



The Role of Dissemination and Implementation Science in Global Breast Cancer Control Programs: Frameworks, Methods, and Examples

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Global disparities in breast cancer outcomes are attributable to a sizable gap between evidence and practice in breast cancer control and management. Dissemination and implementation science (D&IS) seeks to understand how to promote the systematic uptake of evidence-based interventions and/or practices into real-world contexts. D&IS methods are useful for selecting strategies to implement evidence-based interventions, adapting their implementation to new settings, and evaluating the implementation process as well as its outcomes to determine success and failure, and adjust accordingly. Process models, explanatory theories, and evaluation frameworks are used in D&IS to develop implementation strategies, identify implementation outcomes, and design studies to evaluate these outcomes. In breast cancer control and management, research has been translated into evidence-based, resource-stratified guidelines by the Breast Health Global Initiative and others. D&IS should be leveraged to optimize the implementation of these guidelines, and other evidence-based interventions, into practice across the breast cancer care continuum, from optimizing public education to promoting early detection, increasing guideline-concordant clinical practice among providers, and analyzing and addressing barriers and facilitators in health care systems. Stakeholder engagement through processes such as co-creation is critical. In this article, the authors have provided a primer on the contribution of D&IS to phased implementation of global breast cancer control programs, provided 2 case examples of ongoing D&IS research projects in Tanzania, and concluded with recommendations for best practices for researchers undertaking this work. **Cancer** 2020;126:2394-2404. © 2020 American Cancer Society.

KEYWORDS: breast cancer, Breast Health Global Initiative, Consolidated Framework for Implementation Research (CFIR), dissemination and implementation science, Tanzania.

INTRODUCTION

Greater than one-half (52%) of the nearly 1.7 million annual breast cancer cases worldwide and approximately 62% of breast cancer deaths occur in low-income and middle-income countries (LMICs).¹ The ratio of mortality to the incidence of breast cancer is over twice as high (0.51) in low-income countries compared with high-income countries (0.16).² This disparity in outcomes is attributable in part to a sizable gap between evidence and practice in breast cancer control and management, despite decades of research forming the evidence basis behind effective detection and treatment strategies.^{3,4} Closing this gap will require deliberate and active dissemination and the implementation of evidence-based practices into specific settings⁵ by first translating research into contextually appropriate interventions, policies, and guidelines, and subsequently implementing these into practice.⁶ In breast cancer control and management, for example, the first step has been achieved by the Breast Health Global Initiative and the National Comprehensive Cancer Network through the development of evidence-based, resource-stratified guidelines.^{3,7}

However, the development and publication of these resources does not necessarily result in their use,⁸ and strategies to disseminate and implement them are needed to meet the current and projected breast cancer control needs, especially in low-resource settings. Although the term “implementation” is widely used in the literature to describe the execution of an intervention, it often occurs without appropriate attention to dissemination and implementation science (D&IS). D&IS is defined as the scientific study of methods to promote the systematic uptake of evidence-based practices into real-world contexts to prevent disease and improve the quality and effectiveness of health care services.^{9,10} Considerable research has shown that structured implementation strategies designed to target systematically identified barriers can improve guideline uptake.^{11,12} D&IS is a powerful tool to aid in the planning, implementation, evaluation, and iterative

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improvement of translating interventions and guidelines into practice. Used effectively, it can result in the selection of the most effective strategies for a given setting and improvements in cost-effectiveness for the health system as ineffective or poorly implemented interventions are either discarded or improved upon. Key principles of D&IS, such as stakeholder engagement, application of theoretical frameworks, and rigorous ongoing evaluation, can be leveraged to optimize implementation from the individual to the system levels.^{5,13} Concerted, high-quality D&IS research efforts are especially important in cancer control program and guideline implementation, owing to the unique complexity of the field.¹⁴ Moreover, D&IS is particularly relevant in LMICs, where resource constraints require innovative approaches to evidence-based practices, such as task shifting and mobile technology-based patient navigation, which must be systematically explored and evaluated within a given context.^{15,16} D&IS has a role across the breast cancer care continuum from awareness and education to promote early detection, to targeting behavior change among treatment providers, to analysis of health care systems.^{3,4} In this article, we have provided a primer on the frameworks and methods that D&IS contribute to the phased implementation of global breast cancer control programs. We started by defining D&IS and have provided 2 illustrative implementation research examples, and then highlighted common implementation strategies, outcomes, and research designs. Finally, we have provided resources for D&IS and concluded with a summary of best practices for undertaking D&IS research.

