ADAPTATION OF AN EVIDENCE-BASED INTERVENTION (EBI) TO IMPROVE REFERRALS TO HOSPICE FOR HOME- AND COMMUNITY-BASED POPULATIONS

M. Alexis Kirk

A dissertation submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Health Policy and Management in the Gillings School of Global Public Health.

Chapel Hill
2018

Approved by:

Sarah Birken
Morris Weinberger
Franziska Rokuske
Laura Hanson
Byron Powell
ABSTRACT

M. Alexis Kirk: Adaptation of an Evidence-Based Intervention (EBI) to Improve Referrals to Hospice for Home- and Community-Based Populations (Under the direction of Sarah Birken)

Hospice care offers known benefits for terminally ill patients; however, referrals to hospice are often delayed. The objective of this research was to adapt an existing evidence-based intervention (EBI) developed by Casarett et al. to increase hospice care referrals for home- and community-based populations.

First, we identified core components of the Casarett EBI by interviewing 5 members of the Casarett research team. We identified two core components of the Casarett intervention: reframing the hospice conversation to a topic that clinicians felt comfortable discussing and standardizing the conversation in some way.

Next, we engaged a stakeholder panel of three home health agencies to identify context differences between the original and new context and necessary adaptations. We identified 14 adaptations to the Casarett intervention, the majority of which were delivery adaptations. We took the 14 adaptations and coded them to develop a theory of how adaptations impact implementation and intervention outcomes. Our theory built on existing implementation science frameworks and showed that although content and delivery adaptations can be made for any reason, the reason for the adaptation drives the its impact on outcomes. Additionally, different types of adaptations have differential effects on implementation and intervention effectiveness.

Finally, we pilot tested the adapted intervention to assess its feasibility. We tested the adapted intervention in two home health agencies for 9 weeks, collecting quantitative and
qualitative data on outcomes and implementation. Pilot sites implemented intervention activities with high fidelity with relatively low time commitments (5-10 minutes/patient) and minimal restructuring of clinical workflows. We achieved hospice/palliative care election rates (14%) similar to those found by Casarett (20%). Pilot sites suggested further adaptations to the intervention to improve its effectiveness in this patient population and strategies for scale-up of the intervention.

In sum, this research further developed methods for identifying core components, as well as build the foundations for further exploring how adaptations work to influence outcomes through the development of our theory. Through our pilot test, we demonstrated the feasibility of implementing the adapted intervention in practice with minimal support; we offer suggestions for further refining the intervention to increase its usability in practice.
Dedicated to the nurses, social workers, aides, clergy, volunteers, therapists, PAs, physicians, and countless other individuals who provide support, comfort, and courage to terminally ill patients and their loved ones. Your impact is immeasurable.
ACKNOWLEDGEMENTS

First, I would like to thank my chair and mentor, Sarah Birken. Sarah – it will always be my honor to hold the title of your first doctoral student. I cannot express enough my gratitude for your support, advice, and mentorship. To Franzi – beyond this dissertation, your mentorship throughout my career has been invaluable. Here’s to the next phase of my career and us continuing to learn and grow together. To Morris – your leadership and dedication to the department is immeasurable. We are so lucky to have you as our chair, mentor, and friend. Thanks for everything you do (and, of course, for your allegiance to the better blue). To Laura – it’s been an honor working with you over the past several years. Your dedication to improving access to hospice and palliative care is an inspiration, and I have greatly enjoyed learning from your careful thought and insights. To Byron – we’re so delighted you joined the department. I’ve enjoyed learning from you and look forward to continued collaborations.

To the researchers, clinicians, and students that played an invaluable role in this research – I extend my sincerest gratitude. Without the contributions of David Casarett and his research team; UNC and Rex Home Health; and Duke, Transitions LifeCare, and Liberty hospices, this dissertation would not have been possible. To my dear friend and coding buddy, Emily Haines, thanks for being you.

And finally, to my friends and family -- you will never know how much all of your support meant to me. I am here because of you. I could fill entire pages extending my gratitude to every single one of you, but I will try to keep it short. To my mother, who led by example and taught me women can do anything -- I am who I am because of you. To my husband, Curtis, who
believed in me no matter the cost (literally) or circumstance, thank you. (But also, you’re welcome -- the ROI on this degree is putting you one step closer to early retirement). To my dear friend Katie, who was by my side most nights and weekends -- you inspire me to be fearless, no matter what. To my grandmother, who has always kept me well-fed and well-loved, I could not have asked for a better second mother. And to my grandfather, who is my inspiration every day. Your unwavering kindness, humor, and love for all those you meet shows us we can all strive to be better people and never stop growing and learning. Thanks for being you, and for all the joy you bring to our lives.
# TABLE OF CONTENTS

LIST OF TABLES ............................................................................................................ xiii

LIST OF FIGURES ....................................................................................................... xiv

LIST OF ABBREVIATIONS ............................................................................................ xv

CHAPTER 1: INTRODUCTION ......................................................................................... 1

Hospice Care: Benefits and Utilization ................................................................. 1

Existing Interventions to Improve Timeliness of Hospice Referrals .................. 3

Aims of this Research ................................................................................................. 3

Significance and Implications ..................................................................................... 5

Organization of this Dissertation .............................................................................. 6

REFERENCES ............................................................................................................... 7

CHAPTER 2: FINDINGS FROM AIM 1 .......................................................................... 9

Background ................................................................................................................ 9

The adaptation-fidelity continuum and core components ..................................... 9

Identifying and specifying core components ....................................................... 9

Objective of this paper ............................................................................................ 12

Case example ............................................................................................................ 12

Methods .................................................................................................................... 13

Theoretical framework ............................................................................................. 13

Procedures .............................................................................................................. 14

Results ..................................................................................................................... 28

Output 1: Updated description of the intervention ............................................... 28
Output 2: Usual care pathway, including barriers ................................................................. 28
Output 3: EBI Theory of change ............................................................................................. 30
Output 4: Description of core components ......................................................................... 32
Output 5: Overlay of EBI Little T-theory of change with extant Big-T theory ......................... 33
Discussion ................................................................................................................................. 35
Limitations & future directions ............................................................................................... 37
Conclusion ................................................................................................................................. 39
REFERENCES ............................................................................................................................. 40

CHAPTER 3: PART A: USING A CONSENSUS-BASED PROCESS TO PLAN ADAPTATIONS TO AN EXISTING INTERVENTION ................................................................. 46

Background ................................................................................................................................. 46
Methods .................................................................................................................................... 48
Overview of approach ............................................................................................................. 48
Sample overview: The stakeholder panel ............................................................................ 50
Data collection procedures and analysis: Overview ............................................................ 51
Outputs ..................................................................................................................................... 55
Results .................................................................................................................................... 56
Context differences ................................................................................................................. 56
Necessary Adaptations ........................................................................................................... 61
Outputs ..................................................................................................................................... 66
Discussion ................................................................................................................................. 68
Summary ................................................................................................................................. 68
Limitations, future applications and research ....................................................................... 69
REFERENCES ............................................................................................................................. 72
Measurements ....................................................................................................................... 107
Analyses ............................................................................................................................... 110
Results ................................................................................................................................ 112
Feasibility ............................................................................................................................. 112
Patient outcomes .................................................................................................................. 113
Acceptability ....................................................................................................................... 114
Qualitative implementation data ........................................................................................ 120
Discussion ............................................................................................................................ 125
Conclusion ............................................................................................................................ 129
REFERENCES ..................................................................................................................... 131

CHAPTER 5: CONCLUSION ................................................................................................. 133
Significance of this Research .............................................................................................. 133
Aim 1: Summary of Findings and Implications for Research and Practice ......................... 134
Aim 2a: Summary of Findings and Implications for Research and Practice ....................... 135
Aim 2b: Summary of Findings and Implications for Research and Practice ....................... 136
Aim 3: Summary of Findings and Implications for Research and Practice ......................... 137
Future Research .................................................................................................................. 138
Conclusion ............................................................................................................................ 140
REFERENCES ..................................................................................................................... 141

APPENDIX A: ADDITIONAL FILES AIM 1 ................................................................. 142
Additional File 1: Description of Casarett EBI ................................................................... 142
Additional File 2: Updated Interview Guide ....................................................................... 143
Additional File 3: Codebook for Analysis of Interview Data .............................................. 146
Additional File 4. Description of Intervention in Template for Intervention Description and Replication (TIDieR) Format ................................................................. 150

APPENDIX B: ADDITIONAL FILES AIM 2A ................................................................. 163
Additional File 1: Interview Guide – Context Differences: Brainstorming Differences Between Home Health and Nursing Homes ........................................... 163

Additional File 2: Adapting Casarett Intervention from NH to HH ....................... 166

Additional File 3: Adapted Casarett Intervention to Improve Timeliness of Hospice Referrals for Home Health Patients ......................................................... 183

APPENDIX C: ADDITIONAL FILES AIM 2B ........................................................................ 205

Additional File 1: Description of Intervention and Adaptations to move Intervention from Nursing Home to Home Health Setting........................................ 205


APPENDIX D: ADDITIONAL FILES AIM 3 ................................................................. 214

Additional File 1: Casarett Intervention Screening Questions ............................. 214

Additional File 2: Hospice Appropriateness Screening Pilot Study Packet for Nurses ............................................................................................................ 215
LIST OF TABLES

Table 2.1. Recommendations for identifying core components ........................................ 15
Table 2.2. Example interview questions for each major topic area ........................................ 18
Table 2.3. Interview participants .............................................................................................. 21
Table 2.4. Example codes for interview analysis ....................................................................... 23
Table 2.5. Example of core component analysis from Casarett EBI ........................................ 27
Table 2.6. Construct-level breakdown of theory of change for Casarett et al. EBI .................. 31
Table 2.7. Detailed description of core components ................................................................... 33
Table 3.1. Stakeholder panel ...................................................................................................... 51
Table 3.2. Key context differences between nursing home and home health ............................ 58
Table 3.3. Adaptations to Casarett EBI .................................................................................... 64
Table 3.4. Key constructs from Stirman, Moore, and Proctor frameworks and theories .................. 78
Table 3.5. Codes and definitions ................................................................................................ 82
Table 3.6. Quantitative analyses to elucidate pathways ............................................................ 84
Table 3.7. Qualitative analyses to elucidate mediating pathways ............................................ 87
Table 4.1. Adaptations to Casarett Intervention ....................................................................... 103
Table 4.2. Measures and data sources ....................................................................................... 109
Table 4.3. A priori themes for qualitative analysis .................................................................... 111
Table 4.4. A priori codes for analysis of implementation data ............................................... 112
Table 4.5. Suggested additional adaptations to intervention .................................................... 117
Table 4.6. Barriers and facilitators to pilot implementation (mapped to CFIR) ......................... 121
Table 4.7. Implementation strategies (mapped to Powell’s compilation implementation strategies) .................................................................................................................. 123
Table 4.8. Definitions of implementation outcomes ................................................................... 125
LIST OF FIGURES

Figure 2.1. Relationship between core components, adaptable periphery, and the theory of change .............................................................................................................. 11

Figure 2.2. Planned Adaptation Model .................................................................................. 14

Figure 2.3. Usual care pathway visualization .......................................................................... 30

Figure 2.4. Transactional model of stress and coping ............................................................ 35

Figure 3.1. Planned Adaptation Model .................................................................................. 47

Figure 3.2. Delphi Method ........................................................................................................ 49

Figure 3.3. Screenshot of adapted EBI protocol ................................................................... 68

Figure 3.4. A theory of planned adaptations’ influence on intervention and implementation outcomes .............................................................................................................. 89

Figure 4.1. Patient enrollment and outcome data .................................................................. 114
LIST OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADL</td>
<td>activities of daily living</td>
</tr>
<tr>
<td>ALF</td>
<td>assisted living facility</td>
</tr>
<tr>
<td>CFIR</td>
<td>Consolidated Framework for Implementation Research</td>
</tr>
<tr>
<td>CHF</td>
<td>congestive heart failure</td>
</tr>
<tr>
<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
</tr>
<tr>
<td>COPD</td>
<td>chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CPR</td>
<td>cardiopulmonary resuscitation</td>
</tr>
<tr>
<td>EBI</td>
<td>evidence-based intervention</td>
</tr>
<tr>
<td>EMR</td>
<td>electronic medical record</td>
</tr>
<tr>
<td>ESRD</td>
<td>end stage renal disease</td>
</tr>
<tr>
<td>HC-POA</td>
<td>healthcare power of attorney</td>
</tr>
<tr>
<td>HH</td>
<td>home health</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>human immunodeficiency virus/acquired immunodeficiency syndrome</td>
</tr>
<tr>
<td>IRB</td>
<td>institutional review board</td>
</tr>
<tr>
<td>JAMA</td>
<td>Journal of the American Medical Association</td>
</tr>
<tr>
<td>LAR</td>
<td>legally authorized representative</td>
</tr>
<tr>
<td>MMSE</td>
<td>Mini-mental state examination</td>
</tr>
<tr>
<td>NH</td>
<td>nursing home</td>
</tr>
<tr>
<td>NF</td>
<td>nursing facility</td>
</tr>
<tr>
<td>OASIS</td>
<td>Outcome and Assessment Information Set</td>
</tr>
<tr>
<td>OT</td>
<td>occupational therapist</td>
</tr>
<tr>
<td>PAM</td>
<td>Planned Adaptation Model</td>
</tr>
<tr>
<td>POLST</td>
<td>physician orders for life-sustaining treatment</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>PT</td>
<td>physical therapist</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>RN</td>
<td>registered nurse</td>
</tr>
<tr>
<td>SHP</td>
<td>Strategic Healthcare Programs</td>
</tr>
<tr>
<td>SLP</td>
<td>speech language pathologist</td>
</tr>
<tr>
<td>SNF</td>
<td>skilled nursing facility</td>
</tr>
<tr>
<td>SUPPORT</td>
<td>Study to Understand Prognosis and Preferences for Outcomes and Risks of Treatment</td>
</tr>
<tr>
<td>TDF</td>
<td>Theoretical Domains Framework</td>
</tr>
<tr>
<td>TIDieR</td>
<td>Template for Intervention Description and Replication</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
</tbody>
</table>
CHAPTER 1: INTRODUCTION
Hospice Care: Benefits and Utilization

Hospice is a specialized set of services that provides care to terminally ill patients and their families at the end-of-life. In the United States (US), hospice care is used when curative care for a terminal condition is no longer a care option – either due to the nature of the disease and its treatment or due to patient choice. In the US, patients typically elect hospice when they have a life expectancy of 6 months or less, should the disease run its normal course; to elect hospice, most patients must give up curative care for their terminal condition (17-18). Hospice care focuses on palliation with the goal of maximizing quality of life and patient comfort. Hospice services are provided by a multi-disciplinary care team, including nurses, chaplains, aides, volunteers, therapists, pharmacists, physicians, social workers, and counselors (17-18). Hospice services are available to patients in a variety of care settings, including community-based settings, long-term care institutions, and inpatient hospice homes (17-18). Hospice care focuses on pain and symptom management, as well as emotional and psychosocial aspects of death and dying. In hospice, the patient and the family are the unit of care. Services provided to the family include coaching the family on how to care for the patient, providing short-term respite care when pain or symptoms become difficult to manage at home, and providing bereavement care to surviving family and friends (17-18).

Hospice care offers known benefits for terminally ill patients and our healthcare system at large, including improved quality of life, decreases in symptom burden and unmet psychosocial needs (1,2), and lower healthcare costs (16). Research shows that family caregivers
whose loved one received hospice report fewer unmet needs for symptoms like pain and dyspnea and have overall higher rankings of quality of care (1, 2). Additionally, family members whose loved one received hospice also report higher quality of death and peacefulness of dying, and are better informed and prepared of what to expect at the time of death. Finally, hospice care can also decrease unwanted or invasive care at the end-of-life. One study found that hospice enrollees had lower rates of hospitalization, intensive care unit admission, and invasive procedures at the end-of-life (16).

The need for hospice care is increasing as the US population ages and the number of patients with hospice-eligible diagnoses expands. Moreover, the hospice population has shifted in recent decades — now, the majority of hospice patients are elderly patients (age 65+) with chronic illnesses (e.g., congestive heart failure, chronic obstructive pulmonary disease) or neurological conditions (3). The number of elderly patients and the number of patients with chronic and neurological conditions is only expected to rise in coming years. By 2020, 157 million patients will have at least 1 chronic condition (14), and the elderly population will increase by 36% (15).

Despite known benefits of hospice, hospice care is often initiated too late. The median length of stay is 18 days and 80% of hospice patients have a length of stay of stay less than the expert-recommended 3 months (3). A primary reason for underutilization of hospice is delayed referrals from the physician who makes the terminal diagnosis. Physicians are hesitant to refer to hospice for fear of bringing up hospice ‘too early’, lack of training in compassionate discussion of bad news, and clinical difficulty in accurately predicting a prognosis of 6 months or less (7-10).
Late hospice referrals have been linked to poorer outcomes, including lower satisfaction with hospice services. Specifically, bereaved family members reporting late referral to hospice report higher rates of unmet needs regarding expectations at the time of death, lower confidence in providing care for their loved one, greater concerns with care coordination, and lower overall satisfaction with hospice care (4). In addition, delayed referral and election of hospice may also result in additional costs, as well as invasive or unwanted care at the end-of-life (6).

**Existing Interventions to Improve Timeliness of Hospice Referrals**

An intervention to improve referrals exists and has been demonstrated efficacious. An intervention developed and tested by Casarett et al. improved hospice referral and election rates (11). A randomized controlled trial of the intervention was successful – 20% of patients screened were referred to hospice within 30 days (referral rate in the intervention group was 19 percentage points higher than the referral rate in the control group) (11). Moreover, patients in the intervention group had fewer hospital admissions and fewer acute care days. Finally, patients in the intervention group also had higher ratings of quality of care (11). A second unpublished effectiveness study of the intervention also had positive outcomes (12).

The intervention, however, only applies to a minority of hospice-eligible populations, thus limiting the reach and potential impact of the intervention. The intervention was developed and tested in the nursing home setting. Nursing home residents represent a minority (19%) of the hospice general population. Most patients come to hospice from non-institutional settings (community settings and inpatient hospitals account for 70% of hospice referrals) and receive hospice care in the community (51% receive hospice care at home) (13).

**Aims of this Research**

The long-term goal of this research is to improve timeliness of referrals to hospice care for the broader home- and community-based hospice-eligible population in order to promote the
benefits of hospice care for this group, including increased quality of life and reductions in unmet needs at the end-of-life. The objective of this work is to adapt the Casarett et al. EBI for home- and community-based populations and evaluate the implementation and intervention outcomes of the adapted EBI. This research will increase our understanding of how to best adapt evidence-based interventions for new contexts while maintaining their ability to produce desired outcomes. It will also increase our understanding of how to improve access to hospice care for home- and community-based populations.

This work includes 3 specific aims:

- **Aim 1:** Identify core components of the EBI by clearly specifying its theory of change and major activities. I will interview members of the EBI developer team to specify the theory of change (primary causal pathway, moderators, and secondary causal pathways) and major activities of the EBI.

- **Aim 2:** Adapt the EBI from nursing home to home- and community-based settings and populations. I will use the Delphi method to solicit input from relevant stakeholders (e.g., developers of the original EBI, intended target users of the adapted EBI) via self-administered written surveys and in-person focus groups. I will solicit input on: 1) key differences between nursing home and home- and community-based settings and populations and 2) adaptations to the EBI that are necessary to address those differences while maintaining EBI efficacy. Each potential adaptation will be evaluated for fit and valence to ensure that each adaptation is necessary to improve fit of the intervention within the new setting and that the adaptation does not detract from the core component of the intervention as specified in the theory of change.
• **Aim 3: Conduct a pilot feasibility test to evaluate the implementation and outcomes of the adapted EBI.** I will pilot-test the adapted EBI in one home and one community-based practice. Using interviews with practice staff and process metrics, I will collect data on implementation of the adapted EBI (e.g., acceptability, cost, fidelity). I will also collect data on intervention outcomes (e.g., rates of hospice referral and election) to determine whether the adapted intervention produces the desired outcomes in the new context.

**Significance and Implications**

Adapting this intervention for use in broader hospice-eligible populations could improve access to beneficial hospice services for a larger proportion of patients. This research will build on the existing knowledge base regarding intervention adaptation to adapt the EBI for home- and community-based hospice-eligible populations. Building on current knowledge, this research aims to adapt the EBI without compromising its ability to produce desired outcomes.

This research has the potential to fill a knowledge gap that currently exists in the field of implementation science by providing actionable resources (e.g., toolkits) for adapting EBIs. Adapting interventions and the adaptation-fidelity continuum is a burgeoning area of implementation research. Although there exists a knowledge base on general principles and frameworks for intervention adaptation, there are few specific tools and methods that researchers can use to adapt EBIs in a systematic manner. This research will extend the current knowledge base by leveraging existing adaptation frameworks and building on them to develop generalizable tools and methods for adapting interventions. These methods could be packaged (e.g., in toolkits) and disseminated for use by implementation researchers.
Organization of this Dissertation

The remainder of this dissertation is organized as follows: Chapters 2-4 describe each of the three studies that comprise this dissertation (Chapter 2, Aim 1; Chapter 3, Aim 2a and 2b; Chapter 4, Aim 3); Chapter 5 describes the contribution of this work overall, including areas of future research and implications for research and practice.
REFERENCES


13. RTI analysis of HIS data


17. National Hospice and Palliative Care Organization. Hospice Care. [https://www.nhpco.org/about/hospice-care](https://www.nhpco.org/about/hospice-care)

CHAPTER 2: FINDINGS FROM AIM 1

Background

The adaptation-fidelity continuum and core components

Reproducing the level of effectiveness demonstrated in trials is critical when moving an evidence-based intervention (EBI) into practice. Historically, fidelity to EBI protocol was considered paramount for reproducing effectiveness; adaptations were viewed as threats to effectiveness [1-5]. Increasingly, however, researchers and practitioners recognize that adaptations can promote effectiveness by improving fit between the EBI and new contexts (e.g., new organizations, patient populations) [6-8]. In this view of adaptation and fidelity, attention shifts from preserving fidelity at all costs to making adaptations that improve fit between EBIs and context [1, 7, 9-13]. To achieve this goal, specification of an EBI’s core components and adaptable periphery is critical. Core components are the essential EBI components that make an EBI effective; adapting these components risks compromising EBI effectiveness [14]. Conversely, an EBI’s adaptable periphery is comprised of components that can be adapted without compromising effectiveness because they are not necessary to produce desired outcomes [11, 15].

Identifying and specifying core components

To specify core components, one must go beyond listing EBI activities suspected or demonstrated to be core [16]. Core components comprise two portions: the EBI activities and the essential principles necessary to produce desired outcomes [16]. See Figure 2.1. Principles are mechanisms of change, articulating why or how an EBI’s activities produce desired outcomes.
As mechanisms of change, principles are derived directly from an EBI’s theory of change. An EBI’s theory of change specifies all relationships between an EBI and the desired outcomes (e.g., causal pathways, mediators, moderators). As such, a single theory of change may encompass several mechanisms of change (i.e., principles) if the relationship between EBI and outcomes includes multiple causal pathways, mediating relationships, etc. Activities operationalize each theory-based principle by describing the specific actions or behaviors needed to affect change. Delineating principles and activities distinguishes between form and function of an EBI’s components: principles explain the function of an EBI component (why a component matters, how it produces change), while activities denote form (who is doing what, when, and where).

Ultimately, core components illuminate how an EBI achieves desired outcomes to promote intervention effectiveness. In contrast, the adaptable periphery includes EBI activities not needed to operationalize EBI principles. See Figure 2.1. Because the adaptable periphery components do not directly operationalize the underlying mechanisms of change, they are not necessary to achieve an EBI’s effectiveness and can be adapted without compromising EBI effectiveness.
Figure 2.1. Relationship between core components, adaptable periphery, and the theory of change

Core components can be identified experimentally or non-experimentally. Experimentally, researchers can identify core components through causal research designs testing the EBI’s theory of change or the degree to which fidelity to core components produces positive outcomes[16]. However, due to challenges with conducting factorial trials to test the relative impact of each EBI component[17], core components are often identified non-experimentally. This approach includes qualitative methods, process evaluations, or correlational designs to specify a theory of change and supporting activities[16].

Ideally, by the time an EBI is ready for implementation, developers or evaluators have clearly identified core components. In practice, however, this is seldom the case; literature shows that developers or evaluators rarely identify core components or offer recommendations on the dosage, strength, and adherence required to achieve desired outcomes[16].

In the absence of clear descriptions of core components, adaptation frameworks offer guidance to identify them post hoc using secondary data analytic approaches, such as reviewing EBI materials (protocols, reports, logic models) or the EBI’s specified theory of change [18-28].
These frameworks also recommend primary data collection, including interviewing EBI developers[7, 13, 23]. Beyond this high-level guidance on identifying core components post hoc, little has been published on systematic methods and tools. Addressing this gap in the literature is a critical first step to placing more emphasis on identifying core EBI components[12, 16, 29, 30].

**Objective of this paper**

This paper offers a methodology case study to develop systematic methods and tools for identifying core components post hoc. In the Methods section, we describe our tools in detail so others can use and refine them. We also include recommendations for future use based on lessons learned from this case study. Given that most EBI developers and evaluators do not clearly identify core components in publications or EBI materials[16], the Results section provides an example of how researchers and practitioners may report core components. In the Discussion section, we reflect on our experience, discuss the value of our methods and tools, and recommend future research.

**Case example**

For this study, we focused on an EBI developed in 2005 by Casarett et al. (hereafter “Casarett EBI”) to improve the timeliness of hospice referrals for nursing home residents. Although hospice care offers proven benefits to terminally ill patients[31, 32], it is often initiated too late[33-35]. Clinicians may hesitate to refer eligible patients for fear of bringing up hospice “too early”, fear of how the patient might react, lack of training in compassionate discussion of bad news, and general negative cultural perceptions around death and dying[36-39]. To identify residents who may be appropriate for hospice and prompt clinician referral, the Casarett EBI[40] used a 3-question screening to elicit nursing home resident care goals, preferences, and needs. The Casarett EBI was shown to be effective, improving hospice referral rates by 19 percentage-points[40]. For additional information on the Casarett EBI, see Additional File 1. As nursing
home residents represent a minority of all hospice patients served, in this study, we adapt the Casarett EBI to home health to extend its overall reach[41, 42].

Methods

Theoretical framework

Our overall approach was based on the Planned Adaptation Model (PAM)[23]. We selected PAM because of its high level of specificity on inputs (data sources), processes (steps), and outputs (final products) in the adaptation process. PAM includes four steps in the adaptation process (Figure 2.2), two of which focus on identifying core components: 1) specify the theory of change, including primary and secondary causal pathways and moderators of the EBI, and 2) specify all activities of the EBI. Because the core components are some combination of necessary activities and underlying principles, articulating both activities and theory of change should point to the core components of the EBI. This paper extends PAM by developing methods and tools to complete these steps.
Figure 2.2. Planned Adaptation Model

Procedures

To identify an EBI’s core components, we recommend that researchers and practitioners follow the six steps outlined below. Additional recommendations from our application of these steps are listed in Table 2.1.
Table 2.1. Recommendations for identifying core components

<table>
<thead>
<tr>
<th>Step</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| Step 1 - Search for and review existing materials | • Cast a wide net when searching for existing materials – do not limit your search to peer-reviewed literature. Relevant materials may be available as gray literature on program or funder websites. Personal communication with members of the EBI team are also potential sources of existing materials.  
• Even if core components and theory of change aren’t specified in existing materials, existing materials can provide useful in other ways (i.e., to provide context for the intervention or guide development of primary data collection materials). |
| Step 2 – Develop semi-structured interview guide | • Review existing materials to inform development of primary data collection materials.  
• Make sure questions are “participant friendly”: avoid jargon in questions, instead, provide definitions of terms and phrase questions in the context of your specific intervention.  
  o Ex: Instead of “what are the moderators of your intervention?” ask “were there aspects of xxx intervention (or xxx context) that boosted its effectiveness?”  
• Ask about barriers to the outcome of interest encountered in usual care/practice: this can serve as a jumping off point for the rest of the interview, making it easier for participants to think about the theory of change and primary causal pathway. Information on barriers to change was critical in the analysis phase for specifying the theory of change.  
• Core components: Ask about core components directly, after asking about EBI activities and the theory of change. As a lead-in to the questions focusing on core components, provide an explanation of what core components are and why identifying them is important. Again, our explanation avoided jargon and framed core components as the “active ingredients” or “secret sauce” that drove the success of the intervention. We also found it helpful to ask several questions about core components and probe often to ensure respondents were drilling down to “the core” of core components.  
• Probe often to ensure you are drilling down to the underlying principles of why certain activities were important to the overall success of the intervention.  
• Consider developing supplemental materials (e.g., short descriptions of the intervention’s activities) to distribute to interview participants. |
| Step 3 – Recruit interview participants | • Try to maximize heterogeneity in your sampling frame and final sample by recruiting a variety of roles (research assistant, statistician, lead developer) from a variety of perspectives (researcher vs clinician).  
• Employ snowball sampling to maximize variation in perspectives. |
<table>
<thead>
<tr>
<th>Step</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 4 – Conduct interviews</strong></td>
<td>• Use interviews or other bidirectional methods (e.g., focus groups) to allow for probing and follow-up questions</td>
</tr>
</tbody>
</table>
| **Step 5 – Analyze interview data** | • Complete analysis in the following order:  
  o Activities of the intervention  
  o Usual care pathway (focusing on barriers to your outcome of interest encountered in usual care)  
  o Theory of change (primary and secondary causal pathways, moderators)  
  o Core components  
  • Identifying the barriers to outcome of interest encountered in usual care is critical to clearly elucidating the causal pathways in the theory of change. The barriers to change provide a clear “gap” that the primary and secondary causal pathways should (ideally) address  
  • When analyzing data on core components, do not limit your analysis to questions that ask about core components directly. Because core components are a combination of the activities of the intervention as well as the theory of change, data from other portions of the interview may help elucidate and operationalize core components.  
  • Ensure that descriptions of core components resulting from analysis include both the *principle* and *activity*. |
| **Step 6 – Map theory of change onto extant theory from the literature** | • Helpful in “validating” the “Little T” theory of change produced in Step 5 analysis  
  • To identify a relevant Big T theory first consider the type of change your EBI is affecting (e.g., individual-level, system-level). You may have to explore extant, Big T theories from other fields outside of implementation science, based on the level of change and type of change. For example, person-level change in behavior may point to theories from health behavior or psychology; organizational-level change may point to theories from sociology or organizational theory. |
STEP 1: Review existing materials. The first step in identifying core components is to review existing EBI materials to determine if core components or the theory of change have already been specified. To complete this step, we searched for available published and grey literature on the Casarett EBI. We identified one existing public data source: the publication of the randomized controlled trial (RCT) that originally tested the Casarett EBI[40]. This publication did not include a clear description of the core components or the theory of change. We also contacted the research team for a copy of the intervention protocol, which was not publicly available. We conducted an additional literature search to familiarize ourselves with the Casarett EBI and its context. This review of existing materials guided the development of our semi-structured interview guide.

STEP 2: Develop semi-structured interview guide. Because existing materials for the Casarett EBI did not specify the core components, we conducted semi-structured interviews with those involved in EBI development and initial testing. PAM recommends eliciting information on the EBI’s activities, as well as the theory of change to ascertain the core components; these were the first two topics included in our interview guide. The third topic in our interview guide was a direct line of questioning about core components. Table 2.2 contains example interview questions for each topic. After completing our interviews, we updated our final interview guide, refining wording of interview questions and probes (Additional File 2).

Because the RCT of the Casarett EBI occurred ~10 years earlier, we sent a 1-page description (Additional File 1) of the intervention based on the publication[40] to interview participants prior to interviews to refresh their memory. Without prompting, interview participants volunteered that this 1-page description was helpful to review prior to the interviews.
Table 2.2. Example interview questions for each major topic area

<table>
<thead>
<tr>
<th>Topic</th>
<th>Selected Example Interview Questions</th>
</tr>
</thead>
</table>
| **Topic 1: EBI Activities** | ▪ Who were the study staff that carried out the intervention activities? Did they have any qualifications required to perform these activities (e.g., prior experience with nursing home patients or hospice)?  
▪ Where were the screening conversations held? (via phone? In-person at the nursing home?)  
▪ What was the physician’s role beyond certifying the prognosis of 6 months or less and authorizing a hospice referral, if anything? |
| **Topic 2: Theory of Change** | ▪ Irrespective of the original intervention, based on your experience, can you describe barriers to hospice referral you often see or encounter in practice?  
▪ How does the intervention help fix the barriers you described (if at all)?  
▪ Was there anything about nursing home patients or nursing home organizations that made it easier to deliver the intervention in the nursing home than in other settings? |
| - **Topic 2a: Usual Care pathway, including barriers to change** |  
- **Topic 2b: Theory of change, including primary and secondary causal pathways and moderators** |
| **Topic 3: Core Components** | ▪ Which EBI activities contributed most to the success of the intervention? Probe: what about it was essential – e.g., who is conducting the activity; mode of activity (in-person vs written)?  
▪ In an adapted intervention, which activities/principles would you maintain at all costs? |

We recommend phrasing questions in layman’s terms, within the context of the EBI. For example, instead of asking “what are the moderators in this intervention’s causal pathway?”, ask contextual questions, such as “was there anything about the nursing home setting that may have boosted (or limited) the success of the intervention?”. This strategy proved important for our interview participants who, as clinical researchers and practitioners, were unfamiliar with theory-specific terminology. We also recommend frequent probing throughout the interview to elicit the underlying theory of change and core components. For example, if a respondent stated, “a main barrier to referrals to hospice is clinicians feel uncomfortable talking about it”, we probed
for the reason why clinicians felt uncomfortable to better understand the behavioral levers (and barriers) behind the Casarett EBI.

Topic 1: EBI activities:

Regarding what to ask, we recommend focusing only on activities not already detailed in existing materials and publications. We also recommend capturing contextual details for each activity (e.g., who was completing the activity, what prior skills and training they had). Understanding the contextual details behind each activity helped us later classify activities as part of the adaptable periphery or core components. For example, knowing details about who asked the screening questions in the original trial (non-clinician research assistant who had prior knowledge of hospice) helped us discern whether the role of the individual administering screening questions was a core component or part of the adaptable periphery.

Topic 2a: usual care pathway and Topic 2b: theory of change

We asked about major constructs prescribed by PAM: primary and secondary causal pathways and moderators. In addition, to transition into discussion on theory of change, we incorporated a new sub-topic not prescribed by PAM: the usual care pathway, including barriers to change. In our study, this meant asking about the pathway to hospice referral (including barriers to referral) encountered in usual care, without the Casarett EBI. We included this additional sub-topic because we expected participants to be unfamiliar with developing and discussing theory. Thus, we asked about the usual care pathway to stimulate their thinking about primary and secondary causal pathways that the Casarett EBI was intended to address. By asking participants to explain how the EBI addressed barriers to change encountered in usual care, we were better able to elicit information on theory of change. We recommend including the usual care pathway discussion because it helped with interview cohesion, data collection, and analysis.
**Topic 3: core components**

Explicit discussion of core components provided an opportunity for participants to synthesize discussion from prior topics, producing richer data: After discussing activities and barriers to change, participants could more clearly articulate what about the Casarett EBI drove its success. Based on our experiences, we updated our interview questions for core components, and recommend a 3-pronged approach to asking about core components: 1) assess which activities contributed most to the success of the intervention; 2) assess which activities should be maintained at all costs in an adapted intervention, and which could be modified without compromising the intervention’s success; and 3) probe on both questions to ascertain the principle behind the activity that made it core or adaptable.

**STEP 3: Recruit interview participants.** Our sampling frame included all six authors on the Casarett publication. These authors represented a variety of roles, including the lead developer of the intervention, members of the RCT study team (e.g., research assistant, statistician), and staff from the clinical sites. In addition, we employed snowball sampling by asking authors for recommendations on additional participants to interview.

Ultimately, we interviewed 5 of the 6 members of the original research team (1 member declined to participate); **Table 2.3** lists their roles in the Casarett EBI. The wide range of roles helped achieve our research objective. Each participant brought a different perspective, providing richness in our interview data. At a minimum, we recommend a mix of interventionists, evaluators, clinicians, and frontline implementers, including those who were involved in conceptualization of the intervention, administration, testing, or implementation of the intervention, and those who were involved in the evaluation of the intervention. This is important to gain a comprehensive understanding of all facets of the intervention. We did not
recruit any additional participants through our snowball sampling; because the original RCT occurred ~10 years before our interviews, recounts of who else was involved in the RCT may have been subject to recall bias. In future applications of these methods, we recommend that researchers employ a snowball sampling technique to maximize sample heterogeneity, particularly in instances where the sampling frame is over-represented by a particular role or group. For example, because authors comprised our initial sample, researchers were over-represented. Thus, we asked participants to recommend clinical site staff we could speak to about the Casarett EBI.

**Table 2.3. Interview participants**

<table>
<thead>
<tr>
<th>Role in original intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Director of home health &amp; hospice at clinical site that participated in randomized</td>
</tr>
<tr>
<td>controlled trial of original intervention</td>
</tr>
<tr>
<td>• Research assistant on original research team</td>
</tr>
<tr>
<td>• Lead developer of intervention, principal investigator of original research team</td>
</tr>
<tr>
<td>• Statistician on original research team</td>
</tr>
<tr>
<td>• Co-investigator on original research team</td>
</tr>
</tbody>
</table>

*STEP 4: Conduct interviews.* We conducted interviews during a 3-month period between April-June 2017. Interviews were conducted by the lead author (AK) via telephone or in-person. All interviews were between 20 and 60 minutes. Overall, interviews were a useful mode of data collection for our research objectives. Our semi-structured approach yielded rich data. Based on our experience, we would not recommend either close-ended questions or surveys; however, other modes of in-depth data collection (e.g., rapid ethnography[43], focus groups[44, 45]) could provide equally rich data.

