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The RAND-36 measure of health-related quality of life

Ron D Hays and Leo S Morales

The RAND-36 is perhaps the most widely used healthrelated quality of life (HRQoL) survey instrument in the world today. It is comprised of 36 items that assess eight health concepts: physical functioning, role limitations caused by physical health problems, role limitations caused by emotional problems, social functioning, emotional wellbeing, energy/fatique, pain, and general health perceptions. Physical and mental health summary scores are also derived from the eight RAND-36 scales. This paper provides example applications of the RAND-36 crosssectionally and longitudinally, provides information on what a clinically important difference is for the RAND-36 scales, and provides guidance for summarizing the RAND-36 in a single number. The paper also discusses the availability of the RAND-36 in multiple languages and summarizes changes that are incorporated in the latest version of the survey.

Keywords: generic profile measure; health-related quality of life; RAND-36; SF-36.

Ann Med 2001; 33: 350-357.

The RAND-36 measure of health-related quality of life

Health-related quality of life (HRQoL) refers to how health impacts on an individual's ability to function and his or her perceived well-being in physical, mental and social domains of life. The functioning part of HRQoL includes basic activities, such as self-care (eg, bathing, dressing), as well as work-related activities (whether paid or not) such as housework and career. It also includes the extent to which one is able to interact with family and friends (social functioning).

Functioning is thought to be relatively objective because self-report information can be compared with other sources of data such as observations or performance measures (1). The well-being part of HRQoL is somewhat more subjective than the functioning part, because it relies almost exclusively on the internal, subjective perceptions of the respondent. Included is whether the person feels happy, sad, depressed, or anxious (emotional well-being), whether they are in severe pain or have no pain at all, and whether they are energetic or lethargic. Comprehensive measures of HRQoL include items assessing physical, mental, and social domains of life.

A fundamental distinction between HRQoL measures is whether they are disease-targeted or generic. Disease-targeted HRQoL measures are designed to be applicable and relevant to a particular disease such as diabetes or cancer. In contrast, generic HRQoL measures are designed to be applicable to anyone. They are analogous to intelligence tests in that different people can be compared to one another because they have taken the same test. Generic measures have two basic forms: profile and preferencebased. Profile measures are designed to yield scores on multiple aspects of HRQoL. Preference-based measures are designed to produce a single summary score that cuts across the multiple domains of HRQoL. Because this special issue has an economic emphasis, several of the papers are devoted to preference-based measures such as the EQ-5D, Assessment of Quality of Life (AQoL), 15D and Health Utilities Index (HUI). The RAND-36 health survey is an example of a profile

The RAND-36 is perhaps the most widely used HRQoL survey instrument in the world today. It is comprised of 36 items selected from a larger pool of items used in the RAND Medical Outcomes Study (MOS) (2). Twenty of the items are administered using a past 4 weeks' reporting interval. RAND-36 assesses eight health concepts with multi-item scales (35 items): physical functioning (10 items), role limitations caused by physical health problems (4 items), role limitations caused by emotional problems

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(3 items), social functioning (2 items), emotional wellbeing (5 items), energy/fatigue (4 items), pain (2 items), and general health perceptions (5 items). An additional single item assesses change in perceived health during the last 12 months. Physical and mental health summary scores are also derived from the eight RAND-36 scales (see below).

The RAND-36 takes about 7–10 minutes to self-administer. Alternative forms are available for weekly administration (ie, 1-week recall period) and different modes of administration. In addition to self-administration, a trained interviewer can administer the RAND-36 by telephone or in person. McHorney and co-workers (3) found that the telephone mode of administration was more expensive, had a lower response rate, produced fewer missing item responses, and led to more positive reports of health on the RAND-36 than did the mail mode of administration. An internet version of the RAND-36 is also available (4, 5).

The 36 items are distributed by RAND as the RAND 36-Item Health Survey 1.0 (6, 7), by the Psychological Corporation as the RAND-36 Health Status Inventory (8), by the Medical Outcomes Trust as the SF-36 health survey (9, 10), and by the Health Outcomes Institute as the Health Status Questionnaire (see Appendix for RAND-36 items).