Defining D&IS Within the Context of Global Breast Cancer Control

D&IS is one tool with which to enhance the effectiveness of cancer control interventions in real-world settings. It has a role at nearly every step of the translational research continuum, facilitating the uptake of basic research that proves to be efficacious in clinical contexts by real-world individuals, organizations, and decision makers.¹⁷ In global breast cancer control, D&IS is especially relevant in guiding the planning of cancer control programs and evaluating their implementation to inform policy and clinical practice so that programs can be further adjusted and improved.⁴ Some general examples of the types of D&IS questions that are crucial for global breast cancer control are listed in Table 1. The answers to each of these questions rely, in part, on the evidence obtained in research trials regarding the efficacy of the interventions, but also are highly dependent on the setting and level of resources

TABLE 1. Example D&IS Questions for Global Breast Cancer Control

Breast cancer risk reduction	<ul style="list-style-type: none"> • What are the most feasible and effective strategies to promote physical activity, facilitate healthy eating, and reduce the use of alcohol? • How can women at high risk of breast cancer because of a family history or genetic mutation be identified?
Breast cancer early detection and diagnosis	<ul style="list-style-type: none"> • What are the most feasible and cost-effective breast cancer early-detection strategies given the available resources? • How can diagnostic services (imaging, biopsy, and pathology) be scaled up to guide treatment decisions?
High-quality breast cancer treatment	<ul style="list-style-type: none"> • How can access to basic breast cancer treatments be improved and financed? • At what level(s) of the health system should breast cancer treatment(s) be provided? • What strategies can increase guideline-concordant treatment completion?
Strengthening of survivorship care	<ul style="list-style-type: none"> • What are the most feasible strategies to improve the follow-up and care of breast cancer survivors to monitor quality of life and disease recurrence? • How can palliative care needs be met?

Abbreviation: D&IS, dissemination and implementation science.

available; each question may be answered differently depending on the sociocultural, political, and health service context of the individual settings. Therefore, D&IS is a powerful tool for determining how to best choose among different evidence-based interventions, how to adapt their implementation for specific settings in a way that it is most likely to succeed, and how to evaluate the implementation process as well as its outcomes to be able to determine what works and what does not, and adjust accordingly.

D&IS models, frameworks, and theories

A key feature of D&IS is the use of models, frameworks, and theories to guide research and practice.^{18,19} Process models specify the steps, stages, or phases in the process of translating research into practice or, put differently, the process of implementing evidence-based health interventions in real-world settings.¹⁸ Some process models describe a linear process, with feedback loops, that begins with research discovery and the production of evidence-based interventions and moves to the dissemination of those interventions to targeted audiences and their implementation into practice. Others process models provide practical guidance for the planning and execution of implementation efforts. An example of a process model that has research as its foundation but also provides practical guidance is the Quality Implementation Framework.²⁰ Explanatory frameworks and theories describe barriers or facilitators that influence access to or use of evidence-based health interventions and other implementation outcomes.

Unlike process models, which describe steps or stages of implementation, explanatory frameworks and theories identify factors that hinder or facilitate implementation. They are useful for assessing the context of implementation and for guiding the selection of implementation strategies that overcome barriers or harness facilitators. They also can explain the level of implementation attained in a specific setting or the variations in implementation attained among multiple settings. For example, the Consolidated Framework for Implementation Research (CFIR) includes several constructs organized around the intervention characteristics, outer setting, inner setting, characteristics of individuals, and process constructs.^{21,22} Evaluation frameworks provide a conceptual structure for evaluating implementation efforts. Unlike explanatory frameworks and theories, which identify the factors that influence implementation success, evaluation frameworks identify the metrics for gauging implementation success. A commonly used framework to evaluate implementation outcomes in global health is “RE-AIM” (Reach, Effectiveness, Adoption, Implementation, Maintenance), which identifies similar outcomes despite differences in terminology.²³

There are a growing number of examples demonstrating how implementation science is used in developing innovative approaches to tackle cancer diagnosis and treatment in LMICs. They range from research on the local implementation context, to testing the implementation of evidence-based interventions, to conducting cluster randomized trials.²⁴⁻²⁶ These highlight the role of D&IS along the entire research continuum, from identifying barriers to cancer control in one setting all the way up to scaling up programs at the national level. In the current study, we have provided 2 ongoing research examples that highlight the selection and use of different models and frameworks in implementation research focused on breast cancer control in Tanzania.

