nurses to administer an SST with a water swallow component. Findings should facilitate improved quality of care for patients with suspected stroke and improve multidisciplinary collaboration in swallowing screening.

1. Introduction

A well-established best practice in the care of patients with stroke is the early detection of dysphagia as it allows for immediate intervention thereby reducing morbidity, length of stay, and healthcare costs [1–3]. The essential first step to ensure early detection of dysphagia, and to prevent dysphagia-related morbidity, is to screen all stroke patients for signs of swallowing impairment prior to oral intake [1]. When a swallowing screening protocol is implemented, there is a decrease in morbidity over each year that the protocol is in place [4]. Moreover, when hospitals implement a formal swallowing screening protocol for patients with stroke, there is improvement in clinicians' adherence with screening swallowing prior to oral intake [2], and the first dose of aspirin is administered earlier [5].

These findings have led the American Heart Association/American Stroke Association (AHA/ASA) to include screening of swallowing prior to the administration of food, liquid, or medication in individuals presenting with stroke symptoms as part of their guidelines on the early management of adults with acute stroke [6]. Within the Veterans Health Administration (VHA) the importance of dysphagia screening in patient with stroke is reflected in the issuance of multiple directives. The Office of the Inspector General (OIG) issued VHA Directive 2006-032 mandating that the initial nurse assessment must include screening of swallowing, and in 2011 the VHA Directive for Treatment of Acute

Ischemic Stroke (AIS) required that all VHA facilities include dysphagia screening in their stroke care protocols and track performance as a measure of quality stroke care [7].

Completion of dysphagia screening prior to administration of oral intake was a Joint Commission (JC) required performance measure for Primary Stroke Center Certification until 2010 when it was removed due to a lack of systematically defined standards for what constitutes a valid screening tool for swallowing [8]. The discontinuation by the JC, however, does not indicate that screening swallowing in patients with stroke is no longer a best practice. Rather, it suggests that further research is warranted to obtain consensus on validated swallowing screening tools (SSTs).

Dysphagia screening protocols for patients with stroke, nevertheless, should include SSTs that incorporate evidence-based swallowing screening items (SSIs). Evidence-based SSIs have been validated for identifying aspiration in patients with stroke based on instrumental evaluation as the reference standard. A process for identifying evidence-based SSIs is described elsewhere [9] and is considered by the authors to be a legitimate interim approach until consensus is reached on specific SSTs or until a VHA-specific stroke SST is identified. Implementation strategies should also include effective training on administration and interpretation of the SST to ensure reliable results and sustainable swallowing screening skills among nurses and other clinicians administering the dysphagia screening protocol. Finally, it is equally important that SSTs are feasible for implementation in various practice settings because even the most valid and reliable SST will not be used if it is not feasible to administer in practice.

In response to the AHA/ASA guidelines and for compliance with stroke quality performance measures outlined in VHA directives, many VHA facilities have implemented locally developed SSTs for nurses to administer as part of stroke dysphagia screening protocols. There is debate on the need to incorporate trial water swallows with nonswallowing screening items as opposed to using purely nonswallowing screening items in locally developed SSTs. While most SSTs within VHA do not currently include trial swallows [10, 11], water swallows are standard in many SSTs used outside the VHA [12–14]. Furthermore, research provides strong evidence that suggests a water swallow component is critical when screening for dysphagia in individuals with suspected stroke [1, 9]; thus, a water swallow component appears to be an important item to include as part of an evidence-based SST.

Some contend, however, that administration of trial water swallows may compromise patient safety when administered by clinicians without specific expertise in dysphagia screening, such as nurses. There is also the perception that including a trial water swallow component will require extra time to administer thus creating a time constraint that will affect the feasibility of administering the SST. This may be especially true in the emergency department (ED) where there is pressure to complete rapid evaluation and treatment of individuals presenting with suspected stroke. These factors, as well as other unknown barriers, may impede the feasibility of implementing an SST that includes a trial water swallow component.

