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DEPRESSION IN ASSISTED LIVING FACILITIES

By

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A THESIS

**Submitted to
Michigan State University
In partial fulfillment of the requirements
For the degree of**

MASTER OF SCIENCE

Department of Epidemiology

2002

ABSTRACT

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Assisted Living Facilities (ALFs) are a quickly growing component of the senior residential housing market, with over 11,200 facilities nationally providing care for elderly Americans. In 1999, the US Surgeon General reported that although nearly 20% of all Americans have some sort of mental illness, only half will receive treatment. Although the demographic, functional and psychiatric status of nursing home and foster care patients has been well defined in psychiatric literature (3-6), little is known about ALF residents. Given this growth, our proposal seeks to study the characteristics of depression in a novel new setting (the ALF), as a basis for future interventions-based research in ALFs. This project will: (1) determine the prevalence of depression in the ALF; (2) describe the clinical characteristics of the depressed ALF population; (3) delineate the current pattern of depression treatment in an ALF; and (4) highlight the level of unmet clinical need for depression treatment in the ALF population. Using a two-step process patterned after large community survey projects such as the ECA or NDS, we will first screen for depression and then define diagnosis and treatment patterns using three interviews. The first semi-structured interview will include data from the MAI, HAM-DRS, PRIME-MD PHQ and demographics. The second interview will consist of the SCID to determine a diagnosis of major or minor depression. Finally, the third interview will elicit data on current depression treatment patterns as well as barriers to service.

This thesis is dedicated to my grandmother Bernice Banaszak,

Whose life inspired my work.

ACKNOWLEDGEMENTS

My sincere thanks goes out to my thesis committee, Drs. Paneth, Colenda and Gardiner for their guidance, inspiration and helpful advice throughout my program of study.

I am grateful to the Departments of Epidemiology and Psychiatry, for providing both time as well as financial resources to allow me to complete this degree. To the Colleges of Osteopathic and Human Medicine, I thank you for your support.

My friends and family have encouraged this effort in incredible, unselfish ways over the past two years. All of you are special people. My sincere gratitude goes to Lori, Nancy, Linda, John, Sharon, Eric and the staff at Porter Hills, HHS and the Dept of Psychiatry.

To my husband Larry and our children, I am forever indebted. You have supported and sheltered me through this process. I love you all.....*See, I really did need a master's degree!!!*

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LIST OF ABBREVIATIONS

ADLs	Activities of Daily Living
ALFA	Assisted Living Federation
ALFs	Assisted Living Facilities
CES-D	Center for Epidemiological Studies
CIDI	Composite Diagnostic Interview
CMH	Community Mental Health
DIS	Diagnostic Interview Schedule
DSM	Diagnostic and Statistical Manual
ECA	Environmental Catchment Area
ER	Emergency Room
HAM DRS	Hamilton Depression Rating Scale
HMO	Health Maintenance Organization
MAI	Multilevel Assessment Inventory
MDCIS	Michigan Dept of Consumer Industry
MMSE	Mini Mental State Examination
MSU	Michigan State University
NCS	National Comorbidity Survey
PRIME MD PHQ	Prime MD Patient Health Questionnaire
SCID I/P	Structured Clinical Interview for DSM

I. Specific Aims

The primary aims of this proposed study are to:

1. Determine the prevalence of Major and Minor Depression in assisted living facilities (ALF).
2. Describe the clinical and functional status of patients with Major and Minor Depression in an ALF.
3. Describe the adequacy of current depression treatment as compared to “gold standard” depression treatment guidelines.

The secondary aims of this proposed study are to:

1. Identify potential barriers to care that make the ALF a unique setting to provide depression treatment.
2. Establish the level of unmet clinical need for depression care in patients residing in an ALF.

ALFs are a quickly growing component of the senior residential housing market, with over 11,200 facilities nationally providing care for elderly Americans. ALFs provide on-site assistance with daily living activities, meals and domiciliary needs. Up to 7,000,000 older Americans currently need assistance with these activities with this number expected to double by 2020 (1). The ALF industry is projected to continue its rapid expansion as an alternative to nursing home or foster care placements.

In 1999, the US Surgeon General reported that although nearly 20% of all Americans have some sort of mental illness, only half will receive treatment (2). Who is treated for depression in an ALF, the types of treatment available and the nature of the provision of services are largely unknown for the ALF population. Although the demographic, functional and psychiatric status of nursing home and foster care patients has been well defined in psychiatric literature (3-6), little is known about ALF residents.

Given this growth, our proposal seeks to study the characteristics of depression in a novel new setting (the ALF), as a basis for future interventions-based research in ALFs. It is a critical first step in understanding the nature of the problem of depression in ALFs if we are to design meaningful and effective interventions for ALF residents.

II. Background, Significance and Rationale

Although depression is a major public health problem in this country (7), it is an especially devastating illness for older adults. A frail elder living in an assisted living facility (ALF) is vulnerable to the impact of weight loss, decreased mobility, fatigue and impaired sleep that accompanies depression. Family involvement in care may be

limited for ALF residents, leaving only the staff to recognize and seek treatment for depression. Unfortunately, without adequate mental health training, depression may go unrecognized by ALF staff, misconstrued as a normal part of aging. As the ALF is a growing housing market for older adults and is often seen as a better alternative to nursing home treatment, it is imperative that we understand the problem of depression in this setting as well as the degree of unmet clinical need present in the ALF environment.

IIa. Depression: Impact on Cost, Medical Illness and Quality of Life

Depression has broad impact upon the financial, functional and health status of older adults. The healthcare financing system is stressed as depressed elderly patients have more emergency room and outpatient visits as well as twice the annual health care costs (doctor, hospital, pharmacy, laboratory) of non-depressed elderly (8). Examining the care of 13,653 enrollees of a Health Maintenance Organization (HMO), Fischer (9) reported that having depressive symptoms was associated with a 19% increase in the number of outpatient encounters and a 30% increase in total outpatient charges. Depressive symptoms were not associated with increased inpatient utilization or charges.

Major Depression also increases morbidity and mortality from medical illnesses (10). The depressed are three times more likely to die within the first year of treatment while living in a nursing home than when compared to the non-depressed (6, 11-12). In a prospective cohort study, Callahan (1998) followed 3,767 outpatients for 45 months. Using a proportional hazards model he found that baseline depression score, age, gender

and serum albumin value were significant correlates to time of death. In a 6-year prospective cohort study, Schoevers (14) obtained similar results in Britain, suggesting that older persons with depression had a 1.676 fold higher mortality risk than those without depressive symptoms.

An already frail depressed patient who suffers from weight loss may be at risk for dehydration, malnutrition and impaired immunity leading to systemic infection (15). In a sub acute-care facility, Thomas (16) discovered that only 8% of subjects could be classified as well nourished and that elevated scores on the Geriatric Depression Scale were associated with malnourishment for their patient sample ($p=.05$).

Depression can also impact the ability to walk, bathe, dress or feed oneself. Callahan's 6-year prospective cohort study of over 3700 individuals concluded that elderly patients with depressive symptoms had significantly worse physical and psychosocial function scores on the Sickness Impact Profile than did those without depression ($p<.001$) (13). Examining patients with heart failure, Vaccarino (17) noted that individuals with greater than 11 depressive symptoms at baseline, when compared with those with less than 6 depressive symptoms, had an 82% higher risk of either functional decline or death, whereas the immediate levels of depressive symptoms showed intermediate risk ($p=.0003$ for trend).

IIb. Depression: Community-Based Prevalence Surveys

Depression affects 5 million elderly in the United States (7). The prevalence and treatment of depression has been well delineated in some settings (community, primary care, nursing home) and virtually unstudied in other arenas (ALF).

Few community-based surveys have focused exclusively upon the elderly. Most often data for persons age 65+ are found as a subset of a later general adult community survey. One such large community survey is the National Institute of Mental Health's Epidemiological Catchments Area (ECA) project. The ECA was conducted from 1980 to 1985 in 5 sites providing 18571 households and 2290 residents' age 18 or older. After telephone screening using a structured interview designed to detect depressive symptoms, two face-to-face interviews were conducted 12 months apart. These interviews used the Diagnostic Interview Schedule (DIS) (17) to confirm a Diagnostic and Statistical Manual III specific diagnosis of depression. Blazer (18-19) was one of the first psychiatrists to examine the ECA data for late life depression using 3,015 elderly individuals from the ECA Piedmont site in North Carolina. He found 3.5% had Major Depression, 2.1% were Dysthymic and 0.3% experienced Bereavement.

The National Comorbidity Survey (NCS) is another large community-based survey of subjects age 15-75. The NCS was a cross-sectional survey of nationally representative households of 8,098 adolescents and adults age 15-75 conducted from 1990 to 1992. Kessler (20) examined NCS data collected by lay interviewers using a revised version of the Composite International Diagnostic Interview (CIDI). Over 3500 subjects with multi-

system medical illness were first screened for depression using a structured telephone interview followed by a definitive DSM III-R diagnosis using the CIDI. Nearly 50% of elderly reported at least one episode of depression and close to 30% reported at least one 12-month episode of depression. Among people with a lifetime history of three or more comorbid medical illnesses and depression, the proportion who ever obtained specialty sector mental health treatment was less than 50%. No data from ALF residents were reported in the Kessler study.

Recently Narrow (21) reanalyzed ECA and NCS data using DSM-IV TR diagnostic criteria for greater precision in estimates. To operationalize the definition of depression and highlight disability, Narrow examined questions related to life interference, professional treatment or using a medication for symptoms from the DIS for both ECA and NCS community surveys. The focus upon these functional areas was designed to address the disparity between the NCS and DIS report of mood disorder prevalence (3.5% vs. 50%). Using the criteria for functional and clinical significance, 15.2% of individuals age 54 and older had clinically significant depression in contrast to 17.2% of the younger cohort in the combined analysis.