Example 1: The “Time to A.C.T.” study to implement strategies to improve breast cancer care

As the Tanzanian Ministry of Health was developing their first national service delivery policy for the early detection of breast cancer, the “Time to A.C.T.” study was conceptualized collaboratively between Johns Hopkins, the Catholic University of Health and Allied Sciences, and Bugando Medical Center to study the context and opportunities for breast cancer control efforts.²⁷ This ongoing study provides a framework, the Assess-Couple-Test (or “A.C.T.” framework), for an adaptive research approach to transition from phases of formative data collection, to identifying

contextually appropriate and feasible interventions to improve breast cancer control, to studying the implementation of those interventions (see Table 2). The research takes place in a geographically large area, far from the capital, that is served by a zonal hospital that has moderate but increasing capacity for breast cancer diagnosis and the availability of trained surgeons and medical oncologists for treatment.²⁸ However, very little was known with regard to health service operations such as time and losses along the cancer care continuum, provider and patient perspectives and practices, or general community awareness of breast cancer. Therefore, the “Time to A.C.T.” study aimed to: Assess the local context for breast cancer control efforts; Couple evidence-based interventions to overcome the identified challenges by engaging stakeholders in a selection and reduction process; and Test the interventions in a pilot study to inform larger, adapted implementation trials.

Similar to many D&IS studies, “Time to A.C.T.” incorporated both explanatory (CFIR) and evaluation (RE-AIM) frameworks, and used mixed methods (quantitative and qualitative research) in each phase. For example, in the “assessment” phase, a survey of >100 local providers at different level health facilities was conducted to gauge provider knowledge of breast cancer, diagnosis, and treatment generally and within the local capacity context. These surveys then were followed with in-depth interviews to explore the quantitative findings in more detail, and to elaborate on providers’ barriers and suggestions for providing optimal breast care. These results, along with a community-based survey of women’s knowledge-attitudes-practices, a review of nearly 1000 medical charts from multiple facilities, and other in-depth interviews, have been shared with the diverse stakeholder panel (including patient representatives and/or advocates, local providers, leadership in hospital oncology departments, international breast oncologists and researchers) to engage in the process of co-creation. In this “coupling” phase, the stakeholders each contributed, through in-depth interviews focused around a barriers-solutions matrix, to the identification and adaptation of evidence-based interventions that are perceived to be responsive to the local context, feasible to implement now, and likely to contribute to improved breast cancer care for patients in the region. The intervention selected for pilot testing is the development and implementation of standardized clinical pathways at the zonal hospital, which is comprised of 3 implementation strategies: 1) coordination of clinical breast examinations for patients with breast diagnostic evaluations 2) improved workflow for breast diagnostic evaluations and 3) a breast cancer-specific multidisciplinary tumor

TABLE 2. Summary of D&IS Research Elements and Components of 2 Studies Focused on Breast Cancer Control and Treatment in Tanzania

