

Implementation Science: Implications for Intervention Research in Hospice and Palliative Care

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This article provides a general introduction to implementation science—the discipline that studies the implementation process of research evidence—in the context of hospice and palliative care. By discussing how implementation science principles and frameworks can inform the design and implementation of intervention research, we aim to highlight how this approach can maximize the likelihood for translation and long-term adoption in clinical practice settings. We present 2 ongoing clinical trials in hospice that incorporate considerations for translation in their design and implementation as case studies for the implications of implementation science. This domain helps us better understand why established programs may lose their effectiveness over time or when transferred to other settings, why well-tested programs may exhibit unintended effects when introduced in new settings, or how an intervention can maximize cost-effectiveness with strategies for effective adoption. All these challenges are of significance to hospice and palliative care, where we seek to provide

effective and efficient tools to improve care services. The emergence of this discipline calls for researchers and practitioners to carefully examine how to refine current and design new and innovative strategies to improve quality of care.

Key Words: Hospice, End of life, Palliative care, Implementation science, Translational research

Over the last several decades, there has been a continuous stream of innovations in almost every area of health care. Researchers around the world are producing massive amounts of new knowledge about the efficacy of new diagnostic and therapeutic approaches, about the effects of reducing exposures to risk factors, and about the benefits of increasing healthy behaviors (Ebrahim et al., 2011; Liu et al., 2010). Although these innovations hold the promise of improving life expectancy and quality of life of the population, their impact depends

on adoption and implementation by the various stakeholders within the health care community (providers, patients, lay caregivers). Compared with the resources available to developing new innovations, relatively less emphasis has been given to the implementation process. As a result, many effective interventions are never fully implemented and benefits are only partially or not at all gained. Examples of inadequate translation of evidence into practice include inadequate implementation of measures to prevent stroke (McBride, Brüggengjürgen, Roll, & Willich, 2007) and excessive use of unnecessary antibiotics (Korenstein, Falk, Howell, Bishop, & Keyhani, 2012). This gap is even larger for behavioral interventions. For example, in a national survey of 3,881 physicians in the United States by Ewing, Selassie, Lopez, and McCutcheon (1999), less than 20% of all included family physicians and internists reported providing adequate counseling regarding exercise and diet. Such a gap between research and practice affects all areas of biomedical and health sciences, including gerontology where, for example, as described by Rahman, Applebaum, Schnelle, and Simmons (2012), adoption of evidence-based practice guidelines in nursing homes is very slow and problematic.

Barriers to translating research, which result in the gap between evidence and practice, are also evident in hospice and palliative care. In a survey of federally funded research projects focusing on evidence-based symptom management and/or palliative care for cancer patients by O'Mara and colleagues, researchers emphasized that although there is an extensive body of research and development work for standards of care, and published guidelines and recommended procedures, these are often not adopted in practice and pain and cancer treatment-related symptoms continue to be under or poorly treated (O'Mara, St Germain, Ferrell, & Bornemann, 2009). Northouse and colleagues conducted a meta-analysis of 29 randomized clinical trials that tested interventions for family caregivers of cancer patients and found that most of these interventions significantly reduced caregiver burden, improved caregivers' ability to cope, increased their self-efficacy, and improved aspects of their quality of life (Northouse, Katapodi, Song, Zhang, & Mood, 2010). Although interventions were theory-based, with solid evidence for their effectiveness, few if any had ever been implemented in clinical practice settings.

In this article, we provide a general introduction to implementation science—the discipline that studies the implementation process of research evidence—in the context of hospice and palliative care. As hospice and palliative care research is still in its infancy, and funding has only recently come to fruition for researchers, an emphasis on implementation science will be important in ensuring quality research, which actually results in evidence-based interventions that become a standard of practice and result in improved clinical outcomes. By discussing how implementation science principles and frameworks inform the design and implementation of intervention research in palliative care and hospice, we aim to highlight how this approach maximizes the likelihood for translation and long-term adoption in clinical practice settings. Finally, two case studies are presented to demonstrate ongoing research studies that incorporate considerations for translation in their design and implementation.

