

Development of a Health Status Measure for Older African-American Women With Type 2 Diabetes

TOM A. ELASY, MD, MPH
CARMEN D. SAMUEL-HODGE, MPH
ROBERT F. DEVELLIS, PHD

ANNE H. SKELLY, PHD
ALICE S. AMMERMAN, DRPH
THOMAS C. KEYSERLING, MD

OBJECTIVE — To develop a health status measure in older African-American women with type 2 diabetes.

RESEARCH DESIGN AND METHODS — African-American women, age ≥ 40 years with type 2 diabetes, were recruited from central North Carolina to participate in three sequential phases: 1) Seven focus groups were convened and transcripts evaluated to generate questions and identify plausible domains; 2) Ten one-on-one cognitive response interviews were performed to ensure clarity and cultural appropriateness of the questions; and 3) 217 women participated in psychometric evaluation to establish the internal consistency and validity of the instrument.

RESULTS — Three broad categories—mental, physical, and social well-being—captured important issues generated during the focus groups. “My diabetes” was added during the cognitive response interviews as a way of separating the impact of diabetes from coexisting issues that affect health status. The response option was changed from a six- to a four-point Likert scale to accommodate subject preference. Using principal components and subsequent promax rotation, we identified two hierarchical domains (mental and social well-being) and a physical symptom index. The internal consistency (Cronbach’s α) of the mental and social well-being subscales are 0.83 and 0.93, respectively. A priori hypothesized correlations between subscales along with each subscale and glycated hemoglobin, diabetes duration, physical activity, and a perceived health competence scale helped establish the construct validity of the instrument.

CONCLUSIONS — A culturally appropriate disease-specific health status measure for older African-American women with type 2 diabetes has been developed. We have established the internal consistency, construct validity, and factor analytic properties of the measure. This measure should prove useful for investigators who seek a health status instrument that addresses issues germane to African-American women with type 2 diabetes.

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Type 2 diabetes is one of the most common chronic diseases in the U.S., with rates highest among older Americans and minority populations (1). Data from national surveys document that diabetes prevalence is increasing and projects

a continued rise in rates as the population ages and minority populations increase. Among those at highest risk are African-American women, who bear a disproportionate burden of suffering from diabetes and its complications (2).

The impact of a chronic illness such as diabetes on quality of life is influenced by the presence of debilitating and life-threatening complications as well as by the burden of disease management. With recent confirmation of the benefits of improved glycemic control in patients with type 2 diabetes (3), it is important to gauge the benefits and burdens of glycemic control on patient perceptions of health-related quality of life (4). This effort is particularly significant for high-risk groups that could benefit most from improvements in disease management.

Health status, periodically referred to as health-related quality of life (HRQL), is an amalgam outcome variable that represents a patient’s perception of the impact of disease management and complications on their health. Although no uniform approach exists (5), subscales measuring physical, mental, and social well-being are often incorporated within this measure. Current instruments measuring HRQL in people with diabetes (6–10), while adequate for many populations, have limited applicability to older, southern African-American women with type 2 diabetes. Instruments have not been developed for an exclusively type 2 population and have not emphasized issues seminal to older African-American women with type 2 diabetes. As part of an intervention trial aimed at improving nutritional, exercise, and self-care practices in African-American women with type 2 diabetes, we sought to develop a health status measure that was specific to issues germane to this population. Our goal was to develop an instrument that was adequate (reliable and valid), pragmatic (acceptable to participants), and parsimonious (relevant while using a manageable number of concepts).

RESEARCH DESIGN AND METHODS — This study was conducted at five community health centers, one health maintenance organization, and the general medicine clinic of an academic health center, all in central North Carolina. Eligibility criteria included female African-Americans, age ≥ 40 years, with type 2 diabetes. Candidates for participation were identified by two methods, according to

From the School of Medicine (T.A.E.), Vanderbilt University, Nashville, Tennessee; and the School of Public Health (C.D.S.-H., R.F.D., A.S.A.), School of Nursing (A.H.S.), and School of Medicine (T.C.K.), University of North Carolina, Chapel Hill, North Carolina.

Address correspondence and reprint requests to Tom A. Elasy, MD, MPH, Division of General Internal Medicine, Vanderbilt University Medical Center, 7th Floor, Medical Center East, Nashville, TN 37232-8550. E-mail: tom.elsay@mcmail.vanderbilt.edu.

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Abbreviations: HRQL, health-related quality of life.

A table elsewhere in this issue shows conventional and Systeme International (SI) units and conversion factors for many substances.