ECA data has also provided interesting gender differences in the study of Major Depression. Using NIMH ECA data from New Haven CT, Weissman (22) obtained 6-month prevalence based upon a screening phone interview followed by the DIS. Major Depression was more frequent in women than in men (2.4:1) and sex ratios were fairly

consistent across generations, including the elderly. The cohort born before 1936 had an earlier age of onset with higher rates of Major Depression.

Of note, as the ECA and NCS data were based upon older versions of DSM (III and IIIR) using diagnostic measures appropriate for their time such as the CIDI and DIS . As the American Psychiatric Association has completed a new updated manual, the Diagnostic and Statistical Manual IV (DSM-IV TR), our study will use an updated definition from DSM-IV TR. We will use two brief screening instruments for depression (PRIME-MD PHQ)(47) and the Hamilton Depression Rating Scale (HAM-DRS) (49) followed by the Schedule of Clinical and Diagnostic Interview (SCID-I/P)(48). The SCID-I/P provides DSM-IV TR specific diagnosis of both Major and Minor Depression while paralleling the two-step methodology used for the original large ECA and NCS community surveys.

IIc. Depression: Site-Specific Prevalence Studies

The prevalence of clinically significant depression has been described in a variety of arenas. Table I delineates the site, assessment tool and prevalence rate Major Depression for older adults evaluated in several different settings.

Table I: Site-Specific Prevalence of Major Depression in Older Adults

Primary Care	Depression Assessment Method	Patient Age	Sample Size	Prevalence
Oxman, 1990	CES-D*	71.6	90	14.7%
Evans, 1993	GDS#	73 ± 8.4	493	21%
Callahan, 1994	CES-D*	70	108	15%
van Marwijk, 1994	Zung ^k	77 ± 7.7	468	11%
Borson, 1986	SDS^	78.1	406	10%
Nursing Home				
National Nursing Home Survey, 1984	DIS+	80.1	124,33	11%
Katz, 1989	GDS#	69.9 ± 3.2	534	14.1%
Gurland, 1983	GDS#	73.1 ± 6.2	1,005	23.3%
Home Health Care				
Bruce, 1992	DIS+	79.9	2,553	2.3%
Bruce, 2000	SCID-I/P%	78.4	2,003	13.5%

*Center for Epidemiological Studies-Depressed (CES-D) #Geriatric Depression Scale (GDS) &Zung Depression Scale (Zung) ^Zung Self-Acting Depression Scale
 +Diagnostic Interview Schedule (DIS) %Structured Clinical Interview for Axis I Diagnosis

IIc1. Primary Care Settings

Depression assessment in primary care has varied widely. Some studies (23-25) have used screening instruments such as the Center for Epidemiological Studies-Depressed (CES-D) or the Hamilton Depression Rating Scale (HAM-DRS) as a definitive diagnostic tool to identify subjects. False negatives, as well as false positives created by the excessive endorsement of somatic symptoms, makes the use of these screening tools as the definitive criteria for subject inclusion questionable at best. These studies report

prevalence figures 10-12% for Major Depressive disorder. When a more specific screening tool is used that provides DSM-IV TR specific diagnoses such as the PRIME-MD (26), the prevalence of Major Depression is 18.9%. Olfson used the PRIME-MD to examine 1,255 primary care immigrant subjects age 45-83, finding that psychiatric comorbidity was extensive.

IIc2. Home Care Settings

As home care services grow in popularity as a means to decrease hospital stays and avoid nursing home placement, the study of depression within the home environment is increasingly relevant to clinical care. Using ECA data from New Haven, Connecticut Bruce (27) examined depression in 2,553 non-institutionalized elders in New Haven. Employing the DIS as the primary diagnostic tool, Bruce reported that 2.3% of elders had Major Depression and 3.9% had Dysthymia. Depression was twice as prevalent among elders confined to a bed or chair as among non-homebound elders.

In a large follow-up study of 2003 elderly visiting nurse clients residing in New York, Bruce (28) evaluated homebound elders with co-morbid medical conditions. To obtain a DSM-IV TR specific diagnosis of mood disorder, she used the SCID-I/P. Bruce found that 13.5% of medically ill clients suffered from Major Depression while 10.5% had Minor Depression.

IIc3. Gaps in Our Knowledge Base

Our search of the literature confirms the fact that there are no studies establishing the prevalence of depression in an ALF environment. Primary care and homecare populations are most likely to match the demographics and comorbidity profile of the typical ALF resident. Using a two-tiered screening/diagnostic testing methodology well established by the ECA and NCA, this study will first screen ALF residents for depression using the PRIME-MD PHQ and then establish a DSM-IV TR diagnosis using the SCID-I/P. We will further study those patients identified with Major and Minor Depression, examining their functional characteristics, depression treatment patterns and degree of adherence to “gold standard” practice guidelines. The project is in preparation for an intervention study, as characterizing the ALF environment is critical if a proposed intervention is to be accepted and successful for its residents.

Given the critical nature of depression and the impact that effective treatment can have upon function, medical illness and quality of life, we believe the assisted living setting is ready for study, because the area is growing and little literature has been published describing mental health issues in the ALF setting. A systematic literature review of Medline and Psych Info search databases using the terms “quality of life” “mental health” “psychiatric illness”, “depression”, “mood disorder” or “assisted living” “foster care” and “functional status” “homes for the aged” or “domicile” provided no studies evaluating depression and quality of life in the ALF setting

IId. Assisted Living: A novel setting for the study of depression

There are currently 35 million people age 65 and older in America, accounting for 13% of the total US population. The population over age 85 is expected to grow from 4 million in 2000 to 19 million in 2050 (29). While most elderly reside in their own homes, as many as 6.5 million older people need assistance with activities of daily living (ADL's). Nursing homes have historically been the primary place where this type of care has been provided (1).

Assisted living facilities are growing rapidly as an alternative to the high labor costs and turnover, heavy regulation and stigmatization faced in the nursing home industry, while nursing home age-adjusted admission rates have declined over time. Forty-five persons per 1,000 in 2000 compared to 54 per 1,000 in 1985 were admitted to a nursing home. Because the nation has aged since 1985, were these data age-standardized and age-specific, this decline would be even more dramatic. A recent national survey found 11,472 assisted-living facilities nationwide, accommodating 5,558,400 residents (30). Other sources suggest this number is actually much higher. The Assisted Living Federation of America (ALFA), the national for-profit assisted living organization, suggests that ADL care can be provided in a number of for-profit or private assisted living settings (1). About 55% of all ALFs are freestanding, 35% are attached to a campus (usually nursing facility) and 10% are associated with an independent apartment complex (3).

Ile. What is an ALF and Why is it a Service Setting Worth Studying?

Ile1. ALF Study Definition

There is no single national definition for an ALF. Each organization associated with assisted living espouses its own definition of an ALF. The Assisted Living Federation of America (ALFA) (1) defines assisted living as “the combining of housing, personalized supportive services and health care designed to meet the individual needs of persons who need help with activities of daily living (ADL), but do not need skilled medical care provided in a nursing home”. The lack of skilled medical care differentiates the ALF environment from a skilled care nursing home setting. Skilled care may include intravenous medication, tube feeding, physical/occupational therapy and cardiopulmonary treatment.

The US Department of Health and Human Services sponsored a survey in 2000 that detailed the characteristics of ALFs and their residents. Hawes and Phillips (30) surveyed 1500 ALFs across the United States to obtain information on the policies, practices, residents and staff as well as service configurations available in these facilities (32). This is the largest national survey of ALFs available. The research group found that ALFs are almost equally likely to be operated by for-profit as by not-for-profit entities (50% vs. 49%). Two thirds of ALFs were engaged in some type of additional long-term care service (i.e., nursing home, other ALFs) at the time of the survey.

In addition to a variety of definitions available for an ALF, a number of terms have been used interchangeable to describe an ALF environment including “supportive care”, “residential care” “homes for the aged”, “foster care”, “board and care homes” and “group homes”. Each state may use a different term to describe these facilities within their local. No single term has been adopted as a “gold standard” by the United States government or legislature. The United States Department of Health and Human services simplifies the debate by referring to all facilities as “assisted living”, referring to the fact that these facilities provide residents with either routine general protective oversight or assistance with activities necessary for independent living (33).

To add to the confusion, state or federal licensure for ALFs is voluntary in the United States. Unlike nursing homes or hospitals that must pass licensing and accreditation standards to function and receive federal support, an ALF may choose to be licensed or unlicensed. The licensing process is costly and involves a review of the facility and procedures. This licensing dilemma makes it very difficult to track facilities for resident status, medical care and resident outcome.

Given these issues, what ALF definition should we adopt for this study? As the Michigan Department of Consumer and Industry Services (MDCIS) Bureau of Regulatory Systems is charged with regulating and licensing ALFs in the state of Michigan, we will use the MDCIS definition of an ALF. Under this criteria, an ALF is defined as “a supervised personal care facility, other than a hotel, foster care, hospital,

nursing home or county medical facility, that provides room, board, and supervised personal care to 21 or more unrelated, non-transient individuals 60 years of age or older”

(34). The two ALFs we will use for this study, Porter Hills Presbyterian Village and Independence village are licensed by the state of Michigan and meet the study definition criteria. Given this fact, we believe that results obtained by these two facilities will be generalizable to other ALF communities.

Ile2. How Do ALFs Differ From Nursing Homes?