Background

Implementation and Dissemination

The process of translating innovations from research findings into broad application is called the *implementation and dissemination* (I&D) process. Just as any other process, its effectiveness is influenced by multiple factors. The domain of human knowledge that studies such factors, called *implementation science*, is gaining wider recognition in recent years for the reasons described earlier. It is, however, not a completely new discipline, but rather one that emerged from the confluence and expansion of decades worth of research around the factors that influence the sustained adoption of an effective innovation. In this context, seminal scholarship emerged from studying the diffusion of new technological developments, over time, through specific dissemination channels. Rogers' *Diffusion of Innovations* theory, published in 1962, posits that there is an s-shaped innovation curve that describes the diffusion process, which is influenced by the innovation itself, the adopter's degree of innovativeness, the social system, the adoption process, and the diffusion system (Rogers, 2003). Similarly, medical sociology (Burt, 1973), communication studies (Rogers & Kincaid, 1981), and marketing (Bass, 1969) produced important findings on factors that influence the adoption of innovations. However, these initial investigations are limited by a focus on the individual adopter

and the individual innovation, an assumption that an innovation is necessarily an improvement, that adopters have specific personality traits that remain consistent over time, and that diffusion research findings are transferrable to other settings (Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004).

During the last two decades, the focus has shifted from diffusion to implementation, a much more active process of fostering long-term adoption of research evidence. In this sense, the focus of implementation science is mainly on what happens after the initial adoption and on studying the factors that influence sustained adoption and modification. Additionally, the focus has expanded to include not only the individual adopters and the individual innovations, but also the broader organizational, geographical, political, and cultural context in which these factors exist.

To better understand implementation science, Table 1 provides brief definitions for concepts commonly used in different implementation science frameworks (Greenhalgh et al., 2004; Rabin & Brownson, 2012).

Multiple models and frameworks have been described to understand—and influence—the implementation process. Broadly, and according to Rabin and Brownson (2012), we can classify them into *stage models*—those that describe the different stages or phases in an implementation—and into proper *theories and frameworks*. Although the latter may also include stages or phases, theories and frameworks provide a broader description of

the implementation process and the factors influencing its success.

The PARHiS (*Promoting Action on Research Implementation in Health Services*) is a framework that states that a successful implementation (*SI*) is a function (*f*) that depends on the type and nature of the evidence (*E*), the social and organizational context (*C*), and the elements that facilitate the process (*F*) with the resulting formula $SI = f(E, C, F)$. In an attempt to empirically demonstrate the influence that these three factors (type of evidence, context, and facilitators) have on a successful implementation, Rycroft-Malone conducted a qualitative study in which the author confirmed these factors to indeed determine implementation (Rycroft-Malone et al., 2004). There are many forms however that each of these three factors can take; thus, the framework itself is not sufficient to predict or explain a successful implementation.

PRISM (Practical, Robust Implementation and Sustainability Model) is another model that establishes a practical approach to define the elements that influence a successful implementation, which can, in turn, be used by researchers and organizations during development and implementation phases of a project (Feldstein & Glasgow, 2008). This model states that the factors are the program (or intervention), which has an organizational and a patient perspective, the recipients (with also an organizational and a patient perspective), the external environment, and the implementation and sustainability infrastructure.

Table 1. Key Terms and Definitions in Implementation and Dissemination Science (adapted from Greenhalgh et al., 2004 and Rabin & Brownson, 2012)

Term	Definition
Innovation	The object of the implementation process. It captures a broad range, including cognitive behavioral or psychoeducational interventions, a policy, a program, guidelines, educational material, and behaviors. It has multiple attributes that might influence its ability to diffuse and to be adopted.
Diffusion	The passive spread of an innovation.
Dissemination	The active spread of an innovation, usually through specific distribution channels and plans.
Implementation	The process of incorporating an intervention—ideally an evidence-based one—to a specific setting.
Implementation strategy	The collection of systematically organized resources, processes, and activities that are deployed to achieve a successful implementation.
Adoption	The active decision of an individual, an organization or a community to incorporate an innovation.
Sustainability	An attribute of an innovation that reflects its ability to be adopted, and to produce beneficial effects, for longer periods of time and after the stimulus or support from an external agency is over.

Another approach labeled *CFIR* (Consolidated Framework for Implementation Research) was the result of a comprehensive review (Damschroder et al., 2009) that aimed at consolidating various implementation frameworks. This model consists of five themes: intervention characteristics, outer setting, inner setting, characteristics of the individuals, and process. Each theme is also composed of additional constructs related to the theme. For example, the intervention characteristics theme contains the intervention source, evidence strength, relative advantage, adaptability, trialability, complexity, design quality, and cost.

