IMPROVING PALLIATIVE CARE ACCESS THROUGH TELEHEALTH: THE ENABLE CLINICAL TRIALS

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OBJECTIVES

Describe the evolution of the ENABLE intervention and clinical trials.

Identify the features of ENABLE that are particularly well-suited to rural patients and family caregivers.

Propose future efforts that can improve palliative care for patients and family caregivers in rural environments.
• Maebel is 78 yo African American woman with recurrent breast cancer, lymphangic pulmonary metastases & dyspnea.
  • Admitted to local critical access hospital.
  • Baptist, 5 children, 10 grandchildren, 3 great-grandchildren all but 1 live ‘up north’.

• She & family believe she will get better treatment at the academic center 90 miles away.

• Oncology recommends ‘palliative’ chemo; Maebel defers to MD advice.

• Family unable to visit due to transportation issues.

• Maebel gets short of breath, intubated, transferred to ICU.

• She dies alone following lengthy resuscitation effort while MDs attempt to contact family to understand her wishes for life-sustaining treatments.
WHERE IS PALLIATIVE CARE?
Project ENABLE

Educate, Nurture, Advise, Before Life Ends

Goal: Determine a feasible model to introduce palliative/hospice principles at the time of new advanced cancer diagnosis (as recommended by the World Health Organization).

Funded by
The Robert Wood Johnson Foundation
Norris Cotton Cancer Center at Dartmouth Hitchcock Medical Center &
Visiting Nurse/Hospice of Vermont and New Hampshire
ENABLE Program
Educate, Nurture, Advise, Before Life Ends

• Newly-diagnosed advanced cancer patients & caregivers

• Multi-component psycho-educational telehealth
  • In person palliative care assessment

• ENABLE Phone coaching (Patient & Caregiver)
  • Guided by Charting Your Course (CYC): An Intervention With Advanced Cancer and their Family Caregivers
What is ENABLE?

Phone-based

Dyads coached in parallel

Advanced practice nurse coaches

At diagnosis
What ENABLE patients get...

In-person, outpatient palliative care consults

Charting Your Course 6 Sessions (30-60 min)

Monthly check-in calls up to 48 weeks
What is your understanding of your illness?

• Palliative care is...
• [Importance of caregiver role]
• COPE attitude (McMillan, 2007)
• Problem solving support
Self-care and symptom management

Self-care (e.g. healthy eating, staying active)
Symptom management
Depression and Grief
Coping with loss
Spirituality

ENABLE
Session 2
Communication/Decision-Making

Communication skills
Preparation for provider appointments
Support network
Medical decision-making
Decision aids (e.g. Ottawa)
Advance care planning
Charting Your Course
An Intervention for People Living with Cancer
PATIENT GUIDE

Chapter 3

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Medical Decision-Making: Communicating About Your Choices for Care ........................................ 56
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- Activity - Viewing the Shared Decision-Making Program® (DVD/Booklet) ........................................ 57
- Activity - Ottawa Medical Decision-Making Guide ......... 58
Ottawa Example: Should I Pursue Investigational Chemotherapy” .................................................. 60
Advance Care Planning - An Important Medical Decision-Making Tool for ALL ........................................ 61
Problem Solving Worksheet ...................................................... 63
Advance Care Planning Coaching
WHAT ENABLE CAREGIVERS GET...

Charting Your Course Sessions (30-60 min) X 3

Monthly check-in calls

Bereavement call
Tell us about yourself?

Palliative care is...

Importance of caregiver role

COPE attitude (McMillan, 2007)

Problem solving support
Self-care and symptom management
Self-care (e.g., healthy eating, staying active)
Symptom management
Depression and Grief
Coping with loss
Spirituality

ENABLE Caregiver Session 2
Communication/Decision-Making

Communication skills
Preparing for provider appointments
Support network
Medical decision-making
Decision aids (e.g. Ottawa)
Advance care planning
Early group caregivers had:
↓ depressed mood (p=.02)
↓ stress burden (p=.01)
(trend) ↑ QOL (p=.07)
ENABLE is an Evidence-Based Early Palliative Care Intervention

- **ENABLE I** (RWJ-funded demonstration project 1999-2001)
  - primary feasibility data; led to the ENABLE II efficacy RCT

- **ENABLE II** (N=322 patients, NCI R01 CA101704; 2003-2009)
  - 4 sessions by palliative care APN + monthly follow-up vs. usual care
  - Outcomes: ↑QOL, mood; (symptom intensity & survival trends)

- **ENABLE III** (N=207 patients, 122 caregivers; 2010-2013)
  - Early vs delayed intervention (3 months after diagnosis)
  - Early Intervention
    - ↑ patient survival by 15% (p=.003)
    - No difference in PROs
    - Early caregivers: ↑ mood & QOL, ↓ stress burden
Results:
• Four themes: enhanced problem-solving skills, better coping, feeling empowered, and feeling supported.
• Three themes related to trial participation: helping future patients and contributing to science, gaining insight through completion of questionnaires, and trial/intervention aspects to improve.

