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DIETARY INSTRUCTIONS IN THE PRESCRIPTION DRUG REGIMENS OF A GROUP OF COMMUNITY DWELLING OLDER WOMEN: INDICATIONS, FREQUENCY, DELIVERY CHARACTERISTICS AND ADHERENCE

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DIETARY INSTRUCTIONS IN THE PRESCRIPTION DRUG REGIMENS OF A GROUP OF COMMUNITY DWELLING OLDER WOMEN: INDICATIONS, FREQUENCY, DELIVERY CHARACTERISTICS AND ADHERENCE.

By

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ABSTRACT

DIETARY INSTRUCTIONS IN THE PRESCRIPTION DRUG REGIMENS OF A GROUP OF COMMUNITY DWELLING OLDER WOMEN: INDICATIONS, FREQUENCY, DELIVERY CHARACTERISTICS AND ADHERENCE.

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The effects and efficacy of prescription drugs can be changed by drug-food or drug-nutrient interactions, particularly when physiological changes related to aging are concurrent. While these interactions can put older adults at risk for increased morbidity and mortality, they also may produce small decrements in physical and social functioning which must be avoided for optimal quality of life. In this study, community dwelling older women in a subsidized apartment complex were surveyed to determine whether they were given dietary instructions indicated for the prescription drugs they took. When dietary instructions had been given, data were collected to characterize the delivery of the instructions, assess adherence and identify variables which predicted adherence.

Data were collected in two phases: the first, a self-administered survey that addressed demographic information

and prescription drug use screening; the second, a computer-assisted personal interview in the apartment which addressed instruction frequency and delivery characteristics, adherence and adherence prediction variables. Women who returned surveys in the first phase and met specified inclusion criteria formed the sample for the second phase. Delivery of indicated dietary instructions was assessed by interviewer examination of drug containers and medication fact sheets and by interview respondent report. Adherence was assessed with a one-day food and medication record.

Only 3% of respondents received all indicated dietary instructions for their prescription drugs, leaving 97% of respondents at risk for drug-food and/or drug nutrient interactions. The mean percent of indicated dietary instructions given per person was 24.6%. Fifty-six percent of drugs which had dietary instructions indicated had no dietary instructions at all given. When dietary instructions were given, respondents adhered to 81.9%. Respondents viewed the doctor as the ultimate source of drug information and the doctor as a source of oral instruction was significantly associated with adherence. Diabetic meal plans were significantly associated with nonadherence. The only significant predictor of adherence was negative: a dietary instruction intended to prevent a reduced drug efficacy interaction.

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and my grandparents, Helen and George Gardiner.

They believed that I could never acquire enough knowledge

and that I could do whatever I wanted to do.

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INTRODUCTION

STATEMENT OF THE PROBLEM

The United States has been characterized as a nation devoted to youth and youthful attitudes. Although youthful attitudes may prevail, U.S. age demographics indicate that 12% of the population is aged 65 years and over.

Today, women over age 65 outnumber men in their age group 3 to 2. The percentage of older adults is steadily increasing and is expected to continue to rise over the next decades as post-World War II and Vietnam War era "baby boomers" reach senior citizen status. By 2025, older Americans (those over age 65) should represent almost 20% of the population (House of Representatives 1987). Personal independence and optimal quality of life are key objectives for aging Americans and their health care system (Institute of Medicine 1991; Carruth and Boss 1990; Department of Health and Human Services 1990).

Until recently, scant attention has been given to the nutrition status and nutrition-related needs of older adults

in the United States. A substantial proportion of older Americans have dietary intakes or diseases which place them at high risk of malnutrition. Among the risk factors that predetermine poor nutritional status is prescription drug use (Dwyer 1991).

Prescription drugs can influence nutritional status directly through drug-nutrient or drug-food interactions; indirectly through side effects such as appetite change, fatigue or confusion. Conversely, nutrients and foods can alter drug effects and efficacy. Identifying individuals at risk for such interactions provides opportunities for implementation of preventative measures before clinical manifestations of problems are evident and reduces dysfunction, disability, decreased quality of life and, in some cases, morbidity and mortality. The approach for risk screening advocated by the Nutrition Screening Initiative is multi-factorial, emphasizing medical, social, economic and lifestyle factors that are equally important in determining risk (Dwyer 1991).