ALFs differ from nursing homes in structure, financing and philosophy of care. The Center for Disease Control and Prevention (35) defines nursing homes as "skilled facilities providing 24-hour nursing care to sick or disabled patients who do not require hospitalization, but cannot be cared for at home or through other community options." Often nursing home patients are admitted either for brief rehabilitation services not able to be provided in the ALF or for end-of-life hospice comfort measures. According to the National Nursing Home Survey (NNHS) (36), the average nursing home resident is 82.6 years old with multi-system medical disease. The mean length of stay is 45 days with 30% recuperated back to the community, 36% returned to the hospital and 25% dying. Unlike the ALF where residents may live for many years, the nursing home has become a “short-term” stay facility with high medical acuity and medical service needs. These services (e.g. 24 hour nursing, rehabilitative services, face-to-face physician intervention) are not generally provided in an ALF setting.

ALFs are regulated less intensely than are nursing homes. Unlike nursing homes in which licensing is mandated, an ALF may choose to be licensed or unlicensed within the state of Michigan. This creates a diverse set of admission, treatment and discharge criteria among not-for-profit and entrepreneurial assisted living homes. In 1987 Congress passed the Omnibus Reconciliation Act (OBRA-87), which regulated restraints, psychotropic treatment and mental health monitoring in American nursing homes. OBRA-87 legislation caused reduced psychotropic prescribing practices and aggressively monitored nursing home admission practices to filter out mentally ill patients warehoused in nursing homes. However, ALFs do not have comparable regulations in place, leaving the study of how depression is recognized and treated even more important (37).

Philosophical and financial issues also help to distinguish the ALF environment from that of a nursing home. Unlike nursing homes that operate on a medical model of care, the ALF care model falls into one of three categories: 1) the hospitality model offers a “hotel-like” atmosphere; 2) the personal care model offers care for the frail elderly and 3) the aging-in model offers onsite care for chronic conditions (38). Assisted living facilities have espoused an “aging in place” philosophy that provides services in a graduated manner dependent upon resident needs (39), relieving families of the burden of multiple moves at the end of life. In addition, ALFs cost money and are not reimbursed by Medicare or Medicaid. The ALF may contain a growing but unique subgroup of Americans, i.e., those middle-upper class individuals who are able to support a high cost lifestyle (i.e., the typical ALF monthly rental fee is \$2,000 or more) based upon savings or other assets. This financial requirement may exclude individuals of color, those with

low socioeconomic status or those with chronic persistent mental illness such as schizophrenia, who may often find themselves the recipients of care provided by their friends and relatives within a home environment.

Ile3 Who lives in an ALF?

Over 16% of all Michigan residents are age 60 or older ($9,759,306 \times 0.25 = 1,561,489$ persons) (40). Of note, 130,591 of these individuals are over age 85. In Michigan, there are nearly two times more females than males age 65 and older. With respect to race, 80% are white, 14.2% are black, 4% are Hispanic and 1.8% are Asian. Given the fact that of this 85 yr + population only 37% own their own homes ($130,591 \times 0.37 = 48,318$) and 4.4% are in nursing homes ($130,591 \times 0.04 = 5,223$), it is possible that the remainder of elderly over age 85 ($n = 77,050$) may reside in some type of "other" supervised housing situation (family, fee-for-service caregivers or ALFs). Michigan has both licensed and unlicensed ALFs that have a total of 47,761 beds available for residents (41).

According to the US Department of Commerce's Census 2000 (40) the population age 65 or older is approximately 12%. Although the population age 65 and over grew slower than the total population, among the older population, those age 85 years and older showed the highest percentage increase (40). This "old-old" cohort comprises 53% of the older population who may require more intense residential and medical care than their own homes provide. There were fewer people age 85+ living in nursing homes in 2000 than 1990 (18.2% vs. 24.5%), suggesting that other alternatives such as home care

services where meals or therapies are brought to the patient in their own home or ALFs may be growing to meet the increased desire of the elderly to live out their last days in a home-like environment. National Center for Health Statistics data suggest that homecare is growing, with up to 25% of seniors age 65 and older receiving services (42). Interestingly, the NCHS database does not offer demographic data on seniors living in ALFs to serve as a comparison for those in home health care.

In Hawes and Phillip's national survey of ALFs, over half of the residents living in ALFs were age 85 or older (30). Seventy-eight percent (SE=1.11) of the 184,558 ALF residents surveyed were female and 98.7% (SE=0.55) were white. With respect to marital status, 70.8% (SE=1.64) were widowed, 12.1% (SE=1.00) were married, 9.9% (SE=1.23) were never married and 7.2% (SE=0.70) were divorced. Three quarters had living children and 85.9% (SE=1.90) described relatives that lived within an hour. One quarter saw relatives twice a week, another 26.7% (SE=1.44) reported more than one visit weekly and 6.3% (SE=0.91) had daily family visits. The sample was well educated, only 26.8% (SE=2.23) had not graduated from high school while 20.3% (SE=1.80) had a college degree. In terms of financial status, one quarter reported income less than \$14,000, one quarter endorsed income less than \$24,000 and one quarter had less than \$50,000 annual income.

IIf. Depression Treatment for Older Adults: Adequacy and Effectiveness

Older adults respond well to treatment for depression. This treatment may include pharmacotherapy, psychotherapy and/or electroconvulsive therapy (ECT). In a metanalysis of 40 clinical trials using only older adults, McCusker found that both tricyclic and selective serotonin reuptake inhibitor antidepressants were effective in reducing HAM-DRS scores (43). The efficacy of psychotherapy has also been demonstrated in a number of studies. In a meta-analysis of 14 geriatric-specific psychotherapy vs. placebo studies, cognitive-behavior treatment was found more effective than interpersonal therapy or placebo (43). Similarly, ECT remains an effective treatment for older adults with severe Major Depression with psychotic depression. It is also helpful for patients with an inability to tolerate or respond to antidepressant treatment (44).

Undertreatment of older adults with depression is a common problem, especially in primary care (44). To evaluate the adequacy of antidepressant treatment, an Expert Consensus Guideline on the Pharmacotherapy of Depressive Disorders in Older Patients is now available (45-46). We will use this guideline's antidepressant treatment duration and dosage parameters to compare with that of our ALF subjects. This is a critical first step in understanding the adequacy of depression treatment in the ALF.

Ilg. Rationale for this Proposal

Since ALFs may become the fastest growing service sector for longitudinal care of older adults, we must first understand the nature of the problem of depression, the status of available depression treatment in an ALF as well as the level of unmet clinical need within this setting. These are foundational components key to developing effective future intervention studies. Implementing an intervention without understanding the ALF milieu and patient population will put the intervention at risk for failure.

We propose a thorough study of Major and Minor Depression in the ALF in order to establish the prevalence of each condition. These methods include a rigorous methodological study of the prevalence of Major and Minor Depression. Establishing baseline prevalence is essential as a first step to developing effective intervention strategies to appropriately deal with the problem. Using a local ALF we will implement DSM-IV TR specific case identification strategies to carefully identify residents with Major and Minor Depression. These data will then help direct future intervention studies by helping us understand how prevalent depression is in the ALF when compared to other settings such as the primary care office or nursing home.

This project will also examine the nature and adequacy of current Major and Minor Depression treatment for ALF residents. Using a structured clinical interview corroborated with a family and staff interview, we will describe the types of depression treatment provided, as well as frequency of intervention and duration of treatment. We

will then use the Pharmacotherapy of Depressive Disorders in Older Patients Guidelines to access the adequacy of antidepressant dosage as well as duration (45). This information is critical to inform our next intervention, as it will help focus future interventions studies to be well suited and accepted by both ALF residents and staff.

III. Preliminary Studies and Any Results

IIIa. Wagenaar DB, Mickus MA, Luz C, Sawade J. Homes for the Aged: A Survey of Mental Health Needs

Objective: To describe the types of psychiatric disorders found in the assisted living setting as well as mental health service availability.

Design: A Mental Health Needs survey was sent to 176 administrators for Michigan Homes for the Aged.

Participants: The questionnaire was mailed to 176 administrators in Michigan in July-September 2001. Because staffing levels may be variable in an assisted living setting, we chose to survey administrators because of their overall knowledgebase of the home and its residents.

Results: Ninety-four surveys were returned for a response rate of 53%. Ownership was evenly divided between profit and non-profits. Mean resident age was 80.1 (SD=2.4). These data suggest that administrators believe depression is the second most common mental health problem in the ALF. Medications and activity therapy were the most frequently identified treatment modalities available for ALF residents. The primary care physician, followed by the psychiatrist, provided most of the mental health care the ALF residents received. Patient and family resistance to consultation accounted for the most common barriers to obtaining formal mental health services.

