Content Validity and Feasibility of the Care Notebook to Assess Cancer-Related Quality of Life in Hawaii

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Abstract
Background: This study used focus groups to examine the content validity and feasibility of the Care Notebook among Hawaii residents.

Methods: Focus groups were held for Hawaii cancer survivors, caregivers, and cancer clinical trials professionals. The focus groups followed a standardized set of questions, and all participants were provided with the Care Notebook, a 24-item instrument, scored on an 11-point Likert scale, with an open-ended question (“How might we help you improve your health and life?”).

Results: A total of 20 patients, 4 caregivers, and 9 health professionals took part in the focus groups. Focus groups identified two primary themes: quality of life (QoL) concerns are important to cancer survivors; and most patients are comfortable with the idea of using a questionnaire to measure QoL. In terms of the Care Notebook specifically, the groups observed that items on the Care Notebook are relevant to Hawaii cancer survivors; and the “other comments” final question of the Care Notebook is very important and could be expanded to make the questionnaire responsive to the concerns of individuals. Participants also pointed out that there were a few areas where they found the wording was confusing.

Conclusion: Most cancer survivors feel comfortable with using a questionnaire to measure QoL concerns, which are important to them; and caregivers and health professionals agree with these observations. This study gives credence to use of English version of the Care Notebook, as well as provides suggestions for ways it could be improved.

Key Words: questionnaire, content validity, cross-cultural comparison, quality of life (QoL)

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Background

Quality of life (QoL) measures have become key components in cancer survivorship research, clinical trials, and patient care\textsuperscript{3,4}. This has led to increased attention to the development of international QoL instruments that can be used successfully in diverse populations. Although measures such as the European Organization for Research and Treatment of Cancer core questionnaire (EORTC QLQ-C30) and the Functional Assessment of Cancer Therapy Scale-General (FACT-G) have been validated in numerous settings, these questionnaires do not necessarily tap certain aspects of QoL important to patients and clinicians, and their format can be difficult to score and interpret, especially in the context of medical practice. In response to such limitations, the 24-item Care Notebook was developed in Japan to assess QoL efficiently in a clinical oncology setting. Previous studies have validated the reliability and consistency of the Care Notebook\textsuperscript{3,4} as a QoL measure for Japanese cancer survivors.

Since health values vary between countries and cultures\textsuperscript{3}, the objective of this study was to examine the usefulness of the Care Notebook in Hawaii. With individuals of full or part-Japanese ancestry comprising 25% of the state’s population\textsuperscript{4}, Hawaii serves as an ideal ethnic and cultural bridge between Japan and the United States. This study assessed definitions of QoL and feasibility of the Care Notebook from the perspectives of Hawaii cancer patients, caregivers, and care providers.

Methods

Participants

Cancer survivors were recruited from the community though clinic posters, brochures, referrals, health fairs, and support groups. Survivors were eligible for participation if they had received a cancer diagnosis at any time. Health care professionals who worked in the University of Hawaii Cancer Center (UHCC) clinical trials unit par-
Focus Groups

Focus groups for cancer survivors, caregivers, and cancer clinical trials professionals were held at the UHCC Lauhala facility and cancer clinical trials professionals. An additional focus group comprising Japanese and part-Japanese participants only was held at the Pali Momi Medical Center in Aiea, Hawaii. Dr. Gotay served as the moderator for all groups, while the research associate, Ms. Orimoto, took detailed notes of participant responses. The focus groups were held in September and October, 2007. Each focus group discussion was tape recorded and transcribed in its entirety.

The focus groups followed a standardized set of questions (Table 1), and all participants were provided with a copy of the Care Notebook, a 24-item instrument, scored on an 11-point Likert scale. The Care Notebook includes 10 items for response on symptoms and physical conditions, six items on moods and psychological status, and eight items on functioning and life situations. Each item includes a single word or short phrase, accompanied by the associated response scale. The measure ends with an open-ended question ("How might we help you improve your health and life?").

Data Analysis

All participants completed a 14-item demographic paper survey. These surveys were numbered and secured in a locked file. Each item was inspected for missing data and coded into a SPSS database. Descriptive analyses were conducted on the demographic survey for survivors and caregivers and health care professionals. Transcribed versions of each focus group were coded and common themes were abstracted.

Results

Participants

A total of 20 patients, 4 caregivers, and 9 health care professionals took part in the focus groups. We had not originally intended to include caregivers. However, one focus group was held with members of an ongoing, intact support group which includes caregivers as well as cancer survivors, and we could not exclude the three caregivers in attendance. Another caregiver accompanied his wife to the UHCC focus group and wanted to take part. In retrospect, including the caregivers made a positive contribution to the study.