An understanding of the factors which predict adherence to recommended prescription drug dietary modifications is difficult to achieve. Many factors may be involved in producing the desired adherence outcome. It is clear that individuals who never receive instructions for dietary

modification cannot adhere. For those who do receive instructions, the role of environmental factors potentially impinging on individual adherence behavior is also unclear, but clues to factors involved in the adherence of older adults as a group have been presented and are reviewed in a later section.

If the probability of adherence can be determined by a manageable number of variables, such variables could help identify major targets of intervention and strategies for outcome enhancement (Glanz and Eriksen 1993). For example, if self-efficacy is a variable in a predictive model, group discussions or written brochures sharing the successes of others in adherence and offering their tips to make adherence easier could provide an improvement over didactic instruction. Other variables, like multiple medication use, could target individuals who will probably need special instructional attention. The use of a prediction model can improve allocation of intervention resources since all patients may not need the same level of intervention to achieve an outcome (Fedder 1982). Its development could also help fill a gap in research identified by the Nutrition Screening Initiative: core indicators for precise functional assessment of eating-related behaviors of older people (Dwyer 1991).

RESEARCH QUESTIONS, OBJECTIVES AND HYPOTHESES

This study addressed the following research questions and sought to accept the accompanying hypotheses:

Research Question I: When drugs are prescribed for community dwelling older women, are patients instructed to follow indicated dietary modifications to optimize drug effectiveness or minimize adverse drug effects, including known potential drug-food or drug-nutrient interactions?

Objective I: To determine whether respondents received recommended dietary instructions indicated for the prescription drugs they take and to describe the sources and methods of instruction.

Hypothesis I: In the majority of cases (51% or more), respondents did not receive instruction for all indicated dietary modifications.

Research Question II: When older women receive dietary instructions, do they adhere?

Objective II: To determine whether respondents adhere to dietary instructions.

Hypothesis II: Respondents adhere to a majority (51%) of dietary instructions.

Research Question III: What factors predict adherence of older women to dietary instructions recommended for the prescription medications they take?

Objective III: To identify variables related to dietary instruction adherence and formulate a prediction model for adherence.

Hypothesis III: A regression equation can be constructed which will predict dietary instruction adherence.

Review of literature suggests the following domains which may predict adherence:

1) knowledge of the modification's purpose
2) knowledge of consequences of nonadherence
3) understanding of instructions
4) instruction methods
5) instruction sources
6) Medical Outcomes Study SF-36 health status survey scores: Physical Component Summary (PCS) and Mental Component Summary (MCS)

7) self-efficacy

8) number of medications

9) duration of medication use

10) assistance with medication regimen

11) attitude toward medication

12) demographic variables significantly related to adherence

REVIEW OF LITERATURE

Prescription Drug Use

As increasing numbers of people live to old age, the proportion of the population subject to the discomforts of chronic and acute diseases common to aging also increases. To reduce discomfort and the progress of disease, the use of prescription and non-prescription drugs is widespread.

It has been estimated that individuals over 65 years of age consume 30% of the total medications prescribed in the U.S. and the average older person has three diseases treated by an average of eight prescription and/or over-the-counter medications (Anderson 1990). Epidemiological studies have shown that among older adults prescription drugs were used by 60 to 68% of men and 68 to 78% of women; five or more prescription medications were used by 4.6 to 11.8% of men and 6.5 to 13.9% of women (Chrischilles et al. 1992; Magaziner et al. 1989); a significantly greater number of drug classes were used by women than men (Hale et al. 1979).