Conclusions:
• The benefits of the intervention and the positive aspects of trial participation outweighed trial “burdens” (‘not needed when feeling well’)
• Raised important questions: When should a palliative care intervention be initiated? How to include self-care and healthy living in addition to palliative content?
### UNDERSTANDING PATIENT VIEWS ON ENABLE

<table>
<thead>
<tr>
<th>Theme</th>
<th>Exemplar quote</th>
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<tbody>
<tr>
<td><strong>Themes Related to Intervention Participation</strong></td>
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<tr>
<td>Enhanced problem-solving</td>
<td>“I think the steps in…decision making and communication…it was most helpful dealing with my husband and the problem I was having with, you know, juggling between him and an oncologist, and what my needs were and how needy he was….” (P14 Intervention; GI)</td>
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<td>Better coping</td>
<td>“I thought, number one, there’s a listing in the back (of “Charting your Course”) that gives you a lot of outside organizations that can help or give you information….Also, some of the things to help you think through, for example, if you’re diagnosed with an end stage illness, what should you be thinking about, what do you think you ought to be doing right now in preparation?” (P23 Intervention; Lung)</td>
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<td>Feeling empowered</td>
<td>“She’s (nurse educator) given me that nudge when I’ve had some problems. I’ll go back to the doctor and talk with him or something like that. “ (P24 Intervention; GU)</td>
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<tr>
<td>Feeling supported, reassured, and hopeful</td>
<td>“It’s been a supportive mechanism, you know, because, for example, when the nurse and I would talk on the phone, she knew what was going on with me. It wasn’t like I had to explain everything, so that was very supportive.” (P23 Intervention; Lung)</td>
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### Themes Related to Trial Participation

| Helping future patients and contributing to science (altruism) | "I believe that when somebody, for example in my situation, finds out you have a terminal disease, yeah, it’s rocky and it’s emotional, but my thought was, if the study would help other people, that’s a good thing." (P23 Intervention; Lung) |
| Completing questionnaires provided insights into condition and emotions | “I felt in some way, like somebody was hearing my individual situation. It, it was interesting to fill it out. It was sort of like, you know, instead of keeping a diary... ‘How has your last week actually been?’ Well, it’s sort of nice to sit down and think about it.” (P14 Intervention; GI) |
| Trial/Intervention Aspects to Improve | Control patient “I was hoping that it would give me some support, I don’t really feel that it has.” (P28 Control; Breast)  
Didn’t apply to me: “Actually up until a couple of months ago, a lot of the stuff that was in the book wasn’t even appropriate. I mean, it wasn’t necessary for me...at first I couldn’t relate to a lot of the stuff.” (P17 Intervention; GI)  
Reminded me about illness “I did sort of let go for a while on participation, and it was more because I was having too much fun, and I didn’t want to be a patient that day. I don’t want to be a patient every day of my life. And, so the less time I have with the medical profession, the more I feel like a normal person.” (P14 Intervention; GI) |

### ENABLE III Study Modifications

- **JUSTIFICATION FOR PALLIAIVE CARE STUDIES**
- **JUSTIFICATION FOR QUESTIONNAIRES**
- **FAST TRACK DESIGN**
- **DELAYED TIMING**
- **SELF-CARE CONTENT**
There were more decisions and more options than just yes or no. Evaluating a decision aid for advanced cancer patients and their family caregivers.

