Development of a “Changes Toolkit” for Rural Older Palliative Patients and Their Family Caregivers

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Development of a “Changes Toolkit” for Rural Older Palliative Patients and Their Family Caregivers

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Abstract

A “Changes Toolkit” was developed to help rural older palliative care patients and their caregivers deal with multiple concurrent transitions that cause disruption in their lives. The purpose of this article is to describe the development of the “Changes Toolkit” to support rural palliative patients and their families with transitions using the Medical Research Council (UK) guidelines for complex intervention development. The first step was to develop a theoretical understanding of the likely processes of change, by drawing on existing evidence and theory, supplemented by new primary research. The intervention was then developed based on this first step by multidisciplinary experts (step 2), followed by conceptual mapping of the critical inputs of the intervention with the theoretical understanding (step 3). Then an assessment of the feasibility of the intervention was completed (step 4). The preliminary findings of a feasibility pilot study of this toolkit were positive with the majority of participants describing it as acceptable, easy to use, and having potential to help deal with transitions.

Keywords: Changes Toolkit, conceptual mapping, MRC guidelines, Delphi process

1.0 Introduction

Older adults with advanced disease and their families living in rural areas experience unique challenges associated with rural living (Burge, Lawson, & Johnson, 2005b; Castleden, Crooks, Schuurman, & Hanlon, 2010; Duggleby et al., 2011; Goodridge, Hutchinson, Wilson, & Ross, 2011). These include lack of access to specialized services (Burge, Lawson, Critchely, & Maxwell, 2005a; Goodridge, Lawson, Rennie, & Marchiniuk, 2010; Robinson et al., 2009), and changing needs for care as they undergo multiple and complex transitions (Castleden et al., 2010; Duggleby et al., 2011). Transitions are processes of change in which a new situation or experience causes disruption in a person’s life and is then incorporated into their lives (Meilis, 2010). For rural palliative patients and their families common transitions include changes in: 1) roles/relationships, 2) environment, 3) hope, 4) meaning and purpose in life, 5) physical and mental health, and 6) independence (Duggleby et al., 2010; 2011). These transitions may occur suddenly and can be traumatic as they disrupt a person’s life and result in distress and uncertainty (Duggleby et al., 2010). There is a critical need to support persons with advanced disease and their families as they deal with transitions.

The development of complex interventions, such as one to help rural older persons and their families deal with transitions, requires multiple steps. Guidelines to develop such an intervention have been established by the Medical Research Council (MRC) in the United Kingdom (MRC, 2000) with updated guidelines published in 2006. These guidelines recommend 4 steps. The first step is to develop a theoretical understanding of the likely processes of change, by drawing on existing evidence and theory and supplemented if necessary by new primary research. The intervention is then developed based on this first step by multidisciplinary experts (step 2), followed by conceptual mapping of the critical inputs of the intervention based on the theoretical understanding (step 3). Then an assessment of the feasibility of the intervention should be completed (step 4). The purpose of this article is to describe the development of a “Changes Toolkit” to
support palliative patients and their families with transitions using the MRC guidelines and the preliminary findings of a feasibility pilot study of this toolkit.

### 1.1 Theoretical Understandings of Transitions

Several theories exist for understanding social developmental transitions (Kralik, Visten, & van Loon, 2010) such as becoming an adult. Transition theories focused on other significant life changes (such as health and economic changes) (Bridges, 2001; Meleis, 2010; Selder, 1989) do not appear to have been developed based on the experience of rural older persons with advanced disease and their families. As well, the theories focus on transitions at the individual level. According to the World Health Organization (2011), the patient and family is the “unit of care” in palliative care and so there appears to be a gap in the literature on understanding the change processes associated with transitions experienced by palliative patients and their families. The literature has focused on outcomes of transitions such as loss and grief, and specific types of transitions such as transitions of care.