This heavy use of drugs is accompanied by a high rate of

drug-related hospitalizations among older adults. Drug-related problems may contribute to up to one third of hospital and one half of nursing home admissions of older adults (Cooper 1990; Colt and Shapiro 1989). In a Canadian study, older women had significantly more drug-related adverse patient events than men (Grymonpre et al. 1988). Patients aged 65 years and older account for 10 to 28% of hospital admissions for drug-induced symptoms; a situation which does not seem to be improving (Hallas et al. 1990; Col, Fanale, and Kronholm 1990; Grymonpre et al. 1988; Lamy 1988; Ives, Bentz, and Gwyther 1987; Nygaard et al. 1986). Stewart et al. (1991) conducted a longitudinal study of participants in a Florida geriatric health screening program and determined that the mean number of prescribed and nonprescribed drugs used per participant increased by more than 40% over a ten-year period.

It is clear that drug-related problems increase with age, probably due to heavier use of multiple drugs, greater frequency of illness and altered physiology (Michigan Governor's Task Force 1991; Denham 1990; Hale et al. 1979; Williamson and Chopin 1980).

Physiological Changes in Aging

Physiological changes related to aging, although highly individual (Lamy 1982a), can have a direct effect on the efficacy of a drug or its side effects. Aging produces changes in pharmacokinetics that may cause a specific dose of a drug to lead to a higher steady-state concentration in an older adult than a younger person (Blumberg 1985; Schmucker 1984; Greenblatt, Sellers and Shader 1982). It also produces changes in pharmacodynamics that may lead to modifications in drug response.

Pharmacokinetics

The major effect of aging on pharmacokinetics occurs in excretion or drug clearance. There is an overall decline of about 35% in glomerular filtration rate between the ages of 20 and 90 years, although there is considerable individual variability (Rowe, Andres, and Tobin 1976). There are similar declines in effective renal plasma flow and tubular excretory capacity (Davies and Schock 1950). Since most drugs and their metabolites are eliminated via urinary excretion, reduced renal function produces slowed drug clearance and potential drug accumulation. Many of the conditions exhibited by older adults, including heart disease, are treated by the use of drugs with narrow therapeutic indexes which may be toxic at high serum

concentrations (Tregaskis and Stevenson 1990; Lamy 1982a).

Clearance is complicated further when specific drugs are cleared through the liver, particularly via Phase 1 reactions. Substantial research over the past two decades has demonstrated that most medications metabolized through the hepatic mixed oxidase system tend to be metabolized more slowly with age due to reduced induction of enzymes or decreased affinity of enzymes for substrate (Wynne et al. 1988; Kamataki, Maeda, and Shimada 1985; Vestal 1978; Salem et al. 1978; Greenblatt, Allen, and Harmatz 1975; Whittaker and Evans 1970). In addition, a decline in liver size and blood flow may also contribute to reduced biotransformation capacity (Wynne et al. 1988; Kitani 1986; Calloway, Foley, and Lagerbloom 1965). These changes in hepatic function can cause a decrease in the metabolic clearance of drugs and a resulting high serum level.

Changes in body composition with aging, beyond the liver and kidney, include declines in total body size, total body water and lean body mass, accompanied by an increase in body fat stores (Tregaskis and Stevenson 1990). Such changes may also lead to changes in the volumes of distribution of highly lipid or water soluble drugs. Volume of distribution is an essential element in the plasma half life of a drug

(Tregaskis and Stevenson 1990) and the concentration of drug per unit volume (Lamy 1982a).

Age-related declines in serum albumin levels have been associated with reduced plasma protein binding of such drugs as antipyrine, meperidine, diazepam, phenytoin, propranolol, warfarin and salicylates (Tregaskis and Stevenson 1990; Cohen 1986). Increased free drug fractions are seen since total plasma clearance is negatively correlated with serum albumin for many highly bound, lipophilic drugs. Conversely, some drugs which bind preferentially to alpha-1-glycoproteins, which increase with aging and under stress conditions, show increased plasma protein binding (Tregaskis and Stevenson 1990; Mitenko 1986; Lamy 1982a). Other drugs show no change in binding at all in the elderly (Wallace and Verbeeck 1987).