*STEP 5: Analyze interview data.* Interviews were audio-recorded, transcribed verbatim, and analyzed using template analysis, which allowed us to identify a priori and emergent themes[46]. We developed the initial codebook based on a priori themes, which included the key topics and subtopics from the interview guide (*Table 2.2*). We used the literature[15, 23, 29] to
develop the definitions of key constructs in our codebook. Using interview data, we developed
coding rules to further operationalize and distinguish between each construct. Select coding
definitions and examples are presented in Table 2.4; the final codebook is presented in
Additional File 3. Two authors (AK, EH) coded all interviews; following our initial independent
coding, AK and EH met to review coding results. We discussed discrepancies until consensus
was reached. After completion of coding, three authors (AK, SB, EH) discussed themes for each
code.
### Table 2.4. Example codes for interview analysis

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topic 1: Activities of the Intervention</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EBI Activities</td>
<td><strong>Definition:</strong> This code includes any details of the intervention’s activities, including “who, what, when, where” descriptions of activities and intervention components</td>
<td>The RA interviewed the NH residents in-person</td>
</tr>
<tr>
<td></td>
<td><strong>Coding rule:</strong> this code is distinct from the rest in that only text about “the facts” of the intervention should be coded here. Any thoughts about why activities were important or how they boosted (or hindered) the effectiveness of the intervention should not be coded here</td>
<td>A ‘positive’ screen on the 3-question screener was defined as xxxx</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The physician was not involved in discussing hospice with the patient, beyond responding to the fax that was sent to them by study staff</td>
</tr>
<tr>
<td><strong>Topic 2: Theory of Change</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary Causal Pathway</td>
<td><strong>Definition:</strong> This code includes description of why or how the intervention works – the behavioral lever it addresses to affect change.</td>
<td>This intervention works because it removes the barriers described above by reframing the conversation entirely. It’s no longer a conversation about hospice, but a conversation about care goals/needs/preferences.</td>
</tr>
<tr>
<td></td>
<td><strong>Coding rules:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The primary causal pathway may be discussed in the context of barriers to the outcome encountered in usual care (i.e., how the intervention helps overcome those barriers)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The primary causal pathway is distinguished from the secondary causal pathway in that the primary causal pathway is described as the most important factor in getting to the outcome of interest</td>
<td></td>
</tr>
<tr>
<td><strong>Topic 3: Core Components</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core Components</td>
<td><strong>Definition:</strong> some combination of the principles (theory of change, causal pathway) and specific activities necessary to produce desired outcomes</td>
<td>“What was driving the success of the intervention was really 2 things it was xxxxx” “I would think you could change xxx without compromising the effectiveness”</td>
</tr>
<tr>
<td></td>
<td><strong>Coding rules:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Because core components are a combination of principles and activities, make sure to review questions that ask about core components directly, as well as questions that ask about causal pathway and activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• This may be double-coded with activities, primary, and secondary causal pathway</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Mentions of what could be changed and what should not be changed would also be coded as core components</td>
<td>“I would leave x unchanged”</td>
</tr>
</tbody>
</table>
Analysis of Topic 1: EBI activities

We recommend analyzing activities of the EBI first because these findings set a foundation for identifying theory of change and core components (i.e., to understand why or how an intervention is working, you must first understand the intervention itself).

Analysis of Topic 2a: Usual Care Pathway

Although it was not prescribed by PAM, we outlined the pathway from terminal diagnosis to hospice referral (including barriers to referral) encountered in usual care as a preliminary step in developing the Casarett EBI theory of change. Conceptualizing the barriers to hospice referral as gaps that the Casarett EBI should ideally fill allowed us to more easily identify the casual pathways in the theory of change. In this sense, the usual care pathway and EBI theory of change are complementary: the usual care pathway identifies the barriers to change and the theory of change describes the mechanism of change in the intervention that addresses these barriers.

Analysis of Topic 2b: Theory of Change

As prescribed by PAM, the theory of change consists of primary and secondary causal pathways and moderators. We identified the causal pathways by examining barriers to change. For example, one barrier to change for the Casarett EBI was clinician discomfort with discussing hospice. With this in mind, we coded data that addressed this barrier as part of the causal pathway in the theory of change. Regarding the distinction between primary and secondary causal pathways, we did not explicitly ask interview participants to distinguish the two, so this portion of the analysis required discussion among co-authors. In future applications of these methods, we recommend asking participants to rank the importance of causal pathways they
describe based on their knowledge of the intervention. Such ranking could help distinguish between the primary and secondary causal pathways.

Moderators tended to be discrete factors that were often described as barriers or facilitators to implementing or delivering the Casarett EBI (e.g., the research team had an existing relationship with the clinical sites testing the intervention which improved buy-in from clinical staff). Moderators were also often described in relative terms, as factors that made the Casarett EBI easier or harder to implement in one context over another (e.g., nursing homes have fewer attending physicians than home health, facilitating the coordination and hospice referral process in nursing homes).

**Analysis of Topic Area 3: Core Components**

Conceptually, a strong understanding of an EBI’s activities and theory of change is necessary to specify core components appropriately (i.e., articulate core component *activities* and *principles*). Operationally, this meant that to analyze data on core components, we did not limit our coding to questions where core components were explicitly discussed; we also coded interview data from prior topic areas (activities and theory of change) as part of our core components analysis. As such, much of our interview data were double-coded (i.e., excerpts on causal pathway were double-coded as theory of change causal pathway and core components). Because of this, data on core components should be analyzed last.

To identify core components, we first reviewed the data we had coded as core components and theory of change causal pathway; this allowed us to articulate the *principle* portion of our core components. Next, to articulate the *activities* portion of the core components, we reviewed data coded as activities and core components. These data identified which activities activated each principle for each core component. Finally, we delineated between activities (or
portions of activities) that were core and activities that were part of the adaptable periphery. We determined this by relying on the principle behind each core component: if an activity operationalized a core component’s principle, it was considered core; if not, it was considered part of the adaptable periphery. Based on this analytic approach, we were able to clearly present our results as core component principle, core component activity, and adaptable periphery. See Table 2.5.
Table 2.5. Example of core component analysis from Casarett EBI

<table>
<thead>
<tr>
<th>Construct</th>
<th>Example from Casarett EBI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Component 1</td>
<td>The primary core component of the Casarett EBI was reframing the hospice conversation</td>
</tr>
<tr>
<td>Principle</td>
<td>The <em>principle</em> behind this core component was that the re-framing changed the conversations from something clinicians felt uncomfortable discussing (hospice and death/dying) to something clinicians feel comfortable discussing (care goals, needs, and preferences). This re-framing meant clinicians no longer avoided or delayed the conversation.</td>
</tr>
<tr>
<td>Activities</td>
<td>The <em>activities</em> supporting this core component were the introduction, framing, and cognitive conceptualization of the conversation (“I’d like to ask you some questions about your care goals, needs, and preferences.” instead of “Based on your deteriorating condition, I’d like to talk to you about hospice as a care option.”).</td>
</tr>
<tr>
<td>Adaptable Periphery</td>
<td>Other components like the exact wording of the 3-screening questions, who was asking the questions, and whether the questions were asked in-person or via phone were deemed part of the <em>adaptable periphery</em> because they do not impact the frame of the conversation (i.e., they did not compromise the principle underlying the primary core component).</td>
</tr>
</tbody>
</table>

*STEP 6: Map theory of change onto extant theory from the literature.* One primary output resulting from Step 5 is a theory of change for the EBI. Step 5 produced a “Little-T” theory of change. Little-T theories explain a phenomenon, elucidating why or how a relationship functions. However, Little-T theories apply to a narrow context and have not been widely tested and validated[47, 48]. As a final step in our analytic process, we mapped the Little-T theory of change for the Casarett EBI onto an extant “Big-T” theory. Like Little-T theories, Big-T theories seek to explain the mechanism behind a phenomenon; however, Big-T theories are often well-known within a field and have been refined and validated through research[47, 48]. Although this theory mapping is not prescribed by PAM, we included it as a final step because our methods were *post hoc*, non-experimental, and descriptive. Thus, we used this mapping process as an internal validation check for our Little-T theory of change and core component. Our ability to successfully map the Casarett EBI’s Little-T theory onto a Big-T theory increased our
confidence that our context-specific explanation is supported by a broader, generalizable explanation of a phenomenon.

To identify a Big-T theory, we first considered the level of change of our intervention (individual level) and the type of change (cognitive perception of the conversation surrounding hospice referral). This consideration helped us narrow down a field for our Big-T theory search. We chose to search for Big-T theories within psychology, a field that seeks to understand cognitive phenomena at the individual-level. Within psychology, we searched for Big-T theories with similar constructs and levers of change to our Little-T theory.

Results

The outputs from our analysis were: 1) updated description of intervention activities; 2) usual care pathway, including barriers to change; 3) EBI theory of change, including primary and secondary causal pathways and moderators; 4) description of the core components; and 5) overlay of Little-T with extant Big-T theory of change. Although our results are specific to our case example, they may serve as a model for how these types of results could be presented.

Output 1: Updated description of the intervention

We presented our description of the intervention (Additional File 4) within an existing intervention reporting framework, Template for Intervention Description and Replication (TIDieR)[49, 50].

Output 2: Usual care pathway, including barriers

For the usual care pathway, we developed a visual (Figure 2.3) and a text description. This usual care pathway provides a clear foil for the EBI theory of change and core components and clearly outlines the barriers to change that a well-designed intervention should address. For our context, we identified two main barriers to hospice referral that lie on the usual care pathway: 1) waiting on a precipitating event before discussing hospice and 2) discomfort with
the “hospice talk” (broaching hospice as a potential care option with the patient). These two barriers are interrelated, causing a negative feedback loop that further exacerbates delays in hospice referral.

**Barrier 1 – Precipitating Event:** Although a terminal diagnosis alone should trigger the hospice talk, in usual care, clinicians often wait until after a precipitating event (e.g., rapid change in prognosis, steep clinical decline, symptom exacerbation) to discuss hospice as a care option. Waiting for a precipitating event delays hospice referral; this tendency likely stems from barrier two (discomfort with the hospice talk).

**Barrier 2 – General Discomfort around the hospice talk:** Clinicians’ general discomfort discussing hospice leads them to avoid the hospice talk which, subsequently, delays referral. This general discomfort and avoidance also creates a negative feedback loop: because the clinician wants to avoid having the hospice talk, they may second-guess the patient’s terminal prognosis, reinforcing the tendency to wait for a precipitating event to discuss hospice.
Output 3: EBI Theory of change

For the theory of change, we developed a text description for each major construct: primary causal pathway, secondary causal pathway, and moderators (Table 2.6). In short, the Casarett EBI’s causal pathways removed the barriers identified in the usual care pathway by re-framing the hospice talk entirely. The conversation shifted from one about hospice to one about care goals, needs, and preferences, more generally. Clinicians felt equipped to and comfortable with discussing the latter and thus, no longer avoided or delayed these conversations. Additionally, the Casarett EBI screening questions were built into regular clinical workflows and asked of all eligible patients. This standardized the timing of the conversation, eliminating the second barrier encountered in usual care - reliance on a precipitating event to recognize a patient as potentially appropriate for hospice. Most moderators in our theory of change were positive—
i.e., were facets of the original intervention and context that boosted the overall effectiveness of the intervention.

Table 2.6. Construct-level breakdown of theory of change for Casarett et al. EBI

<table>
<thead>
<tr>
<th>Component of theory of change</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary causal pathway</strong></td>
<td></td>
</tr>
<tr>
<td>“Don’t lead the conversation by mentioning the “h” word [hospice], end the conversation by talking about hospice as a solution to self-identified needs”*: Re-framing of the conversation from one about death and hospice to be about patient’s needs, goals, and preferences. For patients who “screened positive”, hospice was presented as a solution to the patient’s specific needs, goals, and preferences that they had expressed during the screening.</td>
<td></td>
</tr>
<tr>
<td><strong>Secondary causal pathway</strong></td>
<td></td>
</tr>
<tr>
<td>“It allows for the potential to identify people who need hospice sooner…by…having these conversations about care goals, preferences, and needs without there being a precipitating event”*: Integrating the re-framed conversation into usual care via standardized patient eligibility criteria for having the conversation and standardized timing of the conversation lessens the tendency to wait for a precipitating event (e.g., decline in clinical status, change in prognosis) to identify someone as needing hospice, improving timeliness of referrals to hospice.</td>
<td></td>
</tr>
<tr>
<td><strong>Moderators</strong></td>
<td>All identified moderators had an effect in the positive direction (denoted as “+” below). Most were specific to the nursing home setting; one was related to the workflow of the original RCT.</td>
</tr>
<tr>
<td>• Clinical condition of nursing home patients (+): nursing home patients are an elderly, frail, sick population. This means there is a bigger pool of potentially hospice-appropriate patients to draw from, compared to other care settings. This is evidenced by the fact that all patients were screened for potential hospice appropriateness.</td>
<td></td>
</tr>
<tr>
<td>• Trial study staff carried out most activities of the intervention (+): in the RCT, study staff carried out main activities of the intervention (conducting 3-question screeners, faxing physicians). This minimized workload for nursing home staff, whose capacity for additional tasks may have been low.</td>
<td></td>
</tr>
<tr>
<td>• Social condition of nursing home patients (+): nursing home patients are often socially isolated from family members, or many of their family members and friends may be deceased. This social isolation may make nursing home residents more amenable to the idea of hospice compared to other patient populations (e.g., younger cancer patients).</td>
<td></td>
</tr>
<tr>
<td>• Physical location of nursing home patients (+): nursing home patients are centralized in one geographical location 24/7. This</td>
<td></td>
</tr>
</tbody>
</table>
alleviates some of the logistical burden that engaging in these conversations may present in other care settings.

- **Number and type of attending physicians at nursing homes (+):** In nursing homes, there are typically few attending physicians (5-10) compared to other care settings and most are geriatricians. Given that, in the original RCT, attending physicians had to “sign off” on the referral to hospice, the low number of physicians facilitated ease of sign off. Additionally, geriatricians may be more amenable to hospice care than other physicians in other specialties (e.g., cardiologists, pulmonologists).

- **Existing relationships (+):** In the original RCT, the nursing home and hospice had an existing working relationship prior to the start of the trial. Additionally, the research team had local champions at clinical sites who supported the research. Clinical sites had also identified a need for the research based on barriers to referral encountered in usual care, increasing their support for the intervention.

*Output 4: Description of core components*

We broke our description into two facets of core components (principles and activities), as well as the adaptable periphery (Table 2.7). The causal pathways from the theory of change guided the formulation of the principle portion of the core components; we then determined which activities were core vs adaptable by evaluating each activity to determine whether it operationalized a principle. Only those activities that operationalized a core component’s principle were considered core.
### Table 2.7. Detailed description of core components

<table>
<thead>
<tr>
<th>Core components: Principle</th>
<th>Core components: Activities</th>
<th>Adaptable Periphery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not lead the conversation by mentioning the “h” word [hospice], start the conversation by discussing care goals, needs, and preferences. End the conversation by talking about hospice as a solution to self-identified needs and goals.</td>
<td>Frame the conversation to be about patient care goals, needs, and preferences; this framing should not be adapted. If, through this discussion of care goals, needs, and preferences, the patient has been identified as potentially appropriate for hospice, only then should the topic of hospice enter the conversation.</td>
<td>Because the driving causal mechanism is the re-framing of the conversation, the exact wording and the screening questions themselves, as well as who is asking the questions, are not core components.</td>
</tr>
</tbody>
</table>

*Why this works:* The driving causal mechanism is the re-framing of the conversation. This re-framing works because it shifts the conversation to a topic the clinician feels comfortable with.

| Standardize the timing of the conversation. | Clearly define timing and criteria for patient eligibility to standardize these conversations to prevent reemergence of conversation avoidance or waiting until precipitating event. | Though the standardization of conversation timing is core, the criteria themselves may not be. This means that, as long as the criteria and timing are well-defined, there is some flexibility in adapting the criteria for determining when and with whom to have these conversations. |

*Why this works:* Standardizing the timing and target population for the conversation eliminates the need to rely on clinical judgement and a precipitating event, thus improving the timing of the conversation and subsequent referrals to hospice.

---

**Output 5: Overlay of EBI Little T-theory of change with extant Big-T theory**

We overlaid the Casarett EBI Little-T theory of change with an extant Big-T theory: Lazarus’ Transactional Model of Stress and Coping ([Figure 2.4]}. We considered a range of other individual psychology theories and ultimately selected Lazarus’s theory because...
of its congruence with our Little-T theory constructs. Moreover, Lazarus’ theory has been validated in several studies, increasing our confidence that our Little T theory of change and core components are legitimate[52, 53, 57-60].

Lazarus’ theory explains both the tendency for clinicians to avoid the hospice talk and why this avoidance behavior is not present when the hospice talk is re-framed as a conversation about care goals, needs, and preferences. In short, Lazarus’ theory posits that our behavior is driven by how we appraise a situation – specifically, whether we see the situation as a threat (primary appraisal) and whether we feel we are equipped to deal with the threat (secondary appraisal). The type of coping behavior exhibited to deal with the threat (stressor) is driven by one’s appraisal of the situation. Feeling equipped to deal with a stressor will lead to positive, problem-based coping in which actions are taken to resolve the stressor. Not feeling equipped to deal with a stressor results in negative, emotional-based coping in which there is a lack of action and avoidance of the stressor. Per Lazarus’ theory, even events perceived as threats can elicit positive coping and positive behavioral responses, provided individuals feel equipped to overcome the threat. In usual care, clinicians may perceive the hospice talk as a stressor they are not equipped to handle, resulting in negative coping behavior (i.e., avoiding the conversation). When the conversation is re-framed as one about care goals, needs, and preferences, this is perceived as a stressor the clinician is equipped to handle, so the clinician exhibits positive coping and takes action (i.e., engages in the conversation).
Figure 2.4. Transactional model of stress and coping

Discussion

To date, literature has focused on articulating the importance of core components as they relate to the adaptation-fidelity continuum, as well as the development of frameworks and general approaches for identifying core components (e.g., reviewing the theory of change)[13, 16, 19-25, 28, 29, 61, 62]. There has been little in the way of developing, testing, and refining methods and tools for identifying core components. This lack of guidance may contribute to gaps
in the core component and adaptation literature. The lack of practical, clearly specified methods may limit the ability of researchers or intervention developers to specify core components; it may also diminish the consistency and specificity with which core components are reported (i.e., reporting core components without clear delineation of activities, principles, and the adaptable periphery). The lack of methods may also contribute to the proliferation of frameworks and approaches that we see in the literature. A recent scoping review identified 13 frameworks for adaptation[18], all of which vary in their acknowledgement of the importance of core components, as well as their approach for identifying core components. Although most frameworks acknowledge understanding the EBI as a step in the adaptation process[13, 19, 23-25, 28, 61, 63, 64], not all acknowledge core components as integral to the adaptation process[20-22]. Among those that do, the process for identifying core components is limited to general approaches (e.g., review existing materials, consult with EBI developers, review the EBI logic model or theory of change)[7, 13, 23]. This leads to a literature base that is discordant, limiting the generalizability of this area of research, as well as our ability to build a knowledge base that promotes comparisons across research findings and contexts.

This paper fills an important gap in the current literature by expanding an existing adaptation framework (PAM) and providing a step-by-step guide – including methods, tools, and recommendations -- for identifying core components post hoc. Although PAM provided a general checklist of what is needed to identify core components (e.g., develop theory of change, establish intervention activities) and suggested some overall methodological approaches (e.g., primary data collection from intervention developers), specific tools were lacking. The methods we developed comprise 6 concrete steps for identifying core components, each accompanied by
specific tools (e.g., interview guides, codebooks). Overall, our methods present an extension and operationalization of the current literature.

Our methods extended PAM by adding two additional steps: 1) identifying the usual care pathway and barriers to the outcome of interest encountered in usual care, and 2) mapping Little-T EBI theory of change onto extant Big-T theory. The usual care pathway and barriers to change outlined the gaps that the intervention should fill, allowing us to clearly articulate the underlying theoretical mechanism of our EBI and, ultimately, its core components. Mapping our Little-T theory onto an extant Big-T theory helped assure us that our theory of change is generalizable to current and new contexts.

Our methods operationalize PAM in several important ways. Where PAM recommended general principles and steps, we have produced specific tools to achieve these steps, including the development of sampling approaches, interview guides, and analytic methods. Our sampling approach recommends recruiting participants with a wide range of experiences and expertise. Our interview guide presents questions for discussing three important topic areas, as well as specific techniques for how to ask about these areas. Our codebook and analytic methods further operationalize the constructs set forth in PAM, and offer recommendations for gleaning core components effectively from interview data. Importantly, we outline a detailed analytic approach for interpreting interview data to identify core components.

Limitations & future directions

Each step in our methods served the larger objective for our case example; however, the exact approaches we used may not apply in all contexts. We also realize that our methods and tools were developed and tested in our single case-study, based on an intervention developed over 10 years ago, potentially subjecting our results to recall bias and limiting the generalizability of our methods. We invite other researchers to extend and refine our approach to
expand the knowledge base for identifying core components *post hoc*. As these methods are applied and refined by other researchers, a compendium of methods for identifying core components – and methods for adaptation on a larger scale – could be disseminated through adaptation platforms or toolkits, such as the adaptome[17]. The adaptome is a concept for a common data platform that could house systematically captured information about the impact of adaptations of EBIs across contexts, building a repository of what works where and in what contexts. A platform like the adaptome could be expanded or developed to house similar information on methods for adaptation and identifying core components to expand our knowledge of what methods work where and in what contexts.

The methods described here may be most appropriate for situations where developers and evaluators of the original EBI have not elucidated a theory of change or core components of the intervention. These methods may also prove useful in instances where a theory of change or core components have been identified because research shows that theory is often misused or used superficially[65-67]. Thus, applying our methods in these cases may result in the generation of a theory of change that is richer and more appropriate to the EBI, ultimately leading to clearer and more accurate identification of core components.

For our own future research efforts, we plan to use the core components we identified for the Casarett EBI as part of a larger effort to adapt the Casarett EBI to a new setting: home health. We plan to use the core components identified here to guide our adaptation process to ensure any proposed adaptations do not compromise core components. In the final phase of our research, we will pilot test the adapted EBI – the updated description of the intervention developed here will serve as the foundation for our intervention protocol for the pilot test.
Conclusion

Our theory-driven approach to identifying core components led to specification of core components that were richly supported by underlying principles and activities. Our methods provide a step-by-step guide that can be used by researchers or practitioners to identify core components post hoc; our results can be used as a model for reporting theories of change and core components. This paper addresses gaps in the current literature base by providing a first step towards a compendium of specific methods that can be used by researchers and practitioners to identify core components.
REFERENCES


5. Rabin B: Fidelity and Adaptation for Implementation Science: how can we reconcile the tension? In *Center for Research in Implementation Science and Prevention (CRISP) Seminar Series; University of Colorado Anschutz Medical Campus*. 2016


12. Proceedings from the 9th annual conference on the science of dissemination and implementation. In *The Annual Conference on the Science of Dissemination and Implementation in Health co-hosted by the National Institutes of Health (NIH) and AcademyHealth; Washington, DC, USA*. Implementation Science December 2016


28. (RTIPs) SRTIP: Guidelines for Choosing and Adapting Programs.


CHAPTER 3: PART A: USING A CONSENSUS-BASED PROCESS TO PLAN ADAPTATIONS TO AN EXISTING INTERVENTION

Background

Adaptations are increasingly recognized as a way to improve the reach of evidence-based interventions (EBIs) by improving fit between EBIs and new contexts in which EBIs are implemented. However, when engaging in adaptation, it is critical to ensure that adaptations do not compromise the effectiveness of the EBI. To help ensure adaptations do not compromise EBI effectiveness, researchers can use adaptation process frameworks to guide their adaptation effort. As described in greater detail in Chapter 2 of this dissertation, we selected an adaptation process framework, the Planned Adaptation Model (PAM) (1) to guide our adaptation of the Casarett EBI (2) from the nursing home setting to the home health setting. Chapter 2 of this dissertation focused on identifying the core components of the Casarett intervention (step 1 in PAM); this chapter will focus on the subsequent phases in PAM’s adaptation process: identifying context differences and adaptations (steps 2 and 3 in PAM, see Figure 3.1).
After identifying core components, the next step in PAM is to identify key differences between the context for which the EBI was originally developed and the context for which the EBI is being adapted (1). Identifying key differences between the original and new context is a critical step in the adaptation process because it is these differences that drive the need for adaptations. Once the key differences are identified, the third step in PAM is to identify necessary adaptations. This is done by comparing the intervention protocol from the original EBI with the key context differences. The purpose of this comparison is to look for discrepancies – areas where an aspect of the new context does not align with the original EBI (1). Once identified, these discrepancies will drive adaptations. For example, for the Casarett EBI, one difference between the original and new context will be that in the original EBI, the screening for hospice appropriateness was conducted by the randomized controlled trial study staff. In the new context, study staff will not be available, thus presenting a discrepancy between the original EBI activities and the new context. This discrepancy will necessitate an adaptation (identifying a person other than study staff to perform the screening in the new context).
Once the list of potential adaptations is generated, each potential adaptation should be reviewed to determine whether the adaptation risks compromising EBI effectiveness. This can be achieved by reviewing the criteria for adaptation developed by Moore et al. (24):

- **Fit**: assesses whether the adaptation is being made to addresses a difference between the original and new context
- **Valence**: assesses whether the adaptation aligns with the core components of the original EBI

If the adaptation fails meet the criteria of fit or valence, it may compromise fidelity to the original EBI, potentially jeopardizing EBI effectiveness. As such, adaptations that do not meet the criteria of fit and valence are not recommended.

**Methods**

**Overview of approach**

The objective of this phase of my research was to 1) identify *context differences* between nursing homes and home health (original and new context) and 2) identify *necessary adaptations* to the original intervention that would address context differences. My overall approach was to engage a stakeholder panel in an iterative, consensus-based approach (i.e., Delphi method) to come to consensus on necessary adaptations that met the criteria of fit and valence.

I employed the Delphi method to build consensus on context differences and necessary adaptations. The Delphi method solicits the opinions of respondents through a series of “rounds” of data collection to develop a consensus of opinion on a specific topic (3-5). In the Delphi method, rounds of input are iterative – between each round, feedback from all participants is

---

1 Note that although timing is the 3rd criterion in Moore et al.’s structure, all adaptations in this study will be planned and will thus meet the timing criterion. As such, timing will not be formally evaluated.
analyzed by the researcher and areas of agreement and disagreement are noted and reported back to respondents prior to the next round of data collection (3-5). See Figure 3.2. Participants discuss areas of disagreement until consensus is reached. Although complete consensus is ideal, it is not required by in Delphi methods. Typically, a cutoff for defining consensus is set *a priori* by researchers; for the purposes of this research, we used a cutoff of 85%, where agreement between 85% of participants would be considered consensus.

In the Delphi method, round 1 is the broadest in focus, and typically serves as a brainstorming effort where participants are asked to generate a wide range of ideas on a topic (28-30). Using the ideas generated in round 1, subsequent rounds focus more narrowly on rationale for input expressed in prior rounds (e.g., why did you express x as a priority in round 1); rank-ordering of priorities (e.g., between x and y, would you rank x or y as most important); and resolving areas of disagreement (e.g., participant a and b disagreed, can we come to a consensus on the points they disagreed on). Ideally, rounds of data collection continue until consensus is reached on each topic area or question.

In the Delphi method, various modes of data collection can be used (e.g., interviews, focus groups, surveys). Typically, researchers decide mode of data collection based on the nature of the topic to be discussed in that round (3-5). Verbal, one-on-one modes of data collection (i.e., interviews) are preferred when questions are open-ended and intended to generate a wide range of ideas. Group discussions (i.e., focus groups) are preferred when questions are open-ended, but would benefit from debate and dialogue amongst participants (e.g., explaining why they selected...
a certain response or discussing the prioritization of a range of responses). Finally, written modes of data collection (i.e., surveys) are preferred when questions are structured (e.g., multiple choice or yes/no questions) and do not require lengthy explanations or discussion. Survey questions tend to be forced-choice (i.e., do not allow an “I don’t know” or “not sure”) response options. Typically, individual data collection (either written or verbal) is preferred in earlier rounds to generate the widest possible range of ideas and avoid group think (thinking or making decisions as a group in a way that discourages creativity or individual responsibility) (6). Group data collection is preferred once a range of ideas have been generated, and group discussion can promote debate among participants about on merits (i.e., pros and cons, importance) of each idea.

**Sample overview: The stakeholder panel**

The objective of this phase of my research was to determine, based on context differences, what about the intervention may need to be adapted to ensure appropriateness for the new context. As such, we wanted the stakeholder panel to comprise a variety of home health agency organizational perspectives. Based on input from clinical experts, we determined there were three main home health organization types: 1) not-for-profit agencies where the home health and hospice agencies are separate entities but are part of the same healthcare system, 2) community-based, not-for-profit, combined home health and hospice agencies; and 3) for-profit, combined home health and hospice agencies. My goal was to recruit one home health agency from each organization type for the stakeholder panel. Three local home health agencies were contacted, and all three agreed to participate in the stakeholder panel. Each organization then nominated staff members who had experience in home health and/or hospice to participate in stakeholder panel data collection activities. Organizations were asked to nominate individuals who had clinical, as well as management, expertise. This ensured stakeholder panel members
could speak to clinical practice, as well as overall operations, management, and workflows at their organization. The final composition of the stakeholder panel is presented in **Table 3.1.** In total, our stakeholder panel comprised 5 members from 3 different organizations.

**Table 3.1. Stakeholder panel**

<table>
<thead>
<tr>
<th>Organization Type</th>
<th>Organization</th>
<th>Staff members engaged in Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not-for-profit, separate home health and hospice agencies that are part of the same healthcare system</td>
<td>Duke Home Health, Durham, NC</td>
<td>• Home health clinical manager (n=1)</td>
</tr>
<tr>
<td>Community-based, not-for-profit, combined home health-hospice agency</td>
<td>Transitions LifeCare, Raleigh, NC</td>
<td>• Home health clinical manager (n=1)</td>
</tr>
<tr>
<td>For-profit, combined home health-hospice agency</td>
<td>Liberty Homecare &amp; Hospice Services, Raleigh, NC</td>
<td>• Hospice clinical director (n=1) • home health operations manager (n=1)</td>
</tr>
</tbody>
</table>

**Context differences: Sample.** For the rounds of data collection focused on identifying context differences, two of the organizations participated in data collection (Duke Home Health and Transitions LifeCare); the home health clinical managers from each organization participated in this data collection effort. The third organization (Liberty Home Care & Hospice Services) was unable to participate due to scheduling conflicts.

**Necessary adaptations: Sample.** All 5 staff members from all three organizations participated in the rounds of data collection focused on identifying necessary adaptations.

**Data collection procedures and analysis: Overview**

To identify context differences and necessary adaptations, I engaged in rounds of data collection with the samples from the stakeholder panel noted above. I used a combination of data collection modes, including one-on-one interviews, focus groups, and written surveys. Data collection mode was chosen *a priori* based on the criteria described above. For rounds that required open-ended discussion where the objective was to generate a wide range of ideas, I used
interviews. For rounds that had structured questions (e.g., yes/no, multiple choice questions) and asked participants to give their individual thoughts, I used written surveys. For rounds that required consensus-building (e.g., asking participants to state their rationale for a decision, rank order priorities, and come to a final consensus), I used focus groups. For rounds that were confirmatory in nature (e.g., asking participants to confirm a decision and rationale from a priori round), written feedback was used. I developed appropriate materials (e.g., interview guides, focus group discussion guides, and written surveys) to support structured and systematic data collection in each round. I did not establish a minimum number of rounds of data collection for each topic, a priori; instead, I continued rounds of data collection until consensus was reached on each topic.

Because the Delphi process is iterative, with respondents confirming the validity of analysis conducted by the researcher after each round, I did not employ traditional qualitative or survey analysis methods to analyze data collected from participants. Instead, my analytic approach following each round was to combine and summarize viewpoints expressed by all participants, flagging areas of consensus and outstanding disagreement for discussion in the next round of data collection. As such, analytic procedures following each round was as follows. First, I combined all responses from all participants for each question. I then reviewed all combined responses, removed duplicate responses, and noted areas of disagreement and complete consensus. I then shared these summarized data with participants prior to the next round of data collection; areas of disagreement served as the starting point for discussion in the next round.

This research was reviewed by the Institutional Review Boards and the University of North Carolina at Chapel Hill and at RTI International and was determined to be non-human
subjects research. This research also complies with recommended guidelines for qualitative research, as appropriate (7-8).

**Context differences: Data collection procedures and analysis.** To elicit general differences between nursing homes and home health, I developed a questionnaire for round 1 of data collection. Because this initial round was open-ended and was focused on generating a wide range of ideas, this round was conducted via one-on-one interviews with the context differences sample. The interview guide covered several domains of care that had been identified by clinical experts as relevant dimensions to establish context differences for: patient populations, care setting and delivery, policy context and external environment, and coordination with hospices. See Additional File 1 for complete interview guide. Interviews took place in August 2017 and each interview lasted 30-40 mins; I took detailed notes during each interview to capture discussion. Following round 1, I combined responses for each question to determine areas of agreement and disagreement. After analysis, combined responses were sent back to participants and participants were asked to send written feedback on any areas of misalignment. There were no responses that were in direct conflict; there were some ideas that were mentioned only by 1 organization, but in the post-round 1 feedback, participants voiced agreement for all ideas, so complete (100%) consensus was reached by the end of round 1. Because consensus was reached, no additional data collection was needed. See Results, Table 3.2 for a full list of key context differences.

**Necessary adaptations: Data collection procedures and analysis.** To elicit input on necessary adaptations, I used the Casarett EBI protocol to guide the first round of data collection; because this first round of data collection consisted of structured questions and required review of the entire Casarett EBI protocol, I conducted the first round of data collection via a written
survey. The survey was sent to the entire necessary adaptations sample and had a 100% response rate. For round 1, I sent all 5 staff participants the Casarett EBI protocol and asked them to flag areas in the protocol that would need modification to adapt the EBI to home health; the response rate was 100%. To guide review and feedback, questions were inserted into the Casarett EBI protocol using the comment feature in Microsoft Word. These questions were generated from the context differences data collection and highlighted the key context differences identified. For example, in the portion of the EBI protocol that covered eligible patients, I inserted a comment bubble that detailed the differences in patient populations between nursing home and home health (e.g., nursing home patients may be further along in their disease trajectory and/or be in worse clinical condition); for each context difference, there was a question to ask whether this context difference necessitated an adaptation to the EBI protocol (e.g., does differences in clinical condition of patients warrant an adaptation to the patient eligibility portion of the protocol?). I instructed participants to respond to each structured question, but I also told participants they were free to insert their own ideas about potential adaptations, independent of the guided questions. Following round 1, I combined responses from all participants, removing duplicates and noting areas of disagreement and complete consensus.

The objective of round 2 of data collection was to discuss areas of disagreement identified in round 1, clarify rationale for responses given in round 1, and rank order responses and priorities identified in round 1. Because the objective of round 2 was to discuss merit and prioritize each potential adaptation, I conducted round 2 via an in-person meeting (i.e., focus group) with the necessary adaptations sample. The focus group took place in September 2017 and lasted approximately 2 hours; I took detailed notes during the focus group to capture discussion. All 5 staff members were invited to participate in the focus group and 100% attended
in-person. To facilitate discussion, each area of the Casarett EBI protocol that had been flagged for adaptation in round 1 was displayed in a Microsoft PowerPoint presentation along with questions to guide the in-person discussion. Questions identified areas of disagreement and prompted participants to provide a rationale for their positions (Additional File 2 provides the Microsoft PowerPoint file that served as the meeting session guide). For each potential adaptation, participants also discussed Moore’s adaptation criteria [i.e., whether the adaptation addressed a context difference (fit) and whether it aligned with the core components (valence)].

Following round 2, responses, rationales, and rank-ordered priorities were combined and sent to all participants for review and comment. Following the post-round 2 feedback, participants voiced agreement for all ideas, so complete (100%) consensus was reached by the end of round 2. Because consensus was reached, no additional rounds of data collection were needed. See Results, Table 3.3 for a full listing of all adaptations.

Outputs

The primary output of this phase of my research was an updated protocol for the adapted EBI that included the necessary adaptations identified by the stakeholder panel. The final, adapted EBI protocol was sent to the stakeholder panel members for review and sign-off to ensure it accurately reflected discussion and consensus reached during the Delphi process. I maintained the overall structure of the original EBI protocol, which included step-by-step procedures for the EBI, as well as scripts for the hospice appropriateness screening questions. In addition to the procedures and scripts, I also added to the protocol a purpose for each step, as well as an implementation worksheet for each step. The purpose for each step was crafted based on earlier phases of this research (see Chapter 2) where the intent and core components of the Casarett EBI was explored in greater detail. Discussion with the stakeholder panel in the current effort also informed the purpose of each step. The implementation worksheet portion of the
protocol was produced based on the discussion with the stakeholder panel during the in-person focus group meeting. A large focus of the stakeholder panel focus group was to make decisions about what would need to change to implement the EBI at a range of home health organization types. This discussion was fruitful and could guide systematic implementation planning for future organizations wishing to adopt and implement the adapted EBI; thus, I included select discussion questions in the protocol to guide future implementation efforts.

