

# Developing a Palliative Care Toolbox for Patients, Family Caregivers, and Clinicians: From Meaning to Market

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# Starting with the Meaning...

- 4 Aunt Gloria
- 4 Dr. Sherwin Nuland, *How We Die*
- 4 Finding a better way to do this: activating patients and family caregivers
- 4 The skill set and the toolbox for self-management

# MCC-PT: A Palliative Care Toolbox

*Managing Cancer Care: A Personal Guide (MCC-PT)*

*Managing Your Symptoms*

*Managing Your Care and Setting Goals*

*Care Options*

*Talking With Your Health Care Providers*

*Talking With Your Family and Friends*

*Managing Transitions*

*Acting Confidently During Uncertainty*

# Evolution of MCC-PT

Step 1: Interview studies

Step 2: Development of MCC-PT/Focus Group

Steps 3&4: Feasibility test with metastatic/  
non-metastatic patients

Step 5: Pilot Randomized Controlled Trial (ongoing)

\*All studies approved by the Yale IRB

# Self-Management (SM)

“the ability of the individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of health conditions”



(Richard & Shea, 2011, p. 261)



# Self-Management



- 4 A dynamic, interactive, daily process
- 4 Optimal SM - ability to monitor the illness and to develop and use cognitive, behavioral, and emotional strategies to maintain a satisfactory quality of life
- 4 Examples of SM: learning about one's health condition; communicating with providers; making treatment decisions

# Care Options/Goals of Care

- 4 Curative care: Cure disease permanently
- 4 Palliative care: Maximize QOL for patients with advanced disease: pain and sx management, psychological, social, and spiritual care
- 4 Hospice care: Support patient (<6 mo. px) and family as they experience the dying process; help them to find physical/emotional peace and acceptance before death

# Alignment of Self-Management and Palliative Care

- 4 SM interventions span a range of serious chronic conditions, but do not all incorporate palliative care
- 4 Patient autonomy and informed participation are central to both= natural and important conceptual connection
- 4 MCC-PT can help establish palliative care as an early and ongoing mainstay of SM interventions in chronic illness

# The Problem

- 4 Confusion about care options arises because they are not distinct; palliative care can be provided concurrently with curative care and is an integral part of hospice care.
- 4 Confusion about care options hinders survivors' ability to self-manage because SM decisions will vary depending on the care option.
- 4 e.g., a survivor with metastatic breast cancer should make plans around control vs. cure of disease

**Step 1:**

# **INTERVIEW STUDIES**

# Interview Studies

- 4 Women with breast cancer (n=15) & ovarian cancer (n=10)
- 4 SM experiences and practices
- 4 Informational needs and preferences
- 4 Transition definition and experiences



# Findings

- 4 Varying SM preferences that changed over time, often related to shifts in emotional states, physical abilities, and personal priorities
- 4 Common SM tasks: developing skills, becoming empowered, and creating supportive networks
- 4 Barriers to SM: symptom distress, difficulty obtaining information, and lack of knowledge about cancer staging and care options

# SM is Overwhelming

*“[Managing my care is] difficult and frustrating, and something I never thought I’d have to do... the fact that there’s—at the beginning anyway—that there is so much out there, and now the fact that there’s so little out there. It’s frightening whenever you make your decisions because you don’t know what’s going to happen if you make the wrong ones.”*

# Time and Effort to SM

*“I used to be one of those Internet junkies, trying to diagnose my own case and get my own stuff. You get tired of that after years of doing it [and] kind of just start to give in, and that’s where I’m at now...it’s just not worth my time and the pain that it causes to try to sit at the computer to try to research stuff... The pain-free time is spent doing things with my kids and not getting on a computer.”*

# Findings

- 4 No knowledge of care options- despite having metastatic cancer, most reported themselves as receiving curative care
- 4 SM usually shared with family caregivers and providers- quality of communication varied
- 4 Transitions experienced as positive, negative and neutral & prompted changes in how actively women self-managed