Research Program Components	Implementation of Strategies to Improve Breast Cancer Control in Mwanza, Tanzania	Implementation of National Cancer Treatment Guidelines in Dar Es Salaam, Tanzania
Team expertise	Implementation scientist, medical/surgical/radiation oncologists, epidemiologist, qualitative researcher, patient advocate	Implementation scientist, medical/radiation oncologists, oncology nurses, health economist, clinical researchers, qualitative researchers
Guiding theoretical frameworks	Expert recommendation for Implementing Change (ERIC), Consolidated Framework for Implementation Research (CFIR)	Capability, Opportunity, Motivation and Behavior/ Behavior Change Wheel (COM-B/BCW) framework
Methods for contextual assessments	Mixed methods: Quantitative surveys and retrospective chart reviews, qualitative interviews, and pathway analysis	Meetings with key stakeholders, field observation, and focus groups with oncologists, residents, and nurses
Key barriers identified	Low community and provider knowledge, lack of capacity at lower facilities, delays in care seeking and in the provision of care, limited diagnostic evaluations, incomplete treatment	Guidelines not readily accessible, little professional value placed on guideline concordance, lack of accountability in patient management
Stakeholder identification	Snowball sampling starting with team members with attention to all levels of the system from patients to directors/leaders	The 7Ps framework (patients/public, providers, purchasers/payers, policymakers, product makers) used to identify stakeholders
Stakeholder engagement	Participatory action research, including quarterly newsletters, data review, in-depth interviews	Series of in-person meetings during project development, biweekly videoconferences with project leaders and key stakeholders, focus groups
Consensus on research focus	Essential to start with gaps in care at the zonal hospital before efforts to increase referrals and patient load	Plan to address guideline implementation at national referral facility Ocean Road Cancer Institute first before expanding to other sites
Selected intervention	Developing, implementing, and monitoring standardized care pathways for patients with breast concerns at the zonal hospital	Newly published Tanzania National Cancer Treatment Guidelines
Implementation strategies	Three sequential strategies, each with a multistep plan: 1) route new breast patients through 2 points of entry; 2) diagnostic referral and capacity; and 3) dedicated multidisciplinary tumor board for patients with breast cancer	Phased implementation strategy: 1) multimodal distribution of guidelines; 2) training for providers and champions at national summit; and 3) longitudinal behavioral reinforcement
Outcome framework	RE-AIM with a focus on reach, effectiveness, and adoption	Logic model of implementation strategy served as a framework for program evaluation; RE-AIM was used to identify outcomes for evaluation
Outcome evaluation design	Preimplementation versus postimplementation evaluation through patient tracking, provider surveys, and new clinical documentation	Preimplementation versus postimplementation field observation including provider surveys and regular debrief sessions with champions

Abbreviations: D&IS, dissemination and implementation science; RE-AIM, Reach, Effectiveness, Adoption, Implementation, and Maintenance.

board for treatment planning. The pilot “testing” phase of the implementation research will be evaluated through a partial application of the RE-AIM framework using a preimplementation versus postimplementation design with the goal of generating data to enhance adaptation and support a larger trial. The “A.C.T.” framework and methods can be readily adapted to different resource levels and types of breast cancer control research (eg, regions that are focusing on community awareness or to countries transitioning to population-based screening).

Example 2: Implementation strategy development and evaluation for Tanzania's new national cancer treatment guidelines

The Muhimbili University of Health and Allied Sciences, Ocean Road Cancer Institute (ORCI), and University of California at San Francisco Cancer Collaboration has conducted research to develop an implementation

strategy for the new Tanzania National Cancer Treatment Guidelines at ORCI using a theory-based approach (see Table 2).²⁹ First, the team identified barriers and facilitators of guideline-based practice at ORCI through meetings with key stakeholders and focus groups with oncologists, residents, and nurses. Second, these barriers and facilitators were categorized using an explanatory framework: the Capability, Opportunity, Motivation and Behavior/Behavior Change Wheel Framework (COM-B/BCW). Based on the COM-B category, a behavior change intervention was selected to address each barrier and identified a feasible mode of delivery.³⁰ Compiling all of these interventions and modes of delivery resulted in an implementation strategy with 3 phases: 1) distribution of the guidelines as hard copies and through a smartphone application, accompanied by a publicity campaign; 2) knowledge and skills training for providers and implementation champions at a national guideline launch summit; and

3) longitudinal reinforcement techniques such as environmental restructuring and point-of-care clinical forms to promote guideline concordance. The RE-AIM framework was used to design an evaluation plan that will assess implementation outcomes through provider surveys and debriefing sessions with champions, as well as clinical data collection.