**Table 5. How was receiving the program timed?**

<table>
<thead>
<tr>
<th>Theme</th>
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<tbody>
<tr>
<td>Right time (49%)</td>
<td>“I think I got it at pretty much the right time. I wouldn’t have wanted it five or six years ago. I was not ready to listen to any of that stuff, but like the people in the video, I’m getting a little tired. So now I’m more accepting to listen to this, where I wasn’t before, because I thought I was indestructible… after having two stents, brain surgery, and a collapsed lung, I know I’m not indestructible… it kind of hit home.” (ID 178, male, renal cancer, age 59)</td>
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Engaged in advance care planning...  
| Became aware of different options (such as palliative and hospice care) | “You know, part of me looks at that situation there [on the DVD], and not that I’m in any position right now where I even need a feeding tube, but do I want to have one? Probably not, but you know, if I got pneumonia and, whatever, you know I just—I think it was a little more gray than black and white, and I just felt like there were more decisions and more options than just yes, or no, or this or that. I guess that was very helpful.” (ID 58, female, breast cancer, age 49) |
Oncology Clinician's Views of Palliative Care for Advanced Cancer Patients

I assess overall symptoms and contributing underlying issues. I try to manage in a holistic approach, whether it's depression, pain management, nutrition, I mean I really do try to do the gamut, uh, spirituality...and also I often need assistance particularly if the usual care doesn't control the problems. Then I generally call Palliative Care to either assist me or to continue to follow the patient...

Referral challenges "Palliative"=hospice; Heme patients are different

Some patients just want to fight

Helping with transitions; timing is everything

Quality vs. quantity of life focus

New diagnosis & other PC referral triggers

Oncology Care

Palliative Care

Primary Care

Diagnosis

When do I refer? Early and often. Our approach from the get-go has been that these patients have an incurable illness and that we have to take care of the whole person, which includes palliative and supportive care, with or without chemotherapy

Other Specialists: Pain Service, GI, Rad. Onc, Surgery

Death

Hospice & Bereavement Care

PCS role consultant to co-manager

PCS shares the load

ENABLE facilitated integration
Early Palliative Care ENABLE Trials (Cancer)
From Stakeholder Need to Effectiveness & Implementation Research

Stakeholder Development
- WHO Guidelines, SUPPORT Study Results, Patient, Family, Clinician Focus Groups
- Project ENABLE In-Person Demonstration Project (RWJF) 1999-2001

Effectiveness Research
- ENABLE II Solid Tumor/Telehealth Efficacy RCT (NCI) 2003-2008
- ENABLE III Solid Tumor, Heme & Caregiver Effectiveness RCT (NINR) 2003-2009

Implementation & Optimization Research
- IMPLEMENTATION ENABLE IV (4 site) (ACS) 2012-2017
  ENABLE-NCORP 48 site VLC vs TA (NCI Funded Oct 2018)
- ENABLE OPTIMIZATION Rural, Low Income UAB/GHSCI (NCI-Submitted 9/18)
Translating and Testing the ENABLE: CHF-PC Concurrent Palliative Care Model for Older Adults with Heart Failure and Their Family Caregivers

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THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
STUDY DESIGN:

PRE-STUDY PHASE
- **ALREADY COMPLETED**
  - Literature review
  - Chart audit

- **NEXT STEP**
  - Form Scientific Advisory Group (aka: clinician focus group webinar meetings... one in Sept. 2012, and another in about a year)

PHASE I: Formative Evaluation
- **WAVE 1**
  - Treat 5 patient/cg dyads
  - Revise

- **WAVE 2**
  - Treat another 5 patient/cg dyads
  - Finalize

PHASE II: Summative Evaluation
- **WAVE 3**
  - Treat 30 patient/caregiver dyads

TIMELINE:
- Dec. 2011
- Sept. 2012
- Dec. 2012
- Feb. 2013
### WAVE 1 SATISFACTION INTERVIEWS

<table>
<thead>
<tr>
<th>Category</th>
<th>Feedback</th>
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<tbody>
<tr>
<td>Booklet</td>
<td>“too dense” “need more graphics”</td>
</tr>
<tr>
<td>Content</td>
<td>“need more content for people feeling well”</td>
</tr>
<tr>
<td></td>
<td>Shorten chapter length (Literacy)</td>
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<tr>
<td>Timing</td>
<td>Wished they had the program sooner; already had learned some of the content by trial and error.</td>
</tr>
<tr>
<td>Nurse coach</td>
<td>Liked having someone to vent to; to help put things in perspective</td>
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ENABLE INCREASES ACCESS TO SPECIALTY PALLIATIVE CARE

REACH OF NINR R01 ENABLE CHF PC (N=415 PARTICIPANTS) LOCATIONS

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
EARLY PALLIATIVE CARE ENABLE TRIALS (NON-CANCER)
FROM TRANSLATION & FORMATIVE EVALUATION TO EFFECTIVENESS & IMPLEMENTATION RESEARCH