Results

Context differences

I identified several key context differences between nursing home and home health (see Table 3.2). Overall, primary key differences were identified within the domains of patient population and care setting and delivery. In home health, the goal of care is independence – to get the patient (or patient and caregiver) back to their baseline of where they were prior to the home health admission. For nursing home patients, restoring function and health so that the patient can be discharged back to the community is typically not a goal. Thus, nursing home care goals focus on maintenance rather than improvement. Additionally, nursing home patient tend to be “worse off” or more complex than home health patients; meaning, they are further along in their disease trajectory or have a worse clinical condition. Regarding care delivery and setting, home health is delivered in the patient’s home where nursing home patients are in an institutional setting. In nursing homes, round-the-clock services are available and the patient receives multiple visits per day whereas in home health, visits occur 1-2 times per week, on average. Another primary difference is the care team – in home health, although the patient may receive care from multiple disciplines, there is a single case manager. In nursing homes, typically there is no case manager; whoever is on shift provides care to the patient. A final key difference is the role of the physician. In nursing homes, the physician is typically the medical director and there
is 1-3 per nursing home. With home health, the physician is the patient’s primary physician from the community that the patient had prior to their home health admission. Sometimes this is a primary care physician, but it can also be a specialist (e.g., oncologist) depending on the patient’s diagnosis. This means that in the home health context, *home health staff are dealing with a multitude of physicians, compared to the nursing home setting.*

Finally, although this is not a difference between nursing home and home health per se, another critical context difference between the Casarett EBI and this research effort was the fact that the Casarett study was conducted as a randomized controlled trial. This difference has important implications for the EBI protocol and pilot testing of the adapted EBI (discussed in Chapter 4 of this dissertation). In the Casarett study, trial staff completed all of the activities of the EBI, including key steps like determining patient eligibility, asking the screening questions and reporting results back to the patient, as well as facilitating coordination with the patient’s physician to initiate a hospice referral, as appropriate. In the home health organizations, no study staff are available, so home health agency staff would be charged with carrying out all activities of the adapted EBI. This key context difference was a primary topic of discussion and drove many of the adaptations; because study staff were not available, we had to adapt the EBI protocol to have home health staff carry out activities originally carried out by study staff in the Casarett trial.
Table 3.2. Key context differences between nursing home and home health

<table>
<thead>
<tr>
<th>Domain 1: Patient Population</th>
<th>Nursing Home (NH)</th>
<th>Home Health (HH)</th>
<th>Both Nursing Home and Home Health</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goals of Care</strong></td>
<td>Restoring function/health so that patients can be discharged back to the community is not typically the goal. As such, goals tend to focus more on maintenance rather than improvement. Instead of functional improvement, safety and injury/infection prevention are also important. Instead of teaching the patient to provide their own care, total care provided by nursing home staff on an ongoing basis is the standard in NHs.</td>
<td>Goal of care is independence and to restore function-- to get the patient (or patient and caregiver) back to their baseline or to where they were before their HH admission -- so that they can be discharged back to the community. Because the goal of care is restoring independence, a main philosophy of care is to teach (not to provide care on an ongoing basis).</td>
<td>Symptom management is a goal of care common to both settings.</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td>For long-stay patients in a NF, patients are more likely to be “worse off” or more complex (e.g., older, more chronic conditions/multiple diagnoses/co-morbidities, total care patients, and/or patients further along in their disease process). Also, more likely to see dementia/Alzheimer’s diagnoses.</td>
<td>Patients are usually admitted to HH due to an acute condition (fall), an acute exacerbation of a chronic condition, or a new diagnosis.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Clinical Condition</strong></td>
<td>Disease trajectory-wise, a NH patient may be further along in their disease trajectory or have a worse clinical condition. This could include patients who may have previously been HH would need a patient who is expected to be able to improve/restore their function.</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>


eligible for home health, but who are no longer able to be cared for safely at home given the capability/availability of the patient or caregiver.

<table>
<thead>
<tr>
<th>Demographics</th>
<th>N/A</th>
<th>May see more self-pay/uninsured in HH</th>
<th>In both HH and NH, mainly older patients (65+) and Medicare and Medicaid are main payers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of Stay</td>
<td>A nursing facility (NF) stay can be indefinite</td>
<td>HH episode is 60 days, most patients are discharged within that time frame</td>
<td>N/A</td>
</tr>
<tr>
<td>Social Conditions</td>
<td>No family caregiver or paid caregiver needed to provide care or assist with ADLs/IADLs. Done by NH staff.</td>
<td>If patient needs assistance, must have caregiver present to safely provide the care the patient needs and assist with ADLs/IADLs. Caregiver can be a family caregiver or a paid caregiver/aide.</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Domain 2: Care Setting and Delivery**

<table>
<thead>
<tr>
<th>Care Delivery</th>
<th>Nursing Home (NH)</th>
<th>Home Health (HH)</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care team includes nursing, PT/OT/SLP, aide, and round-the-clock services are available. Will receive multiple visits per day. Pharmacy services on site. All services are provided in an institution (NF or SNF). NH has control over the physical environment (e.g., can install guard rails, get rid of tripping hazards).</td>
<td>Care team includes nursing, PT/OT/SLP, social worker, aide. Visits from above disciplines 1x or 2x per week (because goal is education/teaching, not care provision). Common to provide more visits early in the stay, then taper off towards the end of stay (to provide smoother transition upon discharge). HH agencies may have nurses with more training than NHs (nurses with 4-year degrees or graduate prepared nurses). Pharmacy services not part of HH; HH not administering medications,</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>Care Team</strong></td>
<td>Whoever is assigned to that patient for that day/shift is who is delivering/managing care (less continuity of care). Also, less likely to have a case manager. Nurse seen as the primary point of contact, but patient may not have the same nurse day-to-day. Also has interdisciplinary meetings.</td>
<td>Care typically managed by the case manager, who will stay with the patient throughout their entire stay (continuity of care). Case manager can be a nurse or therapist, depending on the patient’s primary need. Case manager typically seen as the primary point of contact. Entire team meets every 2 weeks for the interdisciplinary team meeting.</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Role of Physician</strong></td>
<td>Physician is typically the medical director at the nursing home. Some nursing homes have 1 medical director, some have several, but the day-to-day care team is dealing with fewer physicians than in HH, and the physician is located within the organization providing care (whereas in HH the physician may be organizationally unaffiliated with the HH agency). Because the physician on record is the medical director, the patient likely will not have a prior relationship with the physician.</td>
<td>Can’t do anything without a physician order. The physician is the patient’s primary physician from the community, pre-HH admission; this means the patient has an existing relationship with the HH physician on record. The HH physician on record is usually the patient’s PCP, but sometimes is their oncologist or another specialist. Because the physician on record comes from the community, at any given time, a HH agency could be dealing with tens or hundreds of physicians.</td>
<td>Patient has less contact with the physician than with other members of the care team (nurses, therapists)</td>
</tr>
<tr>
<td><strong>Referral Sources</strong></td>
<td>N/A</td>
<td>HH: mainly inpatient units from the hospital and</td>
<td>Decision to admit a</td>
</tr>
</tbody>
</table>
community physicians’ offices (PCP). Some specialists will refer (oncologists, orthopedics). Will also get nursing referrals for wound care, Foleys. Can get referrals from SNFs (acute problem → 100-day SNF stay → HH). patient to NH vs HH: availability of the caregiver and finances (can the patient afford a paid caregiver in the home, if needed).

<table>
<thead>
<tr>
<th>Domain 3: Policy Context and External Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory requirements</strong></td>
</tr>
<tr>
<td>Nursing Home (NH)</td>
</tr>
<tr>
<td>No relevant differences identified</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain 4: Relationship with Hospices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Attitudes and knowledge about hospice among staff</strong></td>
</tr>
<tr>
<td>Nursing Home (NH)</td>
</tr>
<tr>
<td>NH: less knowledge of hospice and less comfort with hospice in general. Can be an aversion to hospice and providing pain medications in particular, because NH staff are afraid they’re going to end up killing the patient.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Care coordination once patient is enrolled in hospice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing Home (NH)</td>
</tr>
<tr>
<td>More continuity of care. Once a patient converts to hospice, the NH staff still provide all the services they were before, hospice is just there to provide additional services.</td>
</tr>
</tbody>
</table>

Note: ALF = assisted living facility; HH = home health; NH = nursing home; SNF = skilled nursing facility; NF = nursing facility; SLP = speech language pathology; OT = occupational therapy; PT = physical therapy.

**Necessary Adaptations**

I identified several adaptations to the Casarett EBI protocol. All adaptations are listed and described in Table 3.3. Of the 6 steps in the Casarett EBI protocol, I made 14 adaptations. Some adaptations were made to the content of the intervention itself (e.g., changing wording of screening questions, changing definition of a positive screen), but most were made to the
delivery of the EBI (i.e., who was delivering which components of the intervention, when, and how). Delivery changes were necessitated by the fact that study staff would not be available in the adapted EBI pilot test, so home health staff would have to fill all roles previously filled by study trial staff.

For certain adaptations, each organization type had different recommendations for exactly how to operationalize the adaptation, based on their individual organizational perspective, patient needs, staffing workflow, and clinical record systems. Thus, to increase reach and generalizability of the adapted EBI, we left some adaptations flexible. For example, regarding patient eligibility, the stakeholder panel determined that unlike the Casarett EBI where all nursing home residents were eligible for the intervention, not all home health patients should be eligible to receive the intervention. Specifically, those home health patients who were admitted due to an acute condition and are expected to make a full recovery should be excluded from the intervention (e.g., orthopedic patients who are recovering from knee surgery and have no other co-morbidities). Thus, the inclusion criterion for home health should be “high-risk” or “frail” patients. The exact definition of high-risk and frail, however, was left flexible in the adapted EBI protocol. Although the stakeholder panel generated some potential definitions for high-risk/frail patients based on their individual patient populations (e.g., patients with a life expectancy of less than 1 year; patients with a high risk of hospitalization as defined by OASIS item M1033), in the adapted EBI protocol, ideas were listed but the final determination for defining high risk and frail was left to the end user (i.e., organization wishing to implement the adapted EBI). The goal was for this flexibility to increase the generalizability of the adapted EBI. All adaptations met the criteria of fit and valence, so all identified adaptations were
recommended and included in the adapted EBI protocol. Further analysis of each adaptation (e.g., classifying each adaptation using existing taxonomies and positing potential impact on implementation and intervention effectiveness) are discussed in Chapter 3b of this dissertation.
Table 3.3. Adaptations to Casarett EBI

<table>
<thead>
<tr>
<th>Adaptation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in overall target population and setting</td>
<td>Changed the setting/target population from nursing home to home health to improve the overall reach of the intervention. NH patients are a minority (19%) of all hospice patients, so adapting the intervention to home health will expand its potential reach.</td>
</tr>
<tr>
<td>Change in definition of eligible patients</td>
<td>In original intervention, all NH residents eligible for intervention; in the adapted intervention, only “high-risk” or “frail” HH patients are eligible. This avoids in appropriate screenings for hospice (e.g., a HH patient who is admitted to recover from a joint replacement and is otherwise healthy and expected to make a full recovery). In adapted intervention, exact definition for “high-risk” or “frail” was left eligible. Potential definitions were listed, but the protocol left it to the discretion of the organization to create their own definition for high risk or frail, provided the definition was based on at least one structured data element (i.e., it was not left solely to clinical judgement to determine high-risk or frail).</td>
</tr>
<tr>
<td>Change in delivery</td>
<td>In original intervention, all intervention activities carried out by RCT staff; in adapted intervention, activities will be carried out by HH staff. This is because it would not be feasible for a home health organization to hire a new staff member to complete these tasks. Responsible Party for specific activities noted below.</td>
</tr>
<tr>
<td>Change in process for how eligible patients will be identified</td>
<td>In original intervention, eligible patients were identified via chart review using explicit criteria; in adapted intervention, patients will be identified concurrent with care using at least 1 explicit criterion. Concurrent identification is less burdensome than chart review.</td>
</tr>
<tr>
<td>Change in determining cognitive status of patients (how)</td>
<td>In the intervention, you need to know cognitive status of the patient to determine if you should ask screening questions of patient or proxy. In original intervention, cognitive status was determined using MMSE; in adapted intervention, will be determined using an existing OASIS item (M1700 where a score of 2-4 indicates cognitive impairment). This decision was made because OASIS data collection is required for all HH patients, and the MMSE is not used in practice. So using an existing data item will reduce burden of data collection for the intervention.</td>
</tr>
<tr>
<td>Change in who delivers screening question</td>
<td>In original intervention, research assistant delivered screening questions. In the adapted intervention, a member of the patient’s home health clinical team will deliver the questions. It was left flexible in the intervention protocol which clinical team member could deliver the questions, as stakeholder panel members felt any clinical team member had the skills to deliver</td>
</tr>
<tr>
<td>Adaptation</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<tr>
<td>the intervention; this flexibility increases generalizability of the protocol by allowing home health agencies to select staff best suited to the task.</td>
<td></td>
</tr>
<tr>
<td>Change in when screening questions are delivered</td>
<td>In original intervention, all hospice appropriateness screening questions were asked in one sitting; in adapted intervention, the timing of the screening question delivery was left flexible. Organizations can ask the questions all at once or in multiple visits. The adapted protocol requires that all questions be asked within first 3 visits or the first week of care, whichever comes first. This adapted timing allows for flexibility at the patient-level (e.g., a patient may be in crisis or overwhelmed at the initial admission visit, so allowing the questions to be asked over multiple visits is a better approach), while still maintain structure to help ensure questions are asked in a timely fashion.</td>
</tr>
<tr>
<td>Change in accountability/responsibility for asking questions</td>
<td>In original intervention, accountability for asking the questions appropriately was handled through the RCT protocol, as part of the research assistant’s job. In the adapted intervention, there will be no study staff, so the patient’s case manager responsible for ensuring 3 questions are asked within the 3 visit/1week timeframe. This adaptation helps ensure questions will be asked in a timely fashion.</td>
</tr>
<tr>
<td>Change in the introduction of the screening conversation</td>
<td>Adapted the wording of how the screening questions conversation is introduced. In the adapted protocol, this portion of the script is now even more “hospice neutral” than in original intervention – there is more focus on care goals/needs/preferences and hospice is not mentioned at the outset. This adaptation strengthens one of the core components of the intervention – which is reframing the conversation.</td>
</tr>
<tr>
<td>Change in screening question content (care goals questions)</td>
<td>In the second domain of hospice appropriateness screening questions (care goals questions) we adapted the questions by removing one of the care goals SUPPORT questions. In the original script, if the respondent was a proxy, the proxy was asked 2 questions about the patient’s care goals – the question was the same, but one asked the proxy to respond based on what the proxy thinks is best (best interest), while the other asked the proxy to respond based on what the patient would want (substituted judgement). We eliminated the best interest question because the stakeholder panel felt a proxy should always be prompted to respond based on what the patient would want, not the course of action they (the proxy) think is best.</td>
</tr>
<tr>
<td>Change in screening question content (symptom questions)</td>
<td>We retained the content of all symptom burden questions; we adapted the structure of the questions to simplify them. Instead of asking 2 questions about each symptom (presence and severity/frequency), we simplified the wording to ascertain both</td>
</tr>
</tbody>
</table>
### Adaptation | Description
--- | ---
| | concepts in 1 question (patient is asked to rate frequency/severity and “none” or “not at all” on the scales equate to symptom not present.
| **Change in definition of positive screen** | In the original intervention, the patient had to score positive on all 3 domains of hospice appropriateness screening questions to be considered a “positive screen” overall and go on to initiate the hospice referral process. In the adapted intervention, we decreased the threshold to 1/3 to be considered positive overall. This is because stakeholder panel members felt strongly that preferences for CPR/ventilation should not impact whether you receive a referral for hospice, as patients are not required to have preferences against CPR/ventilation to elect hospice. In addition, stakeholder panel members thought patients could be hospice appropriate with just 1/3 domains identified, and that this lower threshold would serve the larger purpose of increasing referrals to hospice for appropriate patients.
| **Change in who reports results of screening back to patient** | In original intervention, results of screening were reported back to patient/caregiver by the research assistant; in the adapted intervention, this will be done by case manager (even if case manager is not the staff member who asked the screening questions). Stakeholder panel members felt that having the case manager deliver the results (and broach hospice as appropriate) allows hospice to be introduced by someone the patient trusts (not a clinician the patient may only see 1 time, such as an admissions nurse).
| **Change in when screening results are reported back to patient** | In the original intervention, results of the screening were reported back to the patient/caregiver directly after questions were asked; in the adapted intervention, this will be done at a subsequent visit (i.e., a visit other than the admission visit). This is because the admission visit is hectic and may not be a good time to introduce hospice if patient screened positive.

### Outputs

The main output of this portion of the research was the adapted EBI protocol (see Additional File 3). This adapted EBI protocol will be used in pilot testing of the adapted EBI (see Chapter 4 of this dissertation). The EBI protocol is organized by step (see Figure 3.3); there are six steps in the adapted EBI. For each step, the protocol includes: 1) the purpose of the step 2) procedures for the step 3) scripts for the step (if needed) and 4) an implementation worksheet for the step. The purpose explains the intent and importance of each step and any
describes whether that step is a core component of the intervention. The *procedures* explain necessary actions for each step (i.e., who will do what, when, and how). The *scripts* provide verbatim language that should be used for each step requiring discussion with a patient or caregiver; scripts are included as Appendices to the adapted EBI protocol. The *implementation worksheet* was included to guide implementation of the adapted EBI by future home health agencies. The worksheet includes checklists of activities that should be completed for each step (e.g., decide who will deliver screening questions), as well as decision aides/guided questions for steps in the protocol that were left flexible (e.g., in determining how to define frail or high-risk patients, consider whether there are existing data points in your clinical records that already provide this information; this will reduce burden and unnecessary data collection). There is also explicit instruction in the *implementation worksheet* about which procedures/steps should not be further adapted because they relate to a core component (e.g., maintain at least one structured patient eligibility criterion; do not rely solely on clinical judgement; relying solely on clinical judgement risks delaying the start of the hospice appropriateness screener and conversation).
Figure 3.3. Screenshot of adapted EBI protocol

Discussion

Summary

Several features of our approach were particularly useful for our research. First, the Delphi approach helped key stakeholders successfully come to consensus on adaptations necessary to move the Casarett EBI from the nursing home setting to the home health setting. Second, our two-pronged approach to data collection (discussing key context differences first,
followed by adaptations), helped us ensure our adaptations were systematic and would meet the fit criterion a priori. Third, determining whether each adaptation met the valence criterion would have been impossible without the research conducted in Chapter 2 of this dissertation. Thus, consistent with the adaptation literature, identifying core components is a key first step in any adaptation process. Fourth, the range of organizational perspectives we recruited for our stakeholder panel proved invaluable. Each organization type brings special considerations for their workflow and context, and having representation from each of the major home health agency organization types helped us build adaptations that were more generalizable than they would have been otherwise. Finally, our organization of the adapted EBI protocol was well-received by the stakeholder panel as a way to help future organizations think through the implementation of the adapted EBI at their organization. Stakeholder panel members noted that the explicit direction in the EBI protocol about what not to adapt (because it was part of the core components) was also helpful.

**Limitations, future applications and research**

Although my overall approach (Delphi process) was systematic and comprehensive, a limitation of this approach is that it is likely too resource-intensive to be used by practitioners who are considering adopting and implementing an intervention at their organization. Although the feasibility of this method is low in some contexts, I believe this method was appropriate for my purposes, which was an effort to engage in large-scale adaptation of an existing EBI (i.e., moving an EBI from one context to a completely different context). Thus, I felt the level of detail and comprehensiveness inherent in the Delphi approach was necessary for my purposes, even though it is not scalable in all situations. Although the approach is not likely scalable outside of a research context, a full Delphi process may not be necessary for all adaptation efforts. For example, pending results of the pilot test, the adapted EBI protocol may be ready for additional
testing and/or scale-up. Although individual home health agencies may need to adapt my protocol to suit their individual needs, these adaptations would likely be small scale adaptations (e.g., minor tweaking and tailoring the basic components of our protocol). Thus, the implementation worksheet portion of our protocol may be sufficient for guiding these small-scale adaptations; meaning, a full Delphi process is not necessary in every context. Situations where full Delphi adaptation processes are needed is an area for future research. Future research is needed to assess the structure of our EBI protocol, specifically, the inclusion of the worksheet portion to guide decision-making and tailoring at the local level. This format is not standard among endorsed intervention protocols (e.g., TIDIER) (9-10), and thus may be a feature to add to future iterations of endorsed intervention protocols, should it prove useful and effective.

A second limitation of this research is the potential generalizability of our stakeholder panel members, and, thus, the subsequent adaptations and context differences that were identified. Although my recruitment was purposive (i.e., I specifically targeted different organizational types that represented the major classes of home health agencies in the US), the final sample was still small (1 organization of each type). Despite our small sample, I engaged in several efforts to promote generalizability of the findings. First, during data collection with the stakeholder panel, I encouraged participants to think not only about their individual organization, but also about the “average” or “typical” home health organization and whether context differences and adaptations were applicable to the “average” home health agency in the US. Considering the circumstances of the “average” home health agency was the impetus for leaving some steps in the EBI protocol flexible; stakeholder panel members felt strongly that making pointed decisions about all aspects of the EBI procedures would make the protocol too rigid,
limiting its generalizability. Beyond the planned pilot test of this adapted EBI protocol, future research on the effectiveness and generalizability of the adapted intervention is needed.

A final limitation was the fact that not all stakeholder panel members participated in the context differences data collection. One organization did not participate due to scheduling conflicts. However, I do not believe this had major impacts on the quality and breadth of data collected for this topic. First, findings among the organization that did participate were highly consistent, even in early rounds of data collection. Second, the context differences discussion focused on high-level differences between nursing home and home health overall and was agnostic to any one agency’s workflows, policies, or specific patient populations. Thus, I do not believe the participation of all 3 organizational types for was critical for gaining insight on context differences; participation of all three organizational types was much more important for the discussion of necessary adaptations since this intersected more with an individual agency’s workflows, staffing, and patient populations.
REFERENCES


CHAPTER 3: PART B: A THEORY OF PLANNED ADAPTATIONS’ INFLUENCE ON INTERVENTION AND IMPLEMENTATION OUTCOMES

Background

Adaptations, implementation outcomes, and intervention outcomes: Existing literature and gaps

Many effective interventions go unused in practice (1-4); moreover, when interventions are adopted, their effectiveness is often dampened due to poor implementation (5-10). Often, interventions are not adopted because practitioners feel they do not fit the unique needs of their patient population or context and thus choose to forgo implementation altogether (11). Among those that are adopted and implemented, unplanned adaptations are common (i.e., reactive adaptations made during implementation due to unanticipated obstacles) and risk compromising an intervention’s effectiveness (9-10, 12). To address these problems, planned adaptations are critical to implementation science. Planned adaptations are changes made to an intervention using a systematic approach. Changes made as part of a planned adaptation effort are usually made deliberately (vs on the fly) and are critically appraised in some way before implementing them (i.e., consideration is given to whether the adaptation addresses an important gap or need; whether the adaptation risks compromising the core components of an intervention; and/or the impact or negative consequences the adaptation might have on outcomes) (12). Planned adaptations are increasingly recognized as a way to improve implementability of interventions by improving fit between interventions and new contexts in which interventions are implemented (12-14). As such, planned adaptation represents an opportunity to improve population health by
allowing practitioners to accommodate the needs of diverse contexts and patient populations when implementing new interventions.

Within the realm of planned adaptations, there are two types of adaptations: content adaptations and delivery adaptations. Content adaptations are modifications or changes made to the intervention itself (e.g., adding or removing components of an intervention, changing the order of components) (15). Delivery adaptations are changes or modifications made to how the intervention is carried out (e.g., changes to who is delivering a certain component of an intervention or timing of when components are carried out) (15). Ideally, these adaptations are made for specific reasons – either improve the fit of the intervention with the needs and culture of the target population (i.e., to improve philosophical fit) and/or to improve the fit of the intervention with existing workflows and organizational structures at the implementation site (i.e., to improve contextual fit) (12). In this sense, planned adaptations are ideally made to address a specific discrepancy (area of misfit) between intervention, target population, and implementation context. Although research supports the positive impact that planned adaptations can have on outcomes (12-14), even planned adaptations can risk compromising the effectiveness of an intervention when the adaptations compromise the intervention’s core components (components of the intervention that make it effective) (14, 16).

A chief concern when adapting an intervention is understanding the impact that adaptations have on outcomes of interest: do adaptations enhance or diminish outcomes, and under what circumstances? To date, much of adaptation evaluation research has focused on exploring the what of adaptations, evaluating what impact adaptations have on outcomes of interest. This literature base shows mixed results (15, 17); some adaptation efforts maintain or enhance outcomes of interest while others diminish desired effects (22, 23). However, evidence
is lacking regarding why or how adaptations produce demonstrated impacts on outcomes (i.e., the pathways by which adaptations influence outcomes); the state of the science is such that we cannot systematically explain the circumstances which make adaptations successful in some contexts, but not others.

Equally neglected in adaptation evaluation research is an exploration of whether adaptations influence intervention outcomes, implementation outcomes, or both. Intervention outcomes are the effects of the intervention itself – whether the intervention produced desired patient outcomes (e.g., whether a weight loss intervention reduced body mass index in the target population) or desired service outcomes (e.g., whether a workflow intervention improved wait times in the emergency room) (18). Implementation outcomes, on the other hand, are the effects of “deliberate and purposive actions to implement new treatments, practices, and services”, and include outcomes like fidelity to the intervention, cost of implementation, and acceptability of the intervention (18). The ultimate impact of an intervention is a combination of implementation and intervention outcomes, where successful implementation is necessary but insufficient for achieving desired intervention outcomes.

Overall, the inability to answer these questions is underpinned by a lack of theory in the adaptation literature. Although adaptation frameworks exist to classify adaptations (e.g., Moore, Stirman) (12, 15) and outline processes for engaging in planned adaptation (e.g., Lee, Chen) (14,19), these frameworks are atheoretical and do not explain pathways of why or how adaptations impact implementation and/or intervention outcomes.

Outside of the adaptation literature base, existing causal theories posit pathways between interventions and implementation and intervention outcomes (e.g., Klein and Sorra, Proctor) (18,20); however, these theories do not explicitly address adaptation. Although adaptation (if
done appropriately) is increasingly acknowledged as a way to increase implementability of interventions and positively impact both implementation and intervention outcomes (14), adaptation has not been explicitly integrated into existing implementation-intervention outcome theories.

The lack of causal adaptation theory limits our ability to predict the impact adaptations will have when engaging in planned adaptation efforts in practice; it also limits our ability to explain how or why adaptations are impacting outcomes. The development of a causal adaptation theory would promote the generalizability of findings across studies by providing a common architecture for understanding adaptation; it would also provide an understanding of the causal pathways between adaptations and outcomes, improving our ability to predict and explain the impacts of adaptations.

In this paper, we posit that there exist pathways among 1) types of adaptations 2) the reason for adaptation and 3) adaptations’ relationship with intervention and implementation outcomes (specifically, implementation and intervention effectiveness). Specifically, we contend that certain types of adaptations (i.e., content or delivery) are more likely to be made for certain reasons (to address philosophical or contextual misfit) and that different types of adaptations work through different mediators (e.g., core components of the intervention, acceptability, appropriateness, etc.) to impact implementation and/or intervention outcomes. Building on existing adaptation and intervention-implementation outcome frameworks and theories, we propose a causal theory for understanding these pathways. To develop our theory, we began by selecting relevant constructs from with existing adaptation and intervention-implementation outcome frameworks and theories. Then, using constructs from these existing adaptation and intervention-implementation outcome frameworks and theories, we coded adaptations from a
research study. We then formed the pathways of our theory by analyzing the coded adaptations and using our experience in implementation science and practice.

**Existing frameworks selected for theory development**

Because we hypothesized that there were relationships between type of adaptation, reason for adaptation, and adaptations’ impact on implementation and intervention outcomes, we selected existing frameworks and theories that addressed each of these three areas. Our objective in starting from these frameworks was to build a theory comprised of existing constructs from the literature. Our goal was to take constructs from existing frameworks and identify pathways among them (versus developing a theoretical model *de novo* with our own constructs). We selected three frameworks: two existing, complementary adaptation classification frameworks (Stirman and Moore) (12,15) and an intervention-implementation outcome theory that distinguishes between implementation and intervention and provides specific examples of implementation outcomes (Proctor) (18). We selected these frameworks and theories because they contain constructs related to our hypotheses (i.e., they include constructs related to type of adaptation, reason for adaptation, and implementation and intervention outcomes). A brief overview of each framework/theory is presented below; key constructs are defined in Table 3.4.
<table>
<thead>
<tr>
<th>Framework</th>
<th>Key Construct(s)</th>
<th>Definitions</th>
</tr>
</thead>
</table>
| Stirman (15) | Type of Adaptation | **Content adaptation**: an adaptation made to the intervention itself (e.g., removing components of an intervention, changing the duration of sessions in an intervention)  
**Delivery adaptation**: an adaptation made to how the intervention is carried out (e.g., who does what, when, and how) |
| Moore (12) | Reason for Adaptation (fit) | **Philosophical fit**: adaptations made to address areas of philosophical (mis)fit include those made to align the intervention with the beliefs, values, culture, or needs of the target population  
**Contextual fit** (logistical fit in Moore’s original framework): adaptations made to address areas of contextual (mis)fit include those made to align the intervention with existing workflows, staffing plans, or other logistical considerations |
| Proctor (18) | Intervention Outcomes | **Intervention outcomes**: effects of the intervention itself on the target outcome. Depending on the intervention, intervention outcomes may include patient outcomes (e.g., changes in patient satisfaction); service outcomes (e.g., reduction in wait times, reduction in total patient expenditures). Intervention outcomes can include proximal outcomes, intermediate, or distal outcomes.  
**Implementation Outcomes**: effects of “deliberate and purposive actions to implement new treatments, practices, and services”. Because implementation is a multifaceted construct, there are several types of implementation outcomes. Proctor identifies 8 intermediate implementation outcomes:  
- **Acceptability**: satisfaction with the intervention  
- **Adoption**: uptake or intention to try the intervention  
- **Appropriateness**: perceived fit, relevance, compatibility, or usefulness |
<table>
<thead>
<tr>
<th>Framework</th>
<th>Key Construct(s)</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>of the intervention for the given target population/adopter organization</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cost: cost of implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Feasibility: actual fit or utility of the intervention for use in practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Fidelity: the degree to which the intervention is delivered as intended</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Penetration: the integration of the intervention within an organization</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sustainability: the extent to which the intervention is able to be maintained or institutionalized in practice</td>
</tr>
</tbody>
</table>

These intermediate implementation outcomes ultimately impact the distal implementation outcome of implementation effectiveness, which is defined as consistent, high-quality use of the intervention. Implementation outcomes are necessary but insufficient for achieving intervention outcomes.

The Stirman and Moore frameworks are adaptation frameworks that classify adaptations and the conditions under which they were made. Neither the Stirman nor Moore framework specifies causal pathways among constructs. Stirman’s framework is largely descriptive, presenting a classification system for describing details of adaptations (e.g., who made the adaptation, whether the adaptation applies to an individual or an entire population, and details on the exact nature of the adaptation) (15). We selected one construct from Stirman’s framework -- type of adaptation (i.e., content or delivery adaptation) – to include in the development of our theory. See Table 3.4 for details on this construct.

In contrast to Stirman’s framework, which is largely descriptive, Moore’s framework investigates the conditions under which adaptations were made, including the reason why the adaptation was made, whether the adaptation is aligned with the intervention’s core components,
and whether the adaptation was planned or unplanned (12). We selected Moore’s construct of fit, which describes the *reason for the adaptation* (i.e., to address philosophical or contextual misfit). See Table 3.4 for details on this construct.

The third framework was Proctor’s implementation-intervention outcome theory. Proctor distinguishes implementation outcomes from intervention outcomes, which are the effects of the intervention itself, such as the intervention’s impact on health outcomes or service delivery (18). Proctor specifies eight implementation outcomes (See Table 3.4) and two classes of intervention outcomes (service and client/patient outcomes) (18). Proctor specifies causality and temporality between implementation and intervention outcomes, whereby implementation outcomes are necessary but insufficient to achieving intervention outcomes. However, as noted above, Proctor does not address the influence of adaptation on implementation or intervention outcomes (18). We used the constructs of intervention and implementation outcomes in the development of our theory.

**Methods & Analytic Results**

Our working hypotheses in developing this theory was that there exist causal relationships between types of adaptations, reason for adaptation, and adaptations’ relationship with intervention and implementation outcomes. We posited that certain types of adaptations (i.e., content or delivery) would be more likely to be made for certain reasons (to address philosophical or contextual misfit) and that different types of adaptations work through different mediators to impact implementation and/or intervention outcomes. However, *a priori*, we did not know the exact direction of these pathways (i.e., were content adaptations more likely to be made to address philosophical or contextual misfit? Were delivery adaptations more likely to influence implementation or intervention outcomes?), so we engaged in a coding effort to elucidate potential pathways among these constructs. In addition to this coding effort, we also drew on our
experience in implementation science research and practice to guide the development of pathways in our theory.

**Phase 1. Coding of adaptations**

Three authors (JM, AK, SB) coded a series of planned adaptations from a research study using the constructs detailed in Table 3.4. Our objective in this coding effort was to introduce a real-world planned adaptation effort into the development of our theory. This separate research study was an effort to adapt an existing evidence-based intervention that is designed to improve timeliness of hospices referrals to a new setting and patient population (21). As part of this separate research study, we identified adaptations that would be necessary to move our intervention from the original context (nursing home) to the new context (home health). Through this process, we identified 14 adaptations; a description of each adaptation and the intervention itself is included in Additional File 1. We coded each of the 14 adaptations to determine the following:

- Type of adaptation (Stirman): content or delivery adaptation
- Reason for adaptation (Moore): to address philosophical or contextual misfit
- Predicted impact of adaptation on implementation or intervention outcomes (Proctor): specifically, we coded whether the adaptation was more likely to impact intervention or implementation effectiveness. For this code, we also included a rationale for why/how we thought the adaptation was working to impact the specific outcome.

Final codes and definitions are presented in Table 3.5. Our codebook is presented in Additional File 2. Three authors (JM, AK, SB) coded the adaptations independently and met to discuss any discrepancies in coding. Based on these discussions, we also updated the codebook with refined coding definitions, response options, and examples. We engaged one round of coding and
discussion for Stirman and Moore constructs and two rounds of coding and discussion for the Proctor constructs. Through discussion, we reached consensus on all coding. Our final coding is presented in Additional File 3.

Table 3.5. Codes and definitions

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of adaptation</td>
<td>Describes the broad class of the adaptation being made</td>
<td>• Content: changes made to the content of the intervention itself.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Delivery (known as “context” in Stirman’s original framework): changes made to how the intervention is carried out</td>
</tr>
</tbody>
</table>

**Motivation and Context for Adaptations: Moore’s Framework**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Coding choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason for adaptation (Fit)</td>
<td>Describes the reason the adaptation is being made – what are of misfit the adaptation addresses</td>
<td>• Philosophical: adaptations made to address areas where the intervention did not align with the beliefs, needs, values, or culture of the target group</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Context (logistical in Moore’s original framework): adaptations made to address areas other than beliefs, values, culture, or needs. This would include logistical considerations like adaptations to address workflow, staffing, or environmental needs</td>
</tr>
</tbody>
</table>

**Impact of Adaptations: Proctor’s Implementation and Intervention Outcomes Framework**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Coding choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact on outcomes</td>
<td>Describes whether the adaptation is more likely to have an impact intervention effectiveness or implementation effectiveness</td>
<td>• Intervention effectiveness: Likely to impact intervention effectiveness: the adaptation is likely to impact the ability of the intervention to produce desired outcomes, regardless of the quality of implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Implementation effectiveness: the adaptation is likely to impact consistency and quality of targeted audience’s use of an intervention, irrespective of the effectiveness/efficacy of the intervention itself</td>
</tr>
<tr>
<td>Rationale</td>
<td>Includes a free-text rationale for why/how the adaptation is working to impact the identified</td>
<td>Coding choices:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• N/A – free text</td>
</tr>
</tbody>
</table>
Phase 2. Analysis of coded adaptations & theory development

We then used the coded adaptation data to investigate potential pathways among the menu-like constructs (i.e., constructs where no relationship is posited among them) from the three existing frameworks/theories with the goal of translating them into a causal theory of the influence of adaptations on implementation and intervention outcomes. Our objective was to develop a theory that would highlight causal and mediating pathways. To develop the causal and mediating pathways in our theory, we analyzed coded data and drew on our experience from other implementation research and practice projects to answer four questions:

1. Are content or delivery adaptations more likely to be motivated by areas of philosophical or contextual misfit? (i.e., what is the relationship between type of adaptation and reason for adaptation)

2. What is a more consistent predictor of adaptations’ influence on outcomes – the reason for adaptation or the type of adaptation? (i.e., what is driving adaptations’ influence on outcomes)

3. Which adaptations are associated with which outcomes (implementation or intervention effectiveness)? (i.e., are certain types of adaptations more likely to influence certain types of outcomes?)

4. How or why are adaptations working to impact outcomes? (i.e., what are the mediating pathways for how adaptations influence outcomes)

To answer the questions 1-3, we analyzed proportional relationships among constructs across our coded data (e.g., % of content adaptations made for philosophical reasons, % of content
adaptations made for contextual misfit reasons). (See Table 3.6). The lead author (AK) conducted these proportional analyses. The results from quantitative proportional analyses served as the foundation for development of the causal pathways in our theory where proportions greater than 50% represented a primary pathway (e.g., greater than 50% of delivery adaptations were made to address areas of contextual misfit, which suggests a primary pathway between delivery adaptation and contextual misfit, instead of a pathway between delivery adaptation and philosophical misfit). See Table 3.6 for analytic results and suggested pathways.