Table 1—Participant characteristics

n	217
Age (years)	59 ± 10.5
Duration of diabetes (years)	10.7 ± 9.8
Income*	85% earn <\$30,000/year
Did not complete high school (%)	52
Taking insulin (%)	43
Taking oral medications (%)	56
Glycated hemoglobin	10.9 ± 2.7 (normal range: 5.5–7.8%)
BMI (kg/m ²)	35.5 ± 7.9
Total cholesterol (mg/dl)	204 ± 41
Hypertensive (%)	75
Smokers (%)	17

Data are n, means ± SD, or %. *Only 55% of subjects responded.

study site. When computerized records were available, eligible women were recommended by their primary care provider for possible participation in the study. These patients were invited to participate by a signed letter from their clinician. At sites without computerized records, clinicians invited patients to participate when seen during routine visits. Both methods reflect a convenience sample. Patients expressing an interest in the study were seen for an enrollment visit at their local practice site. After obtaining written informed consent, baseline data were collected at this visit and during three subsequent telephone interviews.

As part of a larger study, A New Leaf: Choices for Healthy Living With Diabetes, our efforts included several phases aimed at generating, clarifying, and confirming questions for a health status instrument. In the first phase, 44 African-American women, 40–75 years of age with type 2 diabetes for >1 year, participated in seven focus groups. Focus groups were convened by convenience sampling at practices in central North Carolina. African-American members of the investigative team with a background in focus group methodology moderated focus group discussions. Discussions were scheduled for 90 min with 30 additional min devoted for refreshments and reimbursements. Participants received a \$20 cash payment. Audio tapes of the encounters were transcribed.

Focus group transcripts were evaluated to generate questions and identify plausible domains. We have reported elsewhere on the details of this process (11). In addition, we asked two African-American health professionals to comment on the relevance of questions generated during this phase and, later, to comment on the adequacy of content breadth. Existing

generic and diabetes-specific HRQL instruments were also reviewed to ensure that our empirical grouping of items (mental, social, and physical well-being) was sensible based on previous work in this area.

Phase 2 incorporated cognitive response interviews to ensure clarity and cultural appropriateness of the questions. A total of 10 one-on-one interviews lasting an average of 90 min employed standard techniques (concurrent think-aloud, paraphrasing, probes) to identify problems in comprehension, culturally appropriate expressions, and acceptability and relevance of the questions as well as feasibility of the format. Individuals were asked, “What does this word mean to you” to ensure that there was no discrepancy between the intended meaning and their understanding. Again participants were reimbursed \$20. Telephone administration of the instrument was tested with 20 subjects to identify barriers to phone administration.

Phone testing of the instrument was performed to determine the psychometric properties and thereby further assess the adequacy of both individual questions and the hypothesized domains. The study protocol was approved by the institutional review board at the University of North Carolina at Chapel Hill. All data were analyzed using STATA 5.0 (Stata, College Station, TX).

Table 2—Internal consistency testing

Domain/cluster	Cronbach's α	Mean score ± SD
Mental well-being domain (n = 9)	0.83	25 ± 7.5
Social well-being domain (n = 9)	0.93	31 ± 8.7
Physical symptom cluster (n = 6)	0.76	N/A

n = number of questions. N/A, not applicable.

RESULTS — A total of 217 subjects completed the health status measure. Table 1 characterizes participants as a generally older, obese, poor population of southern, African-American women with inadequate glycemic control. The mean duration of diabetes was 11 years. The mean cholesterol was 204 mg/dl; 17% were smokers; and 75% had hypertension.

Focus group discussions helped generate potential questions. Three broad domains captured diabetes-related concerns of women during this process: social well-being, emotional well-being, and physical well-being. Social well-being questions centered on issues related to spirituality (especially church-related functions), maintenance of the home, preparation of meals, and interaction with family and friends. Mental well-being questions included both the “burden and worry” of disease management and future complications. Many subjects expressed frustration because of an inability to comprehend the diabetes care plan. Physical well-being concerns, e.g., vaginal yeast infections, were reported during this first phase.

Questions were reviewed by members of the investigative team and two outside African-American health professionals for the adequacy of sampling issues considered relevant to African-American women with type 2 diabetes. The breadth of content area was thought to be adequate.

A set of 10 cognitive response interviews permitted assessment of relevance, feasibility, and acceptability of the questions and format. We reworded most questions so as to include “My diabetes,” because this was a preferred means of referring to the disease. Words like anxiety, ill, and difficult were switched to worry, sick, and hard, respectively. We reformatted the response options to a four-point Likert scale as opposed to a six-point scale because individuals repeatedly and consistently complained about the six-point response option.