A few studies have examined gastrointestinal changes related to aging and the absorption and bioavailability of drugs, but have not shown a direct relationship (Mitenko 1986; Rikans 1986; Rubin, Scott, and Reid 1981; Cusack et al. 1979; Fulton, James, and Rawlins 1979). Studies of the effects of age on drug absorption are very limited, probably due to methodological problems. Available information has primarily come from simple comparison of oral and

intravenous plasma drug concentration against time curves (Tregaskis and Stevenson 1990).

Pharmacodynamics

There is evidence that, beyond alterations in pharmacokinetics, age-associated changes in homeostatic mechanisms and sensitivities of specific receptors and target organs can modify drug responsiveness in older adults (Blumberg and Suter 1991). Age appears to produce a gradual reduction in the ability to adapt to changes in the environment, including drug use. Important homeostatic mechanisms which demonstrate reduced vitality include postural control, orthostatic circulatory responses, thermoregulation, visceral muscle function and higher cognitive function (Blumberg and Suter 1991; Swift 1990). Pharmacologic challenge to these mechanisms in an older person can produce altered and possibly undesired drug effects.

At the site of drug action, age-related changes in drug receptors or in the intrinsic properties of the target tissue can result in altered drug effects, particularly when responses of younger and older adults are compared (Rikans 1986). Although in vivo research with humans is rarely possible, recent work has been done in vitro and through

animal studies to describe age-associated receptor declines in density (numbers), binding sites, binding affinity and transduction of signals (Blumberg and Suter 1991; Swift 1990; Rikans 1986).

Adverse Effects of Prescription Drug Use

The adverse effects of prescription drug use are difficult to identify, categorize or quantify. Various terms and definitions have been used. For reporting, the Food and Drug Administration (1985) defines an adverse drug experience as:

> any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any significant failure of expected pharmacological action.

This definition is broad and open to interpretation. Kramer et al. (1979) suggested that clinical identification of an adverse drug reaction (ADR) is a "nonreproducible act of unspecified subjective judgment."

It is difficult then to sort out drug-age, drug-drug, drug-nutrition, drug-food, drug-allergy, drug-regimen and drug-disease effects (Institute of Medicine 1991; German and Burton 1989). Few drugs produce distinctive adverse effect

signs. If a drug is known to have an association with a particular reaction, it is hard to prove that it is the cause in a particular patient short of unethically challenging the patient with the drug again. Even laboratory tests can seldom differentiate between an adverse drug reaction and underlying disease (Denham 1990).

In addition, older adults and health care professionals may be slow to identify transient symptoms and signs related to medications (German and Burton 1989). British investigators have estimated that three fourths of adverse drug reactions (ADRs), which are carefully and formally tracked through the British National Health System (NHS), are simply an exaggeration of the normal drug response. Even though ADRs do not always result in a hospital admission, it has been suggested that their cost in emotional terms to the patient and the financial cost to the NHS is considerable (Denham 1990).

Elderly individuals often manifest their medical problems in vague and nonspecific symptoms that are hard to interpret (Denham 1990; Ouslander 1981; Hodkinson 1973) and are all too often simply attributed to "getting older" (Blumberg and Suter 1991; American Medical Association Council on Scientific Affairs 1990; German and Klein, 1984).

Complaints like malaise, memory loss, confusion, anorexia, bone pain, changed sleep patterns, gastrointestinal upset and incontinence are frequently considered inevitable signs of old age (Lamy 1982a).

Klein et al. (1984) found that 30% of elderly outpatients taking medications reported adverse reactions to at least one drug and established that the most frequently reported were urinary symptoms, head or chest discomfort, mood/sleep disturbance, balance problems and gastrointestinal upset. Although severe drug reactions are very likely to receive attention, small non-life threatening decrements in functioning may go unnoticed or be considered unimportant. Small decrements may however cause ripple effects, diminishing physical or social functioning (German and Klein 1984) and lowering the quality of life. The Nutrition Screening Initiative has reported that particular attention needs to be paid to the effect of health interventions on function and performance rather than solely on morbidity and mortality (Dwyer 1991).