Finally, *RE-AIM* (Reach Effectiveness Adoption Implementation Maintenance) is one of the most widely used frameworks. It was initially developed to evaluate interventions and later used to plan them (Glasgow, Vogt, & Boles, 1999). The framework focuses on five factors that are key for successful implementations. These factors are as follows:

1. **Reach**—A measure of the extent of participation in the implementation process. The greater the proportion of the target population that is involved in the implementation process, the greater the reach.
2. **Effectiveness**—A measure of the positive (or negative) effects that the intervention might cause to the individuals or the community that is adopting it. In the planning stages, selecting an intervention that is supported by high-quality evidence is key to ensure effectiveness.
3. **Adoption**—The proportion of the individuals, or other units of adoption such as clinics or hospitals, who adopt the intervention.
4. **Implementation**—A measure of adoption by individuals or units of adoption beyond the initial research or pilot group referring to “the extent to which the program is delivered as intended” (Glasgow et al., 1999).
5. **Maintenance**—This represents the extent to which the intervention becomes routine within the implementation units.

These are only a few of the many available frameworks in implementation science that can provide guidance in designing and implementing studies aiming to facilitate and maximize their translation into practice. In the following section using two case studies of ongoing clinical trials, we will illustrate how one of these frameworks (*RE-AIM*) was used to design and implement clinical studies in

order to maximize implementation and long-term adoption in the specific context of hospice and palliative care.

Interventions in Palliative Care and Hospice: Two Case Studies

We present two ongoing clinical trials specifically targeting hospice caregivers with a design and implementation approach aimed to maximize likelihood for translation into practice. Both projects were established by a long-standing interdisciplinary team of researchers committed to intervention research in hospice. The common element for both interventions is that they are delivered through telehealth technologies in an effort to overcome the geographic burden and isolation created through caring for a dying loved one and to improve caregiver quality of life in a potentially cost-effective way.

The first project, called *ACTIVE* (Assessing Caregivers for Team Interventions through Video Encounters), is designed to address challenges that family caregivers face in managing and/or communicating their loved one's pain. The study aims to determine whether regular videoconferencing between hospice patients' informal caregivers (family, spouses, friends, or others who take care of a loved one at the end of life) and the hospice care team alters caregivers' perceptions of pain management and reduces patients' pain. This study is a 4-year clinical trial where caregivers are randomly assigned to either a usual care group or an intervention group where caregivers also participate in biweekly team meetings through videoconferencing or phone conferencing with the hospice interdisciplinary team. All patients received standard care regardless of the group assignment of their informal caregiver. Details of this study design and methods are published elsewhere (Kruse, Parker Oliver, Wittenberg-Lyles, & Demiris, 2013).

The second project, called *PISCES* (Problem Solving Intervention to Support Caregivers in End of Life Care Settings), examines a cognitive behavioral intervention based on problem-solving therapy and the use of videoconferencing in delivering this intervention to hospice informal caregivers. This is also a 4-year clinical trial where informal caregivers are randomly assigned to an attention control group receiving standard care with the addition of friendly visits, an intervention group receiving standard care with the addition of problem-solving therapy delivered face to face, or

an intervention group receiving standard care with the addition of Problem Solving Therapy (PST) delivered via video. The overall goal is to examine how the intervention affects caregiver quality of life, anxiety, and problem-solving inventory and whether the video delivery is equivalent to face-to-face delivery. Pilot work leading to this clinical trial is published elsewhere (Demiris et al., 2012).

Both of these studies were designed with the ultimate goal to demonstrate effectiveness of interventions that can be easily adopted by hospice agencies and are integrated into standard practice. Thus, the emphasis on implementation and translation informed the study design in its earliest phase, as our aim was to maximize the chances for the translation of these interventions. In the following sections, we demonstrate specific strategies pursued in these two projects to address components of the RE-AIM framework as a guide to incorporate efforts for translation and implementation even in the early stages of study design. We organize this discussion by each of the five components of the RE-AIM model, and under each component, we include the checklist items developed by the [National Cancer Institute \(2012\)](#) as relevant attributes that need to be addressed or monitored to ensure that each of these components of the model are being implemented. We provide specific examples of how each of these items were pursued and how each of the five elements of the RE-AIM model were implemented in the two studies.

Reach

It pertains to understanding representativeness of participants, determining whether a program/intervention can actually attract a large and representative percent of the target population and whether people most in need or already underserved can be reached by the program.

Exclusion Criteria.—Both projects utilize information technology for the delivery of the intervention. Instead of narrowing down the residential specifications for the technology use (e.g., exclude people who only have a regular phone, or who do not have Internet, or who only have Internet), we developed a toolkit that would accommodate the largest number of potential participants. That toolkit enables videoconferencing for most settings ranging from residences with a regular phone line only to ones that have high speed Internet.

Percent of Individuals Who Participate.—We monitor on an ongoing basis the percent of individuals who participate, the capture attrition rate, and the characteristics of participants compared with the census data of the participating hospice agencies to ensure that we are recruiting a representative sample. Furthermore, we document all challenges in recruiting participants for interventional research in hospice in order to identify which of these challenges would still apply in practice (Parker Oliver, Demiris, Wittenberg-Lyles, Washington, & Porock, 2010).