1.1. Purpose of the Study. Since screening of swallowing is a best practice that is essential for safe, high-quality care in individuals presenting with suspected stroke and the VHA has established the OIG and AIS directives, it is paramount that evidence-based mechanisms for screening for dysphagia in veterans with stroke are developed and implemented across VHA. Moreover, a swallowing screening protocol for veterans presenting with symptoms of stroke must be efficient and feasible for use by clinicians in any care delivery setting. The overall objective of this performance improvement study was to identify strategies for effective implementation of swallowing screening in patients with stroke symptoms that presented to the ED at a large VHA facility.

2. Methods

2.1. Design. A process improvement approach using a before/after design and qualitative methods was applied to determine the feasibility of implementing an evidence-based SST that included a water swallow component in the ED. The following questions were addressed: (1) Among nurses administering a stroke dysphagia screening protocol in a VHA facility ED, what are the barriers and facilitators to administering an SST with a water swallow component? (2) Does nurses' adherence with screening swallowing prior to oral intake in patients with stroke increase over time after applying process improvement strategies to implement an evidence-based SST with a water swallow component in the ED?

2.2. Setting and Sample. The study took place at the Michael E. DeBakey Veterans Affairs Medical Center (MEDVAMC) located in Houston, TX. The MEDVAMC is certified by the JC as a Primary Stroke Center and has the largest number of stroke admissions within the VHA. The ED is staffed with 20 registered nurses (RNs) and 3 emergency medicine physicians. A convenience sample of ED nurses ($N = 8$) was recruited to participate in semistructured interviews to obtain feedback on barriers and facilitators to implementing an SST with water swallow in the ED. Participants were recruited via personal invitation and email solicitation, and they all provided written consent prior to participation. The study was approved by the Institutional Review Board at Baylor College of Medicine and by the Research and Development Committee at the MEDVAMC.

2.3. Planning and Assessing the Implementation. In meeting study objectives, Plan, Do, Study, Act (PDSA) cycles were applied to identify process improvement strategies for implementation of an evidence-based SST with water swallow in the ED. The PDSA cycle is a well-established process improvement methodology that can be used to implement quality improvement changes in the "real-world" practice setting [15]. Prior to establishing an evidence-based nurse-administered stroke SST, swallowing screening for stroke patients was conducted in a nonstandardized fashion primarily by ED physicians and neurology residents, and infrequently by nurses.

Table 1: Michael E. DeBakey Veterans Affairs Medical Center stroke swallowing screening tool.

Non-swallowing items
Somnolent-difficult to maintain arousal/alertness with vigorous stimulation
Wet, gurgly voice quality-hear audible secretions in the throat with speech or respiration
Dysarthria-slurred speech
Drooling or pooling of saliva in oral cavity-difficulty managing saliva in the mouth
Coughing, choking on saliva
Patient/family reports patient with current difficulty swallowing
Swallowing items
5 mL water ×2
10 mL water ×2
20 mL water ×2

The first step, "Plan" was accomplished by a multidisciplinary team of speech pathologists and nurses with expertise in stroke and dysphagia. From June–September 2009, the team developed an evidence-based stroke SST that included a water swallow component. Items incorporated in the stroke SST were based on literature review [16–19] and expert consensus agreement (Table 1). A stroke dysphagia screening protocol was then developed to guide administration of the SST and clinical interventions based on screening results. The protocol required that nonswallowing "observational" items be administered first. If any nonswallowing item was evident, the screening was discontinued. The patient continued nil per os (NPO), that is, nothing by mouth including medication, and speech pathology was consulted. If none of the observational items were present, trial water swallows were initiated starting with a 5 mL volume. Each volume was administered twice. If cough, throat clear (audible attempt to clear material out of the throat), or wet voice was evident after any water trial, the screening was stopped and no further water was administered. The patient continued NPO status, and speech pathology was consulted. If cough, throat clear, or wet voice was not evident, the patient was considered to have no risk of dysphagia and oral intake was initiated.