The majority of research on transitions for persons with advanced disease have focused on transitions of care from hospital to home, or to long term care facilities (Burge et al., 2005a; Lawson, Burge, Critchely, & McIntyre, 2006) and transitions into palliative care (Larkin, 2007; Ronaldson & Devery, 2001). A few studies have explored the transition experience of persons with advanced disease receiving palliative care services. Two such studies were found that explored transitions in persons with advanced lung disease in palliative care (Goodridge et al., 2011; Reinke et al., 2008). These studies however did not explore the processes of transition that are important to inform the development of an intervention as suggested by the MRC guidelines (2006). Thus we conducted a grounded theory study to explore the processes of change that older rural palliative persons and their family undergo to deal with transitions (Duggleby et al., 2010) and explored in depth how the rural context influenced these processes (Duggleby et al., 2011). The resulting grounded theory entitled “Navigating Unknown Waters” became the theoretical framework for the development of our transitions intervention.

In the grounded theory study, 28 participants described their experiences of dealing with transitions within a rural context of isolation, lack of information and limited accessibility to services, and values of individuality and community connectedness (Duggleby et al., 2010). Six older rural persons with advanced cancer, 10 bereaved family caregivers and 12 palliative care health care professionals from rural areas in Saskatchewan were interviewed. The participants experienced multiple concurrent transitions and dealt with their transitions by: a) coming to terms with their situation, b) connecting with others, and c) redefining normal. Participants described “Coming to terms” not as acceptance, but as an awareness of their changed situation. They were able to come to terms with their situation by reminiscing and reframing their hope. When they were able to come to terms with their situation they then actively sought information, searched for options, and connected with trusted experts to help adapt to transition. With timely communication and information from trusted experiences the participants changed what they considered to be normal. Then they were able to determine when they should worry and seek care. During this process, maintaining their personhood—who they were—was very important. Figure 1 illustrates the “Navigating Unknown Waters Theory”. Details of this study are provided elsewhere (Duggleby et al., 2010).
1.2 Expert Panel

The MRC guidelines suggest that finding the most appropriate components for an intervention may require expertise in the relevant disciplines. The Delphi process has been used with success in developing interventions for palliative patients (Biondo, Nekolaichuk, Stiles, Fainsinger, & Nagen, 2008). As a result we conducted a 3-phased Delphi study with a national expert panel to help identify the essential components of the intervention. Twenty-seven experts were identified by the research team and were invited via email to be part of the panel. They were given an information sheet on the study purpose and data collection procedures. Twelve agreed to be members of the expert panel. The panel consisted of 2 physicians, 2 spiritual coordinators, 1 sociologist, 1 volunteer coordinator, 5 nurses, and 1 social worker. Each member was then assigned a code number.

Phase 1 Delphi

During the Phase 1 of the Delphi study, the expert panel and the research team were sent an email requesting them to brainstorm strategies, ideas, and/or resources for families and persons with advanced cancer living in rural areas to help them deal with transitions. There were three key areas in which strategies were to be identified based on the emerging theory of Navigating Unknown Waters. These areas were: “Awareness of Their Situation,” “Connecting with Others,” and “Redefining Normal.”

Of the original 27 surveys sent out to those identified by the research team as experts, 16 responses were returned via email for analysis. These responses were from 12 expert panel members and four from the research team members. The suggestions from the respondents were grouped under common categories and combined to create a comprehensive list of activities, which could be used within the tool designed for palliative patients and their families. The act of grouping the various suggestions was guided by the theory of Navigating Unknown Waters. The result was a comprehensive list of 26 strategies (approximately 7-9 in each themed category drawn from the grounded theory).
Phase 2 Delphi

In Phase 2, expert panel members were sent the comprehensive list of 26 strategies and were asked to rank each strategy in terms of its effectiveness. Of the original 12 surveys distributed, 10 were returned via email for analysis. The mean rank was calculated from the responses of the expert panel for each of the 26 strategies. The top three strategies under each themed area were determined.