The Role of Dietary Modifications in Optimizing Drug Effectiveness and Minimizing Adverse Drug Events

Diet composition and meal pattern can influence drug efficacy and effects through chemical interactions and a

wide range of physiologically mediated interactions at many stages of drug action. The type, combination, amount and timing of foods consumed can alter the dissolution, absorption, distribution, metabolism and excretion of many drugs (MacLeod and Soldin 1986; Hathcock 1985; Roe 1985; Smith and Bidlack 1984; Lamy 1982b).

Since altered pharmacokinetics and pharmacodynamics may already put older adults at risk for reduced drug efficacy or adverse effects, risk enhancement or risk reduction inherent in dietary practices is an important consideration in their drug regimens. This is particularly true since most information about drugs is obtained through drug testing done on younger adults (McAllister 1986; Roe 1985).

Although much research is still needed on the specific effects of prescription drugs on older adults, a considerable amount is already known about the potential interplay of medications and dietary components and reference materials are readily available (Physicians' Desk Reference 1995; United States Pharmacopeia Dispensing Information 1995; Pronsky 1993; Roe 1992). Since response to prescription drugs and age-associated physiological changes are both highly individual, the absolute need for precise dietary modifications to avoid serious alterations

in drug effects is difficult to predict but the need for risk reduction in the case of older adults is definite. One of the health behaviors cited by the Nutrition Screening Initiative as important to malnutrition prevention is appropriate use of medications, especially those with nutritional effects, and adherence to medication schedules (Dwyer 1991).

In institutional settings, two studies have examined indications for dietary instructions in the prescription drug regimens of adults and subsequent adherence as assessed by examination of drug administration data on medical charts. Lewis, Frongillo and Roe (1995) studied men and women in three long-term care facilities. Most of the subjects were older; mean ages of subjects in the three facilities were 86.5 years, 91.3 years and 84.5 years. Charts were audited and data collected on fifty-three patients from each of the facilities over a period of six months. A computerized algorithm was developed to assess the risk for eight classes of potential drug-nutrient interactions (DNIs). Patients were at risk for a mean of 1.43, 2.69 and 1.43 potential DNIs in each of the facilities, respectively. The most commonly observed DNIs were gastrointestinal interactions affecting drug bioavailability and interactions affecting electrolyte

status. Although the researchers had planned to measure the rate of actual DNIs, they could not do so because of the infrequent availability of laboratory data and sparse documentation of patients' conditions in the records.

In the other study, Strong et al. (1991) investigated adherence to indicated dietary instructions which specified when each of five cardiovascular drugs should be taken in relation to mealtimes. Subjects were adults of various ages, primarily older, at two short-term and two long-term care facilities. Data obtained from medical records revealed that 85 to 93% of 183 patients received one or more drug doses incorrectly in relation to mealtimes during the study period. The researcher concluded that arbitrary medication schedules were used and that there is a need for schedules to be designed with care to achieve the greatest drug bioavailability.

Prescription Drug Regimens

Prescription drug regimen adherence is an important issue since as many as half of prescribed drugs fail to have their desired effects because they have been used improperly, most often because of poor communication to the patient or caregiver. This is especially common when the patient is elderly (Michigan Governor's Task Force 1991; American

Medical Association Council on Scientific Affairs 1990). One of the more serious adherence problems encountered is the practice of many older adults of simply discontinuing a medication when unpleasant side effects occur (Clark 1991; Schoenberger et al. 1990; Spagnoli et al. 1989; Darnell et al. 1986; Ostrom et al. 1985).

As part of a prescription drug regimen, dietary modifications are probably subject to many of the same adherence perils as are other regimen components. Although older adults' adherence to recommended dietary modifications has not been studied specifically, overall prescription drug regimen adherence has been documented in limited population studies. Also, research unrelated to drug regimens has been done to identify factors associated with adherence of older adults to recommended health promoting dietary behavior changes and may be relevant to drug regimens as well.