Table II: Most common mental health problems in the ALF
(Ranked by Percent endorsing)

Dementia	57.4% (n=54)
Depression	24.5% (n=23)
Hallucinations/Delusions	4.3% (n=4)
Anxiety	3.2 % (n=3)
Alcohol	1.1% (n=1)

Table III: Mental health treatments available in the ALF
(More than one response may be endorsed)

Medications	94.7% (n=89)
Activity therapy	64.9% (n=61)
Individual therapy	62.8 % (n=59)
Hospitalization	38.3% (n=36)
Family therapy	30.9% (n=29)
Spiritual counseling	29.8% (n=28)
Electroconvulsive therapy	1.1% (n=1)

Table IV: Mental Health Service Providers in the ALF
(More than one response may be endorsed)

Primary Care physician	59.6%	(n=56)
Psychiatrist	47.9%	(n=45)
Community Mental Health	42.6%	(n=40)
Private Therapist	28.7 %	(n=28)
Staff member	20.2%	(n=19)
Pastor/priest	12.8%	(n=12)

Table V: Barriers that Prevent Residents from Receiving Mental Health Services
(More than one response may be endorsed)

Resident refuses treatment	66%	(n=62)
Family refuses treatment	56.4%	(n=53)
Stigma of mental illness	26.6%	(n=25)
Treatment costs too much	24.5%	(n=23)
Transportation not available	17%	(n=16)
Treatment not available	13.8%	(n=13)
Confidentiality concerns	3.2%	(n=3)

Implications for this proposal: The results of this pilot suggest that ALF administrators believe depression is a clinically significant problem for their residents. The project we propose will take the next step in assessing ALF residents for depression and determining the prevalence of Major and Minor Depression. This will serve to test the accuracy of this pilot survey, helping us compare the ALF administrators' perceptions to objective data obtained through subject assessment with strict diagnostic instruments. In addition, this project will assess the types of mental health services and providers available to ALF residents. The research we propose will serve to validate these the results of our earlier survey in an effort to understand how to most effectively target interventions designed to improve mental health care delivery in an ALF setting. We will see whether the barriers

to depression treatment endorsed by administrators actually match barriers that the ALF resident experiences in obtaining needed mental health services.

IIIb. Wagenaar DB, Colenda CC, Kreft M, Sawade J, Mergos L. Depression treatment patterns in Nursing Homes and Assisted Living Facilities: A pilot study (in submission)

Objective: To study the types and course of depression treatment in two Michigan ALFs. We piloted the methods found in this RO1 submission at a local level to determine feasibility and barriers to completion.

Design: A prospective follow-up study identifying nursing home and ALF residents with depression and following these individuals over the course of 6 months for the purposes of describing treatment characteristics and clinical outcomes. We evaluated mood (Geriatric Depression Scale), functional status (SF-36 (PCS and MCS components) at study onset, month 3 and month 6. In addition, we characterized the amount and types of mental health services provided for these residents.

Participants: Seventeen nursing home and eighteen ALF residents were identified for this study. Resident mean age was 85.3 (SD=85.3), 88 % were female, 77% were widowed and 12% were single in the combined cohort.

Results: Nursing Home and ALF residents did not vary significantly with respect to GDS scores at month 0 (6.65 vs. 7.11, $p < .08$) or month 6 (4.82 vs. 5.47, $p < .11$) however an overall decrease in GDS scores between groups was noted between month 0 and 6 ($p < .04$). Mean SF-36 subscale scores (MCS and PCS) did not vary significantly between the groups at month 0, 3 or 6.

Table VI: Pharmacotherapy provided for NH and ALF residents

	Nursing Home Resident:	Assisted Living Residents
Antidepressants	73.2% (n=12)	55% (n=9)*
Anxiolytics	11.8% (n=2)	24% (n=5)**
Antipsychotics	10% (n=2)	24.5% (n=3)**
Hypnotics	7.7% (n=1)	20.7% (n=3)*
Mood Stabilizers	0	6% (n=1)

* Significant at the $p < .05$ level

** significant at the $p < .01$ level

Overall we found that ALF residents received fewer antidepressants and more multi-drug combination therapy residents than did NH residents. This may be due to the absence of psychotropic regulation in the ALF when compared to highly controlled psychotropic OBRA standards enforced in the nursing home, decentralized medical care or inadequate depression assessment. Each patient may receive medication from more than one drug class. Group means are presented, as small cell size prevents more detailed statistical comparisons. Provider type was not defined.

ALF residents received a wider variety of psychotropic medications in this pilot study. Many of these agents (antipsychotics, hypnotics) may be inappropriately used to address depression in the ALF setting. Of those who received antidepressant therapy,

87% of Nursing Home residents were prescribed an Selective Serotonin Reuptake Inhibitor (SSRI) while only 72% of ALF residents received an SSRI ($p < .05$). ALF residents were more likely to be treated with tricyclic compounds (9% $n=2$) or non-tricyclic antidepressant drugs (9% $n=2$). Of note, antipsychotics were used 24.5% of ALF patients vs. 10% of Nursing Home patients. These medications can have serious permanent neurological side effects (tardive dyskinesia) and may be misused in the ALF setting, as they do not treat depression.

Polypharmacy was more likely in the ALF resident group as 18% ($n=3$) were treated with four psychotropic agents and 37% ($n=5$) were treated with two agents. This is in contrast to the nursing home sample where no resident received four drugs at one time. From these pilot data we conclude that further study of prescribing practices within the ALF group is warranted. It appears that depression is less appropriately treated in this setting, as the frequency of antidepressants is much less than that of a nursing home sample. In addition, poly pharmacy is more widespread, suggesting the need for more active study of how antidepressants are used in the ALF.

Implications for this proposal: This study demonstrates that depression remains fairly consistent over time for both nursing home as well as ALF residents. Our results show that depression is not simply a transient “adjustment reaction” to living in an ALF, but rather a persistent medical problem. This finding makes a more compelling argument for the need to identify effective treatment options for ALF resident.

In addition, this pilot work suggests that ALF resident who did receive treatment for depression experienced more poly pharmacy than did their cohorts in a nursing home. The addition of several classes of psychotropic agents may cause additional medication side effects such as confusion or sedation as well as aggravate pre-existing medical conditions. However, our sample size for this pilot was small (n=9). This proposed study will use a much larger sample size to study psychotropic drug usage patterns in ALF residents, to determine whether excessive use of psychotropic medications or inappropriate dosing is seen in an ALF. This will inform the focus for future research projects toward educating staff and primary care physicians on appropriate depression treatment strategies.

IV. The Epidemiology of Major and Minor Depression in ALFs: Study and Approach

IVa. Overview

This project will: (1) determine the prevalence of depression in the ALF; (2) describe the clinical characteristics of the depressed ALF population; (3) delineate the current pattern of depression treatment in an ALF; and (4) highlight the level of unmet clinical need for depression treatment in the ALF population. This project will sample older adults (age 60+) living in Porter Hills Presbyterian Village in Grand Rapids, Michigan and Independence Village in Lansing, Michigan. These facilities were chosen for the study because they demonstrate a wide spectrum of residents with mild to significant functional impairment and medical problems. They are among the largest ALFs in western and mid-Michigan. As we anticipate that the demographic characteristics of our ALF sample will not be dissimilar from the elderly population in Michigan or the US, we anticipate that our results will generalize to a broader ALF population.

IVb. Approach

To identify depression within ALF residents we will use a two-step methodology to first screen and then definitively identify subjects with Major or Minor Depression. This two-step process is patterned after large community survey projects using ECA or NDS data (18,20-21). Because diagnostic testing is time-consuming and potentially

burdensome for subjects, we wish to avoid excessive burden to our subjects, many of which may be frail elderly with medical and functional issues that limit endurance. A screening methodology using the PRIME-MD PHQ will enable us to identify subjects for further study using the SCID-I/P, thereby minimizing both subject burden as well as study cost (47-48).

The entire community of ALF residents will be invited to participate in a depression-screening project for initial case-identification. Each resident will receive information about the screening program and his or her written consent will be obtained. Those who agree to the study will complete a semi-structured interview to obtain demographic data and clinical history. Information on the degree, onset, duration of current episode of depression, cognitive impairment and co-morbid anxiety features will be obtained during this initial in-person interview. During this time, participants will complete the PRIME-MD PHQ and the Hamilton Depression Rating Scale, the screening tools used to initially identify Major and Minor Depression during Interview #1 (49).

Participants who screen positive for either Major or Minor Depression will undergo a second 2-hour SCID-I/P structured interview to obtain a definitive diagnosis. The SCID-I/P offers a definitive depression diagnosis as well as helps to rule out other co-morbid conditions such as anxiety or dementia. Additional measures of function and overall well-being will be completed including the Multivariable Assessment Instrument (MAI) and Mini Mental State Examination (MMSE) (50-51). These measures will accomplish one of the project's aims, i.e. to describe the clinical and functional status of depressed

ALF residents. The study is expected to take 24 months to obtain an adequate sample size and complete data collection and analysis.

Subjects whose SCID-I/P ratings suggest a diagnosis of Major or Minor Depression will be notified of their diagnosis. In addition, a letter will be sent to their primary care physician explaining this diagnosis as well as the need for additional evaluation and possible treatment. If the subject endorses active suicidal, homicidal or intensive depressive ideation, they will be referred for immediate psychiatric treatment via Community Mental Health at Emergency Services (Lansing, MI) or Cornerstone (Grand Rapids, MI)

During the structured interview process, we will also review current psychiatric treatments the subject is receiving and describe the type and frequency of these therapies. These will include psychotherapy (individual, marital, group), psychotropic medications, activity therapy, spiritual counseling and electroconvulsive therapy. We will inquire about antidepressant dose, length of treatment, frequency of medication administration, side effect profile and mechanism of administration (self-administered vs. staff administered). This project will use the Depression Expert Consensus Guidelines on Pharmacotherapy of Depressive Disorders in Older Patients to assess the quality of pharmacotherapy and adequacy of antidepressant dosing (45).

Based upon data collected during this structured interview, we will calculate the prevalence of Major and Minor Depression. Because the SCID-I/P also provides

information on other DSM-IV TR diagnostic groups (i.e., anxiety, thought disorder, somatoform disorder) we will report the prevalence of these conditions as well in the ALF patient population. Subjects with co-morbid depression plus another Axis I diagnosis will be considered separately in our analyses.