Table 3.6. Quantitative analyses to elucidate pathways

<table>
<thead>
<tr>
<th>Results</th>
<th>Suggested Pathway</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content adaptations were most often made for philosophical reasons, suggesting a primary pathway between content adaptations and philosophical misfit.</td>
<td></td>
</tr>
<tr>
<td>Delivery adaptations were made almost exclusively for contextual misfit reasons, suggesting a primary pathway between delivery adaptations and contextual misfit.</td>
<td></td>
</tr>
<tr>
<td>Content adaptations were less often made for contextual misfit reasons, and delivery adaptations were less often made for philosophical misfit reasons, suggesting a secondary pathway between content adaptations and contextual misfit and delivery adaptations and philosophical misfit.</td>
<td></td>
</tr>
<tr>
<td>Results</td>
<td>Suggested Pathway</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------</td>
</tr>
<tr>
<td>content</td>
<td>• Reason for adaptation was a more consistent predictor of potential impact on outcomes (vs type of adaptation), suggesting that reason for adaptation drives impact of adaptation on outcomes, not type of adaptation</td>
</tr>
<tr>
<td>delivery</td>
<td></td>
</tr>
<tr>
<td>philosophical</td>
<td></td>
</tr>
<tr>
<td>context</td>
<td></td>
</tr>
</tbody>
</table>
To answer our fourth question (how/why are adaptations working to impact outcomes), we conducted a qualitative analysis of the rationale portion of the effectiveness coding. The rationale was included for the effectiveness code to provide an explanation as to how/why each coder suspected the adaptation would impact that particular effectiveness outcome (either implementation or intervention effectiveness). Each coder’s rationales were reviewed by three authors (JM, AK, SB) to identify common themes. These themes were discussed until consensus on themes was reached. These themes ultimately suggested potential mediating pathways between adaptation and effectiveness. See Table 3.7.
Table 3.7. Qualitative analyses to elucidate mediating pathways

<table>
<thead>
<tr>
<th>Constructs</th>
<th>Themes from rationale codes</th>
<th>Suggested Mediating Pathways</th>
</tr>
</thead>
</table>
| Philosophical adaptations’ relationship to intervention effectiveness | • Content adaptations were predicted to change intervention effectiveness when they were related to the core components of the intervention  
• No content adaptations unrelated to core components were predicted to change intervention effectiveness | • Content adaptations’ impact on intervention effectiveness is mediated by changes to the interventions underlying theory of change/core components.  
• This suggests a full mediation pathway as content adaptations unrelated to core components are not predicted to change intervention effectiveness at all |
| Delivery adaptations’ relationship to implementation effectiveness | • Delivery adaptations were predicted to change implementation effectiveness by working through Proctor’s 8 implementation outcomes.  
• Some delivery adaptations worked through multiple implementation outcomes | • Delivery adaptations’ impact on implementation effectiveness is mediated by implementation outcomes – e.g., an adaptation may improve implementation effectiveness overall by working through improvements to feasibility and acceptability of the intervention  
• A single adaptation can impact multiple implementation outcomes, thus there are likely to be both direct and indirect effects of the adaptation |

We then used the suggested pathways from Table 3.6 and Table 3.7 and pieced each individual pathway together to develop a comprehensive theory that shows adaptations’ influence on intervention and implementation outcomes (see Section III. Theory with
Examples). To improve the generalizability of our theory, three authors (JM, SB, AK) reviewed the theory using knowledge from our other implementation research and practice projects to see if the theory was consistent with other implementation and adaptation efforts. We made refinements to the pathways in the theory based on this knowledge and experience. In total, we made one refinement, which was to include a secondary pathway between delivery adaptations and philosophical reasons. In our coding exercise, we did not have any delivery adaptations made for philosophical reasons (we did have one delivery adaptation made for both philosophical and contextual reasons); however, based on our experience, we are aware of delivery adaptations being made for philosophical reasons. Thus, we added this as a secondary pathway in our theory.

Theory with Examples

Our final theory is presented in Figure 3.4. We found two primary causal pathways for how adaptations impact outcomes using two separate but interrelated comprehensive pathways of how adaptations work to influence outcomes (one comprehensive pathway for content adaptations and one for delivery adaptations). For each pathway, the theory shows the type of adaptation (content or delivery), the reason for the adaptation (to address philosophical or contextual fit), how the adaptation is working to impact outcomes (mediation), and which outcomes the adaptation impacts (intervention or implementation effectiveness). In this section, we discuss each pathway in our theory, including examples from our research.
Figure 3.4. A theory of planned adaptations’ influence on intervention and implementation outcomes

Content Adaptations
Changes to intervention itself

Area of philosophical misfit
Misalignment between the intervention and beliefs, values, culture of target population

Impacts intervention effectiveness
Ability of intervention to (re)produce desired outcomes, irrespective of quality of implementation

Delivery Adaptations
Changes to how intervention is carried out

Area of contextual misfit
Misalignment between intervention and the context it’s being delivered in

Impacts implementation effectiveness
Consistency and quality of the use of an intervention, irrespective of the effectiveness/efficacy of the intervention itself

Mediators
Working through changes to the intervention’s theory of change/core components

Outcome of Adaptation (proximal)

Working through implementation outcomes like acceptability, feasibility, etc.

Working through changes to the intervention (re)produce desired outcomes, irrespective of quality of implementation

Overall Impact of Intervention:
Some combination of intervention effectiveness and implementation effectiveness

Ultimate Impact of Adaptation (distal)

Pathway 1
Pathway 2
Content adaptations – pathway 1

Content adaptations (adaptations made to some component of the intervention itself) are most often made to address areas of philosophical misfit (see arrow 1 in Figure 3.4). Content adaptations that are made to address areas of philosophical misfit are those that serve to align the content of an intervention with the beliefs, values, or culture of the target population. These adaptations ultimately work to influence intervention effectiveness by strengthening or enhancing the mechanisms of change of the intervention’s theory of change or core components. For example, in the context of the hospice screening intervention that was the subject of our planned adaptation effort, a core component of the intervention was that it framed screening a patient for hospice appropriateness in a way that was “hospice neutral” – i.e., instead of telling the patient that they would be screened for hospice, patients were introduced the conversation in terms of a conversation about care goals, needs, and preferences. In the adapted intervention, we changed the wording of some of the screening questions to make them even more hospice neutral. This adaptation further aligned the content of the intervention with beliefs of the target audience – which are that providers are more comfortable having conversations with patients when they are “hospice neutral.” This adaptation ultimately improved philosophical fit of the intervention with the beliefs of the target audience. Content adaptations made to improve philosophical fit are predicted to impact intervention effectiveness. We posit that adaptations made for philosophical reasons potentially impact intervention effectiveness by working through changes to the intervention’s theory of change and/or core components, as represented by the mediating pathway in our theory (see arrow 2 in Figure 3.4). We posit that this is a full mediation pathway; meaning, content adaptations made for philosophical reasons will only change intervention effectiveness if the adaptation relates to the core components/theory of change of the intervention. Adaptations unrelated to the core components will not impact
intervention effectiveness. In the example above, the adaptation to re-word the screening questions to make them more hospice neutral was posited to impact intervention effectiveness by strengthening one of the core components of the intervention.

**Content adaptations – pathway 2**

We posit that content adaptations can also be made to address areas of contextual misfit, though we suspect this is a less common reason for making content adaptations (see arrow 3 in Figure 3.4). In these instances, the content of the intervention would be adapted to address contextual misfit and would work to impact implementation effectiveness through intermediate implementation outcomes, like Proctor’s outcomes of feasibility, acceptability, etc. In our case study, we often found that content adaptations made to address contextual misfit were done to decrease burden of components of the intervention. For example, we were able to re-word a series of two pronged questions into a single-pronged question. This change to question wording was a content change, but streamlined data collection as eliminated the need to ask around 12 questions, which reduced the burden of data collection for the clinician. This adaptation was posited to impact implementation effectiveness by working through intermediate implementation outcomes of feasibility and acceptability of the intervention.

**Delivery adaptations – pathway 1**

Our theory posits that delivery adaptations are most often made to address areas of contextual misfit (see arrow 4 in Figure 3.4). In these instances, adaptations would be made to how the intervention is carried out in order to align the intervention’s delivery with the workflow, staffing, structure, etc. of the organization implementing the intervention. Delivery adaptations are hypothesized to impact implementation effectiveness. We posit that the impact on implementation effectiveness is mediated by intermediate implementation outcomes from Proctor’s framework. In other words, delivery adaptations impact implementation effectiveness
working through other intermediate implementation outcomes like acceptability, appropriateness, feasibility. Gains in specific implementation outcomes work to impact implementation effectiveness overall. In our case study, we had several adaptations that were made to improve the delivery of the intervention with current workflow of home health agencies. For example, several adaptations focused on changing who was delivering specific components of the intervention. In the original intervention, a new staff member was hired specifically to deliver the intervention (a research assistant); in the new context, hiring a new staff member would not be feasible and would impede adoption of the intervention. Thus, we adapted who was delivering the intervention. These adaptations were posited to impact implementation effectiveness by improving adoption, feasibility, and acceptability of the intervention. In the delivery adaptation-implementation effectiveness pathway (see arrows 5 and 6 in Figure 3.4) we suspect that delivery adaptations may have a direct and indirect effect on implementation effectiveness (i.e., delivery adaptations are not fully mediated by intermediate implementation outcomes).

**Delivery adaptations – pathway 2**

Delivery adaptations can also be made to address areas of philosophical misfit, though we believe this to less often be the case (see arrow 7 in Figure 3.4). Although we did not encounter an instance of philosophical misfit resulting in a delivery adaptation in our coding, the authors have encountered this adaptation pathway in practice in other research studies. For example, in a project related to implementing maternal health guidelines, (specifically, recommendations related to abortion), delivery adaptations were made to address areas of philosophical misfit in lower-middle income countries. In some countries, there was a philosophical misfit between the recommendations related to abortion and religious values of the target population as it related to abortion. This area of philosophical misfit resulted in some delivery adaptations (e.g., who delivered the recommendations, where, how this information was communicated to women),
thus representing an instance where a delivery adaptation was made to address philosophical concerns. In these instances, the impact on effectiveness followed the delivery adaptation pathway and these adaptations impacted implementation effectiveness, working through intermediate implementation outcomes like appropriateness and acceptability.

**Overall impact of adaptations**

Ultimately, our theory posits that the overall impact of an intervention is determined by some combination of implementation and intervention effectiveness (see arrow 8 in Figure 3.4) and that both types of adaptations (content and delivery) influence the overall impact of an intervention by influencing implementation and/or intervention effectiveness.

**Discussion**

Our theory of adaptations’ influence on outcomes highlights several critical pathways of how adaptations work to influence outcomes. First, our theory shows that although content and delivery adaptations can be made for any reason (i.e., content adaptations can be made to address philosophical or contextual misfit), it is ultimately the reason for the adaptation that drives the adaptation’s impact on outcomes. This underscores the importance of planned adaptation efforts as, ultimately, adaptations should be driven by a discrepancy (area of poor philosophical or contextual fit), not simply by a matter of convenience (12). Second, our theory shows that different types of adaptations have differential effects on implementation and intervention effectiveness. Adaptations made to address areas of philosophical misfit are hypothesized to have a primary impact on intervention effectiveness, but if and only if the adaptation relates to the core components and/or theory of change of the intervention. Adaptations made for philosophical reasons that are unrelated to core components (i.e., part of the adaptable periphery) are unlikely to ultimately change an intervention’s effectiveness. On the other hand, adaptations made to address areas of contextual misfit are most likely to impact implementation
effectiveness by working through intermediate implementation outcomes, like feasibility, fidelity, cost, sustainability, etc. Finally, our theory is agnostic to direction of effect – meaning, adaptations could ultimately have a positive or negative impact on outcomes, depending on their mediating pathways. Philosophical adaptations that detract from the core components we believe would be likely to have a negative impact on intervention effectiveness; those that strengthen core components would have a positive impact on intervention effectiveness; while those that are unrelated to core components are likely to have a neutral impact on intervention effectiveness.

The impact of contextual misfit adaptations on implementation effectiveness we believe to be more complex. A single adaptation made for contextual misfit reasons may influence several intermediate implementation outcomes. Meaning, one adaptation could impact acceptability, feasibility, and fidelity. Moreover, that single adaptation could differentially affect intermediate implementation outcomes (e.g., one adaptation could improve feasibility but worsen fidelity). When adaptations have opposing impacts on intermediate implementation outcomes, it is difficult to predict the impact that adaptation will have on implementation effectiveness overall.

Although the primary objective of this research was to develop our theory, the method for developing our theory included coding a series of planned adaptations to identify the type of adaptation, reason for adaptation, and adaptation’s predicted impact on effectiveness, including a rationale of how/why the adaptation was suspected to impact outcomes. We found this coding exercise to be fruitful in helping us think through the potential impacts of our planned adaptations. Thus, in addition to the value our theory itself provides, we believe our codebook and coding exercise can help researchers and practitioners engaged in planned adaptation efforts to help them systematically think through the impact their adaptations will have on outcomes of
interest. This could help implementation scientists identify potential negative impacts of their adaptation and develop strategies early on to monitor and mitigate any negative impacts.

This research has several limitations. First, although developed systematically, supporting analyses for our theory was based on a small sample. We conducted our analyses from research on a single planned adaptation effort that had a small number of adaptations (n=14). Second, our theory is likely not generalizable to unplanned adaptations. Our theory focuses on planned adaptations – adaptations made deliberately, with systematic consideration given to the reason for the adaptation, whether it risks compromising core components of the intervention, and potential impacts. Although planned adaptations can occur at any point during the implementation process (prior, during, or after implementation), they are distinguished from unplanned adaptations, which are often made without a systematic decision-making process that considers the impact the adaptation will have. Because unplanned adaptations are often reactive and may be made for convenience or personal preference, the causal pathway for how adaptations impact outcomes may differ than the pathways and mediators in our theory. Finally, our theory highlights only how adaptations influence outcomes; we recognize that there are other aspects of intervention implementation that will ultimately impact intervention and implementation effectiveness (e.g., organizational culture, patient attitudes/beliefs), moderating the relationship between adaptation and outcomes. To address such moderators, scientists may choose to integrate other frameworks as appropriate (e.g., CFIR or TDF to address contextual factors) to highlight the impact that moderators may ultimately have on outcomes. Finally, although we applied our theory to additional adaptation efforts in attempts to validate our pathways, we did not complete any empirical analysis using actual planned adaptation and outcome data to validate our theory.
Conclusion

We developed a theory that shows how adaptations work to impact implementation and intervention effectiveness. This paper builds on existing frameworks (12, 15, 18), taking menu-like constructs (i.e., constructs where no relationship is posited among them) from existing frameworks and integrating them into a theory that explains how adaptations work to impact outcomes. This theory will address an important gap in the literature by providing a systematic structure for implementation scientists to predict the impact adaptations will have on intervention effectiveness and implementation. In planned adaptation efforts, this theory can benefit scientists by helping them anticipate the effects of planned adaptations, maximizing potential benefits and minimizing unintended consequences. For example, if an adaptation that addresses an area of contextual misfit that was made to improve fidelity is also suspected to have a negative impact on cost and sustainability, identifying these conflicting impacts early on could help implementation scientists refine their adaptations and plan for implementation strategies to mitigate any suspected negative impacts of adaptations. This theory can also help researchers think through in a structured way whether content adaptations are strengthening or weakening core components of the intervention to help maintain intervention effectiveness. Post-implementation, this theory can help guide systematic evaluations of adaptations. By outlining clear pathways between adaptations and their impacts, this theory can aide researchers in developing their research questions (e.g., which constructs to focus on) and in selection of appropriate variables (i.e., which outcomes would be appropriate to investigate). Moreover, this theory will allow for more precise evaluation of the impact of adaptations by providing conceptual scaffolding for conducting analyses to evaluate the impact of adaptations. The current literature base which comprises classification frameworks for adaptations (e.g., Stirman, Moore) and implementation outcomes (e.g., Proctor) is lacking the clear articulation of mediating
pathways between adaptations (and their attributes) and outcomes. This theory provides such mediating pathways, as well as more precise definitions of which adaptations influence which outcomes.

Although this theory lays the foundation for understanding causal pathways for how adaptations impact outcomes, much future research is needed. First and foremost, empirical research is needed to test the causal pathways outlined by our theory. Such empirical research could be used to validate and refine our theory. Second, additional conceptual and empirical research is needed to assess the relevance of this theory for unplanned adaptations. Unplanned adaptations may be made for different reasons than planned adaptations and, thus, may work through different pathways to impact outcomes. Finally, we welcome refinement of our codebook as other scientists apply our codebook in research and practice to guide their adaptation efforts.
REFERENCES


17. Baker R, Camosso-Stefinovic J, Gillies C, Shaw EJ, Cheater F, Flottorp S, Robertson N. Tailored interventions to overcome identified barriers to change: effects on professional practice and health care outcomes. *Cochrane Database of Systematic Reviews* 2010


CHAPTER 4: RESULTS OF A PILOT TEST OF AN ADAPTED INTERVENTION TO IMPROVE HOSPICE REFERRALS FOR HOME HEALTH PATIENTS

Background

Hospice care offers proven benefits to terminally ill patients near the end-of-life, including improved quality of life and decreased symptom burden and unmet psychosocial needs (1,2). Despite these benefits, hospice services are underutilized by terminally ill patients in the US – about 75% of hospice discharges have a length of stay shorter than the expert-recommended 3 months (median length of stay 17 days), and among Medicare decedents, only 48% died on hospice (3). Shorter-than-recommended lengths of stay limit the benefits patients and caregivers can realize from hospice, resulting in greater unmet needs at the time of death, lower satisfaction with services, and invasive or unwanted care at the end-of-life (4-6). A primary reason for underutilization of hospice is delayed referrals from the physician who makes the terminal diagnosis; research shows that physicians are hesitant to refer seriously ill patients to hospice for several reasons, including fear of bringing up hospice ‘too early’, lack of training in compassionate discussion of bad news, and clinical difficulty in accurately predicting a prognosis of 6 months or less (7-10).

Casarett et al. developed an intervention for nursing home residents to improve physician referrals to hospice (11). Casarett’s intervention screened nursing home residents (or their surrogates for residents that were cognitively impaired) by asking them questions about their care goals (maximizing quality of life vs extending life), care needs (symptom burden and service needs), and care preferences (preferences for cardiopulmonary resuscitation and mechanical ventilation). See Additional File 1 for details on screening questions. Residents
screened positive for potential hospice appropriateness if: 1) they had at least 1 symptom or service need, 2) they had care goals aligned with maximizing quality of life, and 3) they did not want CPR or mechanical ventilation. For residents who screened positive, the results of the screening were shared with them, and their physicians were notified and asked to authorize a hospice informational visit. In a randomized controlled trial (RCT) of the intervention in 3 nursing homes, hospice referral and election increased (1% in control group vs 20% in intervention group, \( p<.001 \)) (11).

The intervention as originally designed is limited in its reach because it was developed and tested only for nursing home residents, who comprise a minority of hospice patients (3). Moreover, it has not been widely adopted even in this setting. Finally, Casarett’s intervention was tested in an RCT where research staff carried out the intervention activities; although Casarett stated the intervention “could feasibly be implemented” in practice and “administered in several minutes by any member of the health care team” the feasibility of implementing this intervention in practice was never formally investigated (11). No additional research was conducted to assess the feasibility of having staff at nursing homes or other organizations screen patients, and nor were other factors affecting implementability of the intervention (e.g., cost, appropriateness, sustainability) investigated.

To address these gaps and improve the reach of the intervention, we adapted Casarett’s intervention for use in home health (18). We adapted the intervention using an approach based on the Planned Adaptation Model (19). We first interviewed Casarett’s research team to identify “core components” of the original intervention (components of the intervention that make it effective) (19, 20). Identifying core components is critical to ensuring that any adaptations to the original intervention do not risk compromising its effectiveness (20). We then engaged a
stakeholder panel of clinicians from three home health agencies with varying organizational characteristics to determine adaptations that would be necessary to move the intervention into home health and have home health staff carry out intervention activities. The stakeholder panel considered whether differences in patient populations (e.g., patient demographics, clinical status), philosophies of care, and care delivery between nursing home and home health necessitated any adaptations to the original Casarett intervention, as well as which home health staff members would be best suited to carry out intervention activities. Ultimately, we made several adaptations to the intervention (n=14), the majority of which were made to the delivery of the intervention (18). Content adaptations included adapting patient eligibility criteria (screening only “frail” or “high-risk” home health patients vs screening all nursing home residents); modifying content of screening questions to cover symptoms more prevalent in home health patients (dyspnea, nausea); changing the definition of a positive screen (lowering the threshold for a positive screen); and changing which service the patient was referred to (expanding the intervention to include referral to hospice or palliative care). See Table 4.1 for a full description of adaptations.
<table>
<thead>
<tr>
<th>Intervention Component</th>
<th>Casarett Intervention</th>
<th>Adapted Intervention</th>
<th>Reason for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible patient population for screening</td>
<td>All nursing home residents eligible, except for those in the nursing home for a respite stay, those already on hospice, or those who were cognitively impaired but no surrogate was available</td>
<td>Only those home health patients identified as “frail” or “high-risk” eligible for screening. In pilot, we operationalized high risk or frail patients as recent admissions who had been flagged in an existing EMR alert as: 1) moderate-high risk for hospitalization or 2) potentially eligible for hospice</td>
<td>Difference in patient population: It would not be appropriate to screen all home health admissions for hospice; specifically, those who are expected to make a full recovery and have few complications or co-morbidities beyond their admitting diagnosis (e.g., home health patients who are receiving physical therapy after a surgery but are otherwise healthy and expected to make a full recovery)</td>
</tr>
<tr>
<td>Screening questions (physical symptoms)</td>
<td>Included screening questions for 6 physical symptoms, including dry mouth</td>
<td>Asked about 7 physical symptoms. Removed dry mouth and added in shortness of breath and nausea</td>
<td>Difference in patient population: Dry mouth deemed a low priority symptom for most home health patients; shortness of breath and nausea determined to be more prevalent and of higher priority for the home health patient population</td>
</tr>
<tr>
<td>Definition of a positive screen</td>
<td>Positive screen defined as screening positive across all 3 domains (i.e., had at least 1</td>
<td>Positive screen defined as screening positive for 1 of 3 domains</td>
<td>Difference in care philosophy: Home health staff felt 3/3 was too high a bar,</td>
</tr>
<tr>
<td>Intervention Component</td>
<td>Casarett Intervention</td>
<td>Adapted Intervention</td>
<td>Reason for Change</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------</td>
<td>----------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>symptom or service need; had care goals aligned with maximizing quality of life; and did not want CPR or mechanical ventilation)</td>
<td>and philosophically disagreed with patients having to state a preference against CPR and mechanical ventilation to be considered a positive screen as these preferences are not a requirement to elect hospice.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up after positive screen</td>
<td>Patients asked if the intervention team could follow-up with their physician to authorize hospice</td>
<td>Patients asked if the home health team could follow-up with their physician to authorize a hospice or palliative care</td>
<td>Difference in care philosophy: Home health staff felt hospice or palliative care was an appropriate referral outcome of this screening and patients may be more amenable to palliative care than hospice at the outset of this type of care transition</td>
</tr>
<tr>
<td>Delivery of intervention activities</td>
<td>Research assistant carried out all activities of intervention (asking screening question, reporting results back to patient). Only involvement from care team was physician’s authorization of hospice</td>
<td>Home health clinical managers identified eligible patients. Home health nurses asked screening questions and reported results back to patient/surrogate. Home health nurse initiated contact with physician and hospice/palliative care as appropriate.</td>
<td>Difference in study design (RCT vs feasibility study): As this was a feasibility study, activities were carried out by staff at the home health agency, not external research/trial staff.</td>
</tr>
</tbody>
</table>
The objective of this research was to investigate whether the adapted intervention could be implemented in practice by conducting a feasibility study of the adapted intervention to determine whether the intervention could be carried out by home health staff as part of routine care delivery. As such, this research focused on assessing feasibility, acceptability, patient outcomes, and implementation of the adapted intervention, instead of effectiveness.

Methods

Study rationale and design

We conducted a 9-week pilot study of the adapted intervention with two home health agencies. Each home health agency selected one home health nurse to use the adapted intervention for the duration of the pilot. Our research team provided training on the intervention to staff at each pilot site; our team was also available throughout the duration of the pilot to answer questions about the intervention.

We collected data on feasibility, acceptability, patient outcomes, and implementation of the adapted intervention. Patient outcomes were assessed on a rolling basis throughout the duration of the pilot. We also conducted process interviews with clinical staff and leadership at pilot sites every two weeks throughout the duration of the pilot to elicit experiences with the adapted intervention and recommendations for improvement.

This research was reviewed and approved by the Institutional Review Board (IRB) at the University of North Carolina and Chapel Hill, as well as the IRB at RTI International.

Setting

The pilot test was conducted at 2 home health agencies in North Carolina. Site 1 was a non-profit, government/state-owned facility that is part of a large academic medical center with an average daily census of 211 and average length of stay of 25.5 days. Site 2 was part of the
same health system as Site 2 and was also a non-profit agency. The average daily census at site 2 was 270 and the average length of stay was 21.5 days.

Intervention

The intervention consisted of delivering the care goals, needs, and preferences screening questions to eligible patients (or their proxies if the patient was cognitively impaired), reporting results of the screening back to the patient or proxy, and authorizing follow-up with the physician for palliative care or hospice, as appropriate. Screening questions were delivered during an in-person home health visit by one registered nurse (RN) case manager at each pilot site. RN case managers delivered the screening questions verbally to patients/proxies and recorded patient responses on paper data collection forms produced by our research team. Pending the results of the screening and the patient or proxy’s approval to contact their physician, the RN case manager would initiate a referral to hospice or palliative care per the usual care referral processes at their respective agencies. See Additional File 2 for the complete intervention protocol and paper data collection form used during the pilot.

Participants, recruitment, and enrollment

Eligible patients for the intervention included “high-risk” or “frail” home health patients. We defined high-risk or frail patients as those home health patients who triggered an alert for moderate to high hospitalization risk or an alert for candidate for transfer to hospice referral in the home health agencies’ electronic medical record (EMR) software add-on analytics package, Strategic Healthcare Programs software (21). Eligible patients were further limited to those who had a skilled nursing start of care and those patients that were in the RN case manager’s geographic service area. The clinical manager of each RN case manager identified eligible patients and alerted the RN once an eligible patient was identified. On the home health next visit,
the RN case manager consented patients (or their proxies for patients that were cognitively impaired) and proceeded with enrollment for patients who agreed to participate.

**Measurements**

*Feasibility.* Feasibility was assessed through (1) enrollment rates and (2) whether the RN delivered the protocol-specific components of the intervention (i.e., fidelity). Enrollment rates and fidelity were assessed through self-reported data that the RNs collected throughout the duration of the pilot using paper forms (*Additional File 2*). Clinical managers uploaded the forms to our research team using a secure server. Fidelity data were monitored throughout the duration of the pilot for missingness (blanks on the paper data collection form) or errors (illogical responses to questions). Any areas of missingness/error were discussed with pilot sites during process interviews (see below for details) to determine why the intervention component was not delivered as intended. For areas of low fidelity, adaptations were made to the intervention protocol and adopted in real-time to improve fidelity. See *Table 4.2* for additional details.

*Acceptability.* Acceptability was assessed by tracking patient/proxy refusal rates and attrition rates. We also conducted process interviews every two weeks with the pilot site clinical teams (RNs delivering the intervention (n=2), their clinical managers (n=2), and the overall director of home health for both agencies (n=1); total participants (n=5)). The purpose of these process interviews was two-fold: 1) to employ a rapid-cycle feedback approach whereby fidelity data were shared with pilot sites to facilitate feedback to research team on why intervention component(s) were not delivered as intended so that refinements to the intervention protocol could be made in real-time and 2) to collect data on early experiences with the intervention and recommendations for improvement. Interviews consisted of open-ended questions; in total, we completed 4 process interviews which lasted 30-45 minutes and took place via telephone. The
lead author (AK) led all interviews and took detailed notes during each interview. Interviews included open ended questions to assess early experiences with the adapted intervention (value added of the intervention), as well as suggestions for improvement (further adaptations to the intervention, considerations for scale-up). See Table 4.2 for additional details.

Patient Outcomes. Patient outcomes included the percentage of enrolled patients that screened positive for potential appropriateness for hospice/palliative care, as well as the percentage of positive-screen patients that elected hospice/palliative care. See Table 4.2 for additional details. Patient outcomes were assessed through data that the RNs collected throughout the duration of the pilot using paper data collection forms (Additional File 2). Clinical managers uploaded the forms to our research team using a secure server.

Implementation data. Our process interviews also included discussion of pilot sites’ experience with implementation of the intervention, specifically: barriers and facilitators to implementation; implementation strategies used by pilot sites to facilitate integrating the intervention into practice for the duration of the pilot; and outcomes of implementation, including pilot site staff’s thoughts on acceptability, appropriateness, cost, feasibility, and sustainability of the adapted intervention.
<table>
<thead>
<tr>
<th>Construct</th>
<th>Measure or Definition</th>
<th>Data Type and Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research Question 1: Feasibility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient enrollment rates</td>
<td>• # and % of eligible patients who enrolled in the study</td>
<td>Quantitative – paper data collection forms submitted by pilot sites for each patient</td>
</tr>
<tr>
<td>Fidelity</td>
<td>• Missing and error rates for each component of the intervention</td>
<td>Quantitative - paper data collection forms submitted by pilot sites for each patient</td>
</tr>
<tr>
<td><strong>Research Question 2: Acceptability</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Patient refusal/attrition rates | • # and % of eligible patients who refused to participate in the study  
• # and % of enrolled patients who dropped out of the study (refused to answer all study questions) | Quantitative - paper data collection forms submitted by pilot sites for each patient |
| Experience with Intervention | • Feedback on value added of the intervention | Qualitative – process interviews |
| Suggestions for improvement:  
• Further refinements to intervention  
• Considerations for scale-up | • Feedback on further refinements to the intervention (changes to intervention content or intervention delivery)  
• Feedback considerations for scale-up (implementation supports that would be necessary to scale-up the intervention within an organization) | Qualitative – process interviews |
| **Research Question 3: Implementation** | | |
| Barriers/Facilitators to Implementation | • Feedback on barriers or facilitators to implementation encountered by pilot sites | Qualitative – process interviews |
| Implementation Strategies | • Strategies used by pilot sites to support/encourage positive uptake of the intervention | Qualitative – process interviews |
| Implementation Outcomes | • Acceptability, Appropriateness, Cost, Feasibility, Sustainability | Qualitative – process interviews |
Analyses

Quantitative data were summarized using descriptive statistics. We did not conduct any comparisons across time (i.e., pre- and post-intervention) because this was a pilot study that was not designed to assess effectiveness. Qualitative data from the process interviews were analyzed using a template analysis approach, which allowed us to identify a priori and emergent themes (14). A priori themes included key topics and sub-topics from the interview guide. See Table 4.3. The lead author (AK) coded all data.
**Table 4.3. A priori themes for qualitative analysis**

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experience with the intervention: Value added of the intervention</td>
<td>Any statements about benefits gained from the intervention or how the intervention added to already existing clinical practices</td>
<td>The intervention provided a platform for having conversations about patient preferences and hospice</td>
</tr>
<tr>
<td>Suggestions for improvement: Further refinements/improvements the intervention</td>
<td>Any mention of changes or adaptations that could be made to the intervention itself or its delivery to improve the intervention for future use</td>
<td>Consider changing how eligible patients are identified as waiting for the SHP alert creates a delay</td>
</tr>
<tr>
<td>Suggestions for improvement: Considerations for scale-up</td>
<td>Any considerations that would need to be taken into place if the intervention were adopted on a large scale. Do not code suggested changes to the intervention itself (or its delivery) here. Do code statements about implementation strategies/wrap-around supports that would be needed to scale the intervention up.</td>
<td>To be effective on a large scale, we would need to make sure we had buy-in from attending physicians</td>
</tr>
<tr>
<td></td>
<td></td>
<td>To be sustainable, we would need to integrate the tool into our EMR</td>
</tr>
</tbody>
</table>

*Qualitative implementation data.* Interview notes were analyzed using a template analysis approach, which allowed us to identify a priori and emergent themes (14). We developed the initial codebook based on a priori themes. Our a priori themes were based on relevant frameworks from the implementation science literature, including: 1) the Consolidated Framework for Implementation Research (CFIR) which assesses barriers and facilitators to
implementation 2) Powell’s compilation of strategies for implementing innovations and 3) Proctor’s implementation outcomes (15-17). See Table 4.4. The lead author (AK) coded all data.

Table 4.4. A priori codes for analysis of implementation data

<table>
<thead>
<tr>
<th>Domain</th>
<th>Relevant Framework</th>
<th>Constructs selected as a priori codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barriers and facilitators to</td>
<td>CFIR</td>
<td>All constructs in the inner setting, outer setting, characteristics of individuals, and characteristics of the intervention</td>
</tr>
<tr>
<td>implementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation Strategies</td>
<td>Powell’s Compilation of Strategies for</td>
<td>All strategies in each of Powell’s 6 implementation process domains</td>
</tr>
<tr>
<td></td>
<td>Implementing Innovations</td>
<td></td>
</tr>
<tr>
<td>Implementation Outcomes</td>
<td>Proctor’s Outcomes for Implementation Research</td>
<td>Acceptability, Appropriateness, Cost, Feasibility, Sustainability</td>
</tr>
</tbody>
</table>

Results

Feasibility

**Enrollment rates.** Throughout the 9-week pilot, 29 eligible patients were approached for participation in the pilot, 28 of whom (96.6%) were enrolled in the study and screened (see Figure 4.1). One patient refused to participate (3.4%).

**Fidelity.** In our adapted intervention, we defined an overall positive screen as any patient who had at least one hospice-aligned care goal, need, or preference (compared to Casarett’s original intervention where patients had to have all three -- hospice-aligned care goals, needs, and preferences). Through analysis of intervention data from weeks 1-2 of the pilot, our research team identified missing data for results of the follow-up conversation, indicating that the RN case managers did not appropriately ask the patient to authorize follow-up with their physician about hospice/palliative care with all patients who screened positive. We discussed this area of
low fidelity in the first process interview. During this interview, the RN case managers stated that the threshold of 1/3 for a positive screen was too low; that if a patient had a symptom need only, hospice/palliative care was not necessarily an appropriate care option for them, as symptoms alone could be managed by the home health team. Thus, for some of these patients, nurses were not discussing hospice/palliative care as an option, even though the patient technically screened positive. To address this issue, we solicited input from the process interview participants about how to improve the definition of a positive screen. Participants suggested refining how a positive screen was defined by creating 4 categories (symptom needs, service needs, care preferences, care goals) where patients with symptom needs only would no longer be considered a positive screen. We implemented this change after the first process interview (week 3 of the pilot).

**Patient outcomes**

Among the 28 screened patients, 27 (96.4%) screened positive for potential hospice appropriateness. Of those 27, 3 entered palliative care and 1 elected hospice (14.8% elected either hospice or palliative care); 2 other patients who screened positive (7.4%) stated they would follow-up with their attending physician about hospice/palliative care as an option (vs having the home health nurse complete this follow-up on their behalf). See **Figure 4.1** for more details.
Figure 4.1. Patient enrollment and outcome data

Acceptability

*Patient refusal and attrition rates.* Among the patients approached for the intervention, one refused to enroll in the intervention. Among enrolled patients, there was no attrition; once enrolled, patients completed all portions of the intervention (i.e., responded to all screening questions).

*Experience with intervention: value-added.* Overall, staff at pilot sites stated that the intervention added value in facilitating conversations about end-of-life care. Clinical managers and the director of home health stated that the intervention provided a “platform” for having these conversations. The RN case managers felt that, although they were already having these conversations with patients, the intervention provided additional value by helping them have these conversations in a systematic and structured way. One RN case manager stated, “…having
the tool as a guide to bring up the topic of palliative and hospice care in an organized fashion has been beneficial”. RN case managers also commented that the tool facilitated these conversations, particularly when patients were uncomfortable discussing end-of-life preferences or the nurses lacked a strong relationship or rapport with the patient. One RN case manager stated, “the tool is especially helpful when you get somebody that is a little uncomfortable discussing it [hospice care/EOL preferences] because it’s like that in between step – it doesn’t have to be like you’re making a decision right then, it allows a little bit of separation and it’s also helpful when you don’t have that really strong relationship with a patient.” Finally, RN case managers felt that the tool provided value as structured data on the patient’s care goals, needs, and preferences. This structured data provided a framework for the conversation, incorporating the patient’s own wishes into the conversation. One RN case manager summed it up: “it touches on more symptoms and I can go back and say ‘you’re having concerns about anxiety; you’re having distressing pain’; I can show them….so I think it’s proof and evidence to the patient [by] having the tool to go back to and summarize and encourage”.