Prescription Drug Regimen Adherence

Prescription drug regimen adherence (or compliance) studies have taken many different approaches but have universally suffered from any agreed upon standard for defining adherence (German and Burton 1989). Within individual studies comparing community dwelling older and younger adults who administer their own medications, drug regimen

adherence based on a single defined standard is not greatly different for the two groups, ranging from 52% to 69% (German et al. 1982; German and Klein 1984). Darnell et al. (1986) found that there was no correlation of adherence with age per se in their study of medication use by ambulatory elderly, although there was correlation with the number of medications taken. This may have accounted for the fact that men adhered more frequently than women, since the mean number of drugs in this study per man was 3.3 compared to 5.0 per woman.

For older adults, factors that contribute to nonadherence include polypharmacy (German and Klein 1984; Inui et al. 1980; Fletcher et al. 1979), complex drug taking schedules (Hulka et al. 1976), side effects (Clark 1991; Inui et al. 1980; Darnell et al. 1986), patient functional limitations (Darnell et al. 1986) or taking specific drug classifications like central nervous system drugs, antibiotics, antihistamines and gastrointestinals (Hulka et al. 1976). Unfortunately, the degree of correlation of such factors to nonadherence is often clouded by the use of statistical methods that do not control for correlations among the factors themselves (Spagnoli et al. 1989).

Factors reportedly involved in adherence to prescription

drug regimens are the knowledge of medication purpose (Helling et al. 1987; Klein, German, and McPhee 1982), knowledge of consequences of nonadherence (German and Burton 1989), patient's understanding of the regimen (Col, Fanale, and Kronholm 1990; Spagnoli et al 1989), patient's attitude toward the medication (Darnell et al. 1986; Inui et al. 1980), patient's level of education (German et al. 1982), source of prescription (ie. general practitioner vs. specialist) (Spagnoli et al. 1989) and regimen counseling and/or memory aids (Michigan Governor's Task Force 1991; Gilchrist, Lee, and Tam 1987; Macdonald, Macdonald, and Phoenix 1977).

Since patient knowledge of drug information is a factor in adherence, it follows that sources of information may also be important. In a random sample of 1100 adults with new prescriptions, Morris et al. (1984) discovered that 70% had received some information about the drug; 95% of those receiving information said that it came from a physician. According to the Iowa 65+ Rural Health Study (Semla et al. 1991), however, 3 percent of all drug purposes reported by participants in that study were inappropriate. When participants cited appropriate purposes, there was no association to whether the medication had been dispensed by a pharmacy or a physician. Interestingly, the highest

percentage of appropriate purpose responses were for drugs dispensed by mail-order pharmacies. An earlier report from the ongoing Iowa study (Helling et al. 1987) cited mail order as a matter of concern since communication between the pharmacist and patient is limited.

Studies have also examined directions given on prescription drug containers. In the Iowa report, the most frequently noted directions were for scheduled daily dosing (>75%), followed in frequency by "as directed/as needed" (8%) and nonspecific directions such as "take with meals"(5.2%). Lundin (1978) found that 25% of 50 people over 60 years of age in a community-based study took medications differently than suggested on container labels, usually because they said their physicians had given them oral instructions to do so. In a study of elderly (mean age of 71.6 years) residents of an urban subsidized apartment building, Darnell et al. (1986) found that standard pharmacy container labels could be read by 79.7% of those surveyed, but inability to read labels did not measurably affect adherence.

There have been recent attempts to expand the sources of information offered to prescription drug users. In England, 3410 adults and 254 pharmacies participated in a national mail survey of the effect of prescription information

leaflets (Gibbs, Waters, and George 1990). The 1809 people who received leaflets knew more about their medicines, especially the side effects, and were significantly more satisfied than the 1601 patients who had not been given additional written information. Ninety-seven percent of participants thought it was a good idea to be given an information leaflet with their prescriptions whether they had been given one or not in the study.

Other studies have reported actual improvements in prescription drug regimen adherence when patient educational aids such as specific counseling (Hawe and Higgins 1990; Gilchrist, Lee, and Tam 1987; Hammarlund, Ostrom, and Kethley 1985; Macdonald, Macdonald, and Phoenix 1977), drug guides (Ross 1991) and drug calendars (Wandless and Davie 1977) were used.

German and Burton (1989) listed the following factors which were considered in successful prescription drug information and education strategies: information/education topic relevance to a patient's need; appropriate degree of individualization of the teaching process; use of feedback and reinforcement; and facilitation of action by the patient.