Effectiveness

It pertains to the program's impact on key outcomes, whether it produces robust effects across subgroups and minimal negative side effects while increasing quality of life or broader outcomes.

Primary Outcomes and Robustness Across Groups.—Our emphasis is on measuring caregiver outcomes that are essential to hospice performance such as caregiver quality of life, anxiety, and caregiver burden (also pain management for the ACTIVE project and problem-solving inventory for the PISCES project). The focus on these clinical outcomes allows for comparison to hospice goals for the same outcomes for their entire population. We have also included measures of anxiety and depression that constitute “broader outcomes” and can be used to compare the effectiveness of these to other interventions and other groups within hospice. Furthermore, we measure short-term attrition rates and potential differential rates by caregiver characteristics ([National Cancer Institute, 2012](#)). Common measures across interventions allow additional analysis not only across groups but also between interventions. ACTIVE evaluates which participants can benefit most from the intervention recognizing; hence, it is not feasible for every caregiver to participate due to the time that would be required.

Use of Qualitative Methods/Data to Understand Outcomes.—For the ACTIVE study, a sample of team meetings where caregivers participate via videoconferencing are digitally recorded. Team interactions and session characteristics (duration, number of questions, amount of information exchange), as well as communication dynamics (opportunities to demonstrate empathy, exploring

team dynamics), are analyzed on an ongoing basis to better understand if any challenges impede the intervention. Semi-structured exit interviews are digitally recorded to evaluate the caregiver experience and capture the perception of the intervention from the caregiver perspective. Finally, the technical quality of video encounters is monitored to ensure that technology does not become a barrier to effective communication.

For the PISCES study, all intervention visits are digitally recorded and analyzed not only as part of the treatment fidelity protocol but also to assess how these encounters unfold, whether caregivers are able to follow the intervention curriculum and how intervention material can be tailored to individual needs. Semi-structured exit interviews are built into the evaluation to evaluate the caregiver experience and to capture the intervention experience from the caregivers' perspective. Additionally, the technical quality of all video encounters is assessed and monitored on an ongoing basis.

Capturing Unintended Consequences.—For both projects, the treatment fidelity protocol and our advisory committees are monitoring the occurrence of any adverse event to assess whether and how it may relate to the intervention.

Adoption

It pertains to how feasible it is for the program to be adopted in real-world settings and whether it can be adopted by low resource settings.

Adoption at Setting Level.—We have placed emphasis on recruiting caregivers from diverse hospice agencies (including both urban and rural ones) of different sizes and in different states. This multisite approach allows not only for greater generalizability of research findings but also for a better understanding of adoption processes among different agencies. We are assessing characteristics of settings that are not only participating in our projects to compare with nonparticipating agencies but also to document approaches or logistics that were most effective in each of these diverse settings.

Use of Qualitative Methods to Understand Adoption at Setting Level.—In preparation for the design of both interventions, we examined organizational factors that affected adoption of telehealth technologies including videoconferencing

in hospice agencies using survey methodology and identified educational and other approaches to ensure organizational buy-in to the interventions (Parker Oliver & Demiris, 2004). Furthermore, we studied settings where technologies had been underutilized or not fully integrated into practice to identify success and failure factors (Day, Demiris, Oliver, Courtney, & Hensel, 2007).

Adoption at Staff Level/Staff Exclusions.—In the ACTIVE intervention, the team members are also participants in the research study. Although staff have the option to refuse to participate and not to be part of the video recording of team sessions, we have not had anyone refuse to participate so far. However, we plan to track percent of any staff who are invited and those who may refuse to participate as well as characteristics that would allow a comparison between staff who participate and those who refuse to do so. We do not have any exclusion criteria for the staff as we want to enhance team meetings for all staff currently participating in them.

For the PISCES project, the cognitive behavioral intervention is delivered during the research study by interventionists/research staff. However, as the goal is to have the intervention be delivered once proven effective by the hospice staff after approximately 20 hr of training, we are actively engaging staff in updates on the intervention and on any revisions in the protocol and in the curriculum material.

Use of Qualitative Methods to Understand Staff Participation.—In addition to organizational readiness, we conducted extensive interviews with hospice staff to understand overall attitudes and perceptions of hospice staff of various disciplines and prepare for training material (Demiris, 2004). Interviews are conducted annually with a sample of staff allowing evaluation of the staff experience and a contrast with the caregiver intervention experience.