Suggestions for improvement: further refinements to the intervention. During the process interviews, pilot sites suggested several changes that could be made to the intervention to improve it for future use. None of these additional adaptations were implemented during the pilot. Potential future adaptations are further described in Table 4.5. Pilot sites stated that it was critical to repeat the screening conversation at multiple timepoints to allow for follow-up and continued conversations about end-of-life preferences. To this end, pilot sites noted that often, patient’s “weren’t ready” to make a decision during an initial discussion, but, given time, may be amenable to hospice/palliative care in the future. Other suggestions included refining how eligible patients were identified to allow clinical judgement in determining patient eligibility; RN
case managers noted several instances where the EMR trigger used to identify eligible patients was not sensitive or specific enough, and that allowing clinical judgement to override the alert trigger would help avoid screening patients inappropriately, or missing patients who could benefit from screening. Pilot sites also suggested having the patient’s nurse case manager deliver the intervention, noting that this would be beneficial if the screening were repeated as the nurse case manager is the staff member patients see most often and develop a rapport with. Finally, pilot sites suggested re-framing some of the questions in the intervention. Specifically, the suggested framing the introduction of the conversation in a neutral way (e.g., it’s something we do as part of routine care for all our patients) because they felt this approach would be less threatening to patients. They also suggested rephrasing how hospice/palliative care is introduced to patients that screen positive. Instead of asking “can we follow-up with your physician” to instead ask “would you like someone to provide an informational visit about these services.” framing why you’re asking patients these questions in a neutral way; and re-phrasing the service need questions to further tailor them to home health.
Table 4.5. Suggested additional adaptations to intervention

<table>
<thead>
<tr>
<th>Activity</th>
<th>Intervention Activity as Piloted</th>
<th>Suggested Future Adaptation</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifying eligible patients</td>
<td>Patients identified using an automated alert in the agencies’ software – eligible patients included those who were flagged as moderate-high risk for hospitalization or as a potential hospice referral.</td>
<td>Consider an alternative strategy for identifying patients and/or allowing clinician judgement to supersede the alert.</td>
<td>Pilot sites mentioned that relying on the alert sometimes caused a delay in initiating the screening conversation. The alert is triggered based on data collection at the initial assessment, so it is not triggered until after the first visit. However, nurses mentioned instances where upon the first visit, they knew the patient was potentially appropriate for hospice. Additionally, nurses mentioned a few false positives or negatives in the alerts; clinician judgement could be used to supplement the alert in these cases, ensuring patients who are truly appropriate for the screening are screened.</td>
</tr>
<tr>
<td>Framing of how hospice/palliative care is introduced to patients who screened positive</td>
<td>In the pilot, for patients who screened positive, nurses introduced hospice/palliative care by stating, “would you like to talk to your physician about PC/hospice?”</td>
<td>Re-word question to say something like “Would you like for somebody to come out and give you an informational session on palliative care/hospice”?</td>
<td>Nurses felt the adapted language would be less threatening as it mitigates the perception that the patient has to make an immediate decision; instead, it frames the question in a way that is less committal.</td>
</tr>
<tr>
<td>Repeating screening/follow-up conversation</td>
<td>In the pilot, the screening questions and introduction of hospice/palliative care happened once.</td>
<td>Repeat the screening conversation at multiple timepoints throughout a patient’s stay.</td>
<td>Nurses stated that they could tell, for many patients, the screening conversation was the first time they were thinking about some of these issues and that most patients aren’t ready to make a decision the first time around. Nurses thought that repeating or following up on</td>
</tr>
<tr>
<td>Activity</td>
<td>Intervention Activity as Piloted</td>
<td>Suggested Future Adaptation</td>
<td>Reason</td>
</tr>
<tr>
<td>----------</td>
<td>----------------------------------</td>
<td>-----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Who is asking screening questions</td>
<td>In the pilot, the nurses asking the questions weren’t always that patient’s case manager</td>
<td>Have the nurse case manager facilitate the conversation</td>
<td>Nurses felt that -- especially if the conversation will be repeated at multiple timepoints -- having the patient’s case manager deliver it the first time will facilitate continuity in the conversation and help build trust.</td>
</tr>
<tr>
<td>Framing of why you’re asking these questions</td>
<td>In the pilot, the reason for initiating the screening conversation was for the purposes of a research study</td>
<td>Retain some framing around why you’re asking these questions that is “neutral” (i.e., not that you’re asking the patient these questions based on any assessment of their clinical condition/prognosis). Consider something like “I’m asking you these questions today as part of a quality improvement initiative at our agency.”</td>
<td>Nurses stated that framing this conversation as being part of a research initiatives helped patients feel comfortable responding to the questions – they felt that answering them under the guise of a research study helped patients feel less threatened by the topic at-hand.</td>
</tr>
<tr>
<td>Phrasing of service need questions</td>
<td>In the pilot, patients were asked if they felt they could benefit from “extra” services (e.g., extra services from a clergy to provide support for spiritual concerns)</td>
<td>Instead say, “if you were no longer on home health, could you benefit from x services?”</td>
<td>Nurses noted that the original phrasing made sense in the context of nursing homes (because when nursing home patients elect hospice, they continue to receive services from the nursing home), but not home health (because when home health patients elect hospice, they can no longer receive home health; so any hospice</td>
</tr>
</tbody>
</table>
Suggestions for improvement (considerations for scale-up). Through our process interviews, pilot sites also identified several considerations for scale-up of the intervention. These considerations were not suggested changes to the intervention itself, but rather strategies that would facilitate implementation, sustainability, and impact of the intervention. First, to be sustainable in the long-term, pilot sites felt the screening tool itself would need to be integrated into existing clinical documentation systems (which for both pilot sites was an EMR) to avoid redundancies with existing assessment practices and streamline data collection. Pilot sites felt that the paper tool used during the pilot was lengthy (8 pages), which, in and of itself, may be a deterrent to scale-up for use by home health nurses at-large. In addition, pilot sites noted several areas of overlap between screening questions and current assessment practices. For example, much of the physical and psychological symptom data is already collected as part of routine care for home health patients. Thus, integrating the screening tool into the EMR and removing duplicate questions would reduce burden of data collection. In addition, for the pilot, the RN case managers were hand-tallying the results of the screening to determine whether the patient screened positive. If integrated into the EMR, pilot sites felt this tallying process could be automated and trigger a pop-up alert for patients that screened positive, further reducing burden of data collection.

Second, pilot sites felt additional outreach with stakeholders could potentially improve impact of the intervention, specifically outreach with attending physicians to increase their buy-in. RN case managers noted specific instances – outside of this pilot effort -- when they had
discussed hospice/palliative care with the patient and the patient was interested in hospice/palliative care as a care option; however, the attending physician was not on-board. RN case managers felt that misalignment between physicians and the home health nursing team could create confusion for the patient and delay them from enrolling in hospice/palliative care, even if that were their preference. Thus, pilot sites felt that additional outreach to physicians could increase buy-in and minimize any instances of conflicting guidance from various clinical teams.

Finally, RN case managers reported that additional training on hospice and palliative care would facilitate implementation of the intervention (i.e., which specific hospice agencies are available in the patient’s service area, exact eligibility criteria for hospice). RN case managers noted that they are not usually the members of the home health patient’s care team who has detailed conversations with patients/families about palliative care/hospice. In usual care, if a nurse identifies a patient as potentially appropriate for hospice, the nurse alerts the social worker who broaches that conversation with the patient/family. Pilot sites felt that additional education on hospice would help home health nurses feel prepared to answer any follow-up questions patients might have or provide more detailed information, as needed.

Qualitative implementation data

Barriers and facilitators to implementation. We identified several barriers and facilitators to implementing the intervention during the pilot, which we mapped to the CFIR (15). Overall, the two pilot sites had a positive implementation climate with few barriers to implementation of the intervention for the pilot. All levels of leadership were engaged and on-board with implementation of the intervention for the pilot, and nurses had high self-efficacy and positive attitudes about the intervention. Additionally, the intervention was compatible with goals of care at each pilot site, as both pilot sites prioritized appropriate referrals to hospice and were
committed to improving timeliness of referrals. Finally, the pilot sites had high levels of *access to resources, knowledge and information* through our pilot research team. The lead author (AK) provided training on the intervention, answered questions about the intervention throughout the duration of the pilot, and assisted in planning and monitoring pilot activities to facilitate implementation. In addition to facilitators, we identified two barriers to implementation. First, *external policies* and procedures of the IRB led to delays in start-up of the pilot and limited our flexibility to adapt the intervention in real-time during the pilot. Second, regular clinical and managerial duties presented some minor delays in the pilot, resulting in re-scheduling of meetings, etc. See Table 4.6 for more details on barriers and facilitators.

Table 4.6. Barriers and facilitators to pilot implementation (mapped to CFIR)

<table>
<thead>
<tr>
<th>Barrier/Facilitator</th>
<th>CFIR domain</th>
<th>CFIR construct</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilitator</td>
<td>Inner setting</td>
<td>Leadership engagement</td>
<td>Had support at all levels (VP, regional director, director, front line managers)</td>
</tr>
<tr>
<td>Facilitator</td>
<td>Inner setting</td>
<td>Implementation climate</td>
<td>Had positive compatibility, relative priority</td>
</tr>
<tr>
<td>Facilitator</td>
<td>Inner setting</td>
<td>Knowledge and beliefs about the intervention</td>
<td>Implementation team had positive attitudes towards the intervention</td>
</tr>
<tr>
<td>Facilitator</td>
<td>Characteristics of individuals</td>
<td>Self-efficacy</td>
<td>Nurses had high self-efficacy (confidence in having these types of conversations)</td>
</tr>
<tr>
<td>Facilitator</td>
<td>Characteristics of individuals</td>
<td>Available resources, access to knowledge/information</td>
<td>Study team provided information on intervention (training to pilot site staff prior to start of pilot; answering questions about intervention during pilot). Also provided</td>
</tr>
<tr>
<td>Barrier/Facilitator</td>
<td>CFIR domain</td>
<td>CFIR construct</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------</td>
<td>-------------</td>
<td>----------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Barrier</td>
<td>Outer Setting</td>
<td>External Policy and Incentives</td>
<td>Complications with IRB delayed start of pilot (staff time commitment to take CITI ethics modules) and prevented the ability to make real-time changes to the intervention during the pilot</td>
</tr>
<tr>
<td>Barrier</td>
<td>Inner Setting</td>
<td>Available Resources</td>
<td>Regular clinical and managerial duties of pilot staff sometimes interfered with pilot meetings</td>
</tr>
</tbody>
</table>

**Implementation strategies.** Although our research team did not prescribe any implementation strategies, the pilot sites self-selected several implementation strategies for the pilot, which we mapped onto Powell’s compilation of implementation strategies (16). First, to aide in identification of eligible patients, the clinical managers set up automated reports in their EMR systems to automatically identify eligible patients and alert clinical managers when an eligible patient had been flagged (remind clinicians). Second, nurse managers modified incentives by adjusting the nurses’ productivity units so nurses would “get credit” in their productivity statistics for participating in the pilot. This helped protect nurses time for participating in pilot activities. Third, prior to the start of the pilot, several meetings took place to build buy-in, initiate leadership and develop relationships. Finally, the check-in interview approach used during the pilot could be considered an implementation strategy in and of itself as
it was a method for *obtaining consumer feedback* and *purposefully re-examining implementation* of the intervention. For more details on implementation strategies, see Table 4.7.

**Table 4.7. Implementation strategies (mapped to Powell’s compilation implementation strategies)**

<table>
<thead>
<tr>
<th>Implementation Process</th>
<th>Strategy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Management</td>
<td>Remind clinicians</td>
<td>Nurse managers set up automated reports to identify eligible patients and alert them when a new patient had been flagged in SHP as eligible</td>
</tr>
<tr>
<td>Finance</td>
<td>Modify incentives</td>
<td>Nurses were given adjustments in their productivity units for participating in pilot activities to protect their time</td>
</tr>
<tr>
<td>Plan</td>
<td>Build buy-in, initiate leadership, develop relationships</td>
<td>Research team met with leadership and pilot team several times before pilot; had regular check-ins throughout pilot</td>
</tr>
<tr>
<td>Quality Management</td>
<td>Obtain customer feedback, purposefully re-examine implementation</td>
<td>Regular check-in calls every 2 weeks helped obtain additional customer feedback on the intervention and re-examined implementation (received input on potential additional adaptations to the intervention to improve its fit with home health; value added of the intervention; and implications for scale-up given current implementation experience)</td>
</tr>
</tbody>
</table>

**Implementation Outcomes.** Regarding implementation outcomes, we collected data on five of Proctor’s implementation outcomes: acceptability, cost, appropriateness, feasibility, and sustainability (17). For definitions of each outcome, see Table 4.8. Regarding *acceptability* and *appropriateness*, pilot sites felt the intervention was both acceptable and appropriate. The pilot
sites stated they “liked” the intervention and thought it fit with their personal and organizational care goals and philosophies. Although the two RN case managers who used the intervention for the pilot had generally positive feelings towards acceptability, they did note that they were both nurses who believed in improving access to hospice care for patients and that other nurses may not been as accepting of this intervention. Pilot sites also felt the intervention was appropriate for their patient population, specifically noting that there were often patients who come on to home health who are more appropriate for hospice or palliative care and thus could benefit from this intervention. Regarding feasibility, the RN case managers felt the tool was generally easy-to-use and not overly time-consuming. They did identify efficiencies that could be gained in data collection, should the intervention be scaled-up for use on all patients (i.e., integration into their EMR), but overall felt the data collection was feasible. Regarding cost to implement the intervention for the pilot, the main costs involved were staff time to participate in pilot activities; no other direct costs were reported by pilot sites. RN case managers reported that it took them about 5-10 minutes per patient to deliver the screening questions and any follow-up. Finally, regarding sustainability of the intervention, as mentioned earlier, pilot sites thought the intervention could be potentially sustainable, but would need to be integrated into their existing EMR to facilitate data collection and avoid duplication with current assessment practices. Additionally, automating some portions of the screening (tallying responses to screening questions to identify patients that screened positive) would make the intervention more sustainable.
Table 4.8. Definitions of implementation outcomes

<table>
<thead>
<tr>
<th>Measure or Construct</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptability</td>
<td>Perception that an intervention is agreeable, palatable, or satisfactory</td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Perceived fit, relevance, or compatibility of intervention for a given practice setting, provider, or consumer; and/or perceived fit of intervention to address a particular issue/problem</td>
</tr>
<tr>
<td>Feasibility</td>
<td>Extent to which a new treatment can be successfully used/carried out within a given setting</td>
</tr>
<tr>
<td>Cost</td>
<td>Cost of an implementation effort</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Extent to which a newly implemented intervention is maintained or institutionalized within a service setting’s ongoing, stable operations.</td>
</tr>
</tbody>
</table>

**Discussion**

This 9-week pilot study assessed feasibility, acceptability, patient outcomes, and implementation of an adapted intervention to improve timeliness of referrals to hospice to determine whether the adapted intervention could be implemented in practice by home health agencies. Overall, our pilot indicates favorable feasibility of implementing this intervention as part of routine practice. With minimal support from research staff, pilot sites successfully implemented intervention activities with high fidelity with relatively low time commitments per patient (5-10 mins) and minimal re-structuring of regular clinical workflows. Patient refusal rates were low (1 patient of 29 eligible refused to enroll). Once enrolled, patients responded to all screening questions, indicating positive acceptability of this intervention by the target patient population.

Regarding patient outcomes, 14% of patients who screened positive elected to begin hospice or palliative care; this is only slightly lower than the 20% observed in the original RCT. At the same time, our pilot used existing clinical staff to deliver the intervention, rather than
relying on research staff as in the original RCT. Pilot site staff reported value added of using the
intervention. Nurses felt this intervention provided a systematic way to approach conversations
around end-of-life and care planning, especially among patients who were uncomfortable having
these types of conversations or patients with whom nurses had not yet built a strong rapport.
Additionally, nurses reported that the tool provided structured, patient-reported data that the
nurse could use to encourage the patient/family to consider hospice/palliative care as these
conversations continued. These findings suggest that this intervention may offer other benefits,
independent of improving hospice and palliative care referral rates, such as improved
communication between clinicians and patients regarding end-of-life care preferences. Thus,
 apart from increasing the number of patients who choose to begin hospice/palliative care, it may
offer value in other areas of importance to home health agencies.

Regrading suggestions for future improvements to the intervention, pilot sites had several
suggestions of ways to change the intervention that could potentially improve its acceptability
and effectiveness. Suggestions included repeating the screening questions and follow-up
conversation at multiple points throughout a home health patient’s stay; re-phrasing how
hospice/palliative care is introduced for patients that screen positive (asking for patients to
authorize an informational visit vs authorize follow-up with their physician); and rephrasing how
the screening conversation is introduced (framing it as something being done as part of routine
care to avoid the notion that specific patients have been “singled out” due to clinical condition or
prognosis). Overall, we believe these suggestions point to a need to further tailor the intervention
to patients’ readiness to elect hospice or palliative care. Our research team heard from pilot sites
several times throughout our process interviews that although nurses can identify a patient as
appropriate and have a conversation with them about hospice/palliative care (the process of care
this intervention was designed to help improve), patients still have to make the decision about whether they want to elect hospice/palliative care and when. Pilot sites told us on several occasions that this decision is often impacted by a patient’s “readiness” for hospice/palliative care, and that many patients aren’t “ready” to make this decision at the initial discussion. The suggestions from pilot sites may help further adapt the intervention to patients that may be hospice or palliative-care appropriate, but not yet ready to commit to a decision to elect hospice/palliative care at the time of the initial discussion. Introducing the conversation in a more neutral way (this is part of our routine practice), loosening the “commitment” the patient has to make that day (authorizing an informational visit vs authorizing follow-up with their physician), and repeating the screening conversation may make the intervention more palatable to patients who are hospice or palliative care-appropriate but not ready. These changes could facilitate further conversations about hospice/palliative care sooner than may happen otherwise, potentially further boosting the impact of this intervention. These changes and the role that patient readiness for hospice/palliative care plays in patient decision-making warrant further research and investigation.

Regarding considerations for scale-up, pilot sites had several suggestions that warrant future research. Although pilot sites thought the time to administer the intervention was feasible (5-10 minutes per patient), they commented that additional supports would be necessary to maximize impact and long-term sustainability of the intervention. Supports suggested by pilot sites centered around creating efficiencies and reducing burden (integrating the tool into existing clinical record systems), as well as conducting additional education/outreach both with targeted users (home health nurses to improve their knowledge of hospice and palliative care) and other stakeholders (attending physicians to increase buy-in). These considerations for scale-up could
benefit from future research as they could have downstream effects on long-term sustainability and impact of the intervention. Further research focusing on long-term impact and sustainability is also critical because although our approach to piloting the adapted intervention was closer to the experience an agency would have in practice if they decided to implement the intervention, pilot sites still received some technical assistance and implementation support from our research team.

Implementation data. Overall, our barriers, facilitators, and implementation outcomes indicate a favorable implementation climate at both pilot sites, which may have contributed to the favorable implementation outcomes, especially in terms of acceptability and appropriateness. This favorable implementation climate may not be generalizable to all home health agencies, so additional research is needed to assess feasibility of implementing this intervention in less favorable climates. Additionally, although we identified several implementation strategies that were self-selected by the pilot sites, we did not use the barriers and facilitators assessment we conducted to select implementation strategies tailored to the pilot sites. Should this intervention be tested on a larger scale, selection of implementation strategies tailored to individual sites’ barriers and facilitators would likely be beneficial.

This research had several limitations. First, this pilot study was based on a small sample of two organizations and <50 patients. Additionally, the two pilot sites had favorable implementation climates (commitment from all levels of leaderships; organizational goals and values aligned with improving referrals to hospice and palliative care), which may not be typical of all home health agencies and could have introduced selection bias. Both of these limitations could limit the generalizability of our findings. That said, the main objective of this pilot was to determine the feasibility of implementing this intervention as part of routine practice in home
health, which we believe we were able to demonstrate, albeit in a small, potentially non-representative sample. Third, although our pilot study had promising results (conversion rates similar to those found in prior research and self-reported value added by pilot sites), our study design did not assess effectiveness of the adapted intervention, nor did we assess long-term impact and sustainability. Finally, our intervention outcome results may not be generalizable to some home health agencies because not all home health agencies have access to palliative care services to which they can refer patients in addition to/in lieu of referring them to hospice. Research shows that how you refer to end-of-life services or services for seriously ill patients matters, and that palliative care may be more palatable to patients than hospice (22,23). This was supported by our pilot in that more patients chose palliative care than hospice. Especially for home health agencies where palliative care is not an option in their service area, additional adaptations such as those mentioned by our pilot sites and additional outreach and education efforts may be even more critical for promoting positive impact of the intervention.

Conclusion

In this study, we adapted an existing intervention to improve timeliness of referrals to hospice for nursing home residents to a new setting and patient population – home health. Our objective was to determine the feasibility of delivering the adapted intervention as part of routine care for eligible home health patients. Though we did not investigate the effectiveness of the adapted intervention, our results showed positive outcomes, both in qualitative and quantitative data, demonstrating the feasibility of implementing this intervention in practice. Overall, we believe the adapted intervention to be a promising tool that could be delivered in real world home health agencies. Through the rapid-cycle feedback approach used in our pilot, we were able to gather useful information about future potential adaptations to the intervention that could be made to potentially improve its effectiveness for this patient population. Future research is
needed to further test the adapted intervention, including studies to investigate additional adaptations, studies to assess effectiveness, and studies to assess long-term impact and sustainability.
REFERENCES


12. RTI analysis of HIS data


CHAPTER 5: CONCLUSION

The objective of this research was to adapt the Casarett et al. evidence-based intervention (EBI) to increase hospice care referrals for home- and community-based populations and evaluate the implementation and intervention outcomes of the adapted EBI. This research included the following aims: 1) identify core components of the EBI by clearly specifying its theory of change and major activities; 2a) adapt the EBI from nursing home to home- and community-based settings and populations; 2b) develop a theory to specify causal pathways of how adaptations influence outcomes; and 3) conduct a pilot test to assess feasibility of implementing the intervention in practice. The long-term goal of this research is to improve timeliness of referrals to hospice care for the broader home- and community-based hospice-eligible population in order to promote the benefits of hospice care for this group.

Significance of this Research

This research was significant in several ways. First, although Casarett and colleagues found their EBI to be efficacious, it was never widely adopted in practice, nor were any additional studies conducted to assess whether the intervention was feasible for use in routine care. Thus, our research was significant as it was the first study to assess the feasibility of implementing this intervention as part of routine care. In addition, by adapting the Casarett intervention for use in home health, we also investigated the feasibility of using this intervention with a new patient population (home health) – one that comprises a majority of hospice patients (1). As such, our study was also the first to assess the feasibility of extending the reach of this intervention to a new patient population.
Our methods and approach also make significant contributions to the field as they fill a gap in the implementation science literature. As part of the process of moving research into practice, adaptations to EBIs are inevitable as few interventions can be used in practice off-the-shelf. Although adaptation of existing EBIs to new contexts is a prominent topic in implementation research, there is little in the way of methods and tools for conducting adaptation; neither is there theory to explain how adaptations influence outcomes. This research provides a foundation for methods to ensure adaptations do not compromise the EBI’s potential benefits. Specifically, the methods used for identifying core components of the intervention and adapting the intervention to a new context (Aim 1 and 2a) could be used by researchers and practitioners to engage in their own adaptation efforts. Moreover, the theory that we developed in Aim 2b fills a gap in the literature by positing causal pathways of how adaptations work to influence implementation and intervention outcomes.

**Aim 1: Summary of Findings and Implications for Research and Practice**

In Aim 1, we identified core components of the Casarett intervention, as well as developed tools that researchers and practitioners can use to identify core components. Overall, we found that specifying the EBI’s theory of change was critical to identifying core components. The theory of change directly relates to the *principle* portion of each core component, and without first specifying the *principle* of each core component, we could not determine which activities were core vs part of the adaptable periphery. For the Casarett intervention, core component principles included re-framing the hospice conversation to a topic that clinicians felt comfortable discussing (patients’ care goals, needs, and preferences). With this principle identified, we were able to discern which activities were core (framing of the conversation) vs part of the adaptable periphery (who was initiating the conversation, exact wording of screening questions). In addition, standardizing the conversation in some way was also a core principle.
Creating clear definitions around eligible patients and timing of the conversations provided structure so clinicians were less likely to rely on clinical judgement alone, which can lead to delays in conversation.

Results from Aim 1 have implications for the development of tools and methods to identify core components of EBIs. In the current adaptation literature base, the lack of practical, clearly specified methods may limit the ability of researchers or intervention developers to specify core components; it may also diminish the consistency and specificity with which core components are reported (i.e., reporting core components without clear delineation of activities, principles, and the adaptable periphery). Current adaptation frameworks that acknowledge the importance of identifying core components only offer general approaches for identifying core components (e.g., review existing materials, consult with EBI developers, review EBI logic model or theory of change) (2-4). Our methods hold promise for providing guidance and consistency for how to identify and report core components, which could contribute to a literature base around core components that is less discordant, more generalizable, and promotes comparisons across research findings and contexts.

Aim 2a: Summary of Findings and Implications for Research and Practice

In Aim 2a, we engaged a stakeholder panel of home health agencies to identify context differences between the original intervention and our context, as well as necessary adaptations to address those differences. Overall, we identified 14 adaptations to the Casarett intervention, the majority of which were delivery adaptations (changes to who was doing what and when) vs content adaptations (changes to the intervention itself). Engaging the stakeholder panel proved invaluable as each home health agency was able to bring a different organizational perspective to help increase the generalizability of our adapted intervention.
Although the exact methods used in Aim 2a (multiple rounds of the Delphi method) may not be practical for routine use by practitioners due to their time intensive nature, the supporting tools used in Aim 2a (discussion guides, analytic codebooks) could be transformed into more practical tools (e.g., worksheets) that could used in practice. Such tools could support practitioners by providing structured thinking around making adaptations.

**Aim 2b: Summary of Findings and Implications for Research and Practice**

In Aim 2b, we developed a theory to describe adaptations’ impact on implementation and intervention outcomes. Our theory built on existing implementation science frameworks (Moore, Stirman, Proctor) and was able to show different pathways based upon reasons for adaptations (philosophical vs contextual reasons) and how types of adaptations (content vs delivery) work to impact types of outcomes (implementation vs intervention effectiveness). Our theory showed that although content and delivery adaptations can be made for any reason (i.e., content adaptations can be made to address philosophical or contextual misfit), it is ultimately the reason for the adaptation that drives the its impact on outcomes. Additionally, our theory shows that different types of adaptations have differential effects on implementation and intervention effectiveness. Adaptations made to address areas of philosophical misfit are hypothesized to have a primary impact on intervention effectiveness, but if and only if the adaptation relates to the core components and/or theory of change of the intervention. Adaptations made for philosophical reasons that are unrelated to core components are unlikely to ultimately change an intervention’s effectiveness. On the other hand, adaptations made to address areas of contextual misfit are most likely to impact implementation effectiveness by working through intermediate implementation outcomes, like feasibility, fidelity, cost, sustainability, etc.

The theory that we developed in Aim 2b has implications for research. Currently, there is a lack of causal theory in the adaptation literature. This limits our ability to predict the impact
that our adaptations might have and to systematically explain the results of research evaluating the impact of adaptations. Although our theory needs additional research to validate the pathways and test its generalizability, it represents a critical first step towards developing overarching causal explanations for exactly how adaptations work to impact implementation and intervention outcomes.

**Aim 3: Summary of Findings and Implications for Research and Practice**

In Aim 3, we pilot tested the adapted intervention to assess its feasibility in routine home health care. We tested the adapted intervention in two home health agencies for 9 weeks, collecting qualitative and quantitative data on the intervention and its implementation. Overall, we found positive results about the feasibility of implementing this intervention. With relatively minimal support from research staff (training on the intervention, answering questions about the intervention, scheduling and facilitating check-in interviews and feedback), pilot sites successfully implemented intervention activities with high fidelity with relatively low time commitments (5-10 mins/patient) and minimal re-structuring of regular clinical workflows. We also achieved hospice/palliative care conversion rates (16%) similar to those found by Casarett in his original trial (20%). Pilot site personnel suggested further adaptations to the intervention to improve its effectiveness in this patient population and also commented on strategies for scale-up of the intervention.

The results of Aim 3 have several implications for practice and policy. First, we demonstrated that our adapted intervention is promising for use by home health agencies. In addition to showing hospice/palliative care conversion rates similar to those seen in the efficacy trial, pilot sites reported that the intervention added value beyond encouraging appropriate care transitions. Nurses stated that the intervention helped facilitate conversation with patients, which could have implications for improving provider-patient communication around end-of-life
preferences and decisions. Of the ~95% of patients screening positive, 14% elected hospice or palliative care. This suggests that there could be room for further refinements to the intervention that could potentially improve its effectiveness in this population. Our results also suggest another construct underlying patients’ decisions to elect hospice care—readiness for the discussion for discussing hospice/palliative care with their physician. Nurses stated many patients who screened positive but did not elect hospice/palliative care stated they would consider hospice when they were ready. Currently, readiness is not assessed by this screening tool; thus, adding it may increase the tool’s effectiveness.

Although Aim 3 was an initial step towards assessing the effectiveness, impact, and sustainability of the adapted intervention, we believe these initial results warrant keeping a few key policy considerations on the horizon. The Centers for Medicare & Medicaid Services (CMS) has long had an interest in measuring, benchmarking, and incentivizing timely referrals to hospice. However, with the current standardized data that are available to CMS in post-acute, outpatient, and acute care settings, there are issues in determining the denominator for patients potentially appropriate for hospice. Ultimately, this tool could be adopted by CMS and other payers as a standardized way to identify patients who are potentially appropriate for hospice.

**Future Research**

This dissertation provides the foundation for several future studies. Aim 1 provides some initial methods and tools for identifying core components that can be further tested in research and practice to assess the utility and generalizability of these approaches for identifying core components in diverse contexts. Identification of core components is particularly critical for interventions relying on individual behavior change or other multi-level change theories, as these interventions tend to rely on theory-driven principles as the levers of change (vs other change mechanisms, like biological pathways seen in traditional drug or clinical research). Using
structured methods to identify core components is critical for both intervention developers who are developing and testing new interventions, as well as those engaged in replication or adaptation efforts, as research shows that even when core components are specified by developers, the core components specified are not always the correct core components (5).

Aim 2b provides an initial architecture for exploring how adaptations work to impact outcomes – future research is needed in which this theory is applied to planned adaptation efforts to help assess its validity. Specifically, this theory (and the underlying coding process) could be used by researchers testing both intervention and implementation outcomes, as part of a hybrid design study. As our theory points to adaptations’ impact on both sets of outcomes, ideally, the theory needs to be applied and tested in contexts assessing both types of outcomes.

Finally, Aim 3 provides the initial evidence for conducting larger studies that would assess the effectiveness, impact, and sustainability of our adapted intervention. Importantly, our research provides valuable insights on the value of this intervention and clear direction (i.e., potential additional adaptations to the intervention) for future researchers to further refine the intervention for the home health population and considerations for scale-up. A hybrid trial, which investigates both intervention and implementation effectiveness, would be an ideal study design for subsequent research as it would allow for the simultaneous, systematic exploration of both intervention and implementation outcomes (6). Given the nascent phase of research on the adapted intervention in the new setting (home health), a type 1 hybrid design (whose primary focus is on intervention outcomes, with some data collection on implementation) may be most appropriate as an immediate next step (6).
Conclusion

The goal of this dissertation was to adapt an existing EBI to improve timeliness of referrals to hospice for home- and community-based populations and evaluate the implementation and intervention outcomes of the adapted EBI. We identified the core components of the original intervention, identified adaptations necessary to move the intervention from nursing home to home health, and assessed the feasibility of implementing the adapted intervention in practice. Overall, we found favorable results indicating initial feasibility of implementing the adapted intervention in practice. In addition, we were able to achieve rates of conversion to palliative care/hospice similar to those found in the initial trial of the original intervention. Moreover, staff at home health agencies reported value added of the intervention, beyond its ability to promote appropriate care transitions. In addition to investigating the utility of the adapted intervention in practice, our dissertation also produces several actionable outputs, including methods and tools for identifying core components and adapting interventions and a theory elucidating how adaptations work to impact outcomes. Results from this dissertation can be used not only by researchers and clinicians to further develop interventions for improving timeliness of referrals to hospice for home health patients, but also by adaptation researchers and practitioners who are engaged in planned adaptation efforts.
REFERENCES

1. RTI analysis of Hospice Item Set (HIS) data


APPENDIX A: ADDITIONAL FILES AIM 1

Additional File 1: Description of Casarett EBI

This is supplementary material that will be distributed to the interview participants prior to their participation in Aim 1 interviews. The purpose of distributing this material will be to refresh participants’ memories about the original intervention. The interview itself will also contain some questions to elaborate on the activities/protocol described here.

The original intervention developed by Casarett et al. was primarily a screening and referral intervention that removed responsibility from the patient’s regular physician for screening and referring the patient to hospice. Main activities of the intervention are described in detail below. Note that in the original intervention, all activities were carried out by the randomized control trial study staff.

1. Screened all patients at participating nursing homes for ‘appropriateness’ for hospice. All nursing home residents were eligible for screening, except for those already on hospice.
2. Screening conducted via telephone or in-person by study staff using a 3-part screener, which included 2 questions on patient care goals and 1 question on symptom burden and service needs. Study staff would speak to the patient or patient’s caregiver (for cognitively impaired patients).
3. If patient screened ‘positive’ as appropriate for hospice care based on responses to all 3 screener questions, the following happened:
   a. Study staff told patient they screened positive, and said “looks like you might benefit from hospice, would it be OK for us to contact your physician about this?”
   b. Contacted physician to let them know the patient “screened positive”.
   c. Asked physician to certify if the patient had a prognosis of 6 months or less and, if so, whether nursing home staff should arrange a hospice educational visit.
4. If physician certified prognosis and authorized visit, study staff coordinated hospice referral and hospice initial educational visit.
5. Hospice staff made educational visit to verify eligibility and discuss election.

<table>
<thead>
<tr>
<th>Appropriateness for hospice care screener:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Care goals: Offer a choice between: 1) a course of treatment focused on extending life as much as possible, but with this course of treatment, you might have more pain and discomfort 2) a course of treatment that focuses on relieving pain and discomfort as much as possible, but with this treatment you might not live as long</td>
</tr>
<tr>
<td>• Care preferences: Assess preference regarding CPR and mechanical ventilation</td>
</tr>
<tr>
<td>o If couldn’t decide, preference for life sustaining treatments inferred</td>
</tr>
<tr>
<td>• Care needs: Assess care needs as noted below</td>
</tr>
<tr>
<td>o Assess 10 needs for symptom management using global distress index of the Memorial Symptom Assessment Scale. Assessed: 1) pain 2) constipation 3) lack of appetite 4) lack of energy 5) drowsiness 6) dry mouth 7) feeling sad 8) worrying 9) feeling nervous 10) feeling anxious</td>
</tr>
<tr>
<td>o Assess 8 needs for palliative care services: 1) additional nursing support 2) physician care focused on comfort 3) practical support with personal care needs 4) help with advance care</td>
</tr>
</tbody>
</table>
Additional File 2: Updated Interview Guide

Thank you for agreeing to participate in the interview today. This interview is part of a larger research study I am conducting to adapt the intervention originally developed by David Casarett and you to improve timeliness of hospice referrals for nursing home patients. I am conducting a larger study to adapt the intervention for home- and community-based settings, specifically home health patients that may benefit from hospice.

The first phase in my research is to learn more about the original intervention. Specifically, I want to: 1) identify the key activities of the original intervention 2) identify ‘core components’ of the original intervention (the essential principles and intervention activities necessary to produce desired outcomes) 3) identify any lessons learned from the original intervention. Since you were a member of the study team involved in the original intervention, I wanted to speak to you to hear your perspective on these issues. I’m then going to use what I learn in these interviews to inform how I adapt the intervention.

Our conversation today should last about 30-60 minutes. Anything you say here today will be kept confidential, meaning anything you say during this interview will not be attributed to you specifically. I will be taking notes today; to fill in any gaps in our notes later, we’d also like to record our call today, is that OK with you?

[Based on response, start recording]

Demographic information on participant

- **Question:**
  1. Could you describe your role on the study team that developed the original intervention?

**Topic Area 1: EBI activities**

Prior to this interview, I provided you with a ‘cheat sheet’ that I put together describing the activities of the original intervention. Since this intervention was developed and tested 10 years ago, hopefully this sheet will help ‘jog your memory’ on the details of the intervention. I developed this ‘cheat sheet’ based on details of the intervention that were described in the associated publication in JAMA. Have you had the opportunity to review this sheet prior to our call today?

If yes, continue. If no, provide ~3-5 mins to review the sheet.

I’d like to confirm some details of the original intervention with you – knowing what activities were done in the original intervention will help me adapt the intervention to the new setting.

- **Questions:**
  1. To the best of your recollection, does the cheat sheet appropriately describe the original intervention?
     - **Probe:** Do you see anything missing from the list? Any gaps in activities you’d like to fill in?
  2. How formalized was the protocol (were there deviations from it)?
  3. I had some specific questions I was hoping you might be able to help me fill in:
     - **Who were the study staff that carried out the intervention activities?**
Did they have any qualifications required to perform these activities (e.g., prior experience with nursing home patients or hospice)?

The screener was 3 questions – to be deemed potentially ‘appropriate’ for hospice, the patient had to screen ‘positive’ on all 3 questions. The *JAMA* publication was unclear as to what counted as a ‘positive’ for each question. Can we go through them?

- For the care goals question, did the patient have to state they preferred the palliative option?
- For preferences, the patient was asked about preference for CPR and mechanical ventilation – was this question asked as part of screener? Or did you look at an advance directive/POLST? Had to state a preference to not have *both*? Or just one?
- For symptom management (10 needs) and palliative care services (8 needs) – had to say yes to all 18?

Where were the screening conversations held (via phone? In-person at the nursing home?)

What did the study staff tell patients (beyond what’s included in the ‘cheat sheet’) after the screening?

- Probe: if they screened ‘positive’ what did they say? What if they screened negative?

What was the physician’s role beyond certifying the prognosis of 6 months or less and authorizing a hospice referral? Any additional conversations?

- Probe: one of your study outcomes collected via surrogate after death interviews was whether the caregiver was told resident had fatal illness and what to expect during the dying process – this was higher in intervention group --- was this something communicated by hospice after enrollment? Or by NH physician as part of referral process?

Who facilitated the referral to hospice once the physician certified the terminal prognosis of <6 months?

- Probe: nursing home staff or study staff? Who?
- How did this happen (e.g., nursing home staff called the hospice)?

