Measuring the Quality of Life of the Elderly in Health Promotion Intervention Clinical Trials

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Synopsis

The Multicenter Trials of Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) is a series of clinical trials of biomedical, behavioral, and environmental interventions to reduce the risks of frailty and injury among the elderly. Reliable assessment of the quality of life reported by the subjects is a central issue in evaluating the interventions. An intervention may have a significant impact on an elderly person's sense of well-being, even though significant improvement is not observed in selected physical outcome measures. Elderly persons' compliance with particular intervention regimens may be influenced by the quality of life effects that they perceive in relation to the intervention.

The researchers review the definition and measurement of quality of life in the trials, with particular attention to issues in determining common measures used at all study locations. Practical considerations in the selection and use of quality of life measures in both community and institutional populations are addressed. Topics discussed include the interrelation of aging, functional capacities, and quality of life; the multi-dimensionality of quality of life in relation to differential intervention effects; and age-related issues in the collection of quality of life data. Preliminary observations are reviewed, and potential contributions of FICSIT to intervention-sensitive quality of life assessments among the elderly are noted.

THE MULTICENTER TRIALS OF FRAILTY AND INJURIES: Cooperative Studies of Intervention Techniques (FICSIT) is a project supported under a cooperative agreement for 1990 through 1993 by the National Institute on Aging and the National Center for Nursing Research, of the National Institutes of Health.

FICSIT is a series of clinical trials of biomedical, behavioral, and environmental interventions designed to increase physical functional capacity and reduce falls and fall-related injuries among the frail elderly. FICSIT differs from other interventions among the elderly in that it is a multi-institutional cooperative investigation. Its interventions are randomized clinical trials, with sample sizes ranging from 100 to 1,250. Participating clinical centers conduct their own proposed interventions and collect associated site-specific data, while simultaneously contributing to a large body of data collected from all sites. A statistical coordinating center and a monitoring board participate with the eight clinical sites in the cooperative effort. Participating sites, their populations, their proposed interventions, and major outcomes of interest are shown in the accompanying box.

A critical element in evaluating the effectiveness of the interventions is being able to consistently assess the quality of life of the subjects. Quality of

Characteristics of the Interventions
(Projects are randomized trials, except at site 7.)

Site 1. Kaiser Permanente, Northwest Region, Center for Health Research, Portland, OR. A control group is compared to a moderate exercise group. The objective is to modify home environment risks to reduce falls. The exercise sessions are in groups of 25 persons.
Sample size: 625 persons receiving exercise intervention and 625 persons in control groups.
Eligibility criteria: 65 years or older; living in the community; ambulatory; at least 1 fall in past year, a near fall in past month, or more than 75 years old.
Outcome measure: Falls and fall-related injuries.

Site 2. Yale University, School of Medicine, Gerontology Research Group, New Haven, CT. Randomized block design. Usual health care plus social visits compared with usual health care plus multidisciplinary program including behavioral and medication changes, education, and exercise.
Sample size: 150 persons in each of 2 groups.
Eligibility criteria: 70 years and older, living in community, ambulatory, no severe cognitive impairment, no participation in vigorous exercise.
Outcome measure: Balance and gait, fear of falling.

Site 3. University of Washington, Department of Health Sciences, Seattle, WA. Modified 2 X 2 factorial design using strength and endurance training. Reduced exercise time in group receiving both interventions. Randomization stratified by sex.
Sample size: 25 persons in each of 4 groups.
Eligibility criteria: 69—85 years old, living in community, unable to tandem walk perfectly, thigh strength index less than or equal to 1.38 Newton-meters per kilogram (Nm per kg) for men, less than or equal to 0.95 Nm per kg for women.
Outcome measure: Strength, aerobic capacity, gait, and balance.