The second step, "Do" involved implementing the swallowing screening protocol in the ED at the MEDVAMC. Implementation strategies began with initial education sessions from December 2009 to mid-January 2010 for all ED nurses in which information was presented on (1) the current guideline-derived best practices for swallowing screening in patients with stroke [6, 7], (2) how to administer the stroke SST with water swallow [16], and (3) specific protocol actions required based on whether the patient passed or failed the SST [6, 7]. After training sessions were completed, the ED nurses implemented the SST with a water swallow component as part of the stroke dysphagia screening protocol starting in December 2009.

The third step, "Study" involved tracking of nurses' adherence to the swallowing-screening protocol as it was implemented over time and also conducting semistructured interviews with ED nurses to identify barriers and facilitators encountered during implementation of the swallowing-screening protocol. Semistructured interviews were conducted in March 2009 and were designed to elicit feedback from the nurses responsible for administering the SST with water swallow. The interviews lasted 20 minutes and were audio recorded for transcription. Participants were asked to describe their experience in administering the SST including barriers and facilitators to completing the screening including the water swallow section, what they liked and disliked about the SST, and what facilitated and impeded documentation in the electronic health record (EHR) and to provide ideas on how to make the process of administering the SST better for ED nurses. Audiotapes from the interview sessions were transcribed and coded using content analysis. Words and word phrases were categorized as being indicative of either a barrier or a facilitator to administering the SST [20]. From March to April, minimal contact with the ED nurses was made as data were analyzed; however, SST implementation continued.

The final step, "Act" was initiated in April 2009 and included implementing multiple strategies and lessons learned based on feedback from ED nursing staff. This involved the application of rapid PDSA cycles [15] to target identified barriers and was an iterative process completed over a 3-month period. One important product was the development of a Stroke Dysphagia Screening Bundle (SDSB) that included (1) an evidence-based SST with water swallow, (2) EHR order sets that automated NPO status and consultation to speech pathology for patients with a positive SST and diet orders for patients with a negative SST, and (3) electronic templates that automated documentation of the entire dysphagia screening process in the EHR.

To address implementation barriers, the same process of PDSA cycles was applied, and implementation methods and education modules were developed and tailored to address the needs of the nurses administering the SDSB. Implementation tools and education modules were made accessible via a web interface for easy access and for booster training as needed.

2.4. Data Analysis of Pre-/Postimplementation Measures. Adherence with implementing an evidence-based SST with water swallow in the ED was assessed before and after implementation of the SDSB. This was accomplished by reviewing the EHRs of patients admitted to MEDVAMC with stroke symptoms and tracking if these patients received screening of swallowing prior to oral intake. EHRs were reviewed from October and November 2009 (the two months prior to implementing the SDSB) with continuation to June 2010 to identify the percent of patients screened each month in the ED post-SDSB implementation. The Cochrane-Armitage test was used to test if there was a trend in the percent of patients screened over the 9 months. Logistic regression was used to calculate the odds of being screened in the 7 months following implementation compared to the 2 months before implementation.

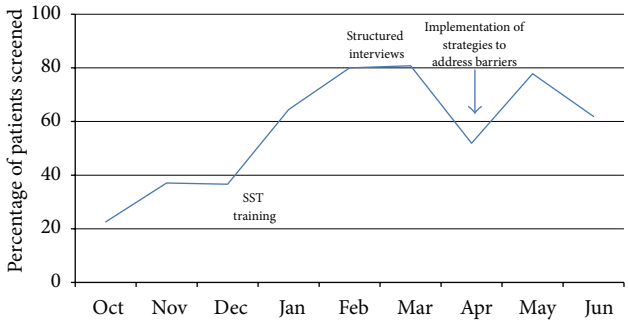

Figure 1: Percentage of patients screened in the emergency department from October 2009 to June 2010.