Implementation Strategies, Outcomes, and Research Designs

Implementation strategies

Implementation strategies³¹ enhance the adoption and sustainability of evidence-based health interventions into routine public health or clinical practice by addressing the barriers to implementation that can operate at the individual, organizational, community, or policy levels. The Expert Recommendations for Implementing Change (ERIC) taxonomy includes 73 discrete implementation strategies³² and highlights the wide range of options available to implementation scientists and practitioners in LMICs. Commonly used implementation strategies in global breast cancer control include guideline dissemination, provider education, audit and feedback (in which health professionals are provided a summary of clinical performance to allow them to assess and adjust their performance), provider and client reminders, task shifting, and quality improvement.^{29,33-37} Systematic reviews have indicated that these strategies have modest effects in terms of changing provider behavior³⁸; however, they are likely to be more effective when selected and deployed to address the specific barriers they are designed to address (eg, reminders provide a cue to action, but do not address knowledge or attitudes) and when the optimal form of strategy is used.³⁹ Audit and feedback, for example, can be performed in many ways, some of which are more efficient or effective than others. Therefore, it is important to study and link barriers or contextual elements to implementation strategies to maximize outcomes, as highlighted by our 2 examples.

Evidence-based interventions and guidelines can be implemented through various models and frameworks. One particular framework that acknowledges that guidelines operate within a complex “system” is the Interactive Systems Framework, which describes 3 systems for dissemination and implementation according to who enacts the evidence-based guidelines.⁴⁰ Delivery system actors are the teams that adopt and integrate guidelines into routine practice; support system actors promote the adoption and implementation of the guidelines by building the capacity of delivery system actors whereas synthesis and translation system actors

synthesize, translate, and disseminate guidelines in various formats. Later, Leeman et al coupled these different actors with action targets and described 5 classes of implementation strategies: 1) dissemination; 2) implementation process; 3) integration; 4) capacity building; and 5) scale up.⁴¹ This classification is practically useful because it identifies actors, action targets, and outcomes used to assess the effectiveness of evidence-based strategies (see Table 3)^{20,32,41-52} and can be applied to breast cancer control guidelines to improve their uptake. The proposed classification system reflects the ongoing efforts of implementation scientists to develop more clear and meaningful ways of communicating about strategies that are necessary for moving evidence-based interventions into real-world practice. The inclusion of strategies for dissemination, integration, and capacity building make it particularly well suited to studying breast cancer control programs in LMICs.

When implementing breast cancer control programs, communication and engagement of stakeholders is important at all stages. Bringing different parties together produces a blend of ideas that lead to a mutually valued outcome, a process known as co-creation. For example, the Ministry of Health in Zambia convened a co-creation workshop to plan for a breast cancer control program that was suitable within a Zambian context. There was consensus that efforts should focus on the early diagnosis of breast cancer to reduce presentations with late-stage disease as a first step toward lowering breast cancer mortality.⁵³ Unfortunately, there are many examples in which local context and stakeholder perspectives are not taken into consideration, leading to negative impacts on the effectiveness of translating evidence-based interventions into practice. One example in which the authors were insightful enough to acknowledge the limitations to their approach was a trial of clinical breast examination from the Philippines in which only 35% of patients completed diagnostic follow-up after a positive clinical breast examination and 42% actively refused further investigation. This example highlights the importance of D&IS because, as the authors concluded, “cultural and logistic barriers to seeking diagnosis and treatment persist and need to be addressed before any screening program is introduced.”⁵⁴ Because stakeholder engagement and context-specific adaptation are integral to D&IS, using established implementation strategies can avoid such pitfalls.

Implementation outcomes

Implementation outcomes are “the effects of deliberate and purposive actions (ie, strategies) to implement new treatments, practices, and services.”⁵⁵ Interventions that