A total of 20 pilot telephone interviews identified barriers to phone administration and gave a preliminary description of indi-

Table 3—Eigenvalues of unrotated factors, and proportion and cumulative variance explained

Factor	Eigenvalue	Proportion of variance explained (%)	Cumulative variance explained (%)
1	9.01	65	65
2	1.97	15	80
3	1.11	8	88
4	0.82	6	94
5	0.53	4	97
6	0.42	3	100

An eigenvalue for a factor represents the sum of the square of each variable's loading for that factor.

vidual question variation and internal consistency values. The instrument took ~10 min to complete by phone. Of note is the absence of variation on questions related to the impact of diabetes on specific spiritual questions. We found no influence of diabetes on issues related to prayer or faith. These questions were subsequently deleted and a single question on the impact of diabetes on participation in church-related activities was kept. Also, when two questions were highly correlated ($r > 0.8$) and on examination appeared to be measuring the same thing, one was deleted if the internal consistency measure, Cronbach's α , for that scale was not adversely impacted.

The initial phases of generating, clarifying, and confirming questions resulted in a 27-question instrument. Psychometric evaluation was then performed on 217 women enrolled in our larger study. Our initial conceptualization of three subscales (physical, mental, and social well-being) was refuted. We found only two subscales. Table 2 gives the internal consistency of the mental and social well-being domains as 0.83 and 0.93, respectively. Using principal components and subsequent promax rotation, factor analysis helped identify the presence of two hierarchical domains and to exclude three questions. Promax rotation approximated simple structure better than varimax rotation. Table 3 reveals the eigenvalues derived from factor analysis. Review of the individual values, proportion, and cumulative variance, as well as the scree plot (not presented), revealed only two factors. Table 4 gives the details of the eigenvectors for each question. Three questions were dropped at this stage: one from the mental well-being subscale and two from the social well-being subscale. None of the questions about diabetes-related physical symptoms were explained by a single factor. This inability to find the influence of a single factor on the physical symptom questions remains despite the fact that when

we artificially grouped the questions into a particular cluster we were able to achieve an acceptable α (0.76).

We proceeded to further evaluate validity by examining associations between our two subscales and relevant diabetes variables. As expected (Table 5), we found a positive moderate correlation between both subscales ($r = 0.52$). Furthermore, we found a positive correlation between both subscales and a perceived health competence scale (12), supporting our hypothesis that improved health competence should be positively associated with both mental and social well-being. We anticipated that glycemic control (HbA_{1c}) should be inversely associated with both subscales. In fact, HbA_{1c} was not associated with either

subscale when examined as either a continuous or categorical variable. This is not unlike the findings of some investigators (13), although others have found an association between HbA_{1c} and subscales of HRQL (6). Of note, HbA_{1c} was not associated with diabetes duration, BMI, or insulin use (data not included). In fact, unlike other studies (6), patients on insulin had a slightly higher (11.4%), though statistically nonsignificant, HbA_{1c} compared with those not taking insulin (10.7%). Physical activity, measured directly by an accelerometer worn for seven consecutive days, correlated positively with social well-being but not with mental well-being. We anticipated this finding because most of the social well-being questions involved some degree of physical activity.

CONCLUSIONS — Health status, or health-related quality of life, is a loosely defined outcome employed by health care investigators in an attempt to assess a patient's perspective on the impact of disease management and complications on their health. Health has been defined by many investigators as physical, mental, and social well-being (14). Part of the challenge in measuring health status is sorting out effects due to health and those concomitant effects that are a consequence of changing

Table 4—Individual eigenvectors for retained questions in the mental and social well-being domains after promax rotation

Question	Mental well-being domain (1–9)	Social well-being domain (10–18)	Unexplained or uniqueness
1	0.54	0.22	0.43
2	0.61	0.05	0.40
3	0.72	0.09	0.37
4	0.70	0.02	0.32
5	0.70	0.10	0.41
6	0.62	0.11	0.39
7	0.58	0.16	0.59
8	0.59	0.13	0.44
9	0.48	0.14	0.43
10	0.10	0.68	0.27
11	0.10	0.68	0.32
12	0.09	0.72	0.22
13	0.13	0.61	0.32
14	0.29	0.68	0.18
15	0.26	0.67	0.27
16	0.11	0.79	0.13
17	0.21	0.71	0.14
18	0.38	0.61	0.25

The loading (eigenvector) of a variable on a factor equals the correlation between that variable and the entire set of variables, including itself.