Site 4. Audie L. Murphy Veterans Hospital, Ambulatory Care Department, San Antonio, TX. Usual care compared with physical therapy. Intervention is focused on general conditioning and functional activity training.
Sample size: 105 persons in the intervention group and 105 in a usual care group.
Eligibility criteria: 60 years or older, nursing home resident, functionally dependent for 2 or more activities of daily living (ADL), Mini-Mental State Examination score 50 percent or more.
Outcome measure: Functional status, physical status, health care utilization cost.

Site 5. Emory University, Wesley Woods Geriatric Center, Atlanta, GA. Randomized into control, static exercise (balance platform), and dynamic exercise (Tai Chi, an ancient Chinese exercise form) groups. Control group attends weekly health and wellness seminars.
Sample size: 67 persons in static exercise groups and control groups. 81 in Tai Chi groups.
Eligibility criteria: 70 years or older, living in community, ambulatory, no major debilitating illness.
Outcome measure: Balance, range of motion, ADLs, instrumental activities of daily living (IADL).

Site 6. Harvard University Medical School, Hebrew Rehabilitation Center for Aged, and the U.S. Department of Agriculture's Human Nutrition Research Center on Aging, Cambridge, MA. 2 X 2 factorial design using strength training and nutritional supplements.
Sample size: 25 persons in each of 4 groups.
Eligibility criteria: 80—99 years old, nursing home resident, ambulatory, 1 or more falls or high risk for fall, no acute or terminal illness, no severe dementia.
Outcome measure: Improved muscle strength. Association between nutritional status and muscle mass.

Site 7. University of Iowa, College of Medicine, Iowa City, together with Iowa State University. Compliance study of subjects in 3 groups, Parkinson's disease, post-hip fracture, and nursing home resident. Compliance to the use of hip pads is measured. Ultimate goal of hip pad project is to reduce fall-related injuries.
Sample size: 30 persons in each of 6 groups. Groups are those living in the community; nursing home residents; those in rehabilitation, primarily for stroke; Parkinson's disease patients; those with previous hip fractures; and residents of senior care facilities.
Eligibility criteria: 65 years and older, risk assessment for falls score is 12 or more, lives within 50 miles, no evidence of terminal illness, no history of psychotic behavior, able to wear hip pads.
Outcome measure: Compliance in wearing hip pads.

Site 8: University of Connecticut, Department of Neurology, Farmington, CT. 2 X 2 factorial design with balance and strength training as the interventions.
Sample size: 4 groups of 30 persons each.
Eligibility criteria: 75 years and older, living in community, ambulatory, no cognitive impairment, no terminal illness.
Outcome measure: Functional status, balance on the balance platform, gait, functional mobility.

life assessments are based on a person's own opinion of his or her physical, emotional, and social well-being. Quality of life has become a major criterion for evaluating health and medical interventions. Determining the optimal way to measure quality of life in clinical trials is a complex issue (*1, 2*).

Assessing quality of life among old persons is difficult, particularly among those who are subjects in health promotion intervention studies. We describe issues involved in age-related quality of life assessment and measurement, together with practical considerations that governed the selection and use of quality of life measures at participating sites in these clinical trials. Quality of life was viewed from the outset of the trials as an important mediator of compliance and intervention effectiveness, as well as an important outcome variable.

Aging and Health Promotion

Few major health promotion efforts have been directed toward old people. Widely held myths discourage including them in such efforts. Among the myths are that health promotion means the prevention of disease rather than improving health status; that old people are unable to tolerate health promotion interventions, as for example, exercise regimens; that old people are not able or willing to change their health attitudes, behaviors, or lifestyles; that old people are difficult to recruit into studies and hard to evaluate; that behavioral or lifestyle changes in late life will have only minimal impact on the health and functioning of old people; and that intervention is not cost effective for the elderly (*3*).

The key point is that because most old people have at least one chronic disease or disability, health promotion efforts for them are important to maintaining function. Disease prevention remains an important goal, but maintenance of function is an equally important and cost-effective objective for health promotion efforts for old persons. All the myths reflect issues that require evaluation in a clinical trial setting.