# Lack of Understanding of Cancer Stage/Goals of Care

*“...they said, “You have Grade 4,” and I said, “Well, how many grades are there?” [The nurse said] “There is no more.” [sic]... [So I said] “So you’re telling me I have the highest grade cancer there is.” She said, “Yes,” so I said, “So, is this a correct assumption? It can only go down, because you can’t go to 5—there is none, so I can go to 3, I can go to 2, I can go to 1, and I can go home.”*

# Transitions

*“I think the major transition point was when we hit the brain lesions. I think that was the key thing and as a family we sat down one morning and just said, “What does this mean? Is our life going to change further?” Because if it is we just didn’t want it and... as a family how do we deal with it? ...Do we have enough care in the house to help us?...[These were] issues that we just hadn’t addressed, and we realized we had to address them.”*

# Implications for MCC-PT

- 4 **Modular design:** obtain desired information in digestible amounts according to preferred role in SM
- 4 **Symptom management info:** to reduce disease burden and enable engagement in SM
- 4 **Content:** SM, care options, transitions, communication, self-efficacy, symptom management as an enabler
- 4 **Multi-user:** usable by patients, family caregivers, and providers to facilitate communication and team SM

# Priorities in Design

- 4 User-friendly/simple (font type/size, numbering)
- 4 Well-organized/attractive (folder, fern motif)
- 4 Culturally sensitive
- 4 Eighth grade or below reading level
- 4 Customizable
- 4 Each module stands alone
- 4 Information, tools, and empowerment to discuss and plan with family caregivers and providers = SM partnerships

# Concerns in Design

- 4 A printed intervention- really?!
- 4 A self-guided SM intervention?
- 4 One size doesn't fit all



**Step 2:**  
**DEVELOPMENT/FOCUS GROUP**

# Step 2: Development/Focus Group

- 4 12 month process
- 4 Development team: 3 individuals with backgrounds in oncology nursing, communication, gerontology, and palliative care
- 4 Shared drafts with Yale Breast Center staff to obtain feedback on relevance and usability in the clinical setting
- 4 Solicited feedback from patient stakeholders

# Intervention Structure

Every module - magazine format:

- 4 Basic information about the topic
- 4 Information on how the topic may apply to the reader
- 4 Definitions of terms used
- 4 “Conversation starters” to facilitate communication with family caregivers and providers
- 4 Targeted links to local and internet resources
- 4 Blank space for notes

# To Enable Personalization

- 4 Worksheets with prompts and examples,
  - 4 e.g., My Goals
  - 4 Prompts/Mneumonics for what to discuss
    - e.g., My Transitions



# Focus Group (n=6)

## Format:

- fern motif meaningful
- more vibrant colors for increased cheer and contrast

## Content:

- more info on spirituality, holistic care, asking for help
- several modifications to care options definitions/diagram
- liked the worksheets and content on return to work

# Sample Module

## Managing Cancer Care: A Personal Guide Managing Your Care and Setting Goals

### Who is involved in managing my care?

Your care is managed by:

- You
- Primary care physician
- Oncologist(s)
- Oncology nurse(s)
- Social worker(s)
- Palliative care specialist(s) - medical professionals who manage your disease while providing you with relief from your symptoms
- Other health care providers, depending on your needs
- Family and friends

An important member of your health care team is YOU. Only you know your preferences for your health care. These should be shared with your health care team. Knowing your preferences will help your health care team create a plan that is right for you. You may also choose to share your preferences with family members or friends.

### What is involved in managing my care?

Managing your care involves bringing together:

- medical services
- psychological services
- social work services
- other services, depending on your needs

### Managing your care can:

- provide you with the services you need
- support your preferences

### Do I have to manage my care?

You can choose how much you want to be involved in managing your care. How much you want to be involved may change over time. For example, you may want to take a break from managing your care, and later go back to it. Talking with your health care team about your preferences for involvement will keep everyone aware of their role in managing your care.

### What is a goal?

A goal is something you want to achieve. You probably have goals for your health and goals for your life. Health goals and life goals are often related. For example, a goal for your health may be to have more energy. A goal for your life may be to spend a holiday with family. Reaching your goal of having more energy will make reaching your goal of celebrating with family easier to achieve.