Tables 2 and Table 3 provide descriptive information about the participants. It can be seen that a wide range of cancer diagnoses is represented. While the majority of participants were within five years of diagnosis, some were long term survivors.

Table 1. A standardized set of questions used in focus groups

| The following questions were used to guide discussion in each focus group: |
| ・ What contributes to the “well-being” of an individual? |
| ・ What does quality of life mean to you? What are the factors? |
| ・ What are your top three factors? Of those, which do you think is the most important? Why? |
| ・ How do you think your definition of quality of life differs from someone in another part of the world? Japan? Why do you think it would be different? |
| ・ Have you talked with your oncologists or other health care professionals about quality of life and your well being? What did you talk about? |
| ・ What did they do well? What do you think they could do better? |
| ・ Regarding the Care Notebook: |
| ・ Any initial reactions to the questions/set-up/wording? |
| ・ In what ways do you think the survey works? |
| ・ In what ways do you think the survey does not work? |
| ・ Is there anything you think is missing from the survey? |
| ・ Is there anything in the survey that you think someone else might find offensive? |
| ・ Do you think that this survey would be effective in helping doctors better their patients’ well being? Why or why not? |
| ・ How would you feel about completing a survey like this during your appointments? |
| ・ Do you have any other suggestions or comments? |

Table 2. Characteristics of participants (%)

| Cancer Survivors & Caregivers (N = 24) | Health Care Providers (N = 9) |
|----------------------------------------|-------------------------------|
| Sex                                    |                               |
| Female                                 | 66.7                          | 88.9                          |
| Male                                   | 33.3                          | 11.1                          |
| Ethnicity                              |                               |                               |
| African American                       | 4.2                           |                               |
| Caucasian                              | 12.5                          | 55.6                          |
| Chinese                                | 4.2                           | 11.1                          |
| Hawaiian/Part Hawaiian                 | 33.3                          |                               |
| Japanese                               | 25.0                          | 22.2                          |
| Native American                        |                               | 11.1                          |
| Spanish/Hispanic/Latino                | 4.2                           |                               |
| Mixed                                  | 16.7                          |                               |
| Education                              |                               |                               |
| High school diploma/GED                | 12.5                          |                               |
| Some college                           | 62.5                          |                               |
| Bachelor’s degree or higher            | 25.0                          | 100.0                         |
| Marital Status                         |                               |                               |
| Never Married                          | 12.5                          | 22.2                          |
| Married                                | 45.8                          | 55.6                          |
| Divorced                               | 33.3                          | 22.2                          |
| Widowed                                | 8.3                           |                               |
| Years in Hawaii                        |                               |                               |
| ≤10                                    | 8.7                           | 55.6                          |
| >20                                    | 91.3                          | 44.4                          |

Note: some items have missing data
Focus Group Findings

The respondents did not answer the focus group questions specifically as written in all cases. As is often the case in focus groups, many in the group “told their stories” and answered several questions simultaneously.

Table 3. Clinical characteristics of survivors (n = 20)

| Clinical characteristic | (%) |
|-------------------------|-----|
| Site of disease          |     |
| Breast                  | 58  |
| Lymphoma                | 16  |
| Multiple primaries      | 16  |
| Other                   | 10  |
| Currently on therapy    |     |
| Yes                     | 30  |
| No                      | 70  |
| Treatment               |     |
| Surgery                 | 65  |
| Radiation               | 70  |
| Chemotherapy            | 65  |
| Years Since Diagnosis   |     |
| ≤5                      | 68  |
| Between 5 & 10          | 21  |
| >10                     | 11  |

Table 4. Quality of Life Definitions: What does quality of life mean to you?