Table VII: Project Scope and Timeline

Project	Aims	Activities	Timeline
Interview and #2	1.Determine prevalence of Major Depression in ALF 2.Determine prevalence of Minor Depression in ALF 3.Describe the clinical characteristics of ALF patients with depression 4. Describe the prevalence of comorbid psychiatric disorders in ALF patients with Major or Minor Depression including anxiety, dementia and psychosis.	1.Recruit all residents of a local ALF to participate in depression screening 2. Screen residents using the PRIME-MD PHQ, HAM-DRS, MMSE and MAI. 3. Structured SCID-I/P clinical interview for subjects who screen positive for depression	Month 1-24
Project	Aims	Activities	Timeline
Interview #3	1. Describe the adequacy of current depression treatment as compared to “gold standard” depression treatment guidelines. 2.Establish the level of unmet clinical need for depression care	1. Develop and implement a third structured clinical interview with each subject to document depression treatment including psychotherapy, antidepressants, group therapy, ECT, activity therapy or other modalities.	Month 3-24

V. Data Collection Procedures

Va. Study Design

This project will employ a cross-sectional study design used to determine the prevalence of Major and Minor Depression in the ALF. This project will accomplish the following primary aim to: (1) determine the prevalence of Major and Minor Depression in ALF; (2) describe the clinical and functional characteristics of ALF patients with depression and (3) describe the adequacy of current depression treatment in the ALF. Secondary aims include the ability to describe potential barriers to effective depression treatment encountered during this project in the ALF environment and establish the level of unmet clinical need for depression care in patients residing in the ALF environment.

Because we are unable to project the prevalence rate for Major or Minor Depression in this setting given the lack of epidemiological studies of the ALF environment and given the financial burden involved with SCID-I/P administration to every ALF resident, we will use a depression screening strategy for our first stage, with definitive diagnostic testing for those assessed positive for depression. To screen for depression we will use a 15-item self-report instrument, the Primary Care Evaluation of Mental Disorders Patient Health Questionnaire (PRIME-MD PHQ). Because the PRIME-MD PHQ has a sensitivity of 75%, we will use a second screening measure (the HAM-DRS) to increase our case finding abilities, as the HAM-DRS has a sensitivity of 88%. A two-phase design has been recommended in community-based settings because the prevalence of

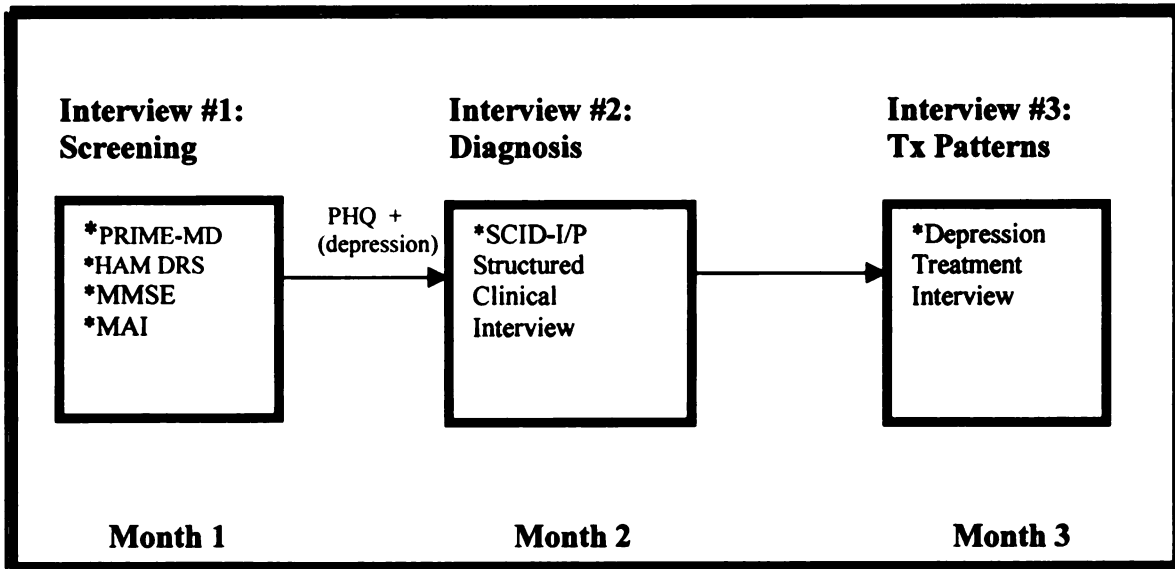
Major Depression is low (52). PRIME-MD PHQ scores will also be used to assess the severity of depression in our ALF subjects. The Multilevel Assessment Instrument (MAI) will be given to each subject during this first interview as well (50). The MAI assesses quality of life and health status issues and is a “gold standard” research tool for geriatric psychiatry. The Mini Mental State Examination will also be administered during the second interview, as a screening measure of cognitive impairment (51). The first interview will occur within the first month that the subject is enrolled within the study.

Those patients who screen positive for depression using the PRIME-MD PHQ and HAM-DRS will undergo a complete SCID-I/P assessment. This SCID-I/P assessment will occur in the second month of enrollment and will serve as a reliability screen for the initial PRIME-MD PHQ screening results. The SCID-I/P interview each subject undergoes will also identify other co-morbid DSM-IV TR disorders such as anxiety, psychosis and somatization. Subjects with a confirmed diagnosis of depression will be notified of this finding and a letter with these study findings will be sent to their primary care physician.

As a part of the third session, subjects will participate in a semi-structured depression treatment interview. In the first two months of the project, the PI will develop and pilot a treatment questionnaire based upon previous in-home health care depression prevalence studies (28). This semi-structured interview will cover onset of treatment, treatment type, frequency of administration, drug doses and duration, medication side effects. Therapy questions will focus on type, frequency of intervention, mental health professional

educational background and the subject's belief about efficacy and current quality of life.

Table VIII: Project Flow Chart



Vb. Interviewers

We will use master's trained mental health clinical specialists to recruit subjects, screen them for depression and perform the structured SCID-I/P interviews on those subjects meeting study criteria. The cost of this study prohibits psychiatrists or psychologists from doing much of the direct subject interviews. Our mental health specialists will have extensive training in dealing with mental health problems as part of their graduate training.

Prior to the study we will provide intensive training in interpersonal skills and subject recruitment as well as the assessment measures used in this study. Each mental health

clinical specialist will attain a SCID-I/P training workshop including training tapes and supervised training interviews. Using both training tapes and live patient interviews, we will assess inter-rater reliability of the SCID-I/P using a test-retest design until 95% inter-rater agreement is obtained among raters.

Vc. Sampling Frame/Eligibility Criteria

The ALF is a unique living environment in that most people who live there are from a higher socioeconomic class in order to be able to afford the costs associated with residence. Major insurance carriers such as Blue Cross, Medicare or Medicaid do not reimburse patients for ALF monthly rental. Expenses are usually paid out of pocket by residents or supportive families. Because of this financial bias, the ALF resident is usually a middle or upper class individual with retirement savings. This phenomenon alone makes the ALF a unique environment to study depression.

Criteria for inclusion in this study are: (1) age 60 or older; (2) ability to speak, read and understand English; (3) permanent resident of Independence Village or Porter Hills Presbyterian Village; (4) ability to give informed consent (determined by the mental health clinical specialist and the patient's primary care physician).

Exclusion criteria include (1) presence of psychosis, dementia or other psychiatric condition that prohibits the subject from understanding the study or giving consent. These conditions may include coma, delirium, schizophrenia etc; (2) severe hearing or

visual disturbance that prevents comprehension of the assessment measures and structured clinical interview.

Given the fact that dementia is present in up to 50% of the population at age 80, cognitive disorders may limit the ability of subjects to participate (53). However, this should be a less pressing issue in the ALF where residents must theoretically be cognitively intact enough to provide their basic activities of daily living and managing their personal affairs. To assess for the presence of dementia that may impair the subject's ability to participate in the study, we will use the Mini Mental State Exam (51). This 30-item screening instrument detects cognitive impairment in persons with an 8th grade or higher education. The MMSE is sensitive (0.85) and specific (0.87) within this age range and setting. We anticipate that 15% of potential subjects will be ineligible for the study because of moderate to severe dementia (MMSE score <18).

Vd. The Study Sites

Two ALF facilities will be used for this study. Porter Hills Presbyterian Village is a large continuum of care facility located in Grand Rapids, Michigan. On 34 acres of land, it offers residential living, assisted living, dementia care and basic as well as skilled nursing care. Porter Hills owns six other assisted living facilities within the greater Grand Rapids area. There are over 800 residents on the main campus and 175 living within in the assisted living portion of the residence. The average resident age is 81.1 years old (SD=3.9), Caucasian (97.5%), Female (77%) and Presbyterian (50%). The length of stay in assisted living is 20.1 months with residents discharged to both home as well as to the nursing center.

Independence Village is a 200 resident assisted living facility in Lansing Michigan. Lansing and Grand Rapids, Michigan are 55 miles apart. The geographic areas for Independence Village and Porter Hills Presbyterian Village are similar in that both are suburban, middle-class, white-collar neighborhoods. The average resident at Independence Village is 78.9 years old (SD=6.3), Caucasian (95%) and Female (70%). Religious preference is unknown.

Ve. Sampling Procedures

Residents of ALF Independence Village and Porter Hills Presbyterian Village will be invited to participate in this study. The ALF Independence Village and Porter Hills' admissions office will provide a roster of potential participants. An informational flyer will be delivered to each resident and orientation coffees will be set up to help recruit subjects. The administration of both ALFs will also provide a letter of support for the study that each resident will receive. Enrollment activities will occur at convenient times for the residents (i.e., mealtimes, early evening) to facilitate exposure to the program. The enrollment phase of this study will occur over the first year of the project, in order to provide adequate time for the mental health clinical specialists to contact all potential subjects residing in each ALF. Residents who have not consented to the program will be individually contacted and encouraged to participate by the clinical psychiatric specialist.