Phase 3 Delphi

During Phase 3 of the Delphi study, the top three ranked strategies from each section were sent to the expert panel members. The panel was then asked to comment on the rankings of the strategies. They were also asked to indicate whether or not they agreed with the results of the rankings. Of the original 12 surveys sent out, 10 were returned via email for analysis. The research team reviewed the results of Phase 3 to determine the critical inputs. Critical inputs are the essential components needed for an intervention to be effective (Sidani & Bradon, 1998). During the final stage of analysis all of the comments and suggestions made during Phase 3 by the expert panel were reviewed by the research team.

1.3 Principles for Development of Intervention

Based on the comments from the expert panel and the research team, and understanding of the rural context in which transitions occur, the following principles for the intervention were determined:

1. The intervention should be theory based, focusing on supporting rural palliative patients and their families as they deal with transitions rather than focusing on one transition. The qualitative data clearly suggested that the participants undergo multiple concurrent transitions.

2. The intervention should be self administered by rural palliative patients and their families to promote independence (an important value for rural living persons).

3. Information is an important component of the intervention. Participants described their information needs as part of the Phase 1 qualitative study.

4. Resources such as websites and contact information for services will be added to the intervention to facilitate connecting rural older palliative patients and their families with their community. Community connectedness was an important value for study participants. Providing a list of resources would also increase their access to information and services since living in rural areas reduced their access to resources. Contact information of local community services, as well as provincial and national services were to be part of the intervention.

5. Descriptions of what they might expect will also be part of the intervention as, in the first qualitative study, participants described the most significant changes were often unexpected.

6. The intervention should be flexible and open ended allowing for the person to use it in the way they wish.

7. Choices should be part of the intervention so that the person’s own transition experience would guide usage.
8. Reading levels need to be at Grade 5 and pictures used as much as possible.

9. Energy to use the tool may be an issue for some. In order to deal with this issue, the instructions for the activities of the interventions should be worded to encourage older rural palliative care patients and their families to just begin them and not worry about completion. Encouraging others to help with the activities if possible will also be included in the instructions.

10. The intervention needs to be portable so individuals can keep using it even when settings change.

11. Parts of the intervention may be shared with others; some may be private.

12. Cultural/language issues may be areas for future research.

1.4 Intervention

The intervention was developed based on the above principles and entitled “Changes Toolkit.” The toolkit is in the form of a binder with the flexibility to add to it, and true portability (principles #6, 7, and 10). The instructions for the Toolkit reflect choice. It can be used whenever or however the person would like to use it. It can be shared or be private (principle #10). Most importantly, it is for the person with advanced disease and/or their caregiver to use (principle #2).

The Changes Toolkit has 8 sections. The first section entitled “Thoughts and Wishes” has 6 activities to help rural palliative patients and their families deal with transition processes. They are worded to encourage persons using the toolkit to begin the activities, not necessarily to finish them (principle #9).

The second section, entitled “Common Changes”, contains examples of transitions experienced by other palliative patients and their families. This section was developed to address principle #4 as it has descriptions of what they might expect. Each example of “common changes” includes quotes from others who have experienced the changes.

A section entitled “Contacts” was developed with the intent of helping to connect with the community and other resources (principle #4). In this section there is space to write down the names and phone numbers of important people in their own lives, such as their doctors, home care nurses, spiritual leader, and so on. Some relevant contacts are also provided in the binder, such as provincial and national contacts for the Canadian Cancer Society, Income Tax, Employment Insurance, etc. This is followed by a section called “Calendar” for people to record their appointments.

The “Resources” section highlights important websites, brochures, and books based on requests from participants in the first qualitative study and the expert panel. Some key resources are provided right within the binder, such as the Caregivers Guide and a DVD copy of the Living with Hope film. Also based on the information requested (principle #3) from the participants is the “Frequently Asked Questions” section. Data from the qualitative study were formulated into questions. These questions were then answered by expert palliative care clinicians. Examples of questions were: If a service I require is not available, how do I access this service? How do I find information about disease and the symptoms I should expect? Can I still make choices/decisions best suited for me?
The final section is entitled “My Important Health Information.” The instructions for this section suggest that a short summary of their medical history, updated list of medication, and copies of their most recent test results and advanced directives be placed in a plastic folder (provided) that can be removed whenever it is necessary to take to the hospital or doctor’s office.