Preventing injuries and reducing loss of function. Physical deficits that contribute to frailty among the elderly occur in skeletal muscle strength; gait speed; range of motion in the joints and musculoskeletal flexibility; postural stability, including balance, coordination, and reaction time; and cardiovascular responsivity. Those conditions contribute to significant functional limitations. For example, survey data suggest that 15 percent of those ages 75–84 years are unable to climb stairs, 23 percent are unable to walk half a mile, 7 percent are unable to walk across a small room, and 24 percent are unable to lift 10 pounds (*4*). These limitations are more common among persons older than 85 years (*5*). A substantial proportion of otherwise healthy old persons have limitations in gait speed severe enough to prevent crossing an intersection quickly enough to comply with traffic signals (*6*).

Deficits in strength, mobility, and balance are prevalent physical problems among the elderly. Their progression can lead to an increased risk of injury and to subsequent inability to live independently. When physical deficits are combined with hazardous social, behavioral, or environmental conditions, the risk for injury rises. Falls are the most prevalent form of injury among old people (*7*). Thirty percent of persons ages 65 years and older living in the community fall each year. The number is higher for the oldest old and those living in nursing homes (*8*). While 5 percent of falls result in fractures, an estimated 5 to 10 percent of falls result in other serious injuries that require medical care (*7*). More than 200,000 old persons suffer hip fractures each year (*5, 9*), primarily as a result of osteoporosis and an increased risk of falling. Falls and other mobility-related injuries are a serious threat to the health and functioning of old people. Falls are likely to be associated with loss of confidence in the ability to function independently, restriction of physical and social activities, and eventual increased dependence (*10*).

Some physical deficits in old people have been shown to be to some extent preventable or reversible. Small-scale studies with old persons indicate that exercise regimens can improve strength and mobility (*11*). Exercise programs may retard the rate of age-related bone loss and increase cardiac fitness (*12*). One large-scale study of fall prevention showed that modification of home environment risks and participation in group health education sessions increased appropriate health practices and reduced the risk of falling for elderly persons (*13*). While these studies suggest that interventions should improve physical function and decrease falls and fall-related injuries, the hypotheses have not been widely investigated.

A clinical trial is an appropriate method to determine the extent to which physical frailty, functional impairment, and risk of injury among old persons could be reduced by appropriate interventions. Those interventions would be designed to improve physical functioning, such as skeletal mus-

cle strength, mobility, flexibility, and balance; decrease environmental hazards; and alter risky health behaviors and lifestyles. The Surgeon General's Workshop on Health Promotion and Aging called for well designed, controlled studies on the effects of preventive strategies on physical function capacities and injury risk and related sequelae among the aged (*14*).

The continuing FICSIT trials are evaluating effects associated with such interventions. Elderly subjects living in the community and in nursing homes are recruited. Various interventions are being tested, with appropriate controls, to determine their efficacy in increasing physical function and decreasing falls. The inclusion of quality of life measures in these trials is important in identifying the differential effects that intervention techniques may have on various quality of life domains and to gain information about the likelihood of acceptance that an intervention can achieve when applied in clinical practice with old people. Interventions that improve physical status, as for example muscle strength and endurance, but that interfere with satisfactory emotional or social function, are likely to elicit low adherence or acceptance among study subjects and the general population.

Quality of life indicators may be predictors of treatment success and should themselves be subjects of intervention. For example, the presence of depressive symptomatology has been documented as an independent predictor of both short-term and long-term recovery from hip fracture (*15*). Participation by the elderly in a health promotion intervention trial may provide them with social support that decreases their likelihood of experiencing depressive symptoms, which in turn may promote improved physical functioning.