RAND-36 scales and two underlying dimensions

The most common scoring approach for the RAND-36 items boils down to transforming every item linearly to a 0-100 possible range (per cent of total possible score) and then averaging all items in the same scale together. However, the Medical Outcomes Trust and the Health Outcomes Institute versions of the RAND-36 have minor deviations in scoring for one or both of the pain and general health scales. Hays and co-workers (6) showed that these differences have minimal effects on scale scores. Nonetheless, the Medical Outcomes Trust scoring increases the correlation between the two pain items because one item is scored conditional on the other. As a result, the internal consistency reliability estimate based on this scoring is biased upward. The Psychological Corporation (RAND-36) version incorporates item response theory (IRT) scoring methods. Correlations between simply-summated and IRT scores for the RAND-36 are substantial (8), but IRT scoring is designed to produce equal interval measures (11).

Different distributors also score physical and mental health summary scores differently. Factor analyses of the RAND-36 health survey in the US provide strong support for a 2-factor model of health, with physical health reflected primarily by measures of physical

Key messages

- The RAND-36 (SF-36) is the most widely used measure of health-related quality of life today.
- The RAND-36 is a profile measure that yields eight scale scores and two summary scores (physical and mental health).
- A preference-based score has recently been developed for the RAND-36.

functioning, pain and role limitations arising from physical health problems, and mental health reflected primarily by measures of emotional well-being and role limitations caused by emotional problems (8, 12). General health perceptions, energy/fatigue and social functioning reflect both dimensions.

The physical (PCS) and mental (MCS) component summary scales derived for the RAND-36 by Ware, Kosinski, Bayliss, and co-workers (13) were forced to be uncorrelated (orthogonal) whereas those derived by Hays, Sherbourne, and Mazel (6) were allowed to correlate (oblique). Product-moment correlations between physical and mental health factors at each of 3 years (baseline, 2-years post-baseline, and 4-years post-baseline) in the MOS ranged from 0.32 to 0.41 (12). Similarly, a correlation of 0.53 between physical and mental health factors was reported in a study of 1053 older individuals (average age 64 years) sampled from an academic general medical clinic (14). In addition, Hays, Prince-Embury and Chen (8) reported a correlation of 0.66 between physical and mental health factors in a sample of 255 females and 245 males stratified by age, race/ethnicity and educational level to reflect the US population.

Orthogonal (uncorrelated) factor rotations yield a less realistic representation of the physical and mental health factors than do oblique rotations (15). In fact, the PCS and MCS scores resulting from orthogonal factor rotation can yield counterintuitive results. For example, a study of 536 primary care patients who initiated antidepressant treatment found that the RAND-36 physical functioning, role limitations caused by physical health, pain and general health perceptions scales improved significantly by 0.28-0.49 SD units, but the PCS did not change significantly (16). Similarly, Nortvedt and co-workers (17) reported in a study of 194 patients with multiple sclerosis large decrements in emotional well-being (0.3 SD), role limitations caused by emotional problems (0.7 SD), energy/fatigue (1.0 SD), and social functioning (1.0 SD) relative to the general population, but the MCS was only 0.20 SD lower. Both of these anomalies occurred because RAND-36 mental health scales 352 Hays • Morales

receive negative weightings on the PCS, and RAND-36 physical health scales receive negative weightings on the MCS. Thus, high mental health scale scores tend to lower the PCS and high physical health scores tend to lower the MCS scores.

Example applications of the RAND-36

Generic profile HRQoL measures, such as the RAND-36, have been used to compare the relative burden of disease for patients with different chronic illnesses. For example, the HRQoL of 2864 HIV-infected adults participating in the HIV Cost and Services Utilization Study, a probability sample of adults with HIV receiving health care in the United States, were recently compared with that of patients with other chronic diseases and to the general US population (18). RAND-36 physical functioning scores were about the same for adults with asymptomatic HIV disease as for the US population but were much worse for those with symptomatic HIV disease or for those who met criteria for the AIDS. Patients with AIDS had worse physical functioning than those with some of the other chronic diseases (epilepsy, gastroesophageal reflux disease, clinically localized prostate cancer, clinical depression, diabetes). RAND-36 emotional well-being was comparable among patients with various stages of HIV disease, but was significantly worse than among the general population and patients with other chronic diseases with the exception of depression (Fig 1).