Table 5—Construct validity

	Mental well-being	Social well-being	Glycosylated hemoglobin	Diabetes duration	Physical activity	Perceived health competence
Mental well-being	1.0	—	—	—	—	—
Social well-being	0.52*	1.0	—	—	—	—
Glycosylated hemoglobin	-0.09	-0.06	1.0	—	—	—
Diabetes duration	-0.14	-0.28*	-0.16	1.0	—	—
Physical activity	0.07	0.28*	0.02	-0.18	1.0	—
Perceived health competence	0.39*	0.27*	-0.19	0.25	0.08	1.0

Data are Pearson product-moment correlations. *Statistically significant ($P < 0.05$) after adjusting for multiple comparisons.

patterns of finance, friendship, family life, responsibilities, expectations, occupation, aging, and so on (15). The effort to measure health status has spawned a large number of instruments of varying quality (16).

We employed several techniques to develop an appropriate health status measure for southern African-American women with type 2 diabetes. We have focused on a specific subset of individuals so as to decrease the potential heterogeneity of factors that are seminal to health status. By restricting our focus to a more homogeneous sample, we decreased the likelihood of missing substantive issues. While this restriction may enhance our “internal validity,” we recognize that it may limit the widespread use of the instrument. Furthermore, we recognize that even within a small subset of the population, great heterogeneity still exists. Nevertheless, given the lack of attention to developing instruments for minority populations, we feel that this one represents an improvement for measuring health status in older African-American women with type 2 diabetes inasmuch as we incorporate hitherto unexamined questions. In particular, our focus group findings suggested the importance of including questions addressing frustration about lack of knowledge, the burden of having diabetes, and the difficulties/guilt of self-management failures in a mental well-being subscale. Issues related to church participation and home management are important new contributions to measuring social well-being. Finally, we included vaginal yeast infections and nocturia in the physical index scale.

In developing this instrument, we used information provided by patients in the focus groups and cognitive response interviews. This approach is different from that of others who generated questions largely through discussions among health care workers (10). Nevertheless, health care pro-

fessionals including a psychologist, nurse, nutritionists, social workers, and physicians were included in an iterative process to refine the questions. We included “My Diabetes” in most of the questions so as to focus attention of disease impact on specific questions. Patients found this a way to direct their attention to the impact of diabetes on the question at hand and not the influence of finances, friendship, family life, etc.

We sacrificed some precision for the sake of pragmatism. Although we knew that a six-point scale would enhance our ability to detect true variation and subsequently improve the reliability of our scale (17), we elected to honor the subjects’ requests for fewer response options. Some thought it was “silly” to have so many options while others clearly struggled to discriminate at a six-point degree of precision.

We revised our original conceptualization after the final data were collected. We had originally conceptualized three subscales. We subsequently refined that to two subscales, social and mental well-being, and a physical symptom index. Factor analytic results strongly supported our grouping of mental and social well-being questions but there was no common factor to explain the variance in the physical symptom questions despite a reasonable measure of internal consistency for these questions ($\alpha = 0.76$). α tells how much variance items have in common. A high α is no guarantee that a set of items reflects the influence of a single common variable. This is readily explained when one considers that questions in a quality of life measure may either be “causal” or “effect” indicators (18). When a set of items share a common cause (i.e., when the items are indicators of the effect of a common underlying variable), summing the items has the effect of aggregating the characteristic that they have in common. At the same time, information that is not shared among the

items is attenuated. Consequently, summing such items into a scale enhances precision, relative to using individual items. Where items are similar in their effect but not in their cause, summing does not necessarily increase precision relative to using individual items. Because we regard items assessing physical symptoms as corresponding to the latter case (an assessment supported by the failure of these items to form a coherent factor), we chose not to aggregate them but to treat them as individual variables.

Finally, several hypotheses were generated to assess the instrument’s construct validity. Like others (13), we were unable to show an association between HbA_{1c} and subscale values or physical symptoms. Nevertheless, the expected subscale associations with one another, diabetes duration and perceived health competence, lend support to the validity of our instrument. We specifically did not administer a “standard” HRQL measure along with this instrument. Since we did not feel that current HRQL instruments were sufficiently focused on issues germane to southern, older African-American women with type 2 diabetes, it seemed inconsistent to administer another HRQL instrument and assess association between ours and a “standard” that we feel is inadequate.

A 24-item culturally appropriate disease-specific health status measure has been developed for older southern African-American women with type 2 diabetes. We have established the internal consistency, factor analytic properties, and content validity of the measure. Initial construct validity findings are encouraging.

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