1.5 Conceptual Mapping of the Intervention

Principle #1 for the intervention was that it should be based on the “Navigating Unknown Waters” grounded theory and its purpose is to support rural older palliative patients and their caregivers as they deal with multiple transitions simultaneously rather than focusing on just one. One way to ensure that this principle was followed was to conceptually map the intervention activities with the theory (Hardeman et al., 2005). Figure 1 illustrates the conceptual mapping of each of the activities and sections to the concepts from the “Navigating Unknown Waters” theory.

2.0 Feasibility Pilot Study

2.1 Purpose

The purpose of this pilot study was to evaluate the “Changes Toolkit” for ease of implementation, feasibility, and acceptability by palliative care patients and their family caregivers in rural communities.

2.2 Method

Using a concurrent mixed method approach, quantitative data were collected using an evaluation questionnaire and open-ended, audio-taped evaluation interviews were conducted by trained research assistants. Ethical approvals were received.
from a university ethics board and cancer research ethics board. Operational approvals were obtained from participating health regions.

2.3 Sample

Inclusion criteria for the study were: 55 years and older, male or female persons receiving palliative care services and their family caregivers (18 years and older, male or female, English speaking, in rural Alberta (living outside Edmonton, Calgary, or Lethbridge) or rural Saskatchewan (living outside of Saskatoon or Regina)). Using convenience sampling, participants were recruited through the Saskatoon Health Region Palliative Home Care Program in Saskatchewan and the Cross Cancer Institute Pain and Symptom Palliative Clinic in Edmonton, Alberta.

2.4 Data Collection

Once participants had signed a written informed consent, a demographic form was completed. Then trained research assistants explained the toolkit using standardized instructions and gave them the Changes Toolkit to look at and work on over a one week time period. The participants kept their toolkits. One week later, the participants completed an evaluation form and an open-ended, audio-taped evaluation interview. A written evaluation questionnaire that was used to assess a) ease of use, b) acceptability, and c) feasibility using the program evaluation frameworks of McKenzie & Smeltzer (1997) and Timmreck (1995). The evaluation form consisted of 6 questions asking participants to rate their agreement using a Likert scale of 5 responses: fully disagree to fully agree. With each question there was room for comments. The interview guide for the evaluation interview included questions such as: what did they like best, what did they like least, and any suggestions for revisions. The guide also explored the effectiveness of the toolkit by asking if they found it useful for dealing with their transitions.

2.5 Data Analysis

Quantitative data such as demographic information and the Likert scale data used in the evaluation questionnaire were analysed using descriptive statistics. All interview data and comments from the evaluation questionnaire were transcribed by an experienced transcriptionist and checked for accuracy with the audiotapes. Qualitative data were analyzed using Thorne’s (2008) interpretive descriptive approach. Transcripts were read as a whole to identify common patterns in the data which were then used to identify themes.

3.0 Results

3.1 Sample

Seven palliative patients and caregivers participated. Six were diagnosed with advanced cancer and one with advanced chronic obstructive pulmonary disease. The mean age of the patients was 64.4 years (SD 12.7). Four were females and 3 males with an average of 12.8 (SD 17.8) months in palliative care. Their caregivers had a mean age 65.5 years (SD 6.38). Three were females and 4 males. Their relationship to the person with advanced disease was: 3 wives, 2 husbands and 2 were children. The caregiver study participants reported care giving 7 days a week and on average 14.75 hours a day.
The results of the quantitative evaluation data are presented below (Table 1), showing an overall positive evaluation of ease of use, feasibility and acceptability of the tool. Fully disagree was scored as 1, disagree as 2, neutral as 3, agree as 4 and fully agree as 5.