The RAND-36 has also been used to assess HRQoL between patients with different diseases over time. For example, patients with hypertension, diabetes and depression (major depression, subthreshold depression) in the MOS were compared at baseline and 2-years post-baseline (19). As expected, patients with depression at baseline had substantially worse emotional well-being than patients with the chronic medical illnesses (hypertension, diabetes) at baseline of the study. Would these differences persist over time? Figure 2 shows the course of emotional wellbeing from baseline to 2 years later. This picture indicates a relatively flat line for the chronic medical illnesses and positive gains in emotional well-being over time for the patients who were depressed at baseline, especially those with major depression. Nonetheless, patients depressed at baseline continued to demonstrate relatively poor emotional well-being 2 years later.

Another longitudinal application of the RAND-36 was illustrated in a study of the associations of physical activity and exercise with HRQoL in the MOS sample (20). For illustrative purposes (Fig 3), MOS patients with chronic medical illness (hypertension, diabetes) or depression were classified at baseline into those spending little or no time exercising (low) vs those spending a lot of time exercising (high). Those who exercised more had better physical func-

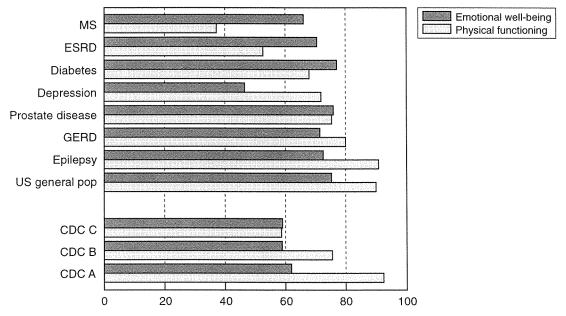


Figure 1. Comparison of RAND-36 emotional well-being and physical functioning scales for 2864 people with HIV infection, patients with chronic disease, and the general US population. MS, multiple sclerosis (n = 178); ESRD, end stage renal disease (n = 165); diabetes, type II diabetes (n = 541); depression, clinical depression (n = 502); prostate disease, prostate cancer (n = 98); GERD, gastroesophageal reflux disease (n = 516); US General Pop., US general population (n = 2474); CDC C, AIDS (n = 1126); CDC B, symptomatic HIV (n = 1495); CDC A, asymptomatic HIV (n = 243).

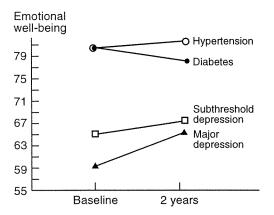


Figure 2. Course of emotional well-being over 2 years for patients in the Medical Outcomes Study.

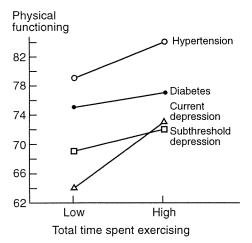


Figure 3. Association of baseline exercise with physical functioning 2 years after baseline in the Medical Outcomes Study.

tioning 2 years post-baseline than those who exercised less, suggesting a possible beneficial effect of exercise.

Minimally clinically important difference

It is generally believed that small differences in HRQoL may be statistically significant yet unimportant. The concept of minimally clinically important difference (MCID) has been proposed to refer to the smallest difference in a score that is considered to be worthwhile or important. Samsa and co-workers (21) reviewed the existing literature and concluded that the MCID for the RAND-36 is 'typically in the range of 3 to 5 points' (p. 149).

The literature on the RAND-36 shows that very small differences on the survey could be interpreted as clinically important. The 3–5 point difference in RAND-36 scale scores noted by Samsa and coworkers (21) as the MCID translates into a 0.09–0.28

effect size range. Consistent with this, persons with mild asthma scored 0.86 points (0.09 SD) below the average US adult on the PCS (10). Low back therapy was associated with a 1.3-point (0.13 SD) improvement on the MCS (22). Intermittent treatment for duodenal ulcer has been shown to be associated with an improvement of 3.2 points (0.32 SD) on the PCS (23). All of these changes are arguably clinically important.