Changing Health Promoting Dietary Behavior of Older Adults

Since changing behavior in any context is a multi-factorial issue, the concept of changing health promoting behavior has been addressed by many researchers with the subsequent publication of many theories about how such change, including dietary change, might be most effectively accomplished (Glanz and Eriksen 1993). Using meta-analysis of nutrition education research, Johnson and Johnson (1985) demonstrated that there is strong evidence that nutrition education promotes positive changes in dietary behavior. More recent studies have also reported successful nutrition education interventions to achieve health-related dietary modifications (Gans et al. 1990; Hackman and Wagner 1990; Hermann et al. 1990; Williams, Kim, and McMullen 1987), although no studies have been directed specifically to dietary modifications recommended for prescription drug use.

Whether reported dietary behavior changes are the sole result of increased nutrition knowledge has been questioned, since meta-analysis has also shown that the theoretical relationship has a small effect size and does not appear to be strong (Axelson, Federline, and Brinberg 1985). Confidence in the relationship of results of tests of nutrition knowledge and dietary behavior change requires confidence in the validity of the measures. Knowledge

measures must reflect the information that is required by the individual to exhibit the dietary behaviors of interest. This confidence may exist in intervention research projects, although meta-analysis shows that it most often does not (Axelson and Brinberg 1992). It would be difficult to achieve in retrospective research of prescription drug dietary modifications which require specific nutrition knowledge and involve instruction for widely different regimens from varied sources, in differing formats, through different methods. A single knowledge measure could not be used to predict adherence to a wide variety of recommended dietary modifications.

In studies examining predictors of other health promoting behaviors, including weight loss, self-efficacy is frequently cited as an important predictor (Bernier and Avard 1986; Strecher et al. 1986; O'Leary 1985; Jeffrey et al. 1984; Weinberg et al. 1984). The value of perceived self-efficacy as a factor in predicting medical recommendations adherence behavior has also been demonstrated (Meichenbaum and Turk 1987; Bandura 1986; Strecher et al. 1986). Self-efficacy theory proposes that a person's perception of capability to perform a task and the likely outcome of such action can affect behavior (Stanley and Maddux 1986; Bandura 1977).

The factors influencing self-efficacy have never been clearly determined, but Matheson et al. (1991) developed a theoretical model to predict the self-efficacy of older adults toward nutrition behaviors. Self-efficacy toward nutrition behavior was defined as people's judgments of their capabilities to organize and execute behaviors to enhance the quality of their diets.

METHODS

Approval to Conduct Study

Approval to conduct this study was granted in June 1994 by the Michigan State University Committee on Research Involving Human Subjects (UCRIHS) prior to administration of surveys or collection of data (Appendix A).

Study Population

Female residents of an East Lansing, Michigan, subsidized senior apartment complex (total = 154) comprised the study population. Residents' 1994 incomes were limited to two levels under HUD Section 236: $11,500 or less for subsidized apartments; $11,500 to $29,650 for sliding scale rental apartments. Income was calculated by the apartment manager according to HUD Section 236 guidelines, which provide formulas for deducting Medicare, health insurance and prescription drug expenses from gross income. Based on the calculated income figure, residents were classified at one of the two income levels. The population was controlled for: gender, geographic location, cooking facilities, public transportation, availability of in-house meal service and

availability of health promotion programs.

Measures

Data collection was done in two phases, as illustrated later in Figure 1. Separate measures were developed and used for each phase.

Phase 1 Self-administered Questionnaire

Prescription drug use screening and baseline demographics information were obtained through a self-administered large-type (6 characters per inch) questionnaire (Appendix B). The questionnaire comprised prescription drug use screening questions and demographics questions taken from the Iowa and Washington Counties baseline questionnaire of the National Institute on Aging Established Populations for Epidemiologic Studies of the Elderly (EPESE) (Cornoni-Huntley et al. 1986). The questionnaire also directed respondents taking prescription drugs to list those by name along with the name of the prescribing doctor on a simple two-column form at the end of the questionnaire.