Table 1. Quantitative Evaluation

<table>
<thead>
<tr>
<th>N=7</th>
<th>Questions</th>
<th>Mean (STD) (min-max)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ease of use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Were the directions clear?</td>
<td>4.4 (0.5)(4-5)</td>
</tr>
<tr>
<td></td>
<td>2. Were you sure of what you were expected to do?</td>
<td>4.4 (0.9)(3-5)</td>
</tr>
<tr>
<td></td>
<td>Feasibility</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Did you have the energy to complete what you wanted to?</td>
<td>3.2 (1.1)(2-5)</td>
</tr>
<tr>
<td></td>
<td>4. Were you able to complete the activities you wanted to?</td>
<td>3.0 (1.8)(1-5)</td>
</tr>
<tr>
<td></td>
<td>5. Did you have time to carry out the activities you wanted to?</td>
<td>4.0 (1.1)(3-5)</td>
</tr>
<tr>
<td></td>
<td>Acceptability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6. Do you feel working with the Changes binder increased your ability to deal with transitions?</td>
<td>3.7 (1.2)(2-5)</td>
</tr>
<tr>
<td></td>
<td>7. Would you do it again?</td>
<td>4.3 (1.1)(3-5)</td>
</tr>
<tr>
<td></td>
<td>8. Would you recommend to someone else?</td>
<td>4.4 (0.8)(3-5)</td>
</tr>
</tbody>
</table>

Qualitative data from the interviews and written comments were then combined to address the specific aims of the pilot study:

### 3.2 Ease of Use

The data from the evaluation questionnaire (Table 1) regarding ease of use (questions 1 and 2) reported mean scores in the “agree” to “fully agree” ranges to suggest that the toolkit was easy to use. This was supported by the qualitative data as the participants described the toolkit as being easy to use. As one participant said, “My favourite part was just being able to grab it at any time.” Most of the patients and all of the caregivers found the directions and the expectations of the activities to be clear. Examples of quotes were: “I find the directions were very clear”; “I find the directions really good.”

Some had experience with using similar aspects of the toolkit. For example, three patients were using an illness-specific tool already. Further, three patients were already performing some of the activities suggested in the toolkit such as journaling, tracking symptoms, and keeping a binder for medications, appointments, and important documents.

### 3.3 Feasibility

The mean and standard deviation score for the evaluation question did you have the energy to complete what you wanted to (question 3 table 1) was in the “disagree” to “fully agree” range suggesting that lack of energy was an issue. Lack of energy was most often cited as the biggest hindrance to using the toolkit in the qualitative data as well. Examples of quotes were: “I, well, couldn’t sit down and
do it all at once...little bits and pieces”; ”When you are where you can’t do it or have the strength to do it, then you have someone to do it for you ‘cause it is important”; “It’s just that I tire easily.”

Although the mean scores reflect the participants were not able to complete the sections they wanted to (question 4), they felt that they had time to carry out the activities they wanted (question 5). Lack of time to complete the sections they wanted was described in the qualitative data.

3.4 Acceptability

The reception towards the toolkit was overwhelmingly positive by both patients and caregivers alike. They all felt the binder was important and worthwhile. Examples of quotes were: “Each section, I think they all have benefit and value”; “I think it is a good thing”; “I think it is an excellent tool”; “I am recommending it to everybody—when I go to these support groups, we bring it along like a little bible.” This data is consistent with the data from the qualitative evaluation that suggests that most participants would use the toolkit again (question 7) and recommend the toolkit to others (question 8).

Most patients and caregivers stated that the toolkit would have been more effective for them if it had been received at the start of their palliative care experience. Then they could have used the binder while they were going through their experience. Examples of quotes were: “I wish I had this binder early on”; “[would recommend it to someone]...if they were just starting out...yes.” This suggestion from the qualitative data is supported by the range of responses as to whether using the toolkit helped them with their transitions (question 6).

3.5 Other Themes

A common theme was that the binder helped communicate with others. As one participant noted: “I am hopeful that it will also improve communication because sometimes it’s difficult to speak to them (family).” Another said: “My husband made a comment not too long ago, he said, ‘I feel so left out of this process,’ because he’s at work all the time and not with me throughout the day and I’m really hoping that this will give him that feeling of connection.” Another theme was that both patients and caregivers were experiencing major life transitions and preparing for an uncertain future.