The quest to identify a clinically meaningful difference in HRQoL research is part of a more general goal of providing familiar anchors to unfamiliar units to aid interpretation. This is a worthwhile endeavour that can help researchers and clinicians better understand the measures they are using. However, the identification of the MCID is often the 'most contentious issue discussed by grant review panels.... In most cases, the opinions of both the researchers and reviewers are arbitrary and unsupported by evidence' (24).

Absolute MCID thresholds are suspect, because they ignore the cost or resources required to produce a change in HRQoL. Just as cost-effectiveness and cost-utility are more comprehensive approaches than examination of outcomes alone, it is also true that the worth of a HRQoL score change depends on the cost to produce it. A small positive change has greater worth by definition if achieving that improvement is possible at lower cost (worth = ratio of incremental improvement to incremental cost). In the extreme case, a therapy that provides an improvement in HRQoL that does not exceed the MCID might still be worthwhile if it were cheap enough or free (25). Hence, we recommend appropriate caution in interpreting 3-5 points on the RAND-36 scales as the MCID.

Summary scores for the RAND-36

If a study shows improvement in some RAND-36 measures and decrements in others, it can be difficult to draw an overall conclusion. For example, Figure 4 illustrates a situation where a new treatment (x) looks better than standard care (o) on physical functioning, but a little worse on pain and emotional well-being, and there is no difference on social functioning. Is the new treatment better than standard care? To make concluding statements, it is necessary to have some method of summarizing the multiple scale scores.

A variety of approaches have been used to help summarize overall HRQoL impact represented in profile measures. As noted above, physical and mental health summary scores have been derived for the RAND-36. Reliability estimates for summary measures have exceeded 0.90 (8). Extensive support for the construct validity of these summary scores has also

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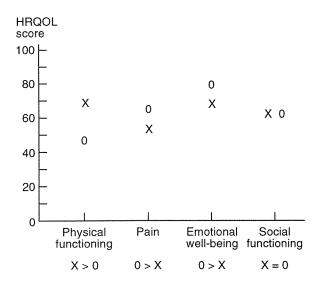


Figure 4. Is new treatment (X) better than standard care (0)?

been provided. For example, the RAND-36 PCS has been demonstrated to be strongly predictive of mortality rates 5 years later (10). Because the PCS and MCS scores were derived from a model that is inconsistent with observed data (ie, uncorrelated factors) and the potential for anomalous results discussed above, it is highly recommended that users employ the summary scores derived by the Psychological Corporation or derive scores by using an oblique factor analysis model.

Regression-weighting methods have been employed to derive a single summary score. Weights are derived by regressing a criterion measure (eg, current health perceptions, visual analogue rating, probability of being in excellent, very good or good health in the future, probability of being dead in the future) on HRQoL scale scores. These weights reflect the relative importance of the scales in predicting the criterion (26).

Attrition of participants in a study over time because of mortality creates a noteworthy problem in applying profile measures. If those who die are dropped from the analysis, results can be biased. Factor analytic and regression-weighting approaches are useful summary methods, but preference-based methods are more desirable because they explicitly combine morbidity and mortality (27). Preferencebased measures are designed to assess the value or desirability of health states. It is important to know what values people attach to different health outcomes in order to provide, as efficiently as possible, more of the outcomes that are desired and fewer of those that are not' (28). Thus, it has been recommended that the RAND-36 be supplemented with a preference measure whenever possible (27).

If a preference measure has not been administered,

it is possible to estimate one. For example, a study of 363 community-dwelling older persons found that comprehensive geriatric assessment lead to improvements in RAND-36 physical functioning scores by 4.69 relative to standard care (29). The estimated 64week intervention costs were US\$ 457 per person. Thus, the cost-effectiveness of the intervention was estimated to be US\$97 per SF-36 physical functioning scale point. Is this an intervention that is worth paying for or not? To help answer this question, Keeler and co-workers (30) estimated the change in quality-adjusted life years (QALYs) equivalent to the 4.69 change in SF-36 physical functioning score. They did this by translating a 0.69 correlation between the SF-36 physical functioning score and the Quality of Well-Being (QWB) scale into a simple regression coefficient (0.003) and multiplying this coefficient by 4.69 to obtain 0.014 as the equivalent change in the QWB. Next, they estimated an increase of 0.07 QALYs over 5 years and a cost per QALY between US\$ 10 600 and 26 500. This is useful information because previously published data indicate that many common medical interventions cost from US\$ 10 000 to 40 000 per QALY, with interventions producing QALYS for less than US\$ 20 000 regarded as worthwhile (31). If Keeler and co-workers had had a preference-based score, they would not have been forced to rely on this crude approach to estimating QALYs.