Measuring Quality of Life

Three major issues in measuring quality of life are seen in clinical trials of this design. The first stems from the multi-dimensionality inherent in quality of life measurement. When health-promotion interventions are directed to specific physical domains, functional status as well as other dimensions of quality of life may be significantly affected. We need to be able to identify differential intervention effects in these domains. A corollary is that investigators must be prepared for possible generalized effects of the interventions. For example, physical exercise to increase muscle strength may alter metabolic rates and endocrine function; weight, emotional function, and cognitive function may be affected. Multi-dimensional assessment covering all functional domains detects potential secondary effects of the interventions.

The second type of measurement issue involves the characteristics of elderly respondents. Do they have visual or cognitive losses that dictate selection of particular types of instruments or particular data collection strategies? To what extent do elders' responses reflect age-specific reference points, such as comparisons to others of the same age? To what extent are such reference end points applied similarly across the total population of study participants?

The third type of issue is age related. The interface between particular interventions and the ability of measures to capture small changes is a key challenge for all intervention studies. However, this may be especially problematic in research with elderly subjects if change is restricted to a more narrow range than can be expected with younger subjects. A related issue is the window of change that the researcher can expect to observe in elderly subjects in response to particular interventions. The time for evaluation should be enough to assess the rate of decay of the intervention effects and to pick up any long-term delayed effects that may occur with age. One hypothesis is that interventions may prepare participants to age more successfully, so that they are better able to cope with each new stage of the aging process. These effects may not be observed for 5 or 10 years. Thus, intervention hypotheses dictate various time spans for purposes of measurement.

Quality of life domains. Quality of life attributes that are being measured in the trials parallel the quality of life attributes that are commonly incorporated in current work on this topic. The attributes or constructs are not labelled identically by all researchers, but there seems to be agreement with Spitzer (*16*) that both quality of life measurement and health status measurement should include indicators of physical function, social function, emotional or mental state or mental status, burden of symptoms, and perception or sense of well-being. The burden of symptoms construct can be addressed by focusing on assessment of pain (*17*). Perceived well-being may refer to perceived physical well-being or to perceived psychosocial well-being.

Measurable dimensions in comprehensive geriatric assessment for clinical decision making consist of similar elements, such as physical health; mental health, including cognitive, behavioral, and emo-

tional status; social and economic status; and functional status (*18*).

Age-related measurement issues. Both data collection issues and data interpretation issues arise when instruments standardized with younger subjects are selected for use with elderly subjects. The role of age-related factors in health assessment is being questioned (*3*). Studies suggest that elderly people may respond to questions on overall health differently than young people. There is evidence that old people tend to be health optimists, having more favorable health perceptions than their levels of physical functioning objectively allow. Old people are likely to use different reference points to rate satisfaction with their own health and even overall satisfaction with life, compared to the reference points that are used by young people. In short, age interacts with feelings about various dimensions of quality of life. These interactions are to be considered in selecting instruments and in interpreting data that are obtained from old persons, using quality of life instruments.

In any research that involves collecting data from elderly subjects, the actual mechanics of collection must be considered.

- If the subjects' cognitive status or ability to communicate is compromised, feedback can be difficult to obtain about quality of life consequences of an intervention, even if objective indicators of improvement, such as reduced incontinence, are evident. Some quality of life questions may be understood by most respondents, such as questions about overall current health status or health status compared with a year ago; other questions, however, may be susceptible to difficulties in comprehension, especially if several different interpretations are possible. Jobe and Mingay (*19*) suggest that including probe questions helps to address the problem.
- Visual impairment may necessitate the use of interviews rather than self-administered data-collection instruments. Hearing impairment may interfere with interview assessments. In all cases, attention must be given to fostering uniform interpretation of instruments and to checking for respondents' tendency to assume a response set for long instruments that tax attention and concentration.
- Visual analogue approaches, such as ratings on a self-anchoring ladder, may be difficult to explain satisfactorily to old respondents, who tend to have more difficulty with abstract concepts (*20*).
- What kinds of information can reliably be obtained from proxy respondents and what are the characteristics of good proxy respondents? Spouses and adult children are the most frequent surrogate respondents in the FICSIT trials. Response precision and response bias are major concerns (*21*). In general, agreement between proxy respondents and study subjects themselves, regardless of subjects' ages, tends to be poor on variables such as overall health ratings (*22*). Because the use of proxies may introduce considerable measurement error, it is important to evaluate and report these potential sources of error (*21*). For the frail, especially if there is cognitive impairment, it is better to use direct observation. Physical performance measures are thought to provide the most valid assessments of physical function (*23, 24*). However, more subjective evaluations, such as reports of pain, do not easily lend themselves to direct observation. Home visits are very expensive to conduct, and self-administered or surrogate-administered questionnaires may be the only feasible data-collection option.