TABLE 3. Five Classifications for Implementation Strategies

Classification	Category of Actor	Action Target (Determinants and Levels)	Example Strategies	Outcomes Used to Assess Effectiveness	Example Strategy Lists and/or Descriptions
Dissemination strategies	Synthesis and translation, support, and delivery systems	Awareness, attitude, knowledge, and intention to adopt a specific EBI; targets levels of intervention and individual	<ul style="list-style-type: none"> Develop EBI messaging, packaging, and pricing customized to audience Distribute customized EBI messages and packages through channels with optimal reach Engage stakeholders Assess context (need, capacity) Establish goals and objectives Select EBI and implementation strategies that fit Adapt EBI, strategies, and context Evaluate processes and outcomes 	Distribution reach to target audience; EBI awareness, knowledge, attitude, and intention to adopt	Dearing & Kreuter 2010 ⁴² Kreuter & Bernhardt 2009 ⁴³
Implementation process strategies	Delivery system	How well teams execute activities required to select, adapt, and integrate EBIs generally; targets level of process	<ul style="list-style-type: none"> Engage stakeholders Assess context (need, capacity) Establish goals and objectives Select EBI and implementation strategies that fit Adapt EBI, strategies, and context Evaluate processes and outcomes 	Extent, quality, and timeliness of the completion of activities related to specific implementation process strategies	Aarons et al 2011 ⁴⁴ Chinman et al 2004 ⁴⁵ Institute for Healthcare Improvement Meyers et al 2012 ²⁰
Integration strategies	Delivery system	Factors that facilitate or impede optimal integration of a specific EBI into a specific setting; targets levels of individual and inner setting	<ul style="list-style-type: none"> Institute reminder systems Revise professional roles Provide supervision Modify medical record systems Implement tools for quality monitoring 	Individuals' motivation, capability, and opportunity to implement an EBI; team coordination and/or communication; fidelity, feasibility, and acceptability	Fixsen et al 2009 ⁴⁶ Mazza et al 2013 ⁴⁷ Powell et al 2015 ³²
Capacity-building strategies	Support system	Motivation and capability to engage in implementation process strategies (in general, not related to a specific EBI); targets levels of individual and processes	<ul style="list-style-type: none"> Training to build general capacity Technical assistance and facilitation for implementation processes Tools to support implementation processes 	Individual and collective self-efficacy and motivation to engage in implementation process strategies; team completion of implementation process strategies	Leeman et al 2015 ⁴⁸ Jacobs et al 2014 ⁴⁹ Wandersman et al 2012 ⁵⁰
Scale-up strategies	Support system	Motivation and capacity to integrate a specific EBI into practice; targets level of individual, inner setting, and outer setting	<ul style="list-style-type: none"> Across multiple settings: <ul style="list-style-type: none"> Training to build EBI-specific capacity Technical assistance and facilitation (EBI specific) Implementation toolkits Quality improvement collaboratives Benchmarking 	Motivation and capacity to implement, and actual implementation of, an EBI across multiple settings	Barker et al 2016 ⁵¹ Millat et al 2016 ⁵²

Abbreviation: EBI, evidence-based intervention, equivalent to evidence-based practice. Adapted from Leeman J, Birken SA, Powell BJ, Rohweder C, Shea CM. Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice. *Implement Sci.* 2017;12:125.⁴¹

TABLE 4. Defining Implementation Outcomes and Examples

Implementation Outcomes and Related Terms	Definition	Examples
Acceptability (comfort, relative advantage, and credibility)	The perception among relevant stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory	Intervention: Community-based CBE performed by community health workers Outcome: How comfortable are women having a CBE performed by a health worker
Adoption (uptake, use, and intention to try)	The intention, initial decision, or action to try or use an innovation or evidence-based practice	Intervention: New treatment guidelines Outcome: Uptake and use of guidelines
Appropriateness (relevance, compatibility, and perceived usefulness or suitability)	The perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer and/or perceived fit of the innovation to address a particular issue or problem	Intervention: Clinical feedback Outcome: Beliefs in usefulness of clinical feedback to improve breast care
Cost (marginal cost, total cost, and numerators for cost utility, cost benefit, and cost-effectiveness)	The cost impact of an implementation effort	Intervention: Provision of guideline-concordant cancer treatment to all patients Outcomes: Total costs and cost-effectiveness of the intervention for the government
Feasibility (practicality and actual fit)	The extent to which a new treatment or an innovation can be successfully used or performed within a given agency or setting	Intervention: Implementation of a unified electronic system for medical files Outcomes: Perceived likelihood of implementing the system in all hospitals
Fidelity (adherence, integrity, quality of program delivery, and intensity or dosage of delivery)	The degree to which an intervention was implemented as it was prescribed in the original protocol, or as it was intended by the program developers	Intervention: Chemotherapy regime Outcomes: Rate of completion of full course of chemotherapy
Penetration (reach, access, service spread, coverage, or effective coverage)	The integration of a practice within a service setting and its subsystems	Intervention: Availability of breast ultrasound in all district hospitals Outcomes: Effective coverage of diagnostic ultrasound
Sustainability (maintenance, continuation, durability, institutionalization, routinization, integration, and incorporation)	The extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations	Intervention: Introduction of a new practice guideline Outcomes: Integration of the practice guideline into routine care

Abbreviation: CBE, clinical breast examination.