- Symptoms
  - Pain, loss of energy, emotional reactions (anxiety, fear, paranoia, fear of recurrence), dizziness, weight loss, appetite changes, memory loss (chemobrain), dental problems, medication side effects
  - Maintaining functional independence
  - Financial concerns
    - Working (being unable to work), paying bills, being forced to move because of the inability to pay the rent, not being able to afford food and medications
  - Social impact
    - Redefining relationships, overcoming stigma
  - Positive life changes
    - Altruism (giving back to the community and others), being thankful, increasing spirituality, learning how to advocate for oneself, adopting a healthier lifestyle, gaining a new perspective on life, accepting cancer as part of life
  - Relationships with health care providers

Table 5. Effects of Culture on Quality of Life

- Ethnic/racial differences in communication
  - Chinese are quiet about illness, Filipinos may not share diagnosis with family, Japanese are reserved and tend to go along with what doctors say, Japanese are not always given cancer diagnosis, Pacific Islanders and women in general not comfortable with questions about sex, “talk story” method is often effective in Hawaii

- Ethnic/racial differences in roles in the family
  - Burden of care falls on oldest son in Japanese families, women must be strong and not show weakness in illness in many cultures, some family roles (e.g., cooking, caregiving) are gender-specific

- Generational/age differences
  - Younger generations tend to be more open, more apt to speak their minds than older generations of Asians

Table 6. Relationships with Health Care Providers: Positive and Negative Experiences

- Provision of information
  - Positive: informative, gave options
  - Negative: not enough time for discussion, didn’t wait for members of the family to be present, didn’t give the information that was desired

- Lack of resources
  - No follow-up psychosocial support, no alternative medicine options

- Health care team
  - Nurse may be easier to talk with than doctor, doctor not expected to provide psychosocial support but to make referrals, use of patient navigator a positive

- Use of QOL survey
  - Acceptable, expected, don’t like idea of computerized survey

Table 7. Feedback about the Care Notebook

- Regarding content
  - Important areas of quality of life not included in the notebook
  - Relationship with your physician, communication with doctors, diet and exercise, family coping
  - Items seen as confusing or unclear
  - Does “confusion” mean “memory loss”? - what is the difference between “severe” and “intense”? - what is meant by “ability to function in daily life” - there are many aspects of this question, what is meant by “peaceful feeling”? consider separating “relationship with family” from “relationship with partner” since these may be different, use the term “sadness” rather than “depression,” should patients be asked to distinguish symptoms of cancer from symptoms of other diseases/conditions they may have?

- Regarding format
  - The scale and items need to be closer together, consider shading or multiple colors for every other item so it is easier to keep the items separate, too many points on the scale, most people read down one page rather than left to right across two pages, consider using icons (e.g., faces) rather than numbers, some words may be too complex for some individuals, provide reference points to make the meaning of the scale numbers more concrete

- Positive features
  - Not offensive
  - Like that is asks about “the past week”
  - Enhance the free response box about help needed to have options for people to check off
  - Would be helpful if physicians actually read it

The health care providers were asked to respond to the questions in terms of patients they had interacted with (as opposed to describing their own quality of life).

The focus group responses were categorized into several areas: (1) definitions of quality of life (Table 4), (2) cultural factors as they affect quality of life (Table 5), (3) relationships with health care providers regarding quality of life issues (Table 6), and (4) feedback and suggestions regarding the Care Notebook (Table 7). The main ideas presented for each of these themes are listed below.
There were no differences we could detect between the groups, nor between the “Japanese only” group, as compared to the other groups. In fact, there was considerable convergence in the issues mentioned, despite the diversity in patient diagnoses, ages, time since diagnosis, and other factors. By the time of the final group, very few new themes were expressed.

It can be seen that a wide variety of issues make up quality of life from the standpoint of these participants (Table 4). Most of the areas mentioned are negative “problem areas” that relate to effects of the disease and/or therapy, but some positive aspects are mentioned as well. Responses were similar in both survivors and care providers, with one exception: the providers mentioned “relationships with care providers” as a key component of quality of life, but this did not come up in any of the patient groups.

Respondents did not identify a large number of cultural factors that affected quality of life and cancer (Table 5). In fact, some people remarked that cancer’s effects were “universal”. The themes listed reflect “common wisdom” prevalent in Hawaii.

The participants identified a number of areas where they believed the health care system could be improved when it came to detecting and managing quality of life issues. At the same time, they were positive about the option of having a quality of life survey incorporated into the caregiving milieu (Table 6).

In terms of English version of the Care Notebook (Table 7), cancer survivors were positive about the non-offensive style of each question. They suggested that the free response box about help needed to include options for respondents to endorse. Further, they expected that it would be helpful if physicians read the results of the Care Notebook. Table 7 provides suggestions regarding the content and format of the questionnaire.