The use of preference measures, such as the standard gamble and time trade-off, as criteria for regression weighting has also been considered, but profile measures tend to account for a relatively small amount of variance (18–43%) in these criteria (32). Fryback and co-workers (33) derived regression equations to predict the QWB Scale from the RAND-36. A 6-variable regression model accounted for 57% of the variance in QWB scores.

One investigative team derived a 6-dimensional health classification scheme by using a subset of items and categories from the RAND-36 physical functioning, social functioning, pain, emotional wellbeing, energy/fatigue, and role functioning scales (34, 35). Multiattribute utility theory was used to derive preference weights for 9000 possible health states. Visual analogue and standard gamble estimating equations were developed to predict preference scores for each possible health state. The 166 participants in the valuation study consisted of health professionals, health service managers and administrators, staff at the University of Sheffield Medical School, undergraduates, and patients at hospital outpatient clinics. A larger study of 611 people from the UK general population has recently been completed by this group of investigators.

Another investigative team identified six health states from the SF-12 in depressed patients in the

MOS (36). The six scales were derived by using cluster analysis in combination with clinical criteria. For each cluster, health state descriptions were written based on SF-12 item responses given by at least half the patients in the cluster. Preference ratings were then derived for the six health states (37).

Availability of RAND-36 in multiple languages

Although the RAND-36 (aka SF-36) has been used in multiple languages, there have been few systematic efforts to produce equivalent translations for use across cultural and linguistic groups. The most important of these efforts is the International Quality of Life Assessment (IQOLA) Project. The IQOLA project is translating and validating the SF-36 for use in 45 countries, including Australia, Belgium, Canada, Denmark, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, the UK (English version), and the USA (English and Spanish versions). The purpose of the IQOLA Project is to produce translations of the SF-36 for use in multinational clinical trials and other international studies (38).

The translation protocol used by the IQOLA Project has four major stages: translation following a standard protocol including multiple forward and backward translations; qualitative and quantitative methods to evaluate the quality of a translation and its conceptual equivalence with the original survey; psychometric studies to test the scaling and scoring assumptions; and analysis of data from clinical trials and other studies to assess validity and comparability of the survey data across countries (39). In addition, normative data are being collected in general population surveys in 11 countries for purposes of normbased interpretation.

Published IQOLA Project translations and English-language adaptations are distributed by the New England Medical Center (NEMC) Health Assessment Lab. (Boston, MA) Currently, published forms are available for Australia/New Zealand (English), Belgium (Dutch and French), Canada (English and French), Denmark, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the UK (English) (40).

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SF-36 Version 2

The SF-36 Version 2 differs from the original survey instrument (version 1) in several respects including: wording changes in instructions and survey items; changes in the layout for questions and response options (41); 5-level response choices in place of dichotomous response choices for seven items in the two role-functioning scales; and 5-level in place of 6level response choices to nine items in the emotional well-being and energy/fatigue scales. These changes are purported to increase the precision of the scores generated by the SF-36 and to improve respondents' comprehension of the instrument. However, unpublished analyses of existing datasets suggest a possible lack of equivalence between the old and new versions of the energy/fatigue items. The original 'full of pep' item was replaced with a 'full of life' item in the second version of SF-36. Product-moment correlations of 0.61 and 0.64 were found between these two items in samples of people in a smoking cessation programme and people with chronic liver disease, respectively (42, 43).

A detailed description of the differences between versions 1 and 2 is available on the internet (44). Although a conversion formula between the two versions of the SF-36 is available (44), studies to further evaluate the equivalence of two versions are currently ongoing.

Conclusion

The RAND-36 is a comprehensive short-form generic profile HRQoL measure. It yields eight scale and two summary scores. When a single summary score is required (eg, cost-utility studies) it is most desirable to use the RAND-36 in combination with a standard preference-based measure (45). When a preference-based measure has not been administered, it is possible to estimate such a score from the RAND-36, but the validity of the existing estimates is subject to question.