Assuming that instruments that work well with elderly subjects are selected and carefully administered so that measurement reliability and validity are maximized, some subjects will show a ceiling effect (no deficits) and others a floor effect (pronounced deficits) using particular instruments. Multiple measures of quality of life domains help to address this concern. Long-term changes, especially subtle changes in activities of daily living, such as toileting, behavior, and mobility, may be difficult to capture. It is important that a study be able to detect such changes, because even very small reductions in functional disability may make major differences in costs of care and quality of life among old people (*25*). Even for the most widely used and well understood measures of quality of life, sensitivity to change remains an issue; relatively little is known about instruments' sensitivity to change in the context of particular trials (*26*). The FICSIT trials offer an opportunity to contribute to understanding this issue.

Intervention effects. The ability to identify differential intervention effects on varying quality of life dimensions is important in FICSIT.

First, improvements in physical frailty indicators, such as muscle strength, endurance, and balance, may not translate into increases in functional capacity or perceived well-being. Interventions aimed at increasing old people's lower leg muscle

strength might be uniformly successful, but will increased muscle strength enable frail old people to be less fearful about falls and to leave their rooms or homes more often? What kinds of quality of life outcomes can be anticipated for what kinds of interventions among elderly subjects?

Second, if an intervention is associated with subjects' perception of unpleasant or dysfunctional quality of life outcomes, such as loss of autonomy, impaired sleep patterns, or sore muscles, its potential usefulness is lessened, even if it is found to be associated with reduced incidence of frailty-related injuries. For example, falls are reduced when patients are restrained to protect them. However, what is the relative benefit of fewer falls at the expense of losses in personal autonomy and independence? In other examples, the balance between functional and dysfunctional outcomes may be subtle. Exercise can be expected to give participants a sense of control over their bodies and over their lives by helping them to schedule time for exercise. This can have generalized effects on all areas of life and functioning. The renewed sense of control will serve to reinforce the intervention effects as persons who feel better become more active and do more things. However, increased activity will increase risks of injury somewhat, especially from overexertion and more exposure to environmental hazards for falls. Going to a park, beach, or mountains is better than staying inside, but one can trip over a rock or a hole in the ground while outside.

Third, the likelihood of health-promotion interventions being accepted for use by the general population will probably be directly proportional to the interventions' success across multiple quality of life dimensions.

FICSIT Quality of Life Assessment

The first requirement for selecting measures to be included in the FICSIT common data base was a measure's established reliability and validity in research with old persons. The second requirement was its applicability to elders living in the community and in nursing homes. In the trials, interventions with elders living in the community are being tested at five sites. Interventions with those living in nursing homes are being tested at three sites.

FICSIT presents special challenges because of the wide range of physical and cognitive functioning expected across the eight sites. Initial discussions showed it would be impossible for all measurements to be identical in both community and institutional populations. Since an estimated 80 percent of nursing home residents are cognitively impaired or have other mental health problems, investigators did not believe they would get valid responses to quality of life assessment instruments that require cognitive differentiation (*27*). Residence in a nursing home alters the range of possible responses in that nursing home residents are not expected to cook their own meals, to shop, or to participate in social visiting outside of the home.