### A well thought-out goal:

- is specific with a clear result
- is a realistic challenge that is not too easy or too hard to achieve
- has a specific date by which you want to reach it



It often helps to write down your goals. Below is a goal-setting worksheet you can use to think about your goals. You should share the worksheet with your health care team.

My Goals						
Broad Goal	Specific Goal	My deadline for reaching my goal is:	What may help me reach my goal?	What may keep me from reaching my goal?	What can I do about problems that may prevent me from reaching my goal?	I should reevaluate my goal:
<i>Example:</i> Talk to my health care team about my return to work	I will return to my usual full-time job	Within 6 months of being diagnosed	Making a plan for return and keeping in touch with my boss; managing my symptoms	Not enough energy; too emotional; afraid to answer questions from coworkers	Discuss ways to boost my energy with my care team; visit a counselor to deal with emotions and to learn how to respond to coworkers	A week after returning to work

**Steps 3 & 4:**

**FEASIBILITY STUDIES WITH  
METASTATIC & NON-METASTATIC  
PATIENTS**

# Purpose

To test the feasibility and acceptability of the MCC-PT to:

- 4 Improve knowledge of care options
- 4 Facilitate SM by improving preference to self-manage, communication skills, and self-efficacy, and by reducing anxiety, depression and uncertainty

# Design

- 4 One-group, pre-post test feasibility for both metastatic and non-metastatic breast cancer
- 4 Each study 2-month duration
- 4 Semi-structured qualitative exit interviews to obtain ratings and comments about the MCC-PT

# Inclusion Criteria

- 4 Women aged 21 or older
- 4 English-speaking
- 4 Living in the State of Connecticut
- 4 Diagnosis of metastatic (Stage IV) or non-metastatic (Stage I-III) breast cancer
- 4 Prognosis of at least three months
- 4 Receiving any kind of treatment

# Procedures

- 4 Recruitment at a cancer center breast clinic January-May 2010 (metastatic) and July 2011-June 2013 (non-metastatic)
- 4 Potential participants approached by their chemotherapy nurse to determine interest in speaking to a researcher
- 4 Research staff member explained study further/consent
- 4 Pre-test data collection/oriented to MCC-PT
- 4 Phone call at 1 month to check use, answer questions, to set time for post-test data collection one month later

# Procedures

- 4 Semi-structured interview after post-test data collection
- 4 Participants asked to rate individual modules and the MCC-PT as a whole on usefulness and appearance (1-10, least/most useful/attractive)
- 4 Data collected on likes/dislikes/suggested changes
- 4 Open-ended questions on how MCC-PT affected communication with family and providers

# Outcome Measures



- 4 Demographic and Clinical data forms
- 4 Knowledge of Care Options test (KOCO)
- 4 Control Preferences Scale (CPS)
- 4 Medical Communication Competence Scale (MCCS)
- 4 Hospital Anxiety and Depression Scale (HADS)
- 4 Uncertainty in Illness Scale (MUIS-C)
- 4 Chronic Disease Self-Efficacy Scale (CDSE)
- 4 Measurement of Transitions (MOT) (Non-metastatic only)

# Data Analysis: Quantitative

- 4 Descriptive statistics for demographic and clinical data
- 4 Paired T-tests for non-parametric data
- 4 Signed Rank Tests performed pre- and post-test
- 4 Cohen's effect sizes calculated with mean differences and standard deviations
- 4 Pearson correlations
- 4 GLM
- 4 Wilcoxon Rank Sum Test



# Data Analysis: Qualitative



- 4 Descriptive statistics for MCC-PT (ratings, frequency of use)
- 4 Content analysis of open-ended interview questions to categorize feedback about strengths, limitations, and suggested improvements

# Sample Description: Metastatic

- 4 33 patients eligible for the study
- 4 3 not interested in speaking to a researcher
- 4 4 refused participation (2 did not want health information; 2 did not want a new activity)
- 4 3 unable to be contacted
- 4 Final sample= 23 participants (all completed pre-test data collection)
- 4 2 withdrew due to being overwhelmed with their situation, 2 died= 19 completed post-test data collection