What was the timeline of activities (time between patient screening, physician notification, facilitation of hospice referral)?

Prior to the hospice coming to do the educational/referral visit, did nursing home or study staff have any conversation with the patient about their ‘terminal’ status/condition?

**Topic Area 2: Theory of change**

*In the second part of the interview, I’d like to discuss the motivation behind the intervention. What problems or barriers exist in usual practice and how the intervention addresses those barriers. This will help me understand why you designed the intervention the way you did and how the intervention works.*

- **Questions - barriers:**
  4. Irrespective of the original intervention, based on your experience, can you describe barriers to hospice referral you often see or encounter in practice?
    - Probe: how do patients usually get referred/into hospice care?
    - Probe: what prevents or delays referrals?

- **Questions – primary/secondary causal pathway**
  5. How did the intervention help fix the barriers you just described (if at all)?
• Probe: make sure respondent describes how the EBI addressed barriers to change, not just which activities

• **Questions – moderators:**
  6. Was there anything about nursing home patients or nursing home organizations that made it easier to deliver the intervention in the nursing home than in other settings?
  7. Was there anything about nursing home patients or nursing home organizations that made it harder to deliver the intervention?
    • Probe:
      ▪ Clinical status of patients?
      ▪ Way care is delivered?
      ▪ Physicians more likely to green light hospice referral for whatever reason?
  8. Anything about the design of the original study itself that made it easier/harder to deliver the intervention than it would be in usual care?
    • Probe: fact that in the original RCT, all intervention activities carried out by study staff?

**Topic Area 3: core components of intervention**

*In this final part of the interview, I’d like to think about what I’m going to do next. I want to take this intervention and adapt it so that it can be used in the home health setting. When I’m making changes to the intervention to use it with home health patients, I want to make sure I don’t change an aspect of the intervention that was critical to its success. So now I’m going to ask you to think a bit about what was driving the success of the intervention – what was the “secret sauce”?*

• **Questions:**
  9. Which EBI activities contributed most to the success of the intervention?
    • Probe: what about it was essential – e.g., who is conducting the activity; mode of activity (in-person vs written)?
  10. In an adapted intervention, which activities/principles would you maintain at all costs?
  11. In an adapted intervention, which activities/principles could be modified while maintaining intervention effectiveness?
    • Probe:
      ▪ Who delivers intervention?
      ▪ Definition of ‘appropriateness’ (for example, what if you just needed 2/3? Or just had the care needs one?)

**Snowball sampling**

• Are there other members of the team you would recommend me speaking with? Those I’ve identified are those listed as authors on the JAMA publication.
• Are there any of the clinical sites that you think could provide valuable insight? Or other organizations who weren’t involved in the original RCT, but you know are using the intervention?
# Additional File 3: Codebook for Analysis of Interview Data

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition and Coding Rules</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topic 1: EBI Activities</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EBI Activities</td>
<td><strong>Definition:</strong> This code includes any details of the intervention’s activities, including “who, what, when, where” descriptions of activities and intervention components. <strong>Coding rule:</strong> this code is distinct from the rest in that only text about “the facts” of the intervention should be coded here. Any thoughts about why activities were important or how they boosted (or hindered) the effectiveness of the intervention should not be coded here.</td>
<td>The RA interviewed the NH residents in-person. A ‘positive’ screen on the 3-question screener was defined as xxxx. The physician was not involved in discussing hospice with the patient, beyond responding to the fax that was sent to them by study staff.</td>
</tr>
</tbody>
</table>

| **Topic 2a: Usual Care Pathway** | | |
| Usual Care Pathway, including barriers | **Definition:** This code includes description/discussion of the usual care pathway, irrespective of the intervention. Meaning, this would include discussion of the pathway to the outcome of interest (timely referrals to hospice) in usual care. This includes discussion of barriers to the outcome of interest. **Coding rule:** because we are looking for the usual care pathway/barriers to the outcome of interest encountered in usual care, do not code text specific to the intervention here. | Usually, clinicians are reluctant to discuss hospice because it’s awkward and they don’t feel comfortable talking about death. Because they feel uncomfortable talking about “the h word” they start second guessing themselves and thinking ‘maybe this patient isn’t ready yet’, which delays the conversation and thus the referral. |

<p>| <strong>Topic 2b: Theory of Change</strong> | | |
| Primary Causal Pathway | <strong>Definition:</strong> This code includes description of why or how the intervention works – the behavioral lever it addresses to affect change. <strong>Coding rules:</strong> - The primary causal pathway may be discussed in the context of barriers. | This intervention works because it removes the barriers described above by reframing the conversation entirely. It’s no longer a conversation about hospice, but a conversation about care goals/needs/preferences. |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition and Coding Rules</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>to the outcome encountered in usual care (i.e., how the intervention helps overcome those barriers)</td>
<td>The other thing the intervention does is remove the need for a precipitating event to happen before the referral is made. Since you have the discussion with all patients and the discussion is not prompted by a precipitating event, this improves timeliness</td>
</tr>
</tbody>
</table>
| Secondary causal pathway | **Definition:** This code includes secondary drivers of change in the intervention. Secondary causal pathways (like primary causal pathways) also describe why or how the intervention works and behavioral levers the intervention address to affect change, but the pathway is secondary (i.e., not the most important)  
**Coding rules:**  
- The secondary causal pathway may also be discussed in the context of barriers to the outcome encountered in usual care (i.e., how the intervention helps overcome those barriers)  
- The secondary causal pathway is distinguished from the primary causal pathway in that the primary causal pathway is described as the *most* important factor in getting to the outcome of interest |  |
<p>| Moderators | <strong>Definition:</strong> This code includes discussion of factors that influence the strength of a relationship between the intervention and the outcome. | The intervention may be easier to implement/work better in nursing homes because xxx (e.g., structural characteristics of nursing homes that boosted the effectiveness of the |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition and Coding Rules</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Coding rules:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Moderators are</td>
<td></td>
</tr>
<tr>
<td></td>
<td>distinguished from the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>primary/secondary</td>
<td></td>
</tr>
<tr>
<td></td>
<td>causal pathway in that</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the factors lying on the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>causal pathway must be</td>
<td></td>
</tr>
<tr>
<td></td>
<td>present for X to affect</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Y. On the other hand,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>moderators do not</td>
<td></td>
</tr>
<tr>
<td></td>
<td>determine whether X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>will affect Y at all, but</td>
<td></td>
</tr>
<tr>
<td></td>
<td>rather the strength of the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>relationship between X</td>
<td></td>
</tr>
<tr>
<td></td>
<td>and Y.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Moderators can have a</td>
<td></td>
</tr>
<tr>
<td></td>
<td>positive or negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>effect on the strength of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the relationship between</td>
<td></td>
</tr>
<tr>
<td></td>
<td>X and Y. If a moderator</td>
<td></td>
</tr>
<tr>
<td></td>
<td>has a positive effect, it</td>
<td></td>
</tr>
<tr>
<td></td>
<td>boosts the relationship</td>
<td></td>
</tr>
<tr>
<td></td>
<td>between X and Y making the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>effect of X on Y larger.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If a moderator has a</td>
<td></td>
</tr>
<tr>
<td></td>
<td>negative effect, it can</td>
<td></td>
</tr>
<tr>
<td></td>
<td>either diminish the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>effect X has on Y or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>reverse the relationship</td>
<td></td>
</tr>
<tr>
<td></td>
<td>between X and Y altogether.</td>
<td></td>
</tr>
</tbody>
</table>

**Topic 3: Core Components**

**Core Components**

**Definition:** some combination of the principles (theory of change, causal pathway) and specific activities necessary to produce desired outcomes

**Coding rules:**

• Because core components are a combination of principles and activities, make sure to review questions that ask about core components directly, as well as questions that

"What was driving the success of the intervention was really 2 things it was xxxxx"

"I would think you could change xxx without compromising the effectiveness"

"I would leave x unchanged"
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition and Coding Rules</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ask about causal pathway and activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• This may be double-coded with activities, primary, and secondary causal pathway</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mentions of what could be changed and what should not be changed would also be coded as</td>
<td></td>
</tr>
<tr>
<td></td>
<td>core components</td>
<td></td>
</tr>
</tbody>
</table>

**Quotable Quotes**

**Definition:** This code includes any good illustrative quotes

**Coding rules:** To be used only as a double-code with one of the codes listed above. This code would be used when something a respondent says is particularly illustrative of another code/theme

149
Additional File 4. Description of Intervention in Template for Intervention Description and Replication (TIDieR) Format

TIDieR item number 1: Brief name

*Brief name or phrase that describes the intervention.*

- Hospice appropriateness screening intervention

TIDieR item number 2: Why

*Rationale, theory, or goal of the elements essential to the intervention.*

- Even when terminally ill patients may be appropriate for a referral to hospice, clinicians often avoid having this conversation with patients due to a multitude of reasons, including fear of bringing up hospice ‘too early’, discomfort/lack of skills in talking about hospice and death, fear of how the patient will react. Because clinicians feel uncomfortable, they avoid or delay having the hospice conversation. This results in late referrals to hospice where patients are referred only after a serious precipitating event (e.g., major decline in status).

- This intervention seeks to improve timeliness of hospice referrals by re-framing the hospice conversation. Instead of having the referring clinician broach hospice as a care option directly with the patient, the clinician initiates the conversation by talking about the patient’s care goals, needs, and preferences. If the patient’s care goals, needs, and preferences align with hospice care, the referral process is then initiated. RE-framing the conversation turns the conversation into something the clinician feels comfortable discussing (care goals, needs, and preferences), eliminating the tendency to avoid or delay the conversation.

- The care goals, needs, and preferences conversation is standardized (asked of all eligible patients at a specific time) which also avoids the reliance on a precipitating event to trigger the conversation/start of the referral process.

TIDieR item number 5: Who provided

*For each category of intervention provider, describe their expertise, background, and any specific training given.*

- Unless otherwise noted in 3b. Procedures, below, all procedures carried out by a research assistant. The research assistant was not a clinician, but had prior knowledge/experience conducting research in hospice and had prior experience interviewing patients as part of clinical research. No special training delivered specific to this intervention protocol.

TIDieR item number 6: How

*Modes of delivery (e.g., face-to-face or telephone) of the intervention and whether it was provided individually or in a group.*

- Specific modes are noted for each step in 3b. Procedures, below. In general, participants were initially contacted via telephone. For delivery of 3 screening questions, if resident was being interviewed, interview was conducted in person, at the nursing home. If surrogate was interviewed, interviews could be conducted via phone. All interviews were conducted individually, or with a patient-surrogate dyad.
TIDieR item number 7: Where

Types of locations where intervention occurred, including any necessary infrastructure or relevant features.

Intervention was delivered in nursing homes; intervention originally tested in 3 nursing homes:

- Urban facility with a high proportion of African American residents; facility contracted with outside hospice organization
- Suburban facility with a largely white, affluent population; facility contracted with outside hospice organization
- VA nursing home with ethnically diverse population; facility has in-house hospice program

TIDieR item number 8: When and how much

Number of times intervention delivered and over what period of time, including number of sessions, schedule, duration, intensity, dose.

- Randomized controlled trial (RCT) of intervention was 1 year (December 2003 – December 2004).
- Intervention (screening questions) delivered once for each patient. Outcome data collected at baseline and at 6 month follow-up or until death.

TIDieR item number 9: Tailoring

Was the intervention planned to be personalized, titrated or adapted, then describe what, why, when and how.

- No tailoring intended, as described in original RCT publication.

TIDieR item number 10: Modifications

If the intervention was modified during the course of the study, describe changes (what, why, when, how)

- No modifications reported as part of original intervention RCT.

TIDieR item number 11 & 12: How well

Planned: if intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity.

Actual: if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

- Adherence and/or fidelity were not assessed as part of intervention RCT.

TIDieR item number 3b: Procedures

Procedures, activities, and/or processes used in intervention, including any enabling or supporting activities.

- Step-by-step procedures for the intervention are reported in detail, below.
Step 1: Determine patient eligibility:

- Conduct chart review of all nursing home residents to determine eligibility. Conduct chart review on all patients who are in a unit at the time of initial chart review.
- Apply the following exclusion criteria. Patient excluded if any of the following 3 criteria are met:
  - Patient already receiving hospice care
  - Reason for admission to nursing home was for a respite stay
  - Patient too cognitively impaired to complete the interview and does not have a surrogate listed in the chart

Step 2: Invite eligible participants

- Send invitation letter to surrogates of eligible participants.
- Invitation letter describes the study and provides an “opt out” option for non-participation. Surrogates can refuse participation by calling a toll free number.

Step 3: Assess cognitive status of patients

- Patients must be screened for cognitive status as cognitively impaired patients will not be able to participate in the main activity of the intervention (responding to the 3 hospice appropriateness screening questions).
- To determine ability to participate in subsequent interviews, screen patients in-person using the Mini-Mental State Examination (MMSE), provided here.
- If patient determined to be cognitively impaired, invite surrogate to participate instead (Step 4). Their surrogate was invited to participate instead. Patients deemed cognitively impaired based on:
  - Their MMSE score or
  - Patient too cognitively impaired to complete MMSE
- If patient determined to not be cognitively impaired, conduct interview with patient and surrogate

Step 4: Contact appropriate respondent (either patient or surrogate) for interview.

- Initiate contact via telephone for surrogates and in-person for patients. Complete a total of 6 contact initiation attempts.
  - If attempt successful, read consent script and begin interview as appropriate.
  - After 3 unsuccessful attempts, read the “3 unsuccessful attempts” script.
  - After 6 unsuccessful attempts, read the “6 unsuccessful attempts” script and cease contact.

Step 5: Consent patient and/or surrogate

- Consent patient and/or surrogate verbally, using the script provided.

Step 6: Deliver hospice appropriateness screening questions

- For patients/surrogate that consent to interview, ask the 3 hospice appropriateness screening questions, using the script provided:
  - Question 1 - Care goals: SUPPORT question to determine whether patient has care goals focused on comfort
  - Question 2 - Care preferences: determine whether the patient refuses CPR and mechanical ventilation
  - Question 3 - Care needs: determine whether the patient has physical symptoms (n=6), psychological symptoms (n=4), or service needs that could be addressed by hospice (n=8)
• Note that demographic data should also be collected at the start of surrogate interviews (marital status, race/ethnicity, age, education, income)

**Step 7: Report “results” of screening to patient or surrogate**

- After asking screening questions, present results to respondent. Using the script provided, make sure to cover:
  - Patient/surrogate’s responses to screening questions
  - Permission to contact physician (for patients that screened positive on all 3 questions)

**Step 8: Get HIPAA permission to review records**

- At conclusion of interview, ask for HIPAA authorization using script provided
- If respondent gives verbal consent to look at patient’s chart, send HIPAA form to respondent and instruct respondent

**Step 9: Complete chart review for baseline data**

- After interview, complete accompanying chart review for baseline data, including:
  - Activities of daily living, including Y/N for: ambulates independently, uses cane, uses wheelchair, bowel continent, bladder continent, needs assistance with feeding, needs assistance with dressing, needs assistance with bathing
  - Current medications
  - Type of insurance
  - Existing diagnoses, which were used to calculate the patient’s Charlson co-morbidity score
  - Existing orders to limit life-sustaining treatment (DNR orders, do not intubate, or do not transfer) and advance directives or chart documentation of preferences to limit such treatment in the future

**Step 10: Complete necessary follow-up with physician**

- Contact patient’s physician via fax to alert physician to screening results and ask about prognosis and authorization for a hospice visit
  - The fax should describe the study aims, inform the physician that an interview had identified one of their patients who might be appropriate for hospice
  - Ask the physician to reply, via fax, indicating whether the resident had a prognosis of 6 months or less and, if so, whether the nursing home staff should arrange a hospice visit
- Send repeated faxes to physicians who do not respond to initial fax

**Step 11: Notify staff to facilitate hospice referral**

- If physician certifies a 6-month prognosis and gives permission for a hospice visit, alert nursing home staff that the hospice should be contacted to conduct an educational/informational visit
  - At this point, intervention converts to “usual care”; hospice staff conducts educational visit to verify eligibility and move forward with enrollment

**Step 12: Follow-up data collection**

- Collect follow-up data via chart review and/or a follow-up interview.
  - Chart review: review patient’s record every 2 weeks for 6 months or until death. Identify: Date of death
- Hospitalizations
- New orders to limit life-sustaining treatment
- Hospice enrollment
  - Interviews: if patient dies during 6-month follow-up period, contact surrogate to participate in another interview about the family’s perception of the quality of end-of-life care. Ask surrogate to evaluate the following aspects of care:
    - Resident’s care in the last week of life on a 1-5 scale
    - Whether a member of the healthcare team discussed what to expect during the dying process
    - Whether the patient had pain or shortness of breath that was not managed as well as it could have been
    - Whether the patient died where he/she would have wanted

**TIDieR Item 3a: Materials**

*Any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or training of intervention providers, including information on where materials can be accessed (e.g., online appendix or URL).*

- Materials for the intervention are reported in detail, below. For each material, we list which step in the procedures the material is used in.

**MMSE (for use in Procedures, Step 3)**
Attempts Scripts (for use in Procedures, Step 4)

- **Successful attempt:** Hello, may I speak with [FAMILY MEMBER]? Hello Mr./Mrs. [FAMILY MEMBER]. My name is ____, I am calling from the University of Pennsylvania, and we’re doing a research study in cooperation with the _______ Nursing home. You may recall reading a letter that was sent to you about two weeks ago telling you about this study. We are trying to find better ways to help patients and their families make decisions about their health care. This interview will take about 30 minutes, and we can pay you $30 for your time. Do you think you might be able to talk to me?
  - (if yes): Great, thanks very much. This interview will take about 30 minutes and we can talk whenever it would be most convenient for you. Would you like me to call back at another time, or do you have time to walk now?
  - (if no: record reason) ______________________________________________
  - Confirm: you are [RESIDENT’S] [RELATIONSHIP], is that right? (record different response): ________________________________

- **After 3 unsuccessful attempts:** Hello, my name is ____ and I am calling from the University of Pennsylvania. I am calling to see if you would be willing to talk to me for a research study about [RESIDENT’S] care in the xxxx nursing home. You may recall receiving a letter in the mail describing the study. It’s a single interview that takes about 30 minutes and we can pay you $30 for your time. I have tried to reach you a few times this week, and I’ll keep trying, but you can

---

### Mini-Mental State Examination (MMSE)

**Instructions:** Score one point for each correct response within each question or activity.

<table>
<thead>
<tr>
<th>Maximum Score</th>
<th>Patient’s Score</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td></td>
<td>“What is the year? Season? Date? Day? Month?”</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>“Where are we now? State? County? Town/city? Hospital? Floor?”</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>The examiner names three unrelated objects clearly and slowly, then the instructor asks the patient to name all three of them. The patient’s response is used for scoring. The examiner repeats them until patient learns all of them, if possible.</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>“I would like you to count backward from 100 by sevens.” (93, 86, 79, 72, 65, …) Alternative: “Spell WORLD backwards.” (D-L-R-O-W)</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Earlier I told you the names of three things. Can you tell me what those were?</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>Repeat the phrase: “No ifs, ands, or buts.”</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>Take the paper in your right hand, fold it in half, and put it on the floor.” (The examiner gives the patient a piece of blank paper.)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>“Please read this and do what it says.” (Written instruction is “Close your eyes.”)</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>“Make up and write a sentence about anything.” (This sentence must contain a noun and a verb.</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>“Please copy this picture.” (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)</td>
</tr>
</tbody>
</table>

| 30 | TOTAL |

---

**Scoring:**

- 24 or higher: normal cognition
- 19-23: mild cognitive impairment
- 10-18: moderate cognitive impairment
- 9 or less: severe cognitive impairment
call us too. If you’d like to suggest a good time to reach you, please don’t hesitate to call the study office at xxxxx. You can also call us if you know that you don’t want to participate, or if you have questions about the study. Again, this is ________ from the University of Pennsylvania calling to talk to you about a research study, and you can reach us at xxxx. Thank you.

- **After 6 unsuccessful attempts:** Hello, my name is __________ and I am calling from the University of Pennsylvania. I am calling to see if you will talk to me for a research study about [RESIDENT’S] care in the xxxx nursing home. I have tried to reach you a few times, but I have been unsuccessful. I will not call again, but if you’d like to call me, that would be great. I can be reached at xxxxx. Thank you.

**Consent (for use in Procedures, Step 5)**

- Before we get started, I’d like to tell you about our conversation today, in order to make sure you understand what we will be talking about today and why. This interview is part of a research study. it is not part of [RESIDENT’S] medical care.
- We’re doing this research study in order to find out how to help people make decisions about health care. During this interview, I will ask you about your [RESIDENT’S] health and how [he/she] has been feeling. I’ll also talk to you in one of several ways about comfort care and hospice.
- Whether, and how I talk to you about hospice is going to be determined by chance. If I do talk to you about hospice, it’s not because I think [RESIDENT] is very sick. In fact, I have no reason to think that. If we do talk about palliative care and hospice, I might explain them in one of several ways, then I’ll ask you some questions to find out whether I did a good job explaining them.
- As part of this study, I will also be reviewing [RESIDENT’S] medical charts for additional medical information, and in order to do this, we will need your permission in writing. So we’ll be sending you an authorization form within the next few days. We will need this form returned to us in order for you to enroll in this study. once we have the form, we’ll officially enroll you in the study and send you the $30 payment. If [RESIDENT] dies, I will also try and get in touch with you to find out how well people did taking care of [him/her].
- If you agree to talk to me, the main risk would be that someone other than myself and the other researchers doing this study with me would know what we’ve talked about. But every attempt will be made by me and the other researchers who work on this study to keep all of the information we gather from you strictly confidential, except for what may be required by a court order or law. If any publication or presentations result from this research, your name will not be used. The University of Pennsylvania Institutional Review Board may be provided access to our research records that do identify you, but they will keep the information confidential.
- Our conversation today will last about 30 minutes. When we’re finished with the interview, we’ll send you an authorization form, and when we get back that form, we’ll mail you a check for $30.
- Do you understand what the interview will be about? [If no or uncertain, repeat explanation.]
- Finally, I want to be sure that you understand you can stop this interview at any time.
- Can we go ahead with the interview?

**Hospice Appropriateness Screening Questions (for use in Procedures, Step 6)**

- **Hospice Discussion**
  - Next, I’d like to tell you about a program that is designed to help people who are in nursing homes. This is a program called hospice. Have you ever heard of hospice?
  - (If yes): what have you heard about it?
  - Now, I want you to remember that we’re not talking about hospice because I think your [RESIDENT] is very sick, OK? We’re just trying to talk to a wide range of people so that we can find better ways of explaining hospice to patients and their families.
Hospice is a team-managed program of services that focuses on improving quality of life for people at the end of their illness. Hospice tries to help patients live their remaining life the best they can. Usually hospice care is for people who are more likely than not to die in 6 months, although people in hospice can live even longer. Hospice doesn’t bring on death. But hospice doesn’t try and hold off death either. Hospice can be provided in a hospice facility, at home, in a hospital, or in the nursing home. Do you have any questions about hospice so far?

AREA 1: SYMPTOMS AND SERVICE NEEDS

- Symptoms:
  - OK, so one way that hospice can help people is by doing a better job in treating their symptoms, can you think of any symptoms that have been bothering [RESIDENT] in the past week that hospice might be able to help?
  - Can you think of anything else?
  - [REVIEW THE SYMPTOMS THEY LISTED]
  - Next, I’d like to ask you a few questions about some additional symptoms that might be bothering [RESIDENT].
  - (Ask about the following 4 psychological symptoms and record the respondent’s answer in the table. Ask Yes/No questions first, then ask How often for “yes” symptoms)

<table>
<thead>
<tr>
<th>(Ask respondent about presence of symptoms in past week and mark yes/no):</th>
<th>(If yes, ask about frequency by providing respondent with options 1-4 and circle correct option)</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the past week, has [RESIDENT] been feeling sad?</td>
<td>How often do you think [RESIDENT] has been feeling sad?</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>During the past week, has [RESIDENT] been worrying?</td>
<td>How often do you think [RESIDENT] has been worrying?</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>During the past week, has [RESIDENT] been feeling irritable?</td>
<td>How often do you think [RESIDENT] has been feeling irritable?</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>During the past week, has [RESIDENT] been feeling nervous?</td>
<td>How often do you think [RESIDENT] has been feeling nervous?</td>
</tr>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Rarely</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
○ (Ask about the following 6 physical symptoms and record the respondent’s answer in the table. Ask Yes/No questions first, then ask about severity for “yes” symptoms)

<table>
<thead>
<tr>
<th>(Ask respondent about presence of symptoms in past week):</th>
<th>(If yes, ask about frequency by providing respondent with options 1-4)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>During the past week, has [RESIDENT] had a lack of appetite?</strong></td>
<td>How much does lack of appetite distress or bother [RESIDENT]?</td>
</tr>
<tr>
<td>□ Yes</td>
<td>0  1  2  3  4</td>
</tr>
<tr>
<td>□ No</td>
<td>Not at all  A little bit  Somewhat  Quite a bit  Very Much  Don’t</td>
</tr>
<tr>
<td><strong>During the past week, has [RESIDENT] had a lack of energy?</strong></td>
<td>How much does lack of energy distress or bother [RESIDENT]?</td>
</tr>
<tr>
<td>□ Yes</td>
<td>0  1  2  3  4</td>
</tr>
<tr>
<td>□ No</td>
<td>Not at all  A little bit  Somewhat  Quite a bit  Very Much  Don’t</td>
</tr>
<tr>
<td><strong>During the past week, has [RESIDENT] had pain?</strong></td>
<td>How much does pain distress or bother [RESIDENT]?</td>
</tr>
<tr>
<td>□ Yes</td>
<td>0  1  2  3  4</td>
</tr>
<tr>
<td>□ No</td>
<td>Not at all  A little bit  Somewhat  Quite a bit  Very Much  Don’t</td>
</tr>
<tr>
<td><strong>During the past week, has [RESIDENT] been feeling drowsy or confused?</strong></td>
<td>How much does drowsiness or confusion distress or bother [RESIDENT]?</td>
</tr>
<tr>
<td>□ Yes</td>
<td>0  1  2  3  4</td>
</tr>
<tr>
<td>□ No</td>
<td>Not at all  A little bit  Somewhat  Quite a bit  Very Much  Don’t</td>
</tr>
<tr>
<td><strong>During the past week, has [RESIDENT] had constipation?</strong></td>
<td>How much does constipation distress or bother [RESIDENT]?</td>
</tr>
<tr>
<td>□ Yes</td>
<td>0  1  2  3  4</td>
</tr>
<tr>
<td>□ No</td>
<td>Not at all  A little bit  Somewhat  Quite a bit  Very Much  Don’t</td>
</tr>
<tr>
<td><strong>During the past week, has [RESIDENT] had dry mouth?</strong></td>
<td>How much does dry mouth distress or bother [RESIDENT]?</td>
</tr>
<tr>
<td>□ Yes</td>
<td>0  1  2  3  4</td>
</tr>
<tr>
<td>□ No</td>
<td>Not at all  A little bit  Somewhat  Quite a bit  Very Much  Don’t</td>
</tr>
</tbody>
</table>

○ So, in the past week, [RESIDENT] has had some problems that hospice doctors and nurses can help with like [READ SYMPTOMS IDENTIFIED ABOVE]

- **Service Needs**
  ○ Hospice can provide extra help and extra services to people in different ways. Can you think of any extra help or services that [RESIDENT] might want?
  ○ Anything else?
[REVIEW WHAT THEY SAID WAS IMPORTANT]
Ok, next I’ll describe several services and I’ll ask you to tell me whether you think these services could help [RESIDENT]
Would it help [RESIDENT] to have an extra nurse who could help treat symptoms that have been bothering [him/her]?

☐ Yes
☐ No
☐ Unsure

Would it help [RESIDENT] to have an extra doctor who could help treat symptoms that have been bothering [him/her]?

☐ Yes
☐ No
☐ Unsure

Would it help [RESIDENT] to have an extra home health aide come in to give [him/her] more help with bathing dressing and eating?

☐ Yes
☐ No
☐ Unsure

Would it help [RESIDENT] to have an extra social worker who could work with [him/her] to arrange [his/her] finances and insurance?

☐ Yes
☐ No
☐ Unsure

Would it help [RESIDENT] to have an extra social worker or chaplain who could provide counseling and emotional support?

☐ Yes
☐ No
☐ Unsure

If [RESIDENT] were to die, do you think it would be helpful for [SURROGATE] to have a bereavement counselor or support group for you?

☐ Yes
☐ No
☐ Unsure
Would it help [SURROGATE] to have an extra chaplain who could provide spiritual support?
- Yes
- No
- Unsure

Would it help [RESIDENT] to have a volunteer who would visit and spend time with [him/her]?
- Yes
- No
- Unsure

So, you think [RESIDENT] might benefit from extra help from some of the services that hospice provides like [REPEAT CHOICES ABOVE]? Is that right?

(If family services (bereavement, clergy) mentioned): you also mentioned that you think [SURROGATE] might benefit from some of the services that hospice provides, like [REPEAT FAMILY SERVICES].

**DOMAIN 2: CARE GOALS**

- **(Substituted Judgement):** OK, now I’d like you to imagine that [RESIDENT] had to make a decision right now about how [his/her] doctors should take care of [him/her]. If [he/she] had to make a decision right now, would [he/she] prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would [he/she] want a plan of care that focuses on relieving pain and discomfort as much as possible, even if that means not living as long?
- **If [RESIDENT] had to make a decision right now, do you think [he/she] would want to:**
  - **(Extending life):** focus on keeping [him/her] comfortable as possible, or
  - **(Palliative care):** focus on helping [him/her] live as long as possible?
  - Don’t know

(If they say both): OK, but if you had to choose just one, which would you choose? [READ OPTIONS AGAIN]

- **(Best Interests):** if you had to make this decision for [RESIDENT], based on what YOU think is best, would you prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would you prefer a plan of care that focuses on relieving pain and discomfort as much as possible, even if that means not living as long?
- **If you had to make decision right now about how you would want [RESIDENT’S] doctors to take care of [him/her] based on what you think is best, would you tell them they should:**
  - **(Extending life):** focus on keeping [him/her] comfortable as possible, or
  - **(Palliative care):** focus on helping [him/her] live as long as possible?
  - Don’t know

(If they say both): OK, but if you had to choose just one, which would you choose? [READ OPTIONS AGAIN]
DOMAIN 3: CARE PREFERENCES

- Some people make plans about how they want their doctors to take care of them. So now, I’d like to talk about how you and [RESIDENT] want [RESIDENT’S] doctors to take care of [him/her].
  - (CPR): For example, if [RESIDENT’S] heart stops beating, do you want [his/her] doctors to try to restart it or not?
    - [ ] Yes
    - [ ] No
    - [ ] Unsure
  - (Vent): OK, if [RESIDENT] isn’t able to breathe on [his/her] own, would you want [his/her] doctors to put [him/her] on a breathing machine?
    - [ ] Yes
    - [ ] No
    - [ ] Unsure

Results of Interview (for use in Procedures, Step 7)

- (Scoring: Record respondent’s answers below)

<table>
<thead>
<tr>
<th>Did respondent have at least ONE symptom or service need?</th>
<th>[ ] Yes</th>
<th>[ ] No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did respondent answer “palliative care” for BOTH care goals questions (substituted judgement and best interest)?</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Did respondent answer “no” to both the CPR and Vent questions?</td>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>Add up “Yes’s” in the right column:</td>
<td>______ total number of yes’s (1-3)</td>
<td></td>
</tr>
</tbody>
</table>

- (Discuss results of screening – if respondent had all 3 yes’s, they screened positive; if not, they screened negative:)

(For respondents that screen positive):

- You said that your [RESIDENT] was having [xxxx] symptoms that hospice might be able to treat better.
- You also said that your [RESIDENT] might want [xxxx] services that hospice offers.
- So it seems like hospice might be able to help your resident with some of [his/her] symptoms and with giving [him/her] extra services.
- You also said that your [RESIDENT] would want to focus on staying as comfortable as possible, even if that means [he/she] might not live as long. That’s what hospice tries to do for people. Hospice doesn’t try to prolong life with aggressive treatment. instead, hospice tries to keep people as comfortable as possible for the time you have left, which is what you said [he/she] would want.
So it sounds like hospice might be right for [RESIDENT].

As I said before, I don’t know whether hospice is the right decision for [RESIDENT]. That’s up to [RESIDENT’S] doctor. If it’s OK with you, I’ll let your [RESIDENT’S] doctor know that we had this conversation so that [he/she] can give you more information and so [he/she] can tell you whether [RESIDENT] should think about hospice now. Is that OK?

☐ Yes
☐ No

(For respondents that screen negative, with symptom or service needs):

- You said [RESIDENT] was having [xxxx] symptoms that hospice might be able to treat better.
- You also said that [RESIDENT] might want [xxxx] services that hospice offers.
- But you also said that your [RESIDENT] would want treatments to prolong [his/her] life, even if it means some pain and discomfort. Hospice tries to keep people as comfortable as possible for the time they have left. Hospice doesn’t usually use treatments to prolong life, so hospice wouldn’t give you some of the treatments to prolong your life that you might want. So it sounds like hospice might not be right for your [RESIDENT].

(For respondents that screen negative, with NO symptom or service needs):

- You said [RESIDENT] didn’t have any symptoms or service needs that hospice could help with.
- You also said that your [RESIDENT] would want treatments to prolong [his/her] life, even if it means some pain and discomfort. Hospice tries to keep people as comfortable as possible for the time they have left. Hospice doesn’t usually use treatments to prolong life, so hospice wouldn’t give you some of the treatments to prolong your life that you might want. So it sounds like hospice might not be right for your [RESIDENT].

HIPAA (for use in Procedures, Step 8)

- Before we stop, there’s just one more thing we’ll need from you. In order to enroll you and [RESIDENT] in this study, we will need permission to look in [RESIDENT’S] chart 3-4 times over the next 6 months to find out what sorts of choices you and [RESIDENT’S] doctors make about [HIS/HER] care. Will that be OK?
  - (If yes): that’s good, thanks. In order to do that, we’ll need your permission in writing. So I’ll be sending you a form to sign within the next week or so, along with a self-addressed, stamped envelope. When you get the form, read it, sign the bottom portion, and return it to us.
  - [verify address]
APPENDIX B: ADDITIONAL FILES AIM 2A

Additional File 1: Interview Guide – Context Differences: Brainstorming Differences Between Home Health and Nursing Homes

The purpose of this discussion is to identify general differences between nursing home (setting/population intervention originally tested in) and home health (new setting/population). The ultimate goal of this phase of my research is to determine what adaptations we’ll need to make to the original intervention to make sure it’s appropriate for the new setting (home health). As a preliminary first step in determining adaptations, understanding the differences between home health and nursing homes will be helpful to me. This will give me a broader picture of the context for this intervention.

The interview questions ask you to compare and contrast home health and nursing homes on several dimensions, including patient population, care setting and delivery, external environment, etc. Note that when I say nursing home patients, I am referring to long-term nursing facility (NF) patients, not patients who may be residing in a nursing home in a (Skilled nursing facility) SNF bed under Medicare SNF coverage. Although I am primarily interested in differences between the two settings, if there are important similarities on the factors listed below, please include those in your responses as well.

Domain 1: Patient Population – how are home health and nursing home patients different in terms of:

- **Goals of care:** How do goals of care differ for nursing home and home health patients? This would include differences (or similarities) between the philosophy/goals of care between nursing home and home health (e.g., rehabilitation vs long term support):
  Response:

- **Diagnosis:** How are nursing home and home health patients different in terms of diagnosis? This could cover differences in terms of primary diagnosis (e.g., nursing home patients are more likely to have dementia than home health patients) or secondary diagnoses.
  Response:

- **Clinical condition:** How does the clinical status of nursing home patients differ to home health patients? This could cover differences in terms of functional and cognitive status, as well as other clinical factors, like risk of hospitalization or likelihood of death within 1 year.
  Response:

- **Demographics:** How are the demographics between nursing home and home health patients different? This could cover differences (or similarities) in terms of demographic factors like age, primary payer, etc.
  Response:

- **Symptom/service needs:** How do the symptom and service needs of these 2 patient populations compare? This would cover differences (or similarities) in terms of symptom (e.g., pain, shortness of breath) and service needs (need of an aide, social worker, clergy, transportation, etc.). This could include physical as well as psychosocial symptoms.
  Response:

- **Length of Stay:** What is the average length of stay like for nursing home vs home health patients?
Response:

- **Social Factors:** What are the major differences in social factors between these two patient populations? This would cover differences (or similarities) in terms of social factors, such as the presence/role of a family caregiver.
  
  Response:

- **Preferences:** Are there any major differences between care preferences for these two patient populations?
  
  Response:

**Domain 2: Care Setting and Delivery**

- **Care delivery model:** How does care delivery differ between the nursing home and home health setting? This would include:
  
  - Who is delivering care (nurses vs MD, what is the role of the MD in care delivery? What is the role of community physicians/clinicians vs HH/NH clinicians?)
    
    Response:

  - Main types of services provided?
    
    Response:

  - How often services are provided?
    
    Response:

  - Where services are provided?
    
    Response:

- **Referral sources:** What are the primary referral sources for each care setting (e.g., community-based geriatricians vs specialists)? What are the triggers for referral (e.g., acute event, decline in cognitive/functional status)?
  
  Response:

- **Agency:** Are there major differences between nursing homes and home health agencies as organizations (e.g., are agencies typically free standing or part of a healthcare system; are agencies for profit? Do agencies always have a physical office? Are most agencies on an EMR?)
  
  Response:

**Domain 3: Policy Context/External Environment**

- **Regulatory requirements/larger policy context:** Are there major differences between the larger policy context or external environment for nursing homes vs home health agencies (e.g., differences in CMS requirements, relationship with other care models, such as ACOs, etc.)?
  