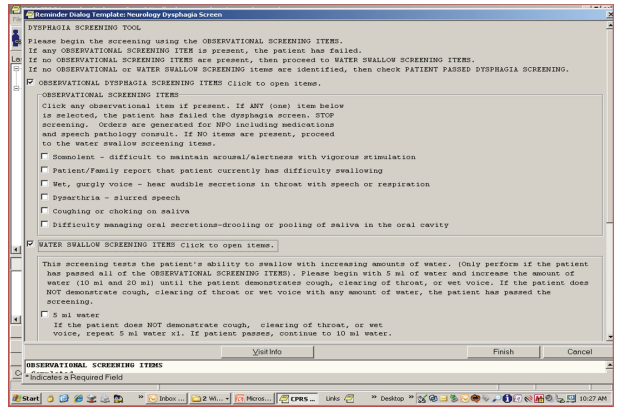

Figure 2: Template of swallowing screening in the electronic health record system.

3. Results

A total of 278 individuals with stroke symptoms were screened in the ED from October 2009 to June 2010. The percentage of patients screened increased from 22.6% in October 2009 to a high of 80.8% in March 2010, followed by a decrease to 61.9% in June 2010. Following implementation of the SST, the percentage of patients screened decreased to its lowest point of 51.9% in April 2010 but rebounded to 77.8% in the following month after implementing strategies to address identified barriers. There was a significant increase in the percentage of patients screened in the ED over time (Cochran-Armitage test $z = -5.1042$, $P < 0.0001$) (Figure 1). The odds of being screened was 4.0 times higher after implementation (95% CI, 2.2 to 7.3), compared to the 2 months before implementation.

Barriers identified from nurses' interview sessions were (1) difficulty finding time to document screening results in the EHR, (2) difficulty recalling all screening items during administration of the SST, (3) inconsistent administration of the SST, and (4) inaccurate interpretation of screening items, (e.g., confusing the item somnolence with the assessment of a patient's level of orientation or administering a patient 5 mL of water using a syringe instead of having the patient drink water from a cup).

Key facilitator themes that were subsequently applied in developing implementation strategies were (1) more education on dysphagia and evidence-based screening of swallowing, (2) efficient processes to support SST administration and interpretation, and (3) multidisciplinary team cooperation and support from ED administrators. The time it took to administer the SST was not formally recorded. However, during interview sessions, nurses reported, on average, the SST took approximately 5 minutes. Interestingly, no nurse reported that administration of the water swallow component was a barrier to completing the SST.

To facilitate the incorporation of the SDSB into daily practice, implementation methods and education materials were tailored to address identified barriers. Pocket cards were provided as a reminder aid (e.g., listed all SST items and steps for administration), and electronic tools (order sets and templates) were developed in the EHR to automate the steps of the SDSB and to facilitate documentation of SST results (Figure 2). An online video training module was produced to illustrate appropriate administration and interpretation of the SST, and booster education sessions were tailored to the specific needs of the nurse and targeted areas of identified deficit.

4. Discussion

This current performance improvement study was designed to determine the feasibility of implementing a nurse-administered stroke SST with a water swallow component and to identify strategies for effective implementation of a dysphagia-screening protocol for patients with stroke symptoms who present to the ED. We are unaware of any previous research that has assessed the feasibility of a nurse-administered SST, particularly an SST for use in the ED. The three major findings of this implementation study were as follows (1) an SST with a water swallow component was feasible for nurses to complete in patients presenting to the ED with symptoms of stroke; (2) an SDSB was created and swallowing screening significantly improved over time after implementation; (3) tailored implementation and education methods with booster sessions improved the sustainability of nurses' adherence with implementing the SDSB. Thus, the bundling of evidence-based SST items, swallowing screening processes, and clinical interventions with tailored implementation and education methods significantly improved stroke dysphagia screening at our facility.

Screening swallowing prior to oral intake in individuals presenting to the hospital with stroke symptoms is an important best practice described in AHA/ASA guidelines [6]. Since many patients with stroke symptoms first present to the ED, screening swallowing in the ED is most appropriate. This is based on the rationale that screening swallowing early, at the first point of patient contact, has the greatest potential to prevent administration of oral intake or oral medications prior to completing dysphagia screening. It is not uncommon for stroke patients in the ED to require immediate interventions to control blood pressure, discomfort, and other medical concerns that are often treated with oral medications.