Implementation

It pertains to the consistency and cost of delivering the program, adaptations that were or have to be made, and whether the program can be consistently implemented across various settings.

Adaptations Made to Intervention During Study.—For the ACTIVE study, pilot work informed adaptations that were necessary including using a

broader technology toolkit so as not to exclude participants based on residential infrastructure, a script to prepare caregivers about their session with the hospice team, handouts that were developed to assist with technology problem solving, staff photos with titles printed so that caregivers are familiar with faces prior to participation, and inclusion of anxiety and depression assessments. For the PISCES study, pilot work also informed adaptations that were found to work better with the intervention such as extending the sessions to people who are bereaved and no longer actively caring for a loved one, including a 40-day postintervention assessment to capture any potential long-lasting effects of the intervention and using a broader technology toolkit to support videoconferencing. The caregiver problem-solving guide was extensively revised for various settings and situations based on pilot data.

Cost of Intervention.—For both projects, we are conducting first a cost and then a cost-effectiveness analysis. For the cost analysis, we utilize the demographic data collected on enrollment in the study to allow for comparisons between groups. These include hospice admission date and diagnosis, patient and informal caregiver age and sex, race, informal caregiver employment status, education and income range, relationship of informal caregiver to patient, and residence of the informal caregiver. For both the cost and cost-effectiveness analyses, we are recording equipment costs (including equipment price and depreciation) and training costs based on time to train staff in the use of equipment and facilitating the interventions. The participating hospice agencies provide client-level data to estimate resource use and costs (such as direct care time for scheduled and unscheduled visits, resources associated with the installation, and maintenance of technology).

Maintenance

It pertains to long-term effects at individual and setting levels and assessing whether the program include features to enhance long-term improvements and maintenance and whether settings can sustain the program over time without added resources.

Maintenance at Individual Level.—Maintenance issues at the individual level include establishing

mechanisms to assess primary outcomes on an ongoing basis and an infrastructure to monitor long-term attrition rates. The PISCES project includes an assessment 45 days postcompletion of the intervention to assess potential long-lasting effects of the intervention.

Maintenance at Setting Level.—We have developed training material for agencies to ensure both implementation and ongoing evaluation of the interventions. These manuals reflect considerations on sustaining interventions with minimal additional resources once staff have adopted the interventions. Given the focus on flexibility and tailoring intervention specifics to the unique settings, maintenance lists are customizable to reflect the available resources of each setting.

Discussion

Recognition for implementation science and evidence-based efforts to maximize translation of research interventions to practice has been growing in recent years; this trend clearly applies to palliative and hospice care where several research studies successfully meet their aims but do not necessarily become integrated into practice once research funding is no longer available. Our case studies demonstrate that adoption and translation should be critical considerations in the early stages of intervention design and not simply an afterthought at completion of a research initiative.

Interventions have to be designed based on existing evidence and a solid theoretical framework. The intervention components need to be explored jointly with representatives of all stakeholder groups to ensure appropriate selection of process and outcome variables. Interventions then need to be pilot tested and then tested more extensively recognizing that implementation efforts require detailed assessment of characteristics of populations served, possible changes in primary and secondary outcomes, and a consideration of implementation, maintenance, and cost at the individual and organizational levels.

Implementation requires planning for available and needed resources and an extensive cost analysis (and cost-effectiveness or cost-benefit analysis). Research investigators need to explore how to continuously engage the community, refine training approaches, and allow for flexibility and adjustments in the intervention protocols. Palliative care and hospice researchers are already familiar with

the notion of flexibility in the research procedures as this setting is quite distinct from other settings where participants have long lengths of stay and processes are predictable.

The significance of implementation science suggests that the National Institutes of Health and other funding agencies should consider formally requiring of all grant applications to include considerations reflected in all stages of a project to maximize translation and to allow for a translation phase at completion of the research study, assuming findings call for translation to practice. This focus on translation is also recognized as a core principle by Palliative Care Research Cooperative (Abernethy et al., 2010).

Implementation science creates generalizable knowledge that can be applied across settings to answer central questions (Madon, Hofman, Kupfer, & Glass, 2007) and meet specific needs. This domain helps us better understand why established programs may lose their effectiveness over time or when transferred to other settings, why well-tested programs may exhibit unintended effects when introduced in new settings or how an intervention can maximize cost-effectiveness with strategies for effective adoption. All these challenges are of significance to hospice and palliative care, where we seek to provide effective and efficient tools to improve care services at a local and national level. The emergence of this discipline calls for researchers and practitioners to carefully examine how to refine current and design new and innovative strategies to improve quality of care.

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