Because the primary focus of the trials is on frailty and injuries, it was important to go beyond activities of daily living measures (*28, 29*) and include a variety of measures of subjects' physical functioning. Standardized assessments of mobility, gait, balance, and strength were included in the common data base, with emphasis placed on observation-based measures to differentiate actual performance from self-reported capability. Subscales of the Sickness Impact Profile (SIP) that assess body care and movement, ambulation, and physical mobility (*30*) were included. The number of chronic conditions and use of medication were measured for each subject. To reduce respondent fatigue, subsets of measures could be completed at separate data gathering sessions.

Other domains of well-being or quality of life are important research interests in the trials. To obtain comprehensive, multidimensional assessments with minimal respondent burden, 17 questions comprising 5 subscales from the Medical Outcomes Study (MOS) Short-Form Health Survey (*17*) were asked. The five subscales measure limited role functioning because of physical health, mental health, and social functioning. The subscales also measure bodily pain and general health perceptions. One question, "In general, would you say your health is excellent, very good, good, fair, or poor," was asked of all subjects. The predictability of this one item for mortality outcomes has been demonstrated in several studies (*31*). Because the remaining 16 questions are only appropriate for community-dwelling subjects, the MOS subscales are part of the common data base for community-dwelling subjects, but not for subjects at nursing home sites. The five subscales yield separate scores that can help to specify the interaction of respondent characteristics with particular quality of life dimensions, which is preferable to a single summary score that may mask the effects of health interventions on specific quality of life domains (*3*).

The Folstein Mini-Mental State Examination (*32*), a crude cognitive screener, was administered

Data Contributed by Participating Sites to Common Data Base

1. **Demographics and health behaviors** (required at all sites): age, sex, race, education, marital status, residence type and length, persons lived with, work hours per week, smoking, drinking, sleep problems, hospitalization, and physician visits in the past year.

2. **Cognitive status** (required at all sites): Folstein Mini-Mental Status Examination.

3. **Depression**: Center for Epidemiologic Studies Depression (CES-D) Scale (community sites), Yesavage Geriatric Depression Scale (nursing home sites).

4. **Quality of Life**: Sickness Impact Profile (SIP) Ambulation and Mobility subscales, self-rated health item from Medical Outcomes Study (MOS) Short-Form Health Survey (MOS-SF) (all sites); 5 MOS-SF subscales (limitations owing to physical health or mental health, social function, pain, health perceptions) (community sites); SIP Body Care and Movement subscale (nursing home sites).

5. **Falls and injuries**

(*a*) Fall questions (required at all sites): frequency of falls and near falls, fainting episodes.

(*b*) Self-report, fall-related injuries (required at community dwelling sites): 18 questions regarding fall-related broken bones, repeated for each fall.

(*c*) Medical records on injuries (required at nursing home sites): source of record; same questions on fractures as in self-reported reports at community dwelling sites; added items on head injuries, lacerations, and joint injuries.

(*d*) Activity restrictions (required at community dwelling sites): fall-related activity restrictions regarding walking in and away from home and daily activities in the home.

(*e*) Fear of falling (required at all sites): 7 required items regarding the extent of a person's fear of falling.

(*f*) Falls self-efficacy scale (optional at all sites): degree of concern regarding subjects' ability to perform each of 10 common daily activities.

6. **Physical functioning**

(*a*) Activities of daily living (ADL) (required at nursing home sites): Katz ADL yields data on 6 ADL.

(*b*) Instrumental activities of daily living (IADL), required at community dwelling sites: data on 16 interviewer-administered and 6 self-administered IADLs.

(*c*) Gait (required at all sites): self-selected walking speed, distance walked, need for assistive devices.

(*d*) Static balance (required at all sites): 10-second stances with feet together, semi-tandem and tandem.

(*e*) Physical characteristics (required at all sites): weight and height; method of measuring height (standing, supine, or knee length).