The ED, however, is extremely busy, with nurses responsible for multiple care processes in the stroke work-up, and completing an SST that includes a water swallow component will add to nurses' responsibilities. Yet, all nurses in this study welcomed the opportunity to objectively determine the feasibility of implementing an SST with water swallow and to identify strategies for effective stroke dysphagia screening in the ED.

4.1. Focused Implementation Strategies. We engaged nursing staff in identifying facilitators and barriers for administration of an SST with water swallow in the ED and sought their input in developing strategies to address identified implementation barriers. Two implementation strategies emerged: (1) "bundling" dysphagia screening processes and (2) "tailoring" implementation and education methods. The multiple sequential actions involved in administering the SST and the required clinical interventions were bundled into an all inclusive SDSB.

Bundles are defined as a set of evidence-based interventions for a specific patient population and setting that when implemented together result in significantly better outcomes than when implemented individually [21]. The Institute for Healthcare Improvement and other groups recommend the use of "care bundles" to improve patient care and clinical outcomes [22]. Bundles have been most effective in improving the quality of care for mechanically ventilated patients by improving healthcare providers' compliance with relevant evidence-based practices. Bundles have also been shown to improve effective assessment of pain, appropriate use of blood transfusions, appropriate sedation, appropriate peptic ulcer prevention, and appropriate deep vein thrombosis prophylaxis [21].

The application of the bundle concept to improve dysphagia screening in patients with stroke is well suited because the primary purpose of a bundle is to pull together the essential evidence-based interventions (SST and associated clinical actions) that target a specific patient population (patients with stroke) undergoing a particular procedure (dysphagia screening) to ensure the best possible patient care and outcomes (prevent dysphagia-associated morbidity/mortality). The essential evidence-based interventions needed to develop an SDSB are as follows: (1) maintain the patient on a NPO status (including medications) until administration and interpretation of an evidence-based SST [6], (2) administer an evidence-based SST and interpret findings, (3) initiate oral diet without dysphagia modifications and initiate oral medications if SST results are negative, (4) continue NPO status and consult speech pathology to complete a swallowing assessment if screening results are positive, and (5) document completion of each SDSB component in the EHR.

Tailoring involves adapting or modifying interventions, implementation strategies, and educational resources to fit a specific population or context. Tailoring appears to be a critical factor related to effective implementation and is associated with improvements in process and patient outcomes [23, 24]. Effective tailoring requires engagement of stakeholders in developing implementation strategies to address identified barriers. For example, when the nurses in this study reported it was difficult to remember each screening item and the specific steps for the water swallow component included in the SST, they suggested developing a pocket card that listed each screening item with instruction on how to administer the water swallow component. Tailoring supports the unique needs of health care providers delivering the intervention but also makes possible adjustments in the intervention based on specific needs [23, 24]. Consistent administration of the SST and documentation of the administration process and findings in the EHR were an identified barrier. Nurses recommended developing an electronic template in the EHR that provided the step-by-step process used to administer the SST and would simultaneously document each step of the SST that was completed as the nurse interacted with the template. Later in the implementation process when the SDSB was developed, automated data sets were also incorporated into the EHR.

In terms of education, tailored strategies included providing ongoing training to nursing staff when deficits were identified. Performance monitoring and feedback that included the percentage of SSTs completed each month was reported to nursing staff in the ED and was used as an incentive and as an indicator of learning need. The investigators produced a video-training module of the SST procedure and made it accessible to all nursing staff on a facility intranet site. This provided easy access for booster training sessions when performance monitoring showed decreases in swallowing screening rates or when learning needs were identified by nursing staff.

4.2. Sustainability. The MEDVAMC receives the largest number of admissions for suspected stroke compared to other VHA facilities. In Fiscal Year 2009, approximately 20 patients with stroke symptoms were admitted monthly. Even with this high volume, an individual nurse may have the opportunity to complete an SST only once a month, so maintaining consistent and reliable administration and interpretation of the SST is challenging and may affect sustainability as evidenced by our fluctuating numbers in screenings during the study period. Consistently high screening numbers were observed following initiation of the screening protocol when education was fresh and the initiative was a new endeavor and again when nurses were engaged in developing strategies to address identified implementation barriers.