Recommendations for additional resources were made (such as a website for natural health products) and the toolkit was revised adding these resources.

4.0 Discussion

Our purpose was to develop an intervention to help rural older palliative patients and their caregivers deal with transitions and to evaluate it for ease of use, acceptability, and feasibility. The focus was on persons who were deemed palliative and receiving palliative care services in rural areas. As the literature suggests a paucity of research exists in this area. As a result we conducted a qualitative study to facilitate our understanding of transitions resulting in the theory used to determine the essential components of the intervention. As well, the data was key in developing certain aspects of the interventions. For example, it determined that a binder may be the most feasible for flexibility and use in different settings. As well the qualitative data was the foundation for determining
what information would be included in the “Common Changes” and “Frequently Asked Questions” sections. Others have suggested that qualitative methods can provide insight and understanding of patient experiences and that interventions can be derived from this understanding (Gamel et al., 2001; Morse, 2000). In our experience the qualitative data were essential for a theoretical understanding of transitions and to tailor the intervention for use by rural palliative patients and their family caregivers.

Although the research team was composed of multidisciplinary experts in the field of palliative care, the addition of an expert panel and using a 3-phased Delphi process was instrumental in identifying the components of the intervention (Changes Toolkit). Similar to other studies using the Delphi process (Biondo et al., 2008; Vandelanotte, Dywer, van Italie, Hanley, & Mummery, 2010) it was an effective method for collecting and synthesizing expert opinions. In this process we also collected and analyzed the comments from the expert panel. Through this analysis of comments and suggestions, along with the qualitative findings of our transition study, we were able to develop key principles for the intervention. These principles ensured that the completed intervention was feasible in a rural setting. From the principles it was clear that the intervention needed to be self administered by rural palliative patients and their family caregivers and not by health care professionals. The consistent presence of health care professionals in rural areas is a challenge, particularly those with palliative/end of life expertise (Robinson et al., 2009).

As suggested by the MRC guidelines, we used a conceptual mapping process to ensure that the intervention was theory driven and included the necessary components to support rural palliative care patients and their family caregivers. In this process we mapped the change processes of the situation specific transition theory (Navigating Unknown Waters) with the specific components of the intervention. Intervention mapping has also been successfully utilized in the development of an intervention program for family caregivers of persons with dementia (Ducharme et al., 2009).

Using a mixed method design was helpful in revising the toolkit, as the study participants provided recommendations for change and gave additional insight into how the intervention might be helpful (i.e. assist in communication). Lack of time to complete what they wanted and the energy to do it was an issue. This maybe because participants were only given one week to look at the binder to get feedback. Initially we had designed the pilot study for use over a time period of 3 weeks. We had to change to one week because of the participant mortality rates. Recruitment and retention of palliative care patients is an issue in many research studies because of advanced disease (Addington-Hall, 2007). The participants recommended that the toolkit should be given on admission to palliative care. This maybe would help with the lack of time to complete what they wanted to and to increase the potential effectiveness of the “Transition Toolkit” in helping with transitions. Future research evaluating the toolkit should target palliative patients and their caregivers on admission to palliative care.

The feasibility pilot was small (n=7). More research is needed with larger sample sizes, with different types of palliative care experiences and in varying rural locations. The MRC guidelines suggest that the next step for the research team would be to further evaluate and understand the intervention.
5.0 Conclusion

The overall positive nature of the results of the feasibility pilot suggests that the tool developed using the MRC framework has potential to help rural older palliative patients and their caregivers deal with transitions. The participants of the qualitative study and subsequently the feasibility pilot described their experience of major life transitions as stressful. This finding underscores the need for interventions with this population. The study was a small feasibility pilot and further pilot testing will be important to further understand the intervention and identifying the possible outcomes of the intervention.

6.0 Acknowledgements


7.0 References