**Discussion**

This study examined the content validity and feasibility of the Care Notebook in a sample of Hawaii cancer patients through the use of a series of focus groups. Several conclusions can be drawn:

- Quality of life concerns are important to cancer survivors.
- Most patients are comfortable with the idea of using a questionnaire to measure quality of life.
- The items included on the Care Notebook are relevant to Hawaii cancer survivors; respondents did not recommend that any items be dropped.
- Additional aspects of quality of life could be added to the Care Notebook.
- There were a few areas where the wording was confusing to respondents, but for the most part, the translation from Japanese appears to have been effective.
- The formatting and wording could be enhanced, particularly linking the scale to the verbal descriptor more closely and using visual devices such as shading and color.
- The “other comments” final question of the Care Notebook is very important and could be expanded to make the questionnaire responsive to the concerns of individuals.

These comments call out for comparison with “Haiku”, a form of poetry, first made popular in Japan, which has become appreciated around the world. Haiku poets are challenged to convey a vivid message in only 17 syllables. Readers make images through the short poem. Like Haiku, patients make images through their endorsements of a single word or a short phrase on the Care Notebook. If the “Haiku” is insufficient to express patients’ QoL concerns, the free response box at the end of the Care Notebook can amplify responses, creating a “novel” form of QoL assessment.

Table 7 identifies a number of areas that respondents believed could be improved. They pointed out that the broad question about “ability to function in daily life” is difficult to answer, since different people have varying concerns about what this means. For example, one cancer survivor is satisfied with continuing his/her work, whereas another cancer survivor is focused with just looking after himself. Although the Care Notebook asks about family, partner and friends, the focus group members pointed out that the relationship with one’s physician or communication with doctors is also an important issue for patients. We recommend that particularly for studies that, investigate patient-physician communication, an item addressing this concern should be added to the questionnaire. The participants also pointed out the English terms “confusion” and “depression” are medical terms, such that ordinary people may not be familiar with them. Future modifications of these terms and other wording will be informed by future results of clinical testing undergoing in Holland. Regarding format in Table 7, the useful suggestions of the focus groups will be incorporated into the next version of the Care Notebook, such that the scale and items will be spaced closer together, and every other item will have shading.

The Japanese (original) version of the Care Notebook was used in a randomized phase III trial (NEJ 002), which compared gefitinib to carboplatin plus paclitaxel for non-small cell lung cancer patients with sensitive EGFR mutations. The questionnaire reflected a significant difference in QoL between the arms; namely, patients harboring EGFR mutations treated by gefitinib maintained QoL longer than those treated with the standard chemotherapy.

This study gives credence to the Care Notebook’s use, as well as provides suggestions for ways it could be im-
proved. It is hoped that these ideas will be helpful to the next iteration of English version of this measure. As seen in its use in NEJ 002, the value of the Care Notebook in clinical settings in Japan is promising, and the availability of an English language version extends its potential reach. However, the real test of the instrument’s effectiveness will come as it is used in additional international research and/or clinical practice settings.

Acknowledgement

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Thinking about the past week, please answer the questions below by circling one number in each row on the right-hand page.

I. Did you have any of these problems?

Please circle the number that best applies to you, using 10 for the worst condition.

- a) Pain?
- b) Shortness of breath?
- c) Nausea?
- d) Loss of appetite?
- e) Trouble sleeping?
- f) Constipation?
- g) Diarrhea?
- h) Abdominal bloating?
- i) Fatigue?
- j) Physical weakness?

I. Symptoms

- a) severe pain
- b) severe shortness of breath
- c) severe nausea
- d) complete loss of appetite
- e) severe trouble sleeping
- f) severe constipation
- g) severe diarrhea
- h) severe abdominal bloating
- i) severe fatigue
- j) severe weakness

II. Did you have any of these problems with feelings or moods?

Please circle the number that best applies to you, using 10 for the worst condition.

- k) Worries?
- l) Anxiety?
- m) Irritation?
- n) Depression?
- o) Anger?
- p) Confusion?

II. Problems with feelings or moods

- k) many worries
- l) severe anxiety
- m) severe irritation
- n) severe depression
- o) intense anger
- p) severe confusion

III. How was your life over the past week?

Please circle the number that best applies to you, using 10 for the BEST condition.

- q) Ability to be physically active?
- r) Ability to function in daily life?
- s) Relationship with your family or partner?
- t) Relationship with your friends?
- u) Peaceful feeling?
- v) Happy feeling?
- w) Quality of life?
- x) Satisfaction with life (considering your condition and treatment)?

III. Your life over the past week

- q) unable
- r) unable
- s) the worst
- t) the worst
- u) none at all
- v) none at all
- w) the worst
- x) none at all

IV. Please tell us how we might help you improve your health and life.

IV. How might we help you improve your health and life?