This finding is in line with much of the literature on the adoption of innovation which claims that adoption of a best practice or innovation is not a one-time occurrence, but rather a complex process that develops over time [25]. Adoption can be described in three stages: preadoption, early use, and established use [26]. The first stage, preadoption, occurs early on with the first introduction to a new innovation. Adoption of the innovation builds as the intended adopters have sufficient knowledge about what the innovation is, how it is used, and how it benefits them. The next stage, early use, includes periods of fluctuation as adoption builds to more consistent use. This occurs when adopters are provided continued access to information about the innovation and

receive sufficient training to support innovation tasks. During the final phase, established use becomes more evident and is related to adopters receiving adequate feedback on performance and sufficient opportunity to adapt and refine the innovation to improve its fit based on setting and context.

The fluctuation seen in the adoption of the SST by ED nurses in this study is most indicative of the stages of preadoption and early use. During the first few months of this 9-month pilot study, nurses were first introduced to the SST and received ongoing information about the SST, training on how to use it, and opportunities to adapt and develop implementation strategies. During the final 3 months of the project, targeted strategies developed by the ED nurses were initiated.

Another trend that may be attributed to the fluctuation in swallowing screening rates is that increases in swallowing screening were observed after periods of engagement with ED nurses (i.e., training and interview sessions) and decreases were observed in swallowing screening during times of minimal engagement with the ED staff. This finding strongly suggests that periodic engagement of the ED staff and availability of educators to answer questions and to provide ongoing booster sessions are important for sustained adoption. Moreover the involvement of the ED staff throughout the implementation process appeared critical to success and sustainability. Although fluctuation in screening adoption was evident, it is important to note that screening adherence never dropped to preimplementation levels further supporting the implementation of an ED nurse-administered SST with a water swallow component.

Since completion of this pilot study, we have continued to track performance with dysphagia screening and provide performance feedback to ED staff. The SDSB has been adopted at the MEDVAMC to implement evidence-based dysphagia screening and now includes ongoing booster education when deficiencies in dysphagia screening are identified. To date, the SDSB has been effective for consistent implementation of evidence-based dysphagia screening for patients admitted with suspected stroke with sustained screening rates between 93% and 100%. These data support adoption of the SDSB at the stage of established use. Subsequent steps are to test the effectiveness of developing site-specific SDSBs and tailored implementation methods and education in multiple VHA facilities.

4.3. Limitations. The time period evaluated was approximately 9 months. Continued longitudinal research is warranted to determine if results are maintained. Furthermore, implementation of this procedure should be completed at large and small medical centers to determine if the implementation process and results are similar. The time to administer any SST is an important focus of future research to ensure feasibility.

Every ED may not be able to complete a stroke SST given high-volume patient load, rapid transfer to patient wards, and/or limited staff. In cases where screening cannot be completed in the ED, it is unclear if this implementation process would work on a hospital ward and requires further research.

While the SST developed for the MEDVAMC is evidence based, it has not been validated. Work is in progress to develop and validate a VHA stroke SST in a separate study. Since several VHA directives have charged VHA facilities with implementing and monitoring dysphagia screening protocols for patients with stroke, evidence-based SSTs and effective implementation strategies are needed now. Thus, implementation studies should be completed in parallel with validation studies and once an SST is validated, effective implementation processes will be in place.

5. Conclusions

It is well established that patient outcomes are improved when dysphagia screening is completed prior to oral intake in individuals with stroke symptoms. This body of work supports the feasibility of nurses screening swallowing using an SST with water swallow in patients with stroke symptoms that present to a busy ED. Engaging nursing staff in the process of identifying barriers and targeted solutions resulted in the development of an SDSB and tailored implementation and education methods that significantly improve dysphagia screening adherence over time. Continued interaction and booster education sessions on administering and interpreting the SST are required for sustained improvement and consistent practice.

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