The support of the Yrjö Jahnsson Foundation is greatly appreciated. @1986, 1992, 2001 by RAND.

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Appendix: RAND-36 items	
Your Health	
This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.	How much bodily pain have you had during the past 4 weeks?
In general, would you say your health is: [Mark an ⊠ in the one box that best describes your answer.]	None Very mild Mild Moderate Severe Very severe
Excellent Very good Good Fair Poor	
1 2 3 4 5	8. During the <u>past 4 weeks</u> , how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?
Compared to one year ago, how would you rate your health in general now?	Not at all A little bit Moderately Quite a bit Extremely
Much better Somewhat About the Somewhat Much now than better now same as worse now worse now	1 12 13 14 15
one year than one one year than one than one	
ago year ago ago year ago year ago	These questions are about how you feel and how things have been with you during the past 4 weeks. For each
\bigcap_1 \bigcap_2 \bigcap_3 \bigcap_4 \bigcap_5	question, please give the one answer that comes closest
	to the way you have been feeling.
The following items are about activities you might do during a tunical day. Does your healt new limit you in	How much of the time during the past 4 weeks
during a typical day. <u>Does your healt now limit</u> you in these activities? If so, how much? [Mark an ⊠ in	All Most A good Some A little None of the of the bit of the of the of the
a box on each line.] Yes, Yes, No, not	time time the time time time
limited limited limited	
a lot a little at all a Vig <u>orous activities,</u> such as ▼ ▼ ▼	a Did you feel full of pep? 1 2 3 4 5 6
running, lifting heavy objects, participating in strenuous sports 1 2 3	b Have you been a very 1 2 3 4 5 6 nervous person?
h Moderate activities, such as moving	c Have you felt so down in
a table, pushing a vacuum cleaner,	the dumps that nothing
о , , , , , , , , , , , , , , , , , , ,	could cheer you up?
c Lifting or carrying groceries $1 1^2 1^3$	d Have you felt calm
d Climbing several flights of stairs 1 2 3	and peaceful?
e Climbing one flight of stairs 1 2 3	e Did you have a lot
f Bending, kneeling, or stooping 1 2 3 Walking more than a mile 1 2 3	of energy?123456
y wanting more than a time	t Have you felt downhearted and blue? 1 2 3 4 5 6
" ''daming <u>2010/412/2010</u>	
i Walking one block	g Did you feel worn out? L1 L2 L3 L4 L15 L6
j Bathing or dressing yourself123	h Have you been a 1 2 3 4 5 6 happy person?
 During the <u>past 4 weeks</u>, have you had any of the following problems with your work or other regular 	
daily activities as a result of your	i Did you feel tired?
physical health? Yes No	10. During the past 4 weeks, how much of the time has your
a Cut down the <u>amount of time</u> you	physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?
spent on work or other activities $\[\] \]^1 \[\]^2$	All of Most of Some of A little None of
b Accomplished less than you would like \[\] 1 \[\] 2	the time the time the time of the time the time
c Were limited in the <u>kind</u> of work or other activities	
d Had difficulty performing the work or	1
other activities (for example, it took extra effort)	11. Please choose the answer that best describes how <u>true</u> or <u>false</u> each of the following statemets is for you.
5. During the past 4 weeks, have you had any of the	Definitely Mostly Don't Mostly Definitely
following problems with your work or other regular	true true know false false
daily activities as a result of your Yes No	a I seem to get sick
· · · · · · · · · · · · · · · · · · ·	other people 1 2 3 4 5
on work or other activities	b I am as healthy as anybody I know 1 2 3 4 5
b Accomplished less than you would like ☐¹ ☐²	
c Didn't do work or other activities as 1 2 carefully as usual	c I expect my health 1 2 3 4 5 5
During the <u>past 4 weeks</u> , to what extent has your physical health or emotional problems interfered it is a state of the state	d My health is excellent 1 2 3 4 5
with your normal social activities with family, friends neighbors, or groups?	
Not at all Slightly Moderately Quite a bit Extremely	
<u> </u>	Thank you for completing these questions!