  Response:

**Domain 4: Relationship with Hospices**

- **Attitudes and knowledge about hospice among:** How are attitudes and knowledge about hospice different among nursing home vs home health from the perspective of:
  
  - Patients?
Response:

- Staff?
  Response:

- **Relationship with hospice once patient is enrolled**: How does the relationship between the patient and the hospice differ once the patient is enrolled in hospice (e.g., does the home health agency/nursing home remain involved in care?)
  Response:

- **Financial relationship with hospice**: How is the financial relationship with the hospice different between home health and nursing home (e.g., pass-through payments)?
  Response:
Adapting Casarett Intervention from NH to HH

September 25, 2017
RTI International
9-11AM

Plan for Today

• Introductions
• Procedures: Walk through intervention protocol
• Scripts: Walk through scripts
Refresher

- Our intervention is to ask HH patients who MAY be hospice appropriate 3 screening questions about care goals, needs, and preferences to determine if they ARE hospice appropriate from a goals/needs/preferences standpoint
- After delivery of the 3 screening questions, physician notified of “results” of screening and asked to approve a referral to hospice if physician certifies patient has prognosis of 6 months or less

Procedures
Step 1a: patient eligibility criteria

- Which HH patients should be screened as potentially appropriate for hospice? (shouldn’t screen all like in NH)
  - By diagnosis (CHF, COPD, HIV/AIDS, Cancer, ESRD, Dementia)
  - Bridge patients
  - “high risk” patients (fragile patients, patients w/poor prognosis, high risk of hospitalization, multiple co-morbidities)
  - Patients above a certain age (say 90 years old)
  - Patients who have voiced preference for hospice/palliative services
  - Clinician judgment
- Why?
  - Why did you choose these groups? What was your thinking process?

Step 1b: finding eligible patients

- How?
  - Chart review?
  - Which of our criteria from Step 1a are in the chart?
- By whom?
  - Admitting clinician (nurse or therapist)
  - Case manager
  - Liaison
- When?
  - On admission
  - Follow-up visits
- Notification of team that pt eligible to be asked 3 screening questions
  - Email, phone, fax, follow-up meeting
Step 2: Invite eligible participants

- In original Casarett study, patients were formally invited via a letter
- Consensus from this group to eliminate this step
  - Why?
- Verbal lead-in to the 3-screening question conversation will serve as “notification”

Step 3: Determine Cognitive Status of Patient

- In original Casarett intervention, used MMSE
- Consensus from this group to use OASIS Item M1700 (cognitive functioning) instead
  - Why?
- Consensus to continue to determine cognitive status of patient prior to asking 3-screening question during pilot test and “in real life”
  - Why?
- Who?
  - (if admitting clinician ultimately asking 3-screening questions) Admitting clinician via chart review or real-time data collection
  - Nurse in office reviewing chart
Step 4: contact patient/surrogate to ask 3-screening questions

• When?
  • As part of normal visit (either admission visit or follow-up visit)
  • Separate telephone call
  • Pros/cons of each?

• How?
  • Moot point if done during normal visit; would be in-person
  • If separate telephone call, done via phone

• By whom?
  • By visiting/admitting clinician if done during visit
  • Who would do if via phone call?

Step 4: contact patient/surrogate to ask 3-screening questions

• Who is caregiver?
  • HCPOA; if no HCPOA, then next of kin; if no HCPOA or next of kin, then friend
  • What about paid caregiver?
  • Note that if patient too cognitively impaired, then caregiver would be present at admission visit and all subsequent visits, so no separate process needed to contact caregiver
Step 5: consent patient/caregiver for asking 3-screening questions

• Who should get consent from patient/caregiver?
  • Whoever is asking the 3 screening questions (admitting clinician)

• Continue getting consent “in real life”?
  • Mix of yes’s/no’s
  • Why did you answer the way you did?

Step 6: Deliver 3 screening questions

• Who?
  • Admitting clinician
  • Is any admitting clinician qualified to deliver q’s? (SN, PT, SW?)

• When?
  • At initial visit

• Re-assessment: range of ideas
  • If patient diagnosed with a terminal illness
  • At OASIS timepoints
  • When changes occur
    • What constitutes a “change”
Step 7: Repeat back results of 3-question screening to patient/caregiver

- 2 options:
  - By same person asking questions immediately following questions — allows for patients own words to be associated with interviews
  - Later by case manager — at admission, it can be difficult to initiate a conversation about hospice or “additional services”, so screening could be done on admission, but it may be that the case manager following-up would have the conversation with the patient/caregiver

Step 8: Get HIPAA permission to review records and provide patient/caregiver with debrief sheet

- This is a step needed only for the pilot test per IRB
- Would not be needed in “real life”
- When to give to patient/caregiver during pilot?
Step 9: Follow-up with physician as necessary

- **Who?**
  - Same person that asked 3 screening questions
  - Administrative staff member
- **How?**
  - Depends on how physician likes to be communicated with (some won't give verbal orders); clinician makes contact via phone and then fax if requested
  - Start with phone call and follow-up with fax or message portal
  - Phone calls are often triaged and would be least effective
- **When?**
- **Multiple contacts for non-responders?**
  - Via phone or fax until verbal is received
  - Start with phone call and follow-up with fax or message portal
  - 2 or 3 re-attempts maximum
- **Additional info**
  - Close the loop and let physician know of “final outcome” (did pt ultimately enroll in hospice/not)

---

Step 10: contact hospice

- **Several ideas:**
  - HH clinician contact hospice via phone
  - If patient in a facility, facility has to initiate hospice order – HH staff would contact facility to see if order has been received or PR makes contact with the facility to get order
  - Order could be obtained verbally or written; if response is sent to physician in EMR or faxed, it can include a separate space for orders to be written
Step 11*: hospice visit

- Not part of original Casarett protocol, but good to discuss
- Have hospice nurse visit with HH nurse, if able. If not, have hospice contact patient to discuss/schedule visit.

Review
Scripts

Appendix A and B

• MMSE
• Attempts script
  • Both of these are N/A; consensus not to use
Appendix C: consent

- No edits to script
- Allow staff to tailor, if they want?
- Keep as-is for “in real life”?  

Our home health agency is participating in a research initiative to help us better address our patients’ care needs. As part of this effort, we are asking our patients questions about their care goals, care preferences, and care needs. Knowing more about your care goals, needs, and preferences will help us ensure you receive all care and services that you may benefit from. It will also help us make sure the care we deliver aligns with your wants and needs.

Answering the questions will take about 5-10 minutes and your responses would be confidential. If you’ve never had a conversation with your healthcare provider about your care goals, preferences, and needs, then some of these questions may seem a bit strange, or you may not know the answer to some of the questions, and that’s OK. You can skip over any question or stop responding to the questions at any time.

Would you be willing to answer a few questions about your care goals, preferences, and needs? (If yes, proceed with asking 3 question hospice appropriateness screener; if no, thank participant and end the conversation.)

- Need to keep yellow parts for “in real life”?
- Need to document affirmation of verbal consent “in real life”? 
Appendix D: 3-screening questions

- No edits to intro
- General consensus that verbal easier with written available, if needed. And that verbal vs written will depend on cognitive status of pt/caregiver. If written, have pt/cg circle responses.
  - When would you need written instead of verbal?

Appendix D: 3 screening questions
Domain 1 – symptom and service needs

- Need to ask all questions?
  - Important to have comprehensive picture, but it is long
  - Don’t need to ask all of them
- Need Y/N and frequency?
  - Y/N not sufficient
  - To cut down, could modify wording (see next slide)
Modified symptom wording:

<table>
<thead>
<tr>
<th>During the past week, have you/your family member been feeling sad?</th>
<th>How often has you/your family member been feeling sad?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes</td>
<td>1 Rarely</td>
</tr>
<tr>
<td>□ No</td>
<td>2 Occasionally</td>
</tr>
<tr>
<td></td>
<td>3 Frequently</td>
</tr>
<tr>
<td></td>
<td>4 Almost constantly</td>
</tr>
<tr>
<td></td>
<td>9 Don't know</td>
</tr>
</tbody>
</table>

Have you/your family member been feeling sad?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
<td>Almost constantly</td>
<td>Don't know</td>
</tr>
</tbody>
</table>

Service needs

• Need to explain what each discipline does?
  • I often encounter that when I ask if a patient would agree to other disciplines outside of nursing or aide that they are often declined. But if I am able to explain the role of the social worker, chaplain, bereavement counselor they have a better understanding of the roles of each team member and are in more agreement to including them in their plan of care. I think that this too may be an issue in this setting.
Appendix D: 3 screening questions
Domain 2 – Care Goals

• From SUPPORT study
• Consensus of no proposed changes to wording of question
• In Casarett original intervention, if caregiver was responding, were asked 2 questions – best interests and substituted judgement. Do we need both?
  • Consensus to ask just 1 (both may get confusing)
  • On which to ask – “If they are responding as a surrogate for the patient then it should be as the patient would respond” (substituted judgement)

Appendix D: 3 screening questions
Domain 3 – Care Preferences

• Are CPR and vent the right preferences?
  • Patient should have the right to choose their on EOL measures
  • CPR or vent should not be a barrier to a patient getting admitted to hospice; this could be a conversation with the hospice team as the patient is more imminent.
  • Vent patients would need to have a timeframe for withdrawal, but this should not be a barrier to receiving hospice services
• Does asking about these imply that if you say “yes” you can’t get hospice? Or does it just mean it shouldn’t count as a “negative” screen?
Appendix E: Results of 3 question screening

| Domain 1 – symptom and service needs: Did respondent have at least ONE symptom or service need? | ☐ Yes □ No |
| Domain 2 – care goals: | ☐ Yes □ No |
| • If patient is respondent – did patient answer “palliative care” for the care goals question? | |
| • If caregiver is respondent - did caregiver “palliative care” for BOTH care goals questions (substituted judgement and best interest)? | |
| Did respondent answer “no” to both the CPR and Vent questions? | ☐ Yes □ No |
| Add up “Yes’s” in the right column: | _______ total number of yes’s (1-3) |

To answer yes:
• Just 1 symptom/service need – but knowing distress/bother helps ascertain need for hospice
• Answer yes to palliative care potion for domain 2
• What to do with domain 3?

Appendix E: Results of 3 question screening

• What counts as a positive screen?
  • 2/3 and CPR/vent is a bonus
  • 1/3
Appendix E: Results of 3 question screening

• For people that screen positive
  • You said that [you/your family member] had some additional symptom and service needs, and had care goals and preferences aligned with maximizing comfort and focusing on quality of life. Based on these responses, there may be some additional services [you/your family member] may benefit from. These additional services specialize in symptom management and psychological and spiritual service needs, as well as maximizing comfort and quality of life.
  • These extra services are available to you through hospice. Have you ever heard of hospice? [If yes] what do you know about it?
  • [Explain a little about what hospice does] Do we need to elaborate more here? One vote for no, that this is generic enough for HH clinician and hospice team will give further detail if needed.
  • I don’t know whether hospice is the right decision for [you/your family member] right now. That’s up to [your/your family member’s] doctor. If it’s OK with you, I’ll let [your/your family member’s] doctor know that we had this conversation so that they can give [you/your family member] more information and so they can tell [you/your family member] whether you should think about hospice now. Is that OK? [Y/N]

• For people that screen negative:
  • Thanks for taking time to tell me more about your care goals and needs. Now we have a better understanding of what you want and what additional services you may be able to benefit from in the future. I’ll make a note of this in your chart and may ask you about your care goals, needs, and preferences again in the future, in case your needs change.

• What do you like/not like about how this is presented to the patient?

---

Appendix E: Results of 3 question screening

• “Typically when I introduce the hospice subject, I have start with the physician has reached out to our group because it was identified that you may need some additional support for your healthcare needs...despite everything that is being done to medically manage your health, he/she feels that you are continuing to have some decline. Your doctor has asked that we evaluate you for our services under the hospice benefit. What is your understanding of hospice? This is used to understand their baseline understanding of hospice care, any barriers or myths that will need to be addressed prior to explaining the election of hospice”
  • Should the HH clinician do some of this as part of presenting results of screening? Or better done by hospice team?
Appendix F: HIPAA form and Debrief sheets

• No comment

Any add’l thoughts?

• Any major barriers to piloting?
• Or doing this “in real life”?
Additional File 3: Adapted Casarett Intervention to Improve Timeliness of Hospice Referrals for Home Health Patients

This protocol is an adapted protocol from an intervention conducted by Casarett et al. in the nursing home setting in 2005. The protocol has been adapted for the home health setting, with input from home health & hospice agencies.

Overview of the intervention:

Overall, this intervention seeks to improve timeliness of referrals to hospice for the target population (now home health patients). The intervention is a screening intervention where eligible patients are asked questions about 3 domains: 1) symptom/service needs 2) care goals 3) care preferences. Based on the results of the screening (i.e., if the patient screened positive by stating they had symptom/service needs and that their care goals/preferences aligned with a palliative approach), the patient is asked to give permission for the physician to be contacted to authorize a referral to hospice, if appropriate. The physician is then contacted, notified of the screening results, and asked to certify if the patient has a prognosis of 6 months or less; if the patient does, a hospice order is initiated.

About this protocol:

This protocol outlines the main activities of the intervention step-by-step. For each step, procedures are outlined, as well as areas where home health & hospice agencies can tailor the intervention to suit their needs. Also noted are areas where it is NOT recommended that you tailor/change the intervention protocol. In these areas, changing the intervention protocol may compromise the effectiveness of the intervention.

Each step is accompanied by a worksheet to help you work through and document the decisions you make about how you may tailor this intervention to implement it successfully at your hospice. It is recommended that you complete these worksheets.

Potential Process for Implementing this intervention/protocol:

- Review this protocol – decide if you want to implement the intervention
- Notify/recruit appropriate staff – gather the staff necessary to implement and carry out the intervention. Also notify staff at your agency who may not be directly involved, but should know that your agency is implementing the intervention (e.g., marketing staff).
- Work with appropriate staff to review this protocol and complete worksheets
- Based on worksheet responses, make the necessary procedural/systems changes (e.g., updating SoPs, updating EMR or documentation systems, updating clinical workflows)
- Train staff on intervention
- Conducting monitoring to ensure implementation is going well
- Modify processes as necessary – update your processes as needed, based on monitoring activities
- Track outcomes to see if this intervention is making a difference
## STEP 1: DETERMINE PATIENT ELIGIBILITY CRITERIA AND HOW ELIGIBLE PATIENTS WILL BE IDENTIFIED

### Purpose of Step 1:

Not all home health patients will be appropriate to receive the hospice screener (e.g., would not be appropriate to screen patients who are on home health because of an acute injury, have no other co-morbidities/frailties, and are expected to make a full recovery). Thus, the purpose of this step is to determine and identify which home health patients may be eligible for the hospice screener.

### Procedures for Step 1:

**Step 1a. Define eligible patients.** In general, eligible patients would be those that are in some way “high-risk” or “frail”. There are many ways to define high risk or frail patients (see list below). To minimize burden, you could define your criteria using existing data fields/sources (e.g., OASIS data or existing clinical chart data fields). Choose at least one standardized criterion from the list below (or another criterion you create) – do not leave patient eligibility up to clinical judgement alone. **Although clinical judgement is important in interpreting data to determine whether a patient may truly be eligible or not, allowing eligibility to be determined solely based on clinical judgement is not recommended as it may result in potentially eligible patients falling through the cracks.**

<table>
<thead>
<tr>
<th>By diagnosis (e.g., CHF, COPD, HIV/AIDS, Cancer, ESRD, dementia)</th>
<th>Patients who have voiced a preference for hospice/palliative services</th>
<th>Patients with multiple co-morbidities</th>
<th>Patients with a poor prognosis (could use OASIS M1034 Overall status, including those who are marked as fragile with serious risk of complications/death or death in 1 year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bridge patients</td>
<td>Patients with a life expectancy less than 1 year</td>
<td>Patients with a high risk of hospitalization (could use OASIS M1033 including those at high risk)</td>
<td>Patients above a certain age (e.g., &gt;90)</td>
</tr>
</tbody>
</table>

**Step 1b. Identifying eligible patients.** Your home health agency may have procedures in place already for identifying high-risk patients as you’ve defined them above. If so, you use these procedures to make use of existing clinical workflows. For example, some software systems (like SHP) analyze OASIS data on diagnosis, re-hospitalization risk, and ADLs and will flag patients who are at risk and may benefit from hospice services. Other home health agencies may already have standardized procedures for identifying “bridge patients” or “fragile” consults; these procedures could be used for identifying eligible patients for the hospice screen. At a minimum, your process for identifying eligible patients should include: 1) how patients will be identified (chart review or other data source); 2) who will identify and flag eligible patients; 3) when eligibility will be defined (on admission, at re-certification, after a major change in status; at all OASIS timepoints); 4) how will the appropriate party be notified that a patient is eligible.
**Worksheet For Step 1:**

What eligibility criteria are you going to use (you should have at least 1 standardized criterion, beyond clinical judgement)

<table>
<thead>
<tr>
<th>Eligibility criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

How will you find eligible patients?

<table>
<thead>
<tr>
<th>How patients will be identified (e.g., existing data items; new data collection)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Who will identify and flag patients (e.g., admitting clinician, marketing liaison at initial consult, case manager, office staff)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>When will patients be identified (e.g., on admission, at re-cert, after a major change in status)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How will appropriate party be notified that patient is eligible (e.g., note in chart; telephone call; message in EMR portal)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
STEP 2: ASSESS COGNITIVE STATUS OF ELIGIBLE PATIENTS and IDENTIFY APPROPRIATE PROXY, AS-NEEDED

Purpose of Step 2:
This intervention screens patients for hospice appropriateness by asking them questions about their care goals, needs, and preferences. If the patient is cognitively impaired, they will not be able to respond themselves and will need to have a proxy/caregiver respond. Thus, assessing the cognitive status of the patient will inform who the respondent for the screening questions will be. If the patient is cognitively impaired, you will need to identify who the appropriate proxy is.

Procedures for Step 2:

Step 2a. Determine cognitive status of patient: Use OASIS item M1700. Cognitive Functioning. Patients scoring a 0 or 1 will be considered to have no cognitive impairment and could respond to the screening questions themselves. Patients scoring 2-4 have moderate-severe cognitive impairment and would need to have a proxy respond to the screening questions. Patients must be screened for cognitive status as cognitively impaired patients will not be able to participate in the main activity of the intervention (responding to the 3 hospice appropriateness screening questions). If you do not wish to use the OASIS item for whatever reason, develop your own process for determining cognitive status of the patient.

FOR UNC PILOT TEST ONLY: I proposed to use the OASIS item with the scoring cutoffs above, so we must use that or amend the IRB application.

Step 2b. For cognitively impaired patients, determine appropriate proxy: if the patient is cognitively impaired, determine the appropriate proxy. The proxy should ideally be the HC POA, but if that person is not available, below are other choices for appropriate proxy. The first/second/third/fourth choice for appropriate proxy noted below is a suggestion; your agency’s preferred order may depend on state law and may vary from patient-to-patient, depending on who knows the patient best (e.g., in some instances, HC POA may be a daughter in a different state but the paid caregiver has been with the patient for a considerable length of time and may understand patient’s needs, goals, and preferences better).

- First choice: HC POA/legally authorized representative
- Second choice: next of kin
- Third choice: friend
- Fourth choice: paid caregiver (if caregiver knows the patient well enough to know their care needs and/or preferences)
FOR UNC PILOT TEST ONLY: per IRB requirements, if patient is cognitively impaired, I proposed to use the legally authorized representative (LAR). So we must use that or amend the IRB application. Here’s specifically what I said:
Decisionally impaired participants will have a legally authorized representative (LAR) who is willing and able to provide proxy consent on behalf of the person with the advanced life-limiting illness. The study follows the informed consent laws applicable to clinical care in North Carolina, identifying the person who has the highest level of legal decision-making authority. The person identified in the medical record with the highest level of legal decision-making authority will be the person who will authorize the patient's participation in the study. The consent will be obtained for the patient subject at the baseline interview to protect the subject.

Worksheet for Step 2:

How will you determine cognitive status of patient? (suggested: OASIS M1700)

For cognitively impaired patients, what is your preferred hierarchy for proxy? (suggested: HC POA, next of kin, friend, paid caregiver)

Any special notes about laws in your state or how to determine who may be most appropriate on a patient-by-patient basis?
STEP 3: DELIVER CARE GOALS, PREFERENCES, AND NEEDS SCREENING QUESTIONS

Purpose of Step 3:

Often, a clinician will identify using their own clinical judgement that a patient may be appropriate for hospice. Despite their clinical intuition, however, the “hospice conversation” often gets delayed in practice because the clinician doesn’t know how to start the conversation or broach the subject in a comfortable way. Re-framing the “hospice conversation” entirely was shown an effective way of overcoming this barrier in the original Casarett intervention. Re-framing the conversation as a conversation about care goals, needs, and preferences increases the clinician’s comfort in starting/having the conversation by removing “hospice” from the conversation. In this sense, we are still able to identify patients who are appropriate for hospice, but in a non-threatening way. The topic is introduced and discussion centers on care goals, needs, and preferences apart from hospice.

Procedures for Step 3:

Step 3a. Determine procedures for the screening conversation: First, your agency will need to determine the process for how these screening conversations will occur. This includes deciding who from the care team will deliver the screening, and when. You want to develop a procedure that is flexible enough to allow for individual patient situations, but rigid enough that responsibility is not overly diffused, causing patients to slip through the cracks. A suggested process is below, but you could modify this based on your agency’s needs.

- **Who:** admitting clinician introduces the screening conversation and starts asking the screening questions, getting through as much as they’re able. If admitting clinician unable to get through all screening questions due to time constraints or other patient factors (patient not comfortable with conversation), the next clinician in to see the patient attempts to finish the conversation.
- **When:** introduce the conversation and start the screening questions. Attempt to ask all questions at initial visit. If not all screening questions are asked at initial visit, ask all remaining questions during next 3 visits or within the first week of care, whichever comes first.
- **Mode:** suggested to introduce the conversation and ask the screening questions in person, to build trust. Additionally, older patients may not feel comfortable doing this over the phone.
- **Documentation:** you may wish to build the screening questions into existing clinical workflows (EMRs, assessment forms), or keep them separate (e.g., on paper)
- **Responsibility:** Although the conversation may be had by someone other than the case manager, ultimately, assign the responsibility for the screening questions getting asked to the case manager. At the end of 3 visits/1 week, it would be the case manager’s responsibility to ensure all questions were asked.

Step 3b. introduce the conversation: The person identified in Step 3a will introduce the conversation. A suggested script for introducing the conversation has been provided in Appendix A. Your agency may modify the script to suit your needs. The script may be helpful as you’re first implementing the intervention, and may prove less important over time as clinicians get comfortable/used to having these conversations. **If you modify the script, do not re-frame the introduction of the conversation to say you are screening patients for hospice.** It’s important to keep the introduction “hospice neutral” and focus on more general aspects of care (discussing care goals, needs, and preferences) to maintain clinician and patient comfort with initiating and having this screening conversation.
FOR UNC PILOT TEST ONLY: here is when you will need to get verbal consent from the patient/proxy. I have IRB approval to get verbal consent and I also have IRB approval to frame the conversation as I have in the script (a conversation about care goals, needs, and preferences). Because this script is part of what I turned in to the IRB, do not modify the wording of the scripted consent.

**Step 3c. Ask screening questions:** The person(s) identified in Step 3a will deliver the care goals, needs, and preferences screening questions. The questions are provided in Appendix B. You may modify the wording of questions as appropriate for your agency. **You may modify the number of questions, but eliminate questions with caution.** Although asking more questions increases burden, it helps provide the most comprehensive picture of the patient’s care goals, needs, and preferences. If you change the wording/number of questions, you want to make sure you maintain a comprehensive set of questions that aligns with the services hospice provides and the goals of hospice care. That way, when you feed the results of the screening back to the patient, you can say “you said you want xyz – xyz is what hospice does”. In short, you will ask questions for the following care domains:

1. Symptom and Service Needs: 4 psychological symptoms; 6 physical symptoms; 8 service needs
2. Care Goals: 1 situational based question about whether your care goals focus on extending life or palliation to maximize QoL
3. Care Preferences: care preferences for CPR and mechanical ventilation

**Step 3d. Record answers to screening questions:** Somehow, you will need to record the patient or proxy’s answers to the screening questions. This could be done by building the screening questions (and a way to document responses) into existing EMRs or assessment forms, or could be done via a separate documentation process (separate paper form).

**Worksheet for Step 3.**

3a. **What will be your procedures for introducing and delivering the screening questions?** (see above for suggested process)

<table>
<thead>
<tr>
<th>Who will introduce conversation and who will delivery screening questions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>When will the conversation be introduced and when will the questions be asked?</td>
</tr>
<tr>
<td>What mode will you use (telephone, in person)?</td>
</tr>
<tr>
<td>Where will the questions be housed (e.g., build into EMR/existing assessment form, keep separate)</td>
</tr>
</tbody>
</table>
Who will ultimately be responsible for ensuring all questions are asked within specified timeframe:

3b. Introduce the screening conversation

✓ Review the script in Appendix A
✓ Decide if you want to modify it. If you do, mark-up the script.
✓ Be sure NOT to change the frame of the conversation (i.e., don’t introduce it as a screening for hospice).

3c. Screening questions

✓ Review the questions provided in Appendix B
✓ Decide if you want to modify it the wording of the questions. If you do, mark-up the script.
✓ Decide if you want to change the number/type of questions asked. If you do, be sure that you have enough questions that you feel comprehensively describe hospice’s services and goals.

3d. Document answers to screening questions

How will you document responses to screening questions (e.g., build fields into EMR or existing assessment form; create separate documentation workflow)
STEP 4: SCORE RESULTS OF SCREEN TO DETERMINE IF PATIENT APPROPRIATE FOR HOSPICE

Purpose of Step 4:
Scoring the results of the screening ultimately determines which patients are potentially appropriate for hospice – and thus which patients will go on to receive physician follow-up and, potentially, a referral to hospice.

Procedures for Step 4:
The scoring sheet for the screening is presented in Appendix C. You’ll need to determine:

- **Who will complete the scoring sheet:** will this be completed by the same person asking the screening questions? the person who asks the last screening question? The case manager?
- **What constitutes a “positive” screen:** it is recommended that a positive screen be defined as a patient having at least 1 of the following:
  - At least 1 symptom or service need
  - Care goals aligned with palliation
  - Preference to not have CPR or mechanical ventilation
You may decide a higher threshold is right for your agency, but know that the higher the threshold, the fewer patients that will receive follow-up with their physician and a possible referral. **It is NOT recommended that you require a preference to NOT have CPR/vent in order to screen positive. This is because you do not have to refuse CPR/vent to be admitted to hospice; all patients – including those on hospice – should have the right to choose their preference for life-sustaining treatment. As such, your threshold for a positive screen should not be 3/3.**
- **Documentation:** your agency will need to determine how you’ll document the results of the screening. You may choose to build the scoring sheet into existing EMR or assessment forms or keep the documentation separate.
- **Notification to care team of patients who screen positive:** Your agency will need to determine how you’ll notify the appropriate care team member(s) that the patient screened positive. This could be via phone call, note in the EMR portal, etc.

Worksheet for Step 4:

<table>
<thead>
<tr>
<th>Who will complete scoring sheet?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>What is the threshold for a positive screen (1/3 suggested; do NOT recommend 3/3)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>How will you document scoring? (e.g., build scoring sheet into EMR; separate system)</th>
</tr>
</thead>
<tbody>
<tr>
<td>How will you notify the appropriate member(s) of the care team that a patient screened positive?</td>
</tr>
</tbody>
</table>
**STEP 5: REPORT “RESULTS” OF SCREENING TO PATIENT OR PROXY**

**Purpose of Step 5:**

Reporting the results of the screening back to the patient allows you to eventually introduce hospice in a non-threatening (less threatening) way. In this intervention, hospice is introduced as a response to the patient’s self-expressed needs and goals – not because something is “wrong” or “imminent”. Reporting the results of the screen back to the patient (e.g., “you said that you’re having trouble with pain and SOB, that you could use some more aide services, and that your care goals are focused on comfort”) allows the clinician to naturally introduce hospice (“did you know there’s an extra set of services available to you that specializes in symptom management and comfort…it’s called hospice”). This keeps the conversation “neutral” – again – you’re not leading with hospice; you’re repeating back the patient’s needs and goals and then offering a potential solution to those needs/goals (hospice).

**Procedures for Step 5:**

After the screening questions have been scored, you will need to notify patients of the “results” of their screen and ultimately, introduce hospice as appropriate. You will need to consider several factors, and some suggested processes and procedures are outlined below.

- **Who:** It is suggested that the case manager be the staff member to report the results back to the patient and introduce the notion of hospice, if applicable. Even if the case manager is not the staff member who asked the screening questions, they may be best to report back the results because this is the home health clinician the patient will build a relationship with throughout their stay. You may change this process to suit the needs of your agency, but do so with caution.

- **When:** It is suggested that the report back occur at a visit other than the admission visit. It also allows the introduction of hospice as a solution to the patient’s needs/wants to happen at a visit other than the hectic, busy admission visit, where the patient and family may be overwhelmed and not receptive to this conversation. You may change this process to suit the needs of your agency, but do so with caution.

- **To whom:** It is suggested that you report the results back to patients who screen positive and negative. It is recommended that you also report results back to patients that screen negative to familiarize the notion of hospice early – even if they’re not appropriate now, you can let them know hospice is an option and available to them at any time if their needs/preferences change. You may change this process to suit the needs of your agency, but do so with caution.

A script to report back the results of the screen is provided in Appendix D. You may modify this script to suit the needs of your hospice, but, for patients that have screened positive, you should always start this part of the conversation by reporting back what you heard from the patient (e.g., “you said that you’re having trouble with pain and SOB, that you could use some more aide services, and that your care goals are focused on comfort”) and you should present hospice as a solution to those identified goals/needs. Do not lead this portion of the conversation by stating something like “we think it might be time to consider hospice”. Part of the script is getting permission from the patient/proxy to contact the physician. It is suggested that this be maintained, though you could modify the wording of how you ask for permission.
### Worksheet for Step 5:

#### Procedures:

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who will report the results of the screening back to patient/proxy</td>
<td></td>
</tr>
<tr>
<td>(case manager suggested)?</td>
<td></td>
</tr>
<tr>
<td>When will the results be presented (at a visit other than the initial</td>
<td></td>
</tr>
<tr>
<td>admission visit suggested)?</td>
<td></td>
</tr>
<tr>
<td>Will you report results to those that screen positive only? Or those</td>
<td></td>
</tr>
<tr>
<td>that screen positive and negative? (both are suggested)</td>
<td></td>
</tr>
</tbody>
</table>

#### Script:

- Review the script in Appendix D
- Decide if you want to modify it. If you do, mark-up the script.

FOR UNC PILOT TEST ONLY: After you discuss the results of the screen, you’ll need to get the HIPAA authorization form (to review their clinical record for dates of hospice referral, date of election, and hospice LOS) and also provide the debrief sheet. These are provided in Appendix E.
**STEP 6: COMPLETE NECESSARY FOLLOW-UP WITH PHYSICIAN TO GET ORDER FOR HOSPICE**

**Purpose of Step 6:**

After the patient is notified of their results and agrees to have physician contacted, physician will need to be contacted to get an order for hospice, if patient is eligible. As such, step 6 initiates the formal referral to hospice.

**Procedures for Step 6:**

At this point, the intervention largely reverts back to usual care, so your agency should use whatever processes is normally used to initiate/receive an order for hospice from the patient’s physician.

**Worksheet for Step 6:**

Outline your usual care process for contacting physicians to get orders for hospice – note any changes you may need to make to this process for the purposes of this intervention.
Appendices -- Scripts and Tools

Appendix A: Introducing the screening conversation (For use in Step 3b)

Verbal consent for non-cognitively impaired patients – read the following to the patient:

Our home health agency is participating in a research initiative to help us better address our patients’ care needs. As part of this effort, we are asking our patients questions about their care goals, care preferences, and care needs. Knowing more about your care goals, needs, and preferences will help us ensure you receive all care and services that you may benefit from. It will also help us make sure the care we deliver aligns with your wants and needs.

Answering the questions will take about 5-10 minutes and your responses would be confidential. If you’ve never had a conversation with your healthcare provider about your care goals, preferences, and needs, then some of these questions may seem a bit strange, or you may not know the answer to some of the questions, and that’s OK. You can skip over any question or stop responding to the questions at any time.

Would you be willing to answer a few questions about your care goals, preferences, and needs?

(If yes, proceed with asking screening questions; if no, thank participant and end the conversation.)

Verbal consent for cognitively impaired patients – read the following to the identified proxy:

Our home health agency is participating in a research initiative to help us better address our patients’ care needs. As part of this effort, we are asking our patients questions about their care goals, care preferences, and care needs. Knowing more about your care goals, needs, and preferences will help us ensure you receive all care and services that you may benefit from. It will also help us make sure the care we deliver aligns with your wants and needs.

Since (patient name) is unable to respond to questions about their care goals, preferences and needs, as (patient name)’s surrogate decision maker, we would like to ask you these questions on behalf of (patient name). Answering the questions will take about 5-10 minutes and your responses would be confidential. If you’ve never had a conversation with your healthcare provider about (patient name)’s care goals, preferences, and needs, then some of these questions may seem a bit strange, or you may not know the answer to some of the questions, and that’s OK. You can skip over any question or stop responding to the questions at any time.

Would you be willing to answer a few questions about (patient name)’s care goals, preferences, and needs?

(If yes, proceed with asking screening questions; if no, thank participant and end the conversation.)
Appendix B: Hospice Appropriateness Screening Questions (for use in step 3c)

- Intro to screening questions Discussion
  - Thanks for being willing to answer a few questions about [you/your family member’s] care goals needs and preferences. Remember, I’m only asking these questions to better understand your goals and needs, not because I think anything is wrong.
  - If you’re not sure of how to answer a question or don’t want to answer it, just say “I don’t know” or “I would like to skip this question”.

DOMAIN 1: SYMPTOMS AND SERVICE NEEDS

- Symptoms:
  - First, let’s talk about symptoms that might be bothering [you/your family member].
  - (Ask about the following 4 psychological symptoms and record the respondent’s answer in the table)

<table>
<thead>
<tr>
<th>Have [you/family member] been feeling sad?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have [you/family member] been worrying?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have [you/family member] been feeling irritable?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Have [you/family member] been feeling nervous?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

- (Ask about the following 6 physical symptoms and record the respondent’s answer in the table)

<table>
<thead>
<tr>
<th>Has lack of appetite been distressing or bothering [you/family member]?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>Not at all</td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Has lack of energy been distressing or bothering [you/family member]?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>Not at all</td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Has pain been distressing or bothering [you/family member]?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>-----</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
</tr>
</tbody>
</table>

**Has drowsiness or confusion been distressing or bothering [you/family member]?**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
</tr>
<tr>
<td>Don’t know</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Has constipation been distressing or bothering [you/family member]?**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
</tr>
<tr>
<td>Don’t know</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Has dry mouth been distressing or bothering [you/family member]?**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
</tr>
<tr>
<td>Don’t know</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- So, in the past week, [you/your family member] has had some problems they could use some help with, like [READ SYMPTOMS IDENTIFIED ABOVE]

- **Service Needs**
  - (Ask questions about service needs and document answer)
  - Ok, next I’ll describe several services and I’ll ask you to tell me whether you think these services could help [you/your family member]
  - Would it help [you/your family member] to have an extra nurse who could help treat symptoms that have been bothering [you/him/her]?  
    - Yes
    - No
    - Unsure
  - Would it help [you/your family member] to have an extra doctor who could help treat symptoms that have been bothering [you/him/her]?  
    - Yes
    - No
    - Unsure
Would it help [you/your family member] to have an extra home health aide come in to give [you/him/her] more help with bathing dressing and eating?

☐ Yes
☐ No
☐ Unsure

Would it help [you/your family member] to have an extra social worker who could work with [you/him/her] to arrange [your/his/her] finances and insurance?

☐ Yes
☐ No
☐ Unsure

Would it help [you/your family member] to have an extra social worker or chaplain who could provide counseling and emotional support?

☐ Yes
☐ No
☐ Unsure

If [you/your family member] were to die, do you think it would be helpful for [family member] to have a bereavement counselor or support group?

☐ Yes
☐ No
☐ Unsure

Would it help [family member] to have an extra chaplain who could provide spiritual support?

☐ Yes
☐ No
☐ Unsure

Would it help [you/your family member] to have a volunteer who would visit and spend time with [you/him/her]?

☐ Yes
☐ No
☐ Unsure

So, you think [RESIDENT] might benefit from extra help from some of the services that hospice provides like [REPEAT CHOICES ABOVE]? Is that right?