Adapted from Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. 2011;38:65-76⁵⁵ and Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. *BMJ*. 2013;347:f6753.⁵⁶

are poorly implemented, or not implemented at all, do not produce expected positive health outcomes. However, even when effectively implemented, interventions still might not produce expected positive health outcomes if the intervention loses effectiveness in the process of implementation (eg, a suboptimal dose is delivered, or efficacy-undermining adaptations made) or the intervention was never effective in the first place. Assessing implementation outcomes offers a means for evaluating implementation success or failure, or stated differently, the effectiveness of the implementation effort or strategy, in terms that are distinct from, yet related to, the health outcomes that interventions expected to produce.

The Implementation Outcomes Framework⁵⁵ identifies 8 implementation outcomes and distinguishes them from service delivery outcomes (which generally are the focus of health services research) and health outcomes (which generally are the focus of outcomes research). The 8 implementation outcomes are: 1) acceptability; 2) adoption; 3) appropriateness; 4) cost; 5) feasibility; 6) fidelity; 7) penetration; and 8) sustainability (see Table 4 for definitions and examples).^{55,56} These outcomes are

important in their own right because they indicate how well an implementation strategy is working or how successful an implementation effort was ultimately. In addition, these outcomes also serve as preconditions for attaining desired service delivery outcomes or health outcomes.

D&IS research is useful for determining the feasibility and appropriateness of specific settings, before major investments are undertaken to implement theoretically useful interventions that may not be successful, or even realistic to undertake, in different contexts. For example, an exercise program for breast cancer survivors that proved successful in a randomized controlled trial to reduce the risk of lymphedema and improve upper body strength was implemented in a community setting. The D&IS approach undertaken allowed for indispensable adaptations of the intervention such as overcoming cost barriers by negotiating with third-party payers for coverage, and the training of clinicians so that they would refer patients to the program.⁵⁷ Thus, it is particularly important to measure and assess these linkages when health interventions

are adapted during implementation, applied to a different population, or delivered in a different setting.

Research designs

Implementation science uses a range of research designs to assess the implementation strategies and outcomes. Many of these study designs are not unique to D&IS. For example, qualitative research methods often are used within the formative research context to identify the barriers and facilitators of implementation, whereas experimental research designs, such as the cluster randomized controlled trial and the stepped-wedge trial, are commonly used to evaluate the effectiveness of implementation strategies. Mixed methods research designs are widely used to investigate the factors that explain the level of implementation success observed in a setting or the varying levels of implementation success observed across multiple settings. A common choice is the explanatory sequential mixed-method design, wherein quantitative data regarding implementation outcomes are used to select cases for qualitative inquiry in to, for example, the factors that differentiate settings or providers that attain high or low levels of implementation. More unique studies, such as the interrupted time series design, the regression continuity design,⁵⁸ and the regression displacement design,⁵⁹ are used infrequently, yet are potentially powerful ways to evaluate the effectiveness of implementation strategies when random assignment is not possible. The implementation-effectiveness hybrid research design, which often takes the form of a randomized controlled trial, is useful for evaluating both implementation outcomes and intervention outcomes.⁶⁰ Although hybrid research designs can be more challenging to conduct, they can provide policy makers and other stakeholders with more information for scale up and spread compared with pure effectiveness trials or implementation trials. Herein, we have provided references for several examples of breast cancer research in diverse settings using many of these different research designs.⁶¹⁻⁶⁷

Resources for Learning, Planning, and Conducting Implementation D&IS Research

There are several publicly and globally available tools with which to facilitate D&IS research to increase and improve breast cancer control in LMICs.⁶⁸⁻⁷⁰ For example, the US-based National Cancer Institute has a website dedicated to education and training opportunities, including >50 free webinars, and research and practice tools for D&IS research. The Guidelines International Network has an Implementation Working Group and a repository of tools to facilitate its members' mission of strengthening

guideline development, adaptation, and implementation.⁷¹ As highlighted above, there is a large number of models and frameworks available in D&IS. Fortunately, there is an online resource that helps researchers understand and select models that are appropriate to their research context.⁷² There are several published commentaries and examples available with which to estimate the impact of providing early diagnosis and treatment interventions in different resource settings, which can help individual countries to identify effective and appropriate phased interventions given their available resources.⁷³⁻⁷⁵