We anticipate that 85% of residents contacted will be eligible for the study. During the first interview we will screen potential subjects for dementia using the Mini Mental State Examination (51). We anticipate that 15% will be disqualified due to cognitive disorders that prohibit them from understanding the nature of the study and giving clear consent. In addition, we expect that up to 20% of all subjects will refuse to participate in the study for other reasons. Table IX delineates the sampling strategy and estimated sample size for this study.

To evaluate the possibility of false negatives, we will use the SCID-I/P interview with 10% of the sample without depression using the PRIME-MD PHQ. This will help us evaluate false negatives as well as bolster validation of this instrument as a depression screener for the ALF setting.

Table IX: Sampling Strategy for ALF Depression Study

Facility	# of ALF resident	# with dementia (15%)	# with Minor Depression (11%)	# with Major Depression (14%)	Total # over a 2 year period
Independence Village	200	30	19	24	86
Porter Hills Presbyterian Village	175	25	17	21	76
Totals	375	55	36	45	162

Vf. Recruitment and Consent

Before the study begins we will distribute information about the project via several avenues. First, each ALF resident will receive an informational flyer about the study. The flyer will encourage participation as well as try to provide facts about the nature and scope of the study. Each ALF resident will be invited to attend an informational coffee held in the ALF lounge. Several sessions will be offered to assure that ALF residents may select from convenient times throughout the day. A member of the research team will conduct the coffee and will offer time for questions and answers during this meeting.

The mental health clinical specialist will then telephone each ALF resident to invite them to participate and sign a consent form. The consent form, approved by the MSU Institutional Review Board, will be provided during an initial appointment made with a member of the research team. During this appointment, we will confirm eligibility for the study and review the consent form, answering questions about its content and obtaining appropriate signatures.

The expected demographics of this sample are listed on Table X. Seventy four percent of individuals age 65+ are female while 26% are male. Fourteen percent of the sample is expected to be black, 5.5% Hispanic and 1.8% “Other” with the remaining 78.7% Caucasian. (40)

Table X: Expected Key Sample Demographics

	Black	White	Hispanic	Other	Total
Male	6	33	2	1	42
Female	17	94	7	2	120
Total	23	130	9	3	162

To evaluate differences in responders and non-responders, we will use demographic information obtained from the ALF administration such as age, gender and date of admission to compare individuals to decline to participate in the study with the demographics of those who agree to participate. This will inform our understanding of potential differences in our sample and the overall ALF population as well as help delineate any type of volunteer bias present within our sample.

Vg. INTERVIEW #1: Depression Screening and Functional Assessment

Interview #1 will serve as a depression-screening interview. The mental health clinical specialist will schedule this interview via telephone. A convenient time will be arranged with the subject and the specialist will come to the subject's room in the ALF campus. During this visit the study consent will be explained, signed and witnessed.

Subjects will then participate in a brief interview in which the PRIME-MD PHQ, MAI, MMSE and clinical features checklist will be completed:

- i. Demographic Profile will include age, gender, race, marital status, educational level and socioeconomic status (SES). SES will be determined using the Multilevel Assessment Instrument (MAI) (50).
- ii. The Primary Care Evaluation of Mental Disorders--Patient Health Questionnaire (PRIME-MD PHQ) will serve as our depression-screening instrument. It screens for the presence of depression and provides a severity measure as well. The PRIME-MD PHQ is a 15-item patient-administered questionnaire that will reduce the clinician time needed to complete the screening interview. When compared to "gold standard" psychiatric assessments, the PHQ shows good reliability ($\kappa = 0.65$, overall accuracy 85%, sensitivity 75%, specificity 90%) for elderly patients. The average time required to complete the assessment is 10 minutes for patients and 3 minutes for clinician review (47).

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iii. The Hamilton Depression Rating Scale (HAM-DRS) will serve as an addition sensitivity measure for case identification. This will complement the low sensitivity of the PRIME-MD PHQ as the HAM-DRS has a sensitivity of 88%, specificity of 90% and an overall accuracy rate of 83% (54). The HAM-DRS is a 22-item measure of the severity of depression used commonly in geriatrics and clinical trials literature (refs). The HAM-D assesses both neurovegetative items (sleep, appetite, weight loss, energy level, etc) as well as mood symptoms (severity of depression, apathy, irritability) (49).

iv. Multilevel Assessment Instrument (MAI) is a 14-item clinician-rated instrument we will use to assess functional disability. The MAI consists of several subscales including the self-maintenance subscale, the instrumental activities of daily living subscale and a global disability score. Unlike an instrument such as the SF-36 that has floor effect with respect to functional disability, the MAI is sensitive to changes in functional level in an already disabled population. The MAI has excellent inter-rater reliability (>.91 intra-class correlations) in its assessment of functional disability and social demographics such as SES. The MAI has been validated in long-term and home-care settings using older adults (50).

iv. Mini Mental State Examination (MMSE) will assess cognition. This is a 30-item screening tool evaluates orientation, attention, short-term memory and higher cortical functions (visual spatial ability, sequencing, language). The MMSE is considered the gold standard tool for dementia screening; a score of >24 suggests cognitive dysfunction. The MMSE is reliable and valid for English speaking subjects with at least an 8th grade

education. For purposes of this study we will use a cut-off of <18 to eliminate subjects with moderate to severe dementia, as their cognitive impairment may preclude them from accurately completing the SCID-I/P and other self-report measures of mood or functioning (51).

Vh. INTERVIEW #2: Definitive Diagnosis (SCID-I/P)

Interview #2 will be entirely devoted to completing the Structured Clinical Interview for DSM-IV TR (SCID-I/P). Eligible subjects who have scored positive for Major or Minor depressive disorder using the PRIME-MD PHQ will be eligible for the second diagnostic interview.

i. Diagnostic Interview (SCID-I/P). The SCID-I/P incorporates operational criteria from the DSM-IV TR into a categorical system for rating symptoms and diagnosing Major and Minor Depression. Ventura found a sensitivity of 87% and specificity of 81% for 20 case vignettes (55). The SCID-I/P has been validated for use in elderly populations. We have found that the SCID-I/P is the only validated diagnostic instrument used in long-term care (56). We anticipate that the SCID-I/P may have significant respondent burden in the frail ALF resident as completion may require several hours. We therefore may be required to split Interview #2 into two one-hour long sessions to increase compliance and prevent fatigue.

To accurately assess the prevalence of Major and Minor Depression while also capturing other comorbid diagnostic groups such as anxiety, somatoform and psychotic disorders, we will administer the complete SCID-I/P to each subject. This will help us to accurately identify depressed patients and will facilitate the identification of comorbid conditions (e.g., Anxiety disorders, Somatoform disorders) as well as other types of depression (Dysthymic disorder, Adjustment disorder).

Vi. INTERVIEW #3: Depression Treatment

The third interview will focus upon current and past depression treatment experiences of the ALF resident. A member of the research team will conduct a 1-hour session with those subjects determined to have Major or Minor Depression via the SCID-I/P during interview #2. Based upon our experiences during our pilot work, information about the nature of current and past depression treatment may be sketchy. The ALF facility is not required by state or federal law to maintain extensive medical records. Thus, a medication list may not be readily available if medications are self-administered by the ALF-resident. In addition, some ALF residents may be unaware of the types of medications they take or their doses. Thus, relying simply on ALF chart information or a sole ALF resident interview may provide incomplete information.

Instead of relying upon chart review in a system beset with inadequate medical records, we will directly interview the ALF resident to obtain treatment information. Interview #3

will be completed with the ALF resident as well as family member to corroborate information given by the resident. Requesting that family members join this interview will help these individuals offer additional data about the subject's treatment, provide memory prompts for the subject and serve as a secondary source to validate the specific details of information given by the subject. Interview #3 will consist of a semi-structured interview focusing upon the following domains of mental health treatment:

1. Current Treatment for Depression: Data obtained in this section will include: psychotropic medications, doses and frequency of administration, date of onset of treatment, monitoring physician, medication side effects, self-report compliance with psychotropic medications. In addition, formal mental health professional contact will be elicited including specialty, frequency of contact, perceived effectiveness and potential barriers to further treatment. Other types of potential ongoing mental health interventions will be covered as well including exposure to group or marital therapy, activity therapy, spiritual counseling, psychiatric hospitalizations and electroconvulsive therapy.

2. Past Treatment for Depression: Similar domains for past depression treatment will next be elicited from each subject including previous history of pharmacotherapy, psychotherapy or other psychosocial therapies.

3. Mental Healthcare Utilization: To obtain this information we will ask each subject to estimate the following activities over the past year: visits to primary care physicians, visits to mental health professionals, ER visits, number of laboratory tests, number of

prescription medications used over the past one year and frequency of ancillary medical services.

4. Expert Consensus Guidelines on Pharmacotherapy of Depressive Disorders in Older Patients: In 2001, an nationally known panel of experts on the treatment of late life depression developed pharmacotherapy practice guidelines for the treatment of depressed elderly. Using literature review and a Delphi-style process, they surveyed 50 national experts on geriatric psychiatry and obtained consensus on 64 questions related to pharmacotherapy principles with the elderly depressed patient. The group achieved consensus on 89% of items and developed “Adequate Dose of Antidepressant Guidelines for the Suggested Treatment of Depression in the Elderly”. These guidelines include recommendations for (1) average starting antidepressant dose; (2) average target antidepressant dose after 6 weeks of treatment and (3) usual highest final acute antidepressant dose (45).