# Sample Description: Metastatic

- 4 Relatively homogenous
- 4 Well-educated (65.2%  $\geq$  college)
- 4 White (87%)
- 4 Married (73.9%)
- 4 Mean age= 56.7 years (SD=12.4, range 40-81)
- 4 Catholic (52.2%)
- 4 Average time since diagnosis= 8.5 years (SD= 9.9, range 2-40)
- 4 Average of 5.9 symptoms (SD= 4, range 0-17)



# Change Over Time: Metastatic

- 4 Knowledge of care options improved ( $p=.0056$ )
- 4 Of the 17 participants with complete CPS data:
  - 7 changed preference to wanting a more active SM role (41.2%, 95% CI=0.18, 0.65)
  - 7 preference stayed the same
  - 3 preferred most active role possible at pre-test = ceiling effect
  - 3 changed preference to wanting a less active role
- 4 6 of 15 participants had concordance between preferred and actual roles (40%, 95% CI=0.15, 0.65)

# Clinical Correlations: Metastatic

- 4 Communication, self-efficacy, anxiety, depression, and uncertainty did not significantly change, but substantive effect sizes observed in some demographic subgroups
- 4 More recently diagnosed participants (median=Pre: 105, SD=12.49; Post: 109, SD= 5.61) improved communication skills slightly more than participants with a longer time since diagnosis (median=Pre: 112, SD=8.47; Post: 109.5, SD= 8.33)
- 4 Although not significant (small sample size), effect sizes were large

# Sample Description: Non-Metastatic

- 4 165 patients eligible for the study
- 4 40 not interested in speaking to a researcher
- 4 15 refused participation (9 did not want a new activity; 3 not well enough to participate; 3 not interested in health information)
- 4 110 participants completed pre-test data collection
- 4 3 lost to follow up; 2 withdrew due to being too ill to participate= 105 completed post-test data collection

# Sample Description: Non-Metastatic

- 4 Mean age= 52.3 years (SD=10.4, range 27-72)
- 4 Well-educated (64.8%  $\geq$  college)
- 4 Higher income (49.5%  $>$  \$80K/year)
- 4 White (78.1%), African American (9.5%), Latino (5.7%), Other (2.9%)
- 4 Married (61.9%)

# Sample Description: Non-Metastatic

- 4 20 (19%) Stage I, 59 (56.2%) Stage II, 26 (24.8%) Stage III
- 4 Average time since diagnosis= 4 months (SD= 2.5, range 0.7-17.6)
- 4 95.2% chemotherapy, 3.8% radiation
- 4 Average of 6.4 symptoms (SD= 3.9, range 0-19)
- 4 32 (30.8%) could not correctly identify their stage of breast cancer

# Associations of Change Among Outcomes: Non-Metastatic

- 4 Increased knowledge of care options associated with decreased uncertainty ( $r=-0.215$ ,  $p=.0311$ )
- 4 Improved health communication is associated with less depression ( $r=0.235$ ,  $p=.0161$ )
- 4 Changes in desired & actual SM not associated with change in other outcomes

# Change Over Time: Non-Metastatic

## 4 Several key outcomes improved

Outcome	Delta	SD	p-value
Knowledge of care options	0.40	1.11	.0004
Desire to SM	-0.28	1.08	.0177
Actual SM	-0.28	1.66	.1310
Health Communication	-1.58	7.31	.0301

4 Anxiety and depression did not change

4 Change in self-efficacy varied by stage of breast cancer: Stage II and Stage III associated with increased self-efficacy, and Stage I with decreased self-efficacy ( $p=.0413$ )

# Clinical Correlations: Non-Metastatic

- 4 Later stage of cancer associated with greater knowledge of care options ( $p=.0319$ ) and greater uncertainty ( $p=.0139$ )
- 4 Greater # of symptoms significantly associated with greater anxiety ( $r=0.411$ ,  $p=.0001$ ), depression ( $r=0.321$ ,  $p=.0008$ ) & self-efficacy ( $r=-0.362$ ,  $p=.0001$ ); this remained significant after controlling for cancer stage