The Breast Cancer Initiative 2.5 provides tools such as the Global Breast Health Analytics Maps (GLOBAM), baseline situation analysis, stakeholder mapping, and focus group guidance. GLOBAM is an interactive data visualization tool that links ecological data concerning breast cancer incidence and mortality, health spending, cancer policies and practices, determinants of health, and more by country. This resource can be used to map health system resource levels, identifying gaps in breast health care and shaping resource-appropriate solutions.⁷⁶ For more granularity, baseline situational analyses can be conducted, ideally followed by person-focused mixed methods assessments of knowledge, practices, barriers, and motivators of breast cancer control. Because education and training often are identified as barriers to program implementation or improvement, Breast Cancer Initiative 2.5 also provides a "knowledge summaries toolkit" to address foundational questions in comprehensive breast cancer care across the life course in resource-limited settings. The toolkit contains 14 knowledge summaries distilled from evidence-based, resource-stratified guidelines, and is aligned with World Health Organization guidance on breast cancer control. Combined, these tools provide a shared platform for stakeholders to engage in decision making appropriate to the local context. The goal is to facilitate evidence-based policy actions and urgently advance implementation of an integrated approach to reduce breast cancer mortality and improve quality of life.^{77,78}

Conclusions

Unlike traditional clinical or epidemiologic research, D&IS research focuses on the inclusion of the heterogeneity that exists in real-world application and uses methods that allow for data triangulation to not only understand whether a dissemination or implementation strategy is working, but why and how (or why not and how not). As highlighted by the main outcome measures, the goal of D&IS research is to identify strategies that are feasible, acceptable, appropriate, cost-effective, will be adopted,

can be used with fidelity, penetrate the target setting, and can be sustained. Of course, these also are the goals of our breast cancer control programs. To guide researchers undertaking this research, we have concluded with suggestions regarding best practices in D&IS in LMICs focused on cancer control:

1. Engage multilevel stakeholders at the beginning of the program to identify the common goal of and motivation for the research.
2. Consider the use of D&IS research to collect data from individuals up to the systems level to inform policy creation and also to guide policy dissemination and implementation from the systems level down to individuals in the target population.
3. Conduct formative research regarding the local context for breast cancer control to prioritize action and identify the most feasible and acceptable interventions in that time and place.
4. Remember that dissemination of knowledge, intervention materials, and policies must precede or be immediately coupled with the implementation strategies that aim to undertake action based on these items, and often involves a research process of its own to maximize the distribution, comprehension, and acceptance of the information.^{37,79,80}
5. Identify evidence-based interventions to address the program goal or problem, and devise a strategic, phased implementation approach that might entail modifying, or adapting, the intervention. Adapting an evidence-based intervention is a balance between ensuring program fidelity and ensuring program fit to the target population (eg, increase contextual responsiveness, acceptability, and feasibility), and there are several frameworks with which to guide and study this process.^{81,82}

Just like breast cancer control programming is relatively new in many LMIC settings, so is the field of implementation science. Although we have reached a consensus that research on the process of disseminating and implementing breast cancer control strategies is essential to improve breast cancer outcomes, there still are many questions for us to consider regarding sufficiency of the “evidence base” for individual interventions, the importance of local context versus generalizable knowledge to select an implementation strategy, proper training in D&IS in LMICs along with funding for this type of work, and who is responsible for communicating the data generated in implementation science research so that policy and practices are adopted and sustained at the population level.

Despite these challenges and areas for future research in D&IS, we must remember that global disparities in breast cancer mortality persist due to inequities in access and the effectiveness of early detection and treatment programs.⁸³ Therefore, we must bring our diverse perspectives and expertise together to pursue research aimed at identifying interventions that can work in our communities.

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CONFLICT OF INTEREST DISCLOSURES

The authors has made no disclosures.

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