Translational Evaluation
- AHA Guidelines, Literature & Chart Reviews, Patient, Family, Clinician Focus Groups
- ENABLE CHF-PC Formative Evaluation Pilot (Dartmouth SYNERGY) 2010-2013

Effectiveness Research
- ENABLE CHF-PC 2-site (NH/AL) Pilot (NPCRC) 2013-2015
- ENABLE CHF-PC Effectiveness RCT (NINR) 2015-2020

MOST, Hybrid & Implementation Research
- ENABLE COPD (EPIC) Single Arm Pilot Iyer (UAB PREP & PCOR K 12) 2016-2019
- ENABLE CORNERSTONE Cancer Caregivers Dionne-Odom (NINR K99 NR015903) 2016-2021
Specific Aim 1 (K99 phase): Tailor telehealth intervention outline for Southern rural-dwelling advanced cancer family caregivers

Specific Aim 2 (R00 phase): Evaluate acceptability of a newly developed intervention and the feasibility of enrolling and retaining 60 participants into a small-scale RCT for 24 weeks

Specific Aim 3 (R00 phase): Evaluate the potential efficacy of the newly developed FCG intervention compared to usual care
2-phase formative evaluation study

Phase 1/Aim 1: Conduct interviews with lay navigators, family caregivers and patients to elicit feedback on an intervention outline

Phase 2/Aims 2-3 (enrollment beginning Oct. 2018): Small scale RCT of newly-developed intervention
Part 1: Experiences and challenges of caregivers

Part 2: Role of caregivers in assisting with prospective decision-making

Part 3: Specific feedback on intervention

Interviews complete: 26 navigators, 20 caregivers, 18 patients
Qualitative themes

- Flexibility needed in number and length of sessions
- Face-to-face contact to establish relationship
- Flexible content based on continuous assessment
- Mixed views on navigator role
- Keep things simple and visual, technology okay but internet access is problematic in rural areas
- Spirituality/faith important but should not be overarching theme

Implications for intervention based on qualitative themes

- 20-60 minute sessions with opportunity for additional sessions
- Mixed in-person + telephone contact (at least 1 in-person visit)
- Adaptive content based on continuous assessment
- Navigator-led with enhanced training and weekly supervision
- Therapeutic alliance building to enhance behavioral activation
Maebel is 78 yo African American woman with recurrent breast cancer, lymphangitic pulmonary metastases & dyspnea admitted to local critical access hospital. Baptist, 5 children, 10 grandchildren, 3 great-grandchildren all but 1 live ‘up north’.

She and 1 her local child are referred to early palliative care. They work with nurse coach to identify Maebel’s goals & values if her disease progresses including local health care/hospice/ home care resources.

Maebel learns about and has conversations with her family about her wishes. She identifies her oldest son (caregiver) as her DPOA for health care and completes an advance directive which is placed in her medical record and copies are given to her MDs and family members.
As her disease progresses she is seen by local palliative care clinician in her home community & a symptom management plan is developed. She continues to attend regular church activities & the congregation prays for her and supports she & her family-attending to meals and chores as needed.

She & family believe she will get “better” treatment at the “academic center” 90 miles away.

Her local and distant family have regular ‘skype’ calls with her local team/MD to answer questions and “get on the same page”. They make a regular schedule to visit and reminisce (life review/legacy work).

Oncology recommends ‘palliative’ chemo; Maebel defers to MD advice.

Family unable to visit due to transportation issues.
• You are caring for Maebel when she gets SOB, intubated, transferred to ICU.

• Maebel and her family decide extra support from home hospice may be a good idea. She lives comfortably at home for months; when death seems to be closer, family and church members gather to say good-byes.

• You are caring for Maebel in ICU when she dies alone following lengthy resuscitation effort while MDs attempt to contact family for DNR.

• As her hospice practitioner you feel a sense of satisfaction knowing that you had an active part in ensuring that Maebel’s wishes were known and followed. You make a bereavement call 3 & 6 months later and her family continues to thank you for your care and know their mother is at peace. They tell all of their friends and congregation about the benefits of palliative care and hospice for their ill family members.
FORGE THE FUTURE-FOR PALLIATIVE CARE FOR EVERYONE EVERYWHERE

• TOGETHER WE CAN DO IT!!!
ACKNOWLEDGEMENTS

• ENABLE Research Team
  • Engler, Ejem, Dionne-Odom
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