# MCC-PT Ratings: Metastatic

- 4 Median ratings for the MCC-PT as a whole 8 on content; 10 on format (range 2-10)
- 4 Highest rated module: *Care Options with* mean rating= 8.3 (range 5-10)
- 4 83% reported that they would recommend the MCC-PT
- 4 Modules described as thorough, provided valuable information, empowering, helpful earlier in the care trajectory

# MCC-PT Ratings: Non-Metastatic

- 4 Median ratings for the MCC-PT as a whole: 8 on content; 9 on format
- 4 Modules described as thorough, provided valuable information, most helpful to get at diagnosis
- 4 Some reported the Care Options and Transitions modules as emotional to read, but important
- 4 A few felt the worksheets were hard to complete or content was not relevant to them

# MCC-PT Comments (both groups)

- 4 Improve communication with family
  - share emotional issues or fears
  - communicate more thoroughly and honestly
  - more open to family input and involvement
  - recognize that patients have a voice
  - assist with symptom management

# MCC-PT Ratings

- 4 Improve communication with providers:
  - know what questions to ask
  - more open and honest
  - believe that the doctor is there to listen
  - be more assertive
  - involve providers more in SM

# Discussion

- 4 MCC-PT was well-received and successful at improving knowledge of care options, desire /actual SM, health communication, and other aspects of SM
- 4 Knowledge of care options is associated with less uncertainty, and less uncertainty is associated with greater self-efficacy
- 4 The better the health communication, the less depression

# Discussion

- 4 Despite potential concerns about bringing up palliative and hospice care, participants were open to these topics and wanted them earlier.
- 4 Being an active self-manager should be encouraged to help survivors specify/work towards SM goals
- 4 “Good” SM may mean taking a more passive role temporarily or long-term
- 4 Passive SM is not poor SM; this choice IS the SM plan

# Limitations

- 4 Outcome measures are self-reports of SM- need to include objective measures (e.g., health care utilization)
- 4 Short follow up - MCC-PT should be tested over a longer period of time to capture changes in SM practices/adoption of SM strategies
- 4 MCC-PT should be tested with a larger and more diverse sample, including other cancer populations, and among men

# Conclusion

- 4 Knowledge of care options is foundational to many other SM activities.
- 4 Development of this knowledge and SM skills is key to helping cancer survivors adapt to disease and disability.
- 4 The MCC-PT offers a feasible and acceptable means of helping breast cancer survivors to do so.

# Practice Implications



In clinical settings, MCC-PT can:

- 4Be given to patients as “homework” (e.g., complete worksheets) to be discussed at the next appointment

- 4Reinforce discussion at family meetings

- 4Lend structure to educational sessions or support group meetings

**Step 5:**  
PILOT RANDOMIZED CLINICAL  
TRIAL

# Specific Aims

- 1) Evaluate effects of MCC-PT on patients' knowledge of palliative care
- 2) Examine preliminary effects on feelings (self-efficacy, anxiety, depression, uncertainty), and behaviors (goals of care conversations, role in SM, communication skills, management of transitions, health care utilization)
- 3) Evaluate feasibility and acceptability of the RCT protocol
- 4) Exploratory: how demographic and clinical factors moderate the effects of MCC-PT/differences in use and outcomes among minority participants

# Sample and Procedures

- 4 RCT, n=60
- 4 Women with Stage I-IV breast cancer
- 4 Attention-control group receives a symptom management booklet
- 4 Family caregivers to report patient communication
- 4 Data collection at baseline, one, and three months (longer follow up than feasibility tests)
- 4 More attention to intervention fidelity (complete worksheets, meeting benchmarks)

# Next Steps

- 4 Test MCC-PT in a powered RCT
- 4 Create companion intervention for family caregivers (MCC-CG)
- 4 Test MCC-PT and MCC-CG in patient-family caregiver dyads
- 4 Test MCC interventions among minority group members to assess acceptability/efficacy

# Getting to Market

- 4 Dissemination at Smilow
- 4 Other Yale network hospitals
- 4 Multisite trial?
- 4 How would you want access?
- 4 Cost?

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**THANK YOU**