Using data obtained from Interview #3, we will compare and contrast the mean starting dose, average target dose after 6 weeks and usual highest final acute dose for ALF residents with the Expert Consensus Guideline values. Using descriptive statistics, we will detail the adequacy the drug treatment for ALF residents when compared to a nationally developed gold standard. This will also facilitate exploration of the relationship between a variety of factors (e.g., demographics, diagnostic groups, functional status) and treatment adequacy in the ALF setting. These data will help us

describe the level of “unmet clinical need” for treatment for depressed ALF patients, critical information that is currently lacking in clinical practice and the literature.

VI. Data Analysis

The specific aims of this project include both descriptive and comparative analysis. This is a two-year cross-sectional study of two Michigan ALFs. It is cross-sectional in nature in that we will use descriptive statistics to capture the prevalence of both Major and Minor Depression in the ALF. This will enable us to describe the clinical and functional characteristics of a sample of ALF residents. We hypothesize that the prevalence of Major and Minor Depression will be higher than a home-care based sample, i.e. that Major Depression will exceed 13.5% and Minor Depression will exceed 10.5% (28).

This study is also comparative in nature in that we will collect data about depression treatment patterns (antidepressant use, psychotherapy, etc) that we will be able to contrast with national practice standards using the Depression Expert Consensus Guidelines on Pharmacotherapy of Depressive Disorders in Older Patients (45). We hypothesize that antidepressant usage and dosing ranges will fall below recommended national practice standards for the ALF subjects in this study.

We will use a number of categorical and continuous variables in this database. Summary statistics will be reported as proportions for categorical variables, and means or

medians for continuous measures. Categorical variables will be analyzed using χ^2 tests, t -tests and correlational methods will be used to assess continuous variables. The outcome measures (PRIME-MD PHQ, HAM-DRS, MAI) will be analyzed as continuous variables in the dataset, based upon the assumption of a normally distributed response. During these analyses, if this assumption is incorrect, transformations of the measures by the logarithmic or square root will be employed to achieve a normally distributed response. Subjects who do not complete the study will be dropped from the analysis and not included in our results.

All statistical analysis will be completed using the Statistical Analysis System (57). A significance level of 5% will be employed on all tests of hypothesis on regression parameters.

VIa. Primary Aim #1: Determine the prevalence of Major and Minor Depression in the ALF.

We will use descriptive analyses to determine the prevalence of Major and Minor Depression, once subjects are defined using the SCID-I/P. In order to accurately depict this proportion, thorough screening and case identification must occur. In addition, the calculation of confidence intervals and sample size will help guide subject recruitment and assure adequate power for our analyses.

i. Improving Case Identification: The use of two screening measures

Although the PRIME-MD PHQ is an excellent mechanism to delineate the difference between major and minor depression and provide a measure of depression severity, its sensitivity is low (75%). Using this instrument alone as our depression screener may result in up to 25% of all potential cases being missed. To address this concern and assure we will not omit potential cases in our study, we will introduce a second screening instrument, the Hamilton Depression Rating Scale (HAM-DRS). The HAM-DRS has a sensitivity of 88% for major depression and should assist in identifying cases that the PRIME-MD could miss. It has been validated for use in the home care population and will provide adequate specificity 90% and overall accuracy (83%). (28,54).

ii. The Calculation of Confidence Intervals and Sample Size

To project the 95% confidence intervals we will use Major and Minor Depression prevalence figures from Bruce's homecare study (28), as this population of elderly living in their homes is likely to most closely match our ALF study sample. To determine the upper and lower confidence interval we will employ the "Exact Two-sided 100% x (1- α) Confidence Limits for Binomial Proportions ($\alpha=.05$) Table" (58). Using Bruce's homecare data, we estimate prevalence (p) of Major Depression at 13.5% and Minor Depression at 10.5% (28). Given the binomial formula npq , where n =anticipated number of subjects enrolled, p =prevalence of subjects with depression and q =prevalence of subjects who are depression-free, $npq=162 (22/162)(140/162)$. The "Exact Two-Sided 100% x (1- α) Confidence Limits for Binomial Proportions ($\alpha=.05$) Table" suggests a

95% confidence interval of (0.07,0.19) for Major Depression and (0.06, 0.16) for Minor Depression in this ALF study.

We have also calculated the minimum sample size based upon a range of prevalence figures for our study. We will use an estimate for the prevalence of major depression based upon home healthcare and nursing home figures (27, 4). If p =sample estimate of P (prevalence of major depression), e =desired error limit (% above or below true prevalence), Z =two tailed critical normal value, n' =sample estimate and n =final sample size, then we may use the formula $n' = p(1-p)(Z)^2$ divided by e^2 to estimate our sample size for a given prevalence estimate. For example, if we estimate that 20% of our sample will have major depression, then p =20% or 0.2 and $(1-p)$ =80% or 0.8, and if e =0.05 so that $Z=1.96$, then $n'=(0.2)(0.8)(1.96)^2$ divided by $(0.05)^2$ then $n' = 245$ ALF residents required for our sample. Using this power calculation, Table XI describes sample size needed for a range of major depression prevalence figures.

Table XI: Sample Size Determinations based upon Depression Prevalence

Estimated Prevalence of Major Depression in Assisted Living	Sample Size Required
10%	138
12%	162
13%	173
15%	195
20%	245

Based upon the work of Bruce in the home healthcare setting, we anticipate that the prevalence of depression in an ALF may be similar, i.e. 12-13% (28). Thus, our current sample size of 162 should be adequate to assess for major depression in this sample. If necessary, we will recruit other local facilities to bolster our sample if recruitment proves inadequate for these calculations.

Vib. Primary Aim #2:. Describe the clinical and functional status of patients with Major and Minor Depression in the ALF setting.

In this project we will use several functional and disease measures as clinical outcome indicators. The MAI will be used to measure functional status in our ALF sample. The PRIME-MD PHQ serves as a measure of depression severity in this study. To correlate these clinical measures with depression type, depression treatment modality and adequacy of depression treatment we will employ logistic regression, multinomial logit models and least squares regression.

All models will include sociodemographic elements including age, gender, marital status, race and socioeconomic status (as determined by the MAI). These data will be collected during Interview #1. Models will be constructed to examine the impact of each sociodemographic/economic element upon type of depression (Major vs. Minor) as well as clinical features (MAI, PRIME MD PHQ).

Vic. Primary Aim #3: Describe the adequacy of current depression treatment as compared to “gold standard” depression treatment guidelines.

We will use the Expert Consensus Guideline values as the “gold standard” for this ALF study. Mean antidepressant dose and duration of treatment will be calculated for each ALF resident and summary scores will be obtained for each antidepressant type. Using these guidelines we will compare ALF residents with the gold standard recommendations, in terms of average starting dose, average target dose after 6 weeks of treatment and usual highest final acute dose. This analysis will also provide an opportunity to examine the relationship between key demographic, diagnostic and functional factors in the ALF sample with adequacy of treatment (dose and duration of treatment). Considering subjects as either antidepressant “therapeutic” or “sub therapeutic”, we will use logistic regression or multinomial logit models to examine each group’s relationship to key clinical factors (MAI and PRIME MD PHQ score) as appropriate. This analysis will help us to describe the level of “unmet clinical need” in the ALF, information that is lacking in the literature and in clinical practice.

VId. Secondary Aim #1: Identify potential barriers to care that make the ALF a unique setting to provide depression treatment.

This is a descriptive aim. As the study begins in each ALF, the master’s trained mental health clinical specialists will maintain a journal of observations about the implementation of methods. Using this journal, the master’s trained psychiatric

specialist will construct a list of barriers encountered during subject recruitment, interview process, collateral contacts and staff interactions. In addition, we will ask ALF residents who did not consent for study participation to describe the reasons for their refusal.

Vle. Secondary Aim #2: Establish the level of unmet clinical services need in depressed ALF residents.

During Interview #3 we will collect data on the frequency of formal mental health intervention (individual/family/marital therapy sessions, psychiatric evaluation, neuropsychological testing, etc) in ALF subjects with Major or Minor Depression. Descriptive analysis will include frequencies of treatment, treatment type and mean treatment length. Ninety-five percent confidence intervals will be determined for each proportion. We will use logistic regression to compare residents receiving formal mental health services to subjects who remain untreated, examining key variables such as race, gender, age, functional status and severity of depression.

VII. Implications of this Study for the Treatment of Depression in ALFs

Assisted living facilities are the vanguard of future service settings for older adults. We need to know the prevalence of key psychiatric conditions in these facilities to ensure that patients have access to and receive effective treatments for depression.

This proposal to study the prevalence of depression will inform our understanding of the problem of depression in the ALF setting. This study will focus on research questions yet unanswered including: (1) the prevalence of Major and Minor Depression; (2) the clinical and functional characteristics of depressed ALF residents; (3) how "depression care as usual" is provided for ALF residents and (4) the degree of adherence of current treatment to national depression practice standards. In addition, we will explore unique potential barriers to the delivery of mental health services in the ALF setting, delineating barriers on the part of ALF staff, residents, families and healthcare providers.

Why is determining the prevalence of Major and Minor Depression an important first step in this research trajectory? Although we already know that depression is devastating in late life, the ways that this disease uniquely manifests itself in an ALF are unstudied. Establishing the baseline prevalence for Major and Minor Depression in an ALF will lend credence to the clinical observation that this condition occurs frequently in an ALF. It will also help us focus future research on identifying ALF residents at risk for depression as well as how to best provide treatment for those individuals already experiencing depression.

Our data on the functional status of ALF residents will also be useful for public health policy and licensing. If our data suggests that our ALF subjects are as frail as the typical nursing home patient, this finding alone may bolster the argument that ALFs need better state and federal regulation in order to assure that adequate care is being provided for these residents. Developing a "profile" of the typical clinical and functional features of patients who are depressed may also help clinicians to target new ALF residents at risk for depression during their stay in the facility.