(If family services (bereavement, clergy) mentioned): you also mentioned that you think [SURROGATE] might benefit from some of the services that hospice provides, like [REPEAT FAMILY SERVICES].
DOMAIN 2: CARE GOALS

- If interviewing patient, ask:
  - OK, now I’d like you to imagine that you had to make a decision right now about how your doctors should take care of you. If you had to make a decision right now, would you prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would you want a plan of care that focuses on relieving pain and discomfort as much as possible, even if that means not living has long?:
    - [ ] (Extending life): focus on keeping [him/her] comfortable as possible, or
    - [ ] (Palliative care): focus on helping [him/her] live as long as possible?
    - [ ] Don’t know

- If interviewing proxy, ask:
  - (Substituted Judgement): OK, now I’d like you to imagine that [your family member] had to make a decision right now about how [his/her] doctors should take care of [him/her]. If [he/she] had to make a decision right now, would [he/she] prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would [he/she] want a plan of care that focuses on relieving pain and discomfort as much as possible, even if that means not living has long?
    - [ ] If [your family member] had to make a decision right now, do you think [he/she] would want to:
      - [ ] (Extending life): focus on keeping [him/her] comfortable as possible, or
      - [ ] (Palliative care): focus on helping [him/her] live as long as possible?
      - [ ] Don’t know

(If they say both): OK, but if you had to choose just one, which would you choose? [READ OPTIONS AGAIN]
DOMAIN 3: CARE PREFERENCES

- Some people make plans about how they want their doctors to take care of them. So now, I’d like to talk about how [you/your family member] want [your/your family member’s] doctors to take care of [you/him/her].
  - **(CPR):** For example, if [YOUR/PATIENT’S] heart stops beating, do you want [his/her] doctors to try to restart it or not?
    - [ ] Yes
    - [ ] No
    - [ ] Unsure
  - **(Vent):** OK, if [YOU/PATIENT] isn’t able to breathe on [his/her] own, would you want [his/her] doctors to put [him/her] on a breathing machine?
    - [ ] Yes
    - [ ] No
    - [ ] Unsure
### Appendix C: Scoring Sheet for Screening Questions (for use in Step 4)

- **(Scoring: Record respondent’s answers below)**

<table>
<thead>
<tr>
<th>Domain 1 – symptom and service needs: Did respondent have at least ONE symptom or service need?</th>
<th>☐ Yes</th>
<th>☐ No</th>
</tr>
</thead>
</table>
| Domain 2 – care goals:  
  - If patient is respondent – did patient answer “palliative care” for the care goals question?  
  - If caregiver is respondent - did caregiver “palliative care” for BOTH care goals questions (substituted judgement and best interest)? | ☐ Yes | ☐ No |
| Did respondent answer “no” to both the CPR and Vent questions? | ☐ Yes | ☐ No |
| Add up “Yes’s” in the right column: if total score is 1 or greater, patient counts as “positive screen” | _____ total number of yes’s (1-3) |
Appendix D: presenting results to patient/proxy (for use in Step 5)

- (Discuss results of screening)

(For respondents that screen positive – total score of 1 or greater):

- You said that [you/your family member] had some additional symptom and service needs [INSERT SOME OF IDENTIFIED SYMPTOM/SERVICE NEEDS HERE], and/or had care goals and preferences aligned with maximizing comfort and focusing on quality of life. Based on these responses, there may be some additional services [you/your family member] may benefit from. These additional services specialize in symptom management and psychological and spiritual service needs, as well as maximizing comfort and quality of life.

- These extra services are available to you through hospice. Have you ever heard of hospice? [if yes] what do you know about it?

- Hospice is a philosophy of care that encompasses a care team to assist in the management of your quality of life. We recognize that everything that can be done medically to support you is being done, but you continue to have a decline in your health. The hospice team’s approach is through mind/body/spirit, and we support not only you but all your family during this. The hospice benefit covers having skilled nurses coming in for medication management, adjustment, and symptom management; a hospice aide that can assist with bathing and dressing; a social worker to assist with any community programs, end of life planning, and provide emotional support for you and your family. There are chaplain services available for spiritual support and volunteers can come for companionship or activities. Hospice covers the cost of hospice medications, medical equipment needs and respite for families that need a break from the caregiving responsibility.

- I don’t know whether hospice is the right decision for [you/your family member] right now. That’s up to [your/your family member’s] doctor. If it’s OK with you, I’ll let [your/your family member’s] doctor know that we had this conversation so that they can give [you/your family member] more information and so they can tell [you/your family member] whether you should think about hospice now. Is that OK?

  - Yes
  - No

(For respondents that screen negative – total score of 0):

- Thanks for taking time to tell me more about your care goals and needs. Now we have a better understanding of what you want and what additional services you may be able to benefit from in the future. I’ll make a note of this in your chart and may ask you about your care goals, needs, and preferences again in the future, in case your needs change.

- As your needs and goals change, you may be appropriate for hospice. Hospice is a service that specializes in symptom management, holistic care – including spiritual and psychosocial care, and focuses on maximizing your comfort and quality of life. We can discuss hospice as an option at any time, if you feel your needs and preferences change.
Appendix D: HIPAA and Debrief Sheet (for use in Step 8)

- **To all:** Before we stop, there’s just one more thing we’ll need from you. As part of the larger research initiative I mentioned earlier, we will need permission to look in [your/your family member’s] chart 3-4 times over the next 6 months to find out what sorts of choices you and [your/your family member’s] doctors make about [your/your family member’s] care. Will that be OK?
  - (If yes): that’s good, thanks. In order to do that, we’ll need your permission in writing. SO could you please sign this form. [give HIPAA form]

- **To all:** Finally, here is some additional information on the conversation we just had and how it fits into the larger research effort we’re a part of. Please follow-up with us or the contacts listed here if you have questions or concerns.

**Debrief form (to be given to all participants in writing)**

Earlier, you responded to some questions about your care goals, needs, and preferences. Your home health nurse mentioned that responding to these questions was part of a larger research effort our agency is participating in to make sure our patients have access to all services that they may benefit from. Specifically, we used your responses to these questions to determine if you may benefit from some additional services that hospice can provide.

We plan to ask these care goals, needs, and preferences questions of about 40 of our current and new patients. Pending the success of this initiative, we may integrate this into our standard care practices.

We appreciate your participation in this research initiative. All the information we received from you about your care goals, needs, and preferences is strictly confidential. The research team will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. In any reports or presentations about this study, there will be no way to identify individual participants.

The only risk to you might be if your identity were ever revealed. But the research team does not have access to your name or identity, so this cannot occur.

If you have questions about this research study, you can contact the principal investigator, Alexis Kirk, at 919-541-6021 with questions about the research study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

If you have any questions about hospice or would like to further discuss your care goals, needs, and preferences, please contact your home health nurse that provides care to you.
APPENDIX C: ADDITIONAL FILES AIM 2B

Additional File 1: Description of Intervention and Adaptations to move Intervention from Nursing Home to Home Health Setting

Description of the Intervention:

The following is a description of the original intervention developed by Casarett et al. to improve timeliness of referrals to hospice for nursing home residents.

The original intervention developed by Casarett et al. was primarily a screening and referral intervention that removed responsibility from the patient’s regular physician for screening and referring the patient to hospice. Main activities of the intervention are described in detail below. Note that in the original intervention, all activities were carried out by the randomized control trial study staff.

1. Screened all patients at participating nursing homes for ‘appropriateness’ for hospice. All nursing home residents were eligible for screening, except for those already on hospice.
2. Screening conducted via telephone or in-person by study staff using a 3-part screener, which included 2 questions on patient care goals and 1 question on symptom burden and service needs. Study staff would speak to the patient or patient’s caregiver (for cognitively impaired patients).
3. If patient screened ‘positive’ as appropriate for hospice care based on responses to all 3 screener questions, the following happened:
   a. Study staff told patient they screened positive, and said “looks like you might benefit from hospice, would it be OK for us to contact your physician about this?”
   b. Contacted physician to let them know the patient “screened positive”.
   c. Asked physician to certify if the patient had a prognosis of 6 months or less and, if so, whether nursing home staff should arrange a hospice educational visit.
4. If physician certified prognosis and authorized visit, study staff coordinated hospice referral and hospice initial educational visit.
5. Hospice staff made educational visit to verify eligibility and discuss election.

<table>
<thead>
<tr>
<th>Appropriateness for hospice care screener:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Care goals:</strong> Offer a choice between: 1) a course of treatment focused on extending life as much as possible, but with this course of treatment, you might have more pain and discomfort 2) a course of treatment that focuses on relieving pain and discomfort as much as possible, but with this treatment you might not live as long</td>
</tr>
</tbody>
</table>
| • **Care preferences:** Assess preference regarding CPR and mechanical ventilation
   o If couldn’t decide, preference for life sustaining treatments inferred |
| • **Care needs:** Assess care needs as noted below
   o Assess 10 needs for **symptom management** using global distress index of the Memorial Symptom Assessment Scale. Assessed: 1) pain 2) constipation 3) lack of appetite 4) lack of energy 5) drowsiness 6) dry mouth 7) feeling sad 8) worrying 9) feeling nervous 10) feeling anxious
   o Assess 8 needs for **palliative care services:** 1) additional nursing support 2) physician care focused on comfort 3) practical support with personal care needs 4) help with advance care planning 5) counseling and emotional support 6) bereavement support for family members 7)
Adaptations to move Intervention from Nursing Home to Home Health Setting:

The following adaptations were identified through engaging a stakeholder panel of 3 home health/hospice agencies in a Delphi approach. We engaged the stakeholder panel to identify context differences between nursing home and home health and to identify adaptations necessary to address those context discrepancies. Consensus was reached on all adaptations below.

<table>
<thead>
<tr>
<th>Adaptation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in overall target population and setting</td>
<td>Changed the setting/target population from nursing home to home health to improve the overall reach of the intervention. NH patients are a minority (19%) of all hospice patients, so adapting the intervention to home health will expand its potential reach.</td>
</tr>
<tr>
<td>Change in definition of eligible patients</td>
<td>In original intervention, all NH residents eligible for intervention; in the adapted intervention, only “high-risk” or “frail” HH patients are eligible. This avoids in appropriate screenings for hospice (e.g., a HH patient who is admitted to recover from a joint replacement and is otherwise healthy and expected to make a full recovery). In adapted intervention, exact definition for “high-risk” or “frail” was left eligible. Potential definitions were listed, but the protocol left it to the discretion of the organization to create their own definition for high risk or frail, provided the definition was based on at least one structured data element (i.e., it was not left solely to clinical judgement to determine high-risk or frail).</td>
</tr>
<tr>
<td>Change in delivery</td>
<td>In original intervention, all intervention activities carried out by RCT staff; in adapted intervention, activities will be carried out by HH staff. This is because it would not be feasible for a home health organization to hire a new staff member to complete these tasks). Responsible Party for specific activities noted below.</td>
</tr>
<tr>
<td>Change in process for how eligible patients will be identified</td>
<td>In original intervention, eligible patients were identified via chart review using explicit criteria; in adapted intervention, patients will be identified concurrent with care using at least 1 explicit criterion. Concurrent identification is less burdensome than chart review.</td>
</tr>
<tr>
<td>Change in determining cognitive status of patients (how)</td>
<td>In the intervention, you need to know cognitive status of the patient to determine if you should ask screening questions of patient or proxy. In original intervention, cognitive status was determined using MMSE; in adapted intervention, will be determined using an existing OASIS item (M1700 where a score of 2-4 indicates cognitive impairment). This decision was made because OASIS data collection is required for all HH patients, and the MMSE is not used in practice. So using an existing data item will reduce burden of data collection for the intervention.</td>
</tr>
<tr>
<td>Change in who delivers screening question</td>
<td>In original intervention, research assistant delivered screening questions. In the adapted intervention, a member of the patient’s home health clinical team will deliver the questions. It was left flexible in the intervention protocol which clinical team member could deliver the questions, as stakeholder panel members felt any clinical team member had the skills to deliver the intervention; this flexibility increases generalizability of the protocol by allowing home health agencies to select staff best suited to the task.</td>
</tr>
<tr>
<td>Change in when screening questions are delivered</td>
<td>In original intervention, all hospice appropriateness screening questions were asked in one sitting; in adapted intervention, the timing of the screening question delivery was left flexible. Organizations can ask the questions all at once or in multiple visits. The adapted protocol requires that all questions be asked within first 3 visits or the first week of care, whichever comes first. This adapted timing allows for flexibility at the patient-level (e.g., a patient may be in crisis or overwhelmed at the initial admission visit, so asking the questions to be asked over multiple visits is a better approach), while still maintain structure to help ensure questions are asked in a timely fashion.</td>
</tr>
<tr>
<td>Change in accountability/responsibility for asking questions</td>
<td>In original intervention, accountability for asking the questions appropriately was handled through the RCT protocol, as part of the research assistant’s job. In the adapted intervention, there will be no study staff, so the patient’s case manager responsible for ensuring 3 questions are asked within the 3 visit/1 week timeframe. This adaptation helps ensure questions will be asked in a timely fashion.</td>
</tr>
<tr>
<td>Change in the introduction of the screening conversation</td>
<td>Adapted the wording of how the screening questions conversation is introduced. In the adapted protocol, this portion of the script is now even more “hospice neutral” than in original intervention – there is more focus on care goals/needs/preferences and hospice is not mentioned at the outset. This adaptation strengthens one of the core components of the intervention – which is reframing the conversation.</td>
</tr>
<tr>
<td>Change in screening question content (care goals questions)</td>
<td>In the second domain of hospice appropriateness screening questions (care goals questions) we adapted the questions by removing one of the care goals SUPPORT questions. In the original script, if the respondent was a proxy, the proxy was asked 2 questions about the patient’s care goals – the question was the same, but one asked the proxy to respond based on what the proxy thinks is best (best interest), while the other asked the proxy to respond based on what the patient would want (substituted judgement). We eliminated the best interest question because the stakeholder panel felt a proxy should always be prompted to respond based on what the patient would want, not the course of action they (the proxy) think is best.</td>
</tr>
<tr>
<td>Change in screening question content (symptom questions)</td>
<td>We retained the content of all symptom burden questions; we adapted the structure of the questions to simplify them. Instead of asking 2 questions about each symptom (presence and severity/frequency), we simplified the wording to ascertain both concepts in 1 question (patient is asked to rate frequency/severity and “none” or “not at all” on the scales equate to symptom not present.</td>
</tr>
<tr>
<td>Change in definition of positive screen</td>
<td>In the original intervention, the patient had to score positive on all 3 domains of hospice appropriateness screening questions to be considered a “positive screen” overall and go on to initiate the hospice referral process. In the adapted intervention, we decreased the threshold to 1/3 to be considered positive overall. This is because stakeholder panel members felt strongly that preferences for CPR/ventilation should not impact whether you receive a referral for hospice, as patients are not required to have preferences against CPR/ventilation to elect hospice. In addition, stakeholder panel members thought patients could be hospice appropriate with just 1/3 domains identified, and that this lower threshold would serve the larger purpose of increasing referrals to hospice for appropriate patients.</td>
</tr>
<tr>
<td>Change in who reports results of screening back to patient</td>
<td>In original intervention, results of screening were reported back to patient/caregiver by the research assistant; in the adapted intervention, this will be done by case manager (even if case manager is not the staff member who asked the screening questions). Stakeholder panel members felt that having the case manager deliver the results (and broach hospice as appropriate) allows hospice to be introduced by someone the patient trusts (not a clinician the patient may only see 1 time, such as an admissions nurse).</td>
</tr>
<tr>
<td>Change in when screening results are reported back to patient</td>
<td>In the original intervention, results of the screening were reported back to the patient/caregiver directly after questions were asked; in the adapted intervention, this will be done at a subsequent visit (i.e., a visit other than the admission visit). This is because the admission visit is hectic and may not be a good time to introduce hospice if patient screened positive.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition and Examples</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of adaptation</td>
<td>• Content adaptations: changes made to the content of the intervention itself. Examples of content adaptations may include (but are not necessarily limited to):</td>
<td>Choose between content and delivery adaptation; in deciding between content vs delivery, consider whether you are changing something they do (content) or changing how/when/who does it/who they do it do (delivery)</td>
</tr>
<tr>
<td></td>
<td>o Tailoring/tweaking/refining: minor change to intervention that leaves all major intervention principles/components in tact to make intervention more appropriate, applicable (e.g., modifying language, cultural adaptations)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Changing: major change to intervention – still leaves core components intact, but is a larger change than just tweaking or refining (e.g., in a screening intervention, changing the definition of how a “positive” screen is defined)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Adding elements: adding additional materials/activities consistent with fundamentals of the intervention</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Removing elements: skipping intervention components or activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Shortening/condensing pacing/duration: a shorter duration or fewer sessions used to complete intervention</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Lengthening pacing/duration: a longer duration or more sessions used to complete intervention</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Substituting elements: a module or activity is replaced with something that is different in substance</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Re-ordering elements: modules or activities conducted in a different order.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Integrating another approach: intervention is used as starting point, but aspects of different approaches/interventions also used</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Integrating the intervention into another approach: another intervention is used as starting point, and elements of the intervention of interest are introduced</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Repeating elements: using an activity more than prescribed</td>
<td></td>
</tr>
</tbody>
</table>
- Loosening structure: elements intended to structure intervention sessions do not occur as prescribed
- Drift: departing from the intervention – not using intervention in a specific setting/context or stopping intervention

- Delivery (context in Stirman’s original framework): changes made to how the intervention is carried out. Examples of delivery adaptations may include (but are not necessarily limited to):
  - Format: changes made to channel of treatment delivery (e.g., one-on-one sessions now group sessions; in-person now via phone)
  - Setting: intervention being delivered in a different setting or location (e.g., from hospital to outpatient setting; at physician’s office to in-home)
  - Personnel: intervention being delivered by a person with different characteristics (physician to nurse)
  - Population: intervention designed for one target population now being delivered to another (from patients with depression to patients with anxiety)
  - Timing: changes made to when an element is delivered (e.g., deliver screening questions 3 days from admission instead of 5 days from admission). This is distinguished from the condensing pacing and lengthening pacing code above because those codes above are about condensing content into less time where this code would apply to situations where content remains the same, but when the content is delivered changes. So this code is more about timing whereas the other is about duration.
**Moore Classification System**

*Overall, the Moore classification system describes the context for the adaptation, including why the adaptation was made (i.e., reason for adaptation), which is our area of focus.*

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition and Examples</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Reason for adaptation (fit in Moore’s original framework) | Describes why the content/delivery adaptation was made:  
- **Philosophical:** the intervention did not align with the principles of the organization/provider (e.g., intervention as-is does not align with the organization’s views about causes of maladaptive behavior and how to address them). Also includes adaptations made for reasons of cultural fit – whether it be adaptations made to address cultural misfit of the intervention + target population or misfit of the intervention + culture of the organization implementing the intervention. Philosophical applies in situations where there is a divergency of beliefs (i.e., “we don’t believe what you believe”). In rare cases, it may apply to an extreme convergence in beliefs (i.e., “I agree with your beliefs so much, I want to change something to strengthen how the intervention operationalizes these values”)  
- **Context:** adaptations that address misfit between the way the intervention was designed and the context of where the intervention is being delivered. Adaptations made for reasons of contextual misfit would address discrepancies that may arise in delivery of the intervention. Philosophical has to do with values/culture/beliefs, whereas logistical/contextual has to do with other source of misfit besides values/culture/beliefs (e.g., misfit between EBI and workflows, structures, environment, staffing, volume of patients, time etc.)  
- **Buy-in:** adaptations that might be made to increase the likelihood that an intervention will be adopted. This code is distinguished from philosophical in that philosophical is “I don’t believe what you believe” where buy-in is “I believe what you believe, but I need to tweak something to increase buy-in for my context” | In most situations, we expect only 1 reason to apply, though in rare cases, both may apply.  
Further notes on distinguishing philosophical and context/logistical:  
- On the organizational side, philosophical has to do with values, culture, beliefs, not physical, structural, workflow aspects. So this method doesn’t align with our culture would be philosophical fit vs we don’t have an EMR and must use fax is contextual.  
- On the patient side, philosophical fit would have to do with values, views, beliefs or culture of the patients. So “this example is not culturally relevant for my patient population” would be philosophical (mis)fit, but “this patient...
| sub-group only comes to after-hours visits so I need to deliver the intervention after-hours instead of during business hours” would be contextual (logistical) (mis)fit |
**Proctor’s Intervention-Implementation Outcome Framework**

Proctor’s framework distinguishes between implementation and intervention outcomes, where implementation success is necessary but insufficient for achieving intervention success. This codebook has selected intervention and implementation effectiveness as the two outcomes of focus.

<table>
<thead>
<tr>
<th>Construct</th>
<th>Definition and Examples</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Adaptation likely to impact intervention or implementation effectiveness? | **Step 1:** Choose the type of effectiveness the adaptation is *most likely* to impact – intervention or implementation effectiveness. Respond Y/N as to whether the adaptation is hypothesized to have any effect/impact on intervention effectiveness.  
  - **Intervention effectiveness** is defined as: the ability of the intervention to produce desired outcomes, *regardless of the quality of implementation* (how consistently or how well the intervention is used). In other words, assuming perfect implementation, consider whether the adaptation is going to move the needle on your outcome of interest.  
  - **Implementation effectiveness** is defined as: whether the adaptation is likely to impact consistency and quality of targeted audience’s use of an intervention, irrespective of the effectiveness/efficacy of the intervention itself. Adaptations impact implementation effectiveness by working through implementation outcomes (e.g., feasibility, appropriateness, etc.) |
|                               | **Step 2:** state a rationale for your coding (i.e., your choice of intervention or implementation effectiveness) and specify how/why you expect the adaptation to impact intervention or implementation effectiveness. Because effectiveness is complex and you are trying to predict a hypothesized effect, specifying rationale may help elucidate mediators and multiple casual pathways of impact. It may also be helpful to consider the expected direction of the effect (positive, negative, neutral) in the rationale.  
  - Example: Because NH patients are a minority of all hospice patients, changing the target population and setting will impact implementation through penetration. This change will be positive because it will improve the reach of the intervention.  
  To aide in coding of this construct, it is recommended that coders specify the following prior to coding each adaptation:  
    - **Definition of intervention effectiveness:** although intervention effectiveness is broadly...  
                                                                 |                                                                                                                                                                                                                     | Intervention and implementation effectiveness are distinct in that intervention effectiveness is about how well the intervention works where implementation is about how well people use the intervention.  
                                                                                                                                                                                                                      | Direction of effect (positive, negative, neutral) irrelevant for this code.                                                                                                                                   |
defined as the ability of the intervention to produce the desired outcome (assuming perfect implementation), specifying the specific outcome of interest (e.g., reduction in A1C levels, reduction in ER wait time, increase of appropriate referrals) will aide in coding consistency and specificity
  o Example: for this intervention, we are defining intervention effectiveness as the change in rates of referrals to hospice (not other outcomes, like hospice election rates or length of stay in hospice)

  • **Referent point**: when hypothesizing the impact of the adaptation, it is important to specify the referent point for the adaptation. For example, are you trying to predict the effect of the adaptation compared to an earlier trial? Or are you trying to predict the effect of the adaptation over another alternative adaptation? Referent point is important because the direction/impact of the adaptation could vary based on what you’re comparing the adaptation to.
    o Example: Referent point: compared to leaving the intervention as-is (NH patients only), how will this adaptation impact effectiveness?

References to distribute to coders as part of coding exercise:

There are several references that will be helpful in completing coding. Some potential reference materials are listed below:

  • **Protocol of the intervention**: an understanding of the intervention overall will help coders in completing their coding
  
  • **Descriptions of the adaptations and why they were made**: a detailed description of each adaptation, and the reason why it was made, will help ensure accuracy and consistency in coding. The reason why it was made was critical for coding certain constructs (e.g., reason for adaptation from Moore’s framework, and impact on effectiveness outcomes)

  • **Listing and description of core components**: Core components are critical for determining certain constructs, including Moore’s valence criterion and intervention effectiveness.
  
  • **Measures for intervention effectiveness and referent point for each adaptation**: see “Adaptation likely to impact intervention or implementation effectiveness?” in codebook for more information
### APPENDIX D: ADDITIONAL FILES AIM 3

Additional File 1: Casarett Intervention Screening Questions

<table>
<thead>
<tr>
<th>Domain</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Needs</td>
<td>Asked about 2 types of care needs:</td>
</tr>
<tr>
<td></td>
<td>- Symptom burden:</td>
</tr>
<tr>
<td></td>
<td>o Physical symptom burden: pain, constipation, lack of appetite, lack of energy drowsiness, dry mouth</td>
</tr>
<tr>
<td></td>
<td>o Psychological symptom burden: feeling sad, worrying, feeling nervous, feeling anxious</td>
</tr>
<tr>
<td></td>
<td>- Service needs: additional nursing support, physician care focused on comfort, practical support with personal care needs, help with advance care planning, counseling and emotional support, bereavement support for family members, spiritual support, and visits from a volunteer to provide company</td>
</tr>
<tr>
<td></td>
<td>For each symptom, asked about presence/absence of symptom and its frequency/burden. For service needs, asked Y/N questions about whether the patient could use additional support.</td>
</tr>
<tr>
<td>Care Goals</td>
<td>Asked whether care goals were focused on maximizing quality of life or extending life</td>
</tr>
<tr>
<td>Care Preferences</td>
<td>Asked whether patient had preferences for or against:</td>
</tr>
<tr>
<td></td>
<td>- CPR if the patient’s heart stopped beating</td>
</tr>
<tr>
<td></td>
<td>- Mechanical ventilation if the patient wasn’t able to breathe on his/her own</td>
</tr>
</tbody>
</table>
Additional File 2: Hospice Appropriateness Screening Pilot Study Packet for Nurses

Overview of process/checklist for each patient:

For each patient determined eligible for the pilot:

✓ STEP 1: Determine their cognitive status using OASIS M1700 – if cognitively impaired, all consents and questions will be asked of proxy
✓ STEP 2: Read verbal consent to patient or proxy
✓ STEP 3: Ask hospice appropriateness screening questions (care goals, needs, and preferences questions) of patient or proxy
✓ STEP 4: Record responses to screening questions in this packet
✓ STEP 5: Score screening questions and report results back to patient or proxy
✓ STEP 6: Give patient or proxy debrief sheet

Note: Also included at the end of this packet is a leave-behind info sheet for patients who say they don’t want to answer now, but may want to answer later. If this happens, tear off the leave behind sheet and leave with patient.
STEP 1 - DETERMINE COGNITIVE STATUS OF PATIENT:

Through usual OASIS assessment processes, determine cognitive status of patient and enter the appropriate code in the item below.

<table>
<thead>
<tr>
<th>Enter Code</th>
<th>Cognitive Functioning: Patient's current (day of assessment) level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently.</td>
</tr>
<tr>
<td>1</td>
<td>Requires prompting (cuing, repetition, reminders) only under stressful or unfamiliar conditions.</td>
</tr>
<tr>
<td>2</td>
<td>Requires assistance and some direction in specific situations (for example, on all tasks involving shifting of attention) or consistently requires low stimulus environment due to distractibility.</td>
</tr>
<tr>
<td>3</td>
<td>Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time.</td>
</tr>
<tr>
<td>4</td>
<td>Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium.</td>
</tr>
</tbody>
</table>

- **If patient scores 0 or 1:**
  - Patient NOT cognitively impaired; proceed with consent and screening questions directly with patient
- **If patient scores 2, 3 or 4:**
  - Patient cognitively impaired; proceed with consent and screening questions with proxy
  - For pilot, proxy is defined as “The study follows the informed consent laws applicable to clinical care in North Carolina, identifying the person who has the highest level of legal decision-making authority. The person identified in the medical record with the highest level of legal decision-making authority will be the person who will authorize the patient's participation in the study.”
STEP 2: GET CONSENT FROM PATIENT OR PROXY

Verbal consent script for non-cognitively impaired patients – read the following to the patient:

Our home health agency is participating in an initiative to help us better address our patients’ care needs. As part of this effort, we are asking our patients questions about their care goals, care preferences, and care needs. Knowing more about your care goals, needs, and preferences will help us ensure you receive all care and services that you may benefit from. It will also help us make sure the care we deliver aligns with your wants and needs.

Answering the questions will take about 5-10 minutes and your responses would be confidential. If you’ve never had a conversation with your healthcare provider about your care goals, preferences, and needs, then some of these questions may seem a bit strange, or you may not know the answer to some of the questions, and that’s OK. You can skip over any question or stop responding to the questions at any time.

Would you be willing to answer a few questions about your care goals, preferences, and needs?

☐ Yes → proceed with Step 3 – asking hospice appropriateness screening questions
☐ No → thank participant and end pilot data collection/conversation
☐ Not now, but maybe later → thank participant and tear off “leave behind” sheet (page 9 of this document) to leave with patient

Verbal consent for cognitively impaired patients – read the following to the identified proxy:

Our home health agency is participating in an initiative to help us better address our patients’ care needs. As part of this effort, we are asking our patients questions about their care goals, care preferences, and care needs. Knowing more about your care goals, needs, and preferences will help us ensure you receive all care and services that you may benefit from. It will also help us make sure the care we deliver aligns with your wants and needs.

Since (patient name) is unable to respond to questions about their care goals, preferences and needs, as (patient name)’s surrogate decision maker, we would like to ask you these questions on behalf of (patient name). Answering the questions will take about 5-10 minutes and your responses would be confidential. If you’ve never had a conversation with your healthcare provider about (patient name)’s care goals, preferences, and needs, then some of these questions may seem a bit strange, or you may not know the answer to some of the questions, and that’s OK. You can skip over any question or stop responding to the questions at any time.

Would you be willing to answer a few questions about (patient name)’s care goals, preferences, and needs?

☐ Yes → proceed with Step 3 – asking hospice appropriateness screening questions
☐ No → thank participant and end pilot data collection/conversation
☐ Not now, but maybe later → thank participant and tear off “leave behind” sheet (page 9 of this document) to leave with patient
STEP 3 AND 4: ASK SCREENING QUESTIONS AND DOCUMENT RESPONSE TO QUESTIONS

Netsmart Patient Number: ___________ SOC Date: ______________Who responded (highlight one): pt or proxy

**Domain 1 – symptoms:**
Let’s talk about symptoms that might be bothering you/your family member. (Highlight the response)

<table>
<thead>
<tr>
<th>Have [you/family member] been feeling sad?</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
<td>Almost constantly</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Have [you/family member] been worrying?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>None</td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
<td>Almost constantly</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Have [you/family member] been feeling irritable?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>None</td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
<td>Almost constantly</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Have [you/family member] been feeling nervous?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>None</td>
<td>Rarely</td>
<td>Occasionally</td>
<td>Frequently</td>
<td>Almost constantly</td>
<td>Don’t know</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Has lack of appetite been distressing or bothering [you/family member]?</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Has lack of energy been distressing or bothering [you/family member]?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Has pain been distressing or bothering [you/family member]?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Has drowsiness or confusion been distressing or bothering [you/family member]?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
<td>Don’t know</td>
<td></td>
</tr>
<tr>
<td>Has constipation been distressing or bothering [you/family member]?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Not at all</td>
<td>A little bit</td>
<td>Somewhat</td>
<td>Quite a bit</td>
<td>Very Much</td>
<td>Don’t know</td>
<td></td>
</tr>
</tbody>
</table>

| Has dyspnea/shortness of breath been distressing or bothering [you/family member]? |
|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 9 |
| Not at all | A little bit | Somewhat | Quite a bit | Very Much | Don’t know |

| Has nausea been distressing or bothering [you/family member]? |
|---|---|---|---|---|---|
| 0 | 1 | 2 | 3 | 4 | 9 |
| Not at all | A little bit | Somewhat | Quite a bit | Very Much | Don’t know |
Domain 2: Service Needs

- Ok, next I’ll describe several services and I’ll ask you to tell me whether you think these services could help.
- Would it help to have an extra nurse who could help treat symptoms that have been bothering [you/him/her]?
  - Yes
  - No
  - Unsure
- Would it help to have an extra doctor who could help treat symptoms that have been bothering [you/him/her]?
  - Yes
  - No
  - Unsure
- Would it help to have an extra home health aide come in to give [you/him/her] more help with bathing dressing and eating?
  - Yes
  - No
  - Unsure
- Would it help to have an extra social worker who could work with [you/him/her] to arrange [your/his/her] finances and insurance?
  - Yes
  - No
  - Unsure
- Would it help to have an extra social worker or chaplain who could provide counseling and emotional support?
  - Yes
  - No
  - Unsure
- If [you/your family member] were to die, do you think it would be helpful for [family member] to have a bereavement counselor or support group?
  - Yes
  - No
  - Unsure
Would it help [family member] to have an extra chaplain who could provide spiritual support?

- Yes
- No
- Unsure

Would it help [you/your family member] to have a volunteer who would visit and spend time with [you/him/her]?

- Yes
- No
- Unsure

Domain 3: Care Goals

- If interviewing patient, ask the following (only read what is in italics):
  
  OK, now I’d like you to imagine that you had to make a decision right now about how your doctors should take care of you. If you had to make a decision right now, would you prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would you want a plan of care that focuses on relieving pain and discomfort as much as possible, even if that means not living has long?

  - (If they say both): OK, but if you had to choose just one, which would you choose? [READ OPTIONS AGAIN]
    Responses – check one:
    
    - Palliative Care: focus on keeping [him/her] comfortable as possible
    - Extending life: focus on helping [him/her] live as long as possible
    - Don’t know

- If interviewing proxy, ask the following substituted judgement question:
  
  OK, now I’d like you to imagine that [your family member] had to make a decision right now about how [his/her] doctors should take care of [him/her]. If [he/she] had to make a decision right now, would [he/she] prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would [he/she] want a plan of care that focuses on relieving pain and discomfort as much as possible, even if that means not living has long?

  - (If they say both): OK, but if you had to choose just one, which would you choose? [READ OPTIONS AGAIN]
    Responses – check one:
    
    - Palliative Care: focus on keeping [him/her] comfortable as possible, or
    - Extending life: focus on helping [him/her] live as long as possible?
    - Don’t know
Domain 4: Care Preferences

- Some people make plans about how they want their doctors to take care of them. So now, I’d like to talk about how [you/your family member] want [your/your family member’s] doctors to take care of [you/him/her].
  - **(CPR):** For example, if [YOUR/PATIENT NAME] heart stops beating, do you want [your/his/her] doctors to try to restart it?
    - □ Yes
    - □ No
    - □ Unsure
  - **(Vent):** OK, if [YOU/PATIENT NAME] isn’t able to breathe on [your/his/her] own, would you want [your/his/her] doctors to put [you/him/her] on a breathing machine?
    - □ Yes
    - □ No
    - □ Unsure
STEP 5 – SCORING AND REPORTING RESULTS BACK TO PATIENT:

Note: for first two weeks of pilot, symptom and service needs were combined and a positive screen was defined as having 1/3 (symptom/service need; care goals; care preferences). This was changed to exclude symptom needs only patients in week 3 of the pilot.

Symptoms (not part of screening tally):

<table>
<thead>
<tr>
<th>Domain 1 – Symptoms:</th>
<th>□ Yes  □ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Did patient have at least ONE symptom need?</td>
<td></td>
</tr>
</tbody>
</table>

Service needs, Care goals, preferences:

<table>
<thead>
<tr>
<th>Domain 2 – Service Needs:</th>
<th>□ Yes  □ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Did patient have at least ONE service need?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain 2 – Care Goals:</th>
<th>□ Yes  □ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Did patient or proxy respond “palliative care” to care goals question?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain 3 – Care Preferences:</th>
<th>□ Yes  □ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Did respondent answer “no” to both the CPR and the Vent questions?</td>
<td></td>
</tr>
</tbody>
</table>

Add up “Yes’s” for service needs, care goals, and care preferences: if total score is 1 or greater, patient counts as “positive screen”.

(1-3)

If patient screened positive (had a total score of 1 or greater for service needs, care goals, preferences):

- You said that [you/your family member] had some additional symptom and service needs [INSERT SOME OF IDENTIFIED SYMPTOM/SERVICE NEEDS HERE], and/or had care goals and preferences aligned with maximizing comfort and focusing on quality of life. Based on these responses, there may be some additional services [you/your family member] may benefit from. These additional services specialize in symptom management and psychological and spiritual service needs, as well as maximizing comfort and quality of life.

- I don’t know whether these extra services are the right decision for [you/your family member] right now. That’s up to [your/your family member’s] doctor. If it’s OK with you, I’ll let [your/your family member’s] doctor know that we had this conversation so that they can give [you/your family member] more information. Is that OK?

  □ Yes  → initiate appropriate follow-up with physician to get hospice or palliative care order

  □ No  → do not follow-up with physician; give patient debrief sheet

If patient screened negative (had a score of symptom need only):

- Thanks for taking time to tell me more about your care goals and needs. Now we have a better understanding of what you want and what additional services you may be able to benefit from in
the future. I’ll make a note of this in your chart and may ask you about your care goals, needs, and preferences again in the future, in case your needs change.

STEP 6: MAKE SURE TO GIVE PATIENT DEBRIEF FORM. THIS IS REQUIRED BY THE IRB. DEBRIEF FORM IS ON THE NEXT PAGE, WHICH YOU CAN TEAR OFF AND GIVE TO PATIENT/PROXY

Debrief Sheet:

Earlier, you responded to some questions about your care goals, needs, and preferences. Your home health nurse mentioned that responding to these questions was part of a larger research effort our agency is participating in to make sure our patients have access to all services that they may benefit from. Specifically, we used your responses to these questions to determine if you may benefit from some additional services that hospice or palliative care can provide.

We plan to ask these care goals, needs, and preferences questions of about 50 of our new patients. Pending the success of this initiative, we may integrate this into our standard care practices.

We appreciate your participation in this research initiative. All the information we received from you about your care goals, needs, and preferences is strictly confidential. The research team will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. In any reports or presentations about this study, there will be no way to identify individual participants. The only risk to you might be if your identity were ever revealed.

If you have questions about this research study, you can contact the principal investigator, Alexis Kirk, at 919-541-6021 with questions about the research study. All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

If you have any questions about hospice or would like to further discuss your care goals, needs, and preferences, please contact your home health nurse that provides care to you.
**Leave-Behind Information Sheet:**

Our home health agency is participating in a research initiative to make sure our patients have access to all services that they may benefit from. As part of this initiative, we are asking patients about their care goals, needs, and preferences. We are asking these questions to better understand your needs and wishes, and to make sure you are receiving all services you could benefit from.

If you are interested in answering these questions, let us know and we can talk about these questions at any time. There would be no financial or time-consuming obligations as part of this initiative. Any information that you would provide to us as part of this research initiative would be strictly confidential.