(*f*) Handgrip dynamometry (required at all sites): handgrip strength of dominant and nondominant hand, repeated three times.

(*g*) Chair stand (required at nursing home sites): three trials with times recorded. Method of standing, such as use of assistive devices.

(*h*) Passive knee range of motion (optional at all sites): using goniometer, measure knee extension in degrees on both legs. Does the knee extend to neutral position (yes or no).

(*i*) Passive ankle range of motion (optional at all sites): using goniometer, ankle plantarflexion and dorsiflexion is measured on both legs. Dorsiflexion to the neutral position (yes or no).

(*j*) Chronic conditions (required at all sites): using medical records or self report, record history of cancer, myocardial infarctions, stroke, diabetes, hip and other fractures, Parkinson's disease, chronic obstructive pulmonary disease, arthritis, amputation, cataracts, and urinary incontinence.

(*k*) Medications (required at all sites): record all drug names and, optionally, dose and frequency.

(*l*) Bioelectric impedence (optional at all sites): use bioelectric impedence machine and standardized protocol to perform total body water and body composition analysis.

(*m*) Near-vision acuity (required at all sites): measure visual acuity using standardized protocol.

to all subjects, using a version adapted by the Consortium of Epidemiology Research on Alzheimer's Disease, or CERAD (*33*). Scores on the MMSE can be used to exclude subjects who cannot perform complex behaviors required by particular interventions. However, a universal cognitive status eligibility cutoff score was not established in these trials because we believed that the individual interventions are beneficial to different populations. For example, cognitive abilities may be less essential to compliance with nursing home regimens requiring wearing hip pads than to compliance with intensive daily exercise protocols carried out in the home. Cognitive assessment is useful for characterizing and comparing study populations. Significant improvement in cognitive ability is not anticipated in response to participation in the trials, but cognitive status may be a useful predictor of subject compliance or of the success of a particular intervention.

Additional information about subjects' mental health is obtained by collecting responses to standard measures of depression. There is an expected increase of depression with aging (*34*). Depression is measured in all subjects not only as a screening measure but as an indicator of emotional distress that can be compared before and after interventions.

Depression may be a predictor of intervention outcomes. As noted, the presence of depressive symptomatology has been documented as an independent predictor of both short-term and long-term recovery from hip fracture (*15*). The short version of the Yesavage Geriatric Depression Scale (*35*) is the instrument used in nursing home sites. The Center for Epidemiologic Studies Depression (CES-D) Scale (*36*) is the instrument used by sites conducting trials with elders living in the community. The Yesavage instrument only requires a *yes* or *no* response to items and is therefore considered to be easier to complete.

For nursing home residents, the living environment is more controlled than for those living in the community, and assessment of the environment (a recognized crucial element in comprehensive geriatric assessment) can be included as a variable in analyses of intervention outcomes for nursing home residents. The Multiphasic Environmental Assessment Procedure (MEAP) is a useful instrument for evaluating nursing home subjects' environment. MEAP (*37*) covers a broad range of physical, social, and managerial domains, including recreational activities, the decision-making process in the facility, rules regarding problem behaviors, characteristics of rooms that are available to residents, backgrounds of staff members and volunteers, the background and health status of the resident, general physical and environmental characteristics of the facility, and the nature and quality of treatment of residents.

In addition to contributing to the common data base, individual sites provide other measures, depending on site-specific hypotheses and relative emphases on quality of life as the primary outcome. For example, to complement fall reduction as a primary outcome, some sites are assessing subjects' fear of falling. Interventions may affect the degree of the self-efficacy regarding ability to avoid falls, even if they cannot be differentiated with respect to fall-related injuries because of a lack of statistical power for rarer events. The accompanying box summarizes the measures incorporated in the trials and specifies the sites where they are being obtained.

Preliminary observations. The collaborative nature of the trials facilitates feedback on the experiences of the different sites with collecting data for the common data base. Observations from the data-collection effort may be informative for other researchers on similar studies.