The results of this study are critical to inform us about mental health resources and treatment in the ALF. If we determine that depression is problematic in the ALF, we must also learn something about how depression "care as usual" is delivered, in order to find key elements of current treatment that require improvement. If we can study ALF patients currently treated for depression, we will be able to evaluate whether current antidepressant treatment received by these individuals meets national depression practice guideline standards (Pharmacotherapy of Depressive Disorders in Older Patients, Alexopolous, 2001). These data will then help us design interventions that specifically deal with the mental health treatment delivery issues we identify during this study. To develop an intervention without knowing the current availability of treatment options or the receptivity of the ALF environment to mental health services could doom an intervention to failure.

This is also a study of barriers. Can effective mental health care be delivered to this segment of our population? Will current staffing patterns and education allow for the

expedient identification of a depressed ALF resident? How do ALF residents perceive the adequacy of their depression care? This proposal will allow us to identify key obstacles in subject recruitment, data collection and baseline mental health service delivery so that we can set the stage to answer a number of important questions. This study will also help us prepare to outline strategies for interventional research focused upon improving access to mental health care and depression treatment.

Given that the ALF industry is growing and may house elderly residents who in earlier years would have been placed in a nursing home, the federal government may be interested in the results of this study. In 1987, Congress passed the OBRA-87 Act to regulate the misuse of psychotropic medications in nursing homes and provide a mechanism for psychiatric assessment and mental health service delivery (37). This program has demonstrated effectiveness with the reduction of chemical and physical restraints (59). If data from our ALF study suggests either polypharmacy or inadequate dosing of antidepressant medications, this may focus more federal attention upon implementing psychotropic regulatory mechanisms such as OBRA for the ALF environment.

The second potential policy impact is on the relationship between the ALF industry and the community public mental health sector. Providing care for the mentally ill with minimal insurance resources, state-funded community mental health (CMH) centers are charged with providing care for all ages. Often in a CMH center, staffing resources are severely stretched, allowing staff to only provide services for nursing home or

ambulatory patients. ALF residents may not be receiving in-house CMH services. If this study finds these counseling services are not easily available for ALF residents, it may convince CMH to allocate their staff resources toward services the ALF instead of only the nursing home. Redirecting clinician manpower from the nursing home to the assisted living environment could impact the quality of life for the average ALF resident for a longer period of time than if the resident lived in a nursing home.

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APPENDICES

APPENDIX A

RESEARCH CONSENT FORM DEPRESSION IN ASSISTED LIVING

APPENDIX A

RESEARCH CONSENT FORM DEPRESSION IN ASSISTED LIVING

Introduction

Depression is a common problem for many assisted living residents. The goal of this research is to understand how common depression is in the assisted living facility and understand what types of mental health care are currently being provided for the assisted living resident.

Study Overview

The purpose of this study is to understand how often depression occurs in the assisted living facility and to help us understand how it may be treated. Faculty members from Michigan State University's Department of Psychiatry will be conducting the study. Members of this research team include MSU faculty and master's trained mental health clinical specialists experienced in working with older adults and their families.

If you agree to participate in this depression study, a member of the research team will interview you three times during the next 3 months. During the first interview, the

master's trained mental health clinical specialists will ask you questions from a number of standard screening instruments (the PRIME MD PHQ, the Hamilton Depression Rating Scale, the Mini Mental State Examination and the Multilevel Assessment Inventory). This interview will take about one hour to complete. You will be notified of the results of testing at the conclusion of the interview. If you have evidence of poor memory, we will refer you to your primary care physician for further testing.

If you qualify for the study, you will then participate in a SCID interview designed to help the research team understand how your mood is doing. This interview may take up to 2 hours to complete. We will complete the interview at your own pace, taking breaks as needed throughout testing. Finally, a third brief interview will follow in about one month to learn more about any types of depression treatment you may be receiving (counseling, medications, activity therapy, etc). This interview will last about 30 minutes. If you are unable to remember the names of your medications or medical conditions, we will ask the assisted living staff to provide us with a list of these items. By signing this consent you agree that the assisted living staff can provide this medical information for our study.

If your testing indicates the presence of depression, you may be offered a number of treatments including medication, therapy or therapeutic activities. Specific treatment options and decisions should be discussed with you and your physician. The research team will offer one free evaluation session at the MSU Psychiatry Clinic with a trained mental health professional who may help triage your case to appropriate mental health

professionals in the community. Treatment beyond this session will be the responsibility of the study participant and may vary depending upon community and financial resources.

Risks

This project should present minimal risk to you. Possible risks include increased anxiety or depression that may occur as you are interviewed by the research team. Members of the research team recognize the sensitive nature of depression discussions. They will insure that the interview setting is private and confidential. If you were to become anxious or upset during the interview, the research team member will immediately stop the interview, contact the assisted living social worker and additional support will be provided for you. If you feel suicidal or homicidal during the interview, the assisted living social worker will work with you to help you with these feelings, assure your safety and help you obtain additional mental health help.

The risk of confidentiality will be minimized by never identifying you by name. All study data will be kept confidential, kept in a locked secured area within the research office. Study results will never identify a patient, family, guardian or facility by name.

Benefits

You may directly benefit from this study in that if depression is identified, you and your doctor along with the assisted living staff will be notified. You may be offered a variety of treatments to help with this condition.

Costs

There will be no cost to you or your family.

Questions

If you have further questions, you may contact Dr Deborah Wagenaar (517-353-4362) or her master's trained mental health clinical specialists. For questions relating to your rights as a study participant, please call Dr Ashir Kumar, MD, Chairperson of the University Committee on Research Involving Human Subjects at 517-355-2180.

Consent

I have read this consent form and my questions are answered thus far. I voluntarily consent to participate in this study with the understanding that I may withdraw my consent at any time.

Resident Signature

Date

Witness Signature

Date

APPENDIX B

MINI MENTAL STATE EXAMINATION

APPENDIX B

MINI MENTAL STATE EXAMINATION

ORIENTATION

1. What is the: season_____date_____year_____month_____day_____

2. What is the name of this:

city_____state_____county_____place_____floor of this building_____

REGISTRATION

3. Name three objects, "apple-table-penny". Score one point for each correct on FIRST TRIAL.

ATTENTION AND CALCULATION

4a. Ask the patient to subtract 7 from 100 and then continue subtracting 7 until told to stop. Stop after 5 subtractions. Score one point for each correct subtraction.

4b. Spell "world" backwards. Record number of correct letters. DO NOT include this in total score.

RECALL

5. Recall 3 objects repeated earlier. Score one point for each.

LANGUAGE

6. Point to objects one at a time. Score one point for each object correctly named.

7. Repeat "no ifs and or buts". Allow only one trial. Score one point for EXACT repetition.

8. Three state command: "Take this piece of paper in your right hand, fold it in half, and give it back to me". Score one point for each stage.

9. Read and obey "Close your eyes". Score one point if he closes his eyes.

10. Ask the patient to write a sentence. Score one if the sentence is sensible and has a verb and a subject.

11. Copy intersecting pentagons.

APPENDIX C

THE PRIME MD PHQ

Appendix C

PRIME MD PHQ

For the last 2 weeks have you had any of the following problems nearly every day?

- | | | |
|---|-----|----|
| 1. Trouble falling or staying asleep, or sleeping too much | yes | no |
| 2. Feeling tired or having little energy? | yes | no |
| 3. Poor appetite or overeating? | yes | no |
| 4. Little interest or pleasure in doing things? | yes | no |
| 5. Feeling down, depressed or hopeless? | yes | no |
| 6. Feeling bad about yourself---or that you are
a failure or have let yourself or family down? | yes | no |
| 7. Trouble concentrating on things, such as reading
the newspaper or watching television? | yes | no |

8. Being so fidgety or restless that you were moving around
a lot more than usual? yes no
9. In the last 2 weeks, have you had thoughts that you
would be better off dead or of hurting yourself in some way? yes no
10. Are answers to five or more of #1 to #9 yes?

Appendix D

MULTILEVEL ASSESSMENT INSTRUMENT

Appendix D

MULTILEVEL ASSESSMENT INSTRUMENT

A. Type of housing

B. Do you live alone?

C. Who lives with you?

1. About how often do you go out of this house in good weather?

2. About how often do you leave the neighborhood?

3. Do you own and drive a car now?

4. Do you use the telephone?

5. Why is it that you don't use the telephone?

6. Do you get to places out of walking distances?

Why is it that you have help/don't go at all?

Can you get to places out of walking distance?

How long have you been having these difficulties?

Have you changed how frequently you get to places outside of walking distance?

Have you changed the method you use to get places outside of walking distance?

How did you change this?

Why did you change this?

M1. How many city blocks do you usually walk on a typical day?

- M1a Do you walk 3 blocks/1/4 mile?
- M1b Why is that you don't walk?
- M1c Can you walk without help from others?
- M1d About how long have you been having these difficulties?
- M1e Have you changed how frequently you walk?
- M1f How did you change this?
- M1h Why have you changed this?
- M2 How many times a day do you climb a flight of stairs?
- M2b Why is it that you don't climb stairs?
- M2c Can you walk up and down a flight of stairs?
- M2d About how long have you been having these difficulties?
- M2e Have you changed how frequently you climb stairs?
- M2f Have you changed the method that you use to climb stairs?
- M2g How did you change this?

- 7. Do you shop for groceries?
- 8. Do you prepare your own meals?
- 9. Do you do your own housework?
- 10. Do you do your own handyman work?
- 11. Do you do your own laundry?
- 12. Do you take any medicines or use any medications?
- 13. Do you manage your own money?
- 14. Do you ever have trouble getting to the bathroom on time?

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