Respondents' cognitive status has implications for assessment of function at both ends of the continuum. Old persons often feel threatened by being asked to complete the Mini-Mental State Examination and may even attempt to memorize the basic recall words in order to achieve a good score. A lead-in script indicating that some questions may be easy and others hard helps to reassure old respondents. In the nursing home setting, investigators have reported difficulty in obtaining physical functioning measures from cognitively impaired persons who have the ability to perform, such as to walk a certain distance in a certain time period, but who cannot follow instructions. A helpful strategy is for the assessor to model the desired behavior by showing the respondent what is wanted as instructions are given. Usually respondents understand and are able to perform the requested task.

In the Medical Outcomes Study Short Form, response codes vary frequently. Data collectors working with elderly respondents have found that showing subjects response cards so that they can point to their desired response can be helpful in making responses more specific when administering instruments for which varying response codes prove cumbersome.

Finally, investigators need to be sensitive to the

effects of the order of administration of separate quality of life instruments. Old subjects who complete a depression scale may be made aware of losses and unhappiness in their lives, and their responses to subsequent instruments may reflect an enhanced level of negative affect. Questioning should begin with items that have low emotional impact and lead the respondent logically through subsequent items. It may be necessary to interject brief explanatory statements about the need to ask certain questions (*38*).

Events in the outside world may have a confounding effect on quality of life response frameworks. An example is, "Normally I am a happy person, but I am upset about the outbreak of war," especially when such events take on heightened salience for particular people. Investigators who were attempting to obtain quality of life information from residents of a primarily Jewish nursing home, for example, found that they had to temporarily suspend data-gathering efforts when the missile attack on Israel began in early 1991. Whenever questions prove stressful or fatiguing for old persons, it is important to provide a respite. More agreeable or positive questions can be interjected, or the respondent may be given time to stretch or otherwise relax before continuing with the questioning. Concluding the data gathering session on a positive note is always recommended (*38*).

Project Agenda

Data gathered during these trials will add highly useful and previously unavailable information about quality of life research with old people. Issues of particular interest include

- the effectiveness of different indicators of the same quality of life domain in terms of feasibility of administration to elderly persons;
- the sensitivity of quality of life measures to changes in function resulting from particular interventions; a comparison of long and short forms of instruments, such as measures of physical functioning, should provide valuable information about the sensitivity of briefer measures;
- the interaction of different quality of life measures with age and various comorbidities;
- the extent to which observed relationships hold between different populations of elderly persons, such as between community residents and nursing home residents, and between an HMO population and old people who are evaluated in their own homes.

An important contribution of quality of life assessments in the trials is their usefulness for economic analyses. Without common measures of intervention outputs, it is not possible to compare the relative productivity of the different intervention strategies. In order to draw public policy implications, it is important to be able to specify which interventions produce the greatest return per dollar of investment. The interventions represent a wide range of resource intensity, from team-oriented clinical interventions with several professionals caring for an individual patient, to group health behavior interventions with a ratio of 1 interventionist to 10 or 15 participants. The average cost per participant varies substantially in the trials, which is a strength from the perspective of health economists. Quality of life assessments will help us to determine whether high intensity interventions are worth their additional cost, or if low technology methods are better values, when costs per year of quality of life gained are specified.

The trials required multidisciplinary involvement to allow the interaction of biomedical, behavioral, and social factors to be incorporated in the research. Within this framework, the potential for well designed interventions to lead to maintenance and improvement of functioning can be explored. The multicenter trials focus on both community-dwelling and institutionalized elderly persons, and information is obtained in participants' own homes as well as in centralized research settings. A large common data base allows investigators to examine trends that emerge across varied settings and in different intervention protocols.

The role of quality of life issues in the trials demonstrates the interdependence of geriatric and psychosocial considerations in maintaining functioning and preventing disability of the aging (*39*).

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