An additional demographics question was developed to determine whether the respondent's apartment was subsidized or sliding scale as a proxy for income. Income proxy was used since two levels of income were adequate for this study

and efforts to determine specific income information from older adults are often not successful (Wallace 1991; Gibson and Aitkenhead 1983). Previous studies have shown no relationship between medication use and income (Chrischilles et al. 1992; Nolan and O'Malley 1988), so it is unlikely that there is a relationship with dietary modification. In the EPESE study care was taken to assure reporting of income, offering dollar income range categories to address this sensitive issue, but "refused/don't know/missing" responses were still high (Cornoni-Huntley et al. 1986). Questions about income may also tend to prejudice respondents against further participation in a study for fear that too many personal details will be exposed (Wallace 1991; Gibson and Aitkenhead 1983).

Landry et al. (1988) demonstrated that the self-administered mail questionnaire, which is analogous to the Phase 1 self-administered questionnaire, can be a valid source of information about prescription drugs. They compared data obtained from community dwelling older adults, aged 65 and over, by three methods: in-home examination of drug containers and a personal interview; telephone interview; and mail questionnaire. When overall percent agreement rates were calculated for each person comparing in-home data to the mail questionnaire data, the median and modal percent

agreement rate was 100%. Respondents with less than 100% agreement on prescription drug use by mail and in-home assessment were older and lower on two functional status measures, Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL).

The questionnaire was submitted to a panel of experts for review. They each provided one or more of the following areas of expertise: survey research, data entry and analysis, nutrition and food consumption of older adults, prescription drugs and drug regimens, demographics, and epidemiology.

A focus group evaluation of the questionnaire along with its introduction/instructions letter, which incorporated informed consent for Phase 1, was conducted with seven women volunteers from a nearby town's senior citizen center. The women evaluated the questionnaire for appropriate language, instruction clarity, question sensitivities, response alternatives, sources of confusion, difficulty/time burden, and format/type size. They commented on the questionnaire as a whole and on individual questions.

The revised questionnaire was submitted to the same women who participated in the focus group to complete it as a

pilot. There were no additional revisions necessary before the questionnaire was distributed in Phase 1. There were several comments noting the ease of reading the questionnaire from respondents who actually completed it during Phase 1.

Phase 2 Computer-assisted Personal Interview

The basic computer-assisted personal interview questionnaire (Appendix C) comprised the following:

- drug and drug container information sections filled in by the interviewer which were adapted from the EPESE studies' forms discussed earlier
- questions addressed to respondents about hypothesized variables which were adapted from similar questions used in the EPESE studies
- specific questions addressed to respondents about dietary instructions which were developed for the interview
- self-efficacy toward dietary instruction questions which were addressed to respondents and adapted from the alternate measures of self-efficacy described by Lust, Celuch, and Showers (1993), based on the concepts of Bandura (1986) and Ozer and Bandura (1990)

The personal interview computer questionnaire was submitted for review to the same group of experts and the same focus group who reviewed the Phase 1 self-administered questionnaire. It was revised initially based on their comments. It was then converted into a format suitable for direct data into Epi Info software and adjusted so that computer monitor screen views allowed smooth question transitions, legible interviewer instructions, and clear sight of legal code values used for responses.

The focus group members and two members of the apartment complex resident advisory council, who did not meet the inclusion criteria for Phase 2, were respondents in a pilot of the entire computer-assisted personal interview session. The session included administration of the health status survey, review of the 1-day diet and medication record, and review of the consent forms, all discussed in following subsections. The pilot respondents provided feedback to the interviewer about individual questions and the personal interview questionnaire as a whole, considering appropriateness of language, clarity, question sensitivities, response alternatives, and sources of confusion.

The interview pilot was also used to assess the feasibility

of data collection procedures and convenience and flexibility of the procedures for coding and data entry (Aday 1989). Phase 2 respondents said that the computer entry during the actual interview did not bother them, that they were used to seeing computers used.

Phase 2 Medical Outcomes Study 36-Item Short Form Health Survey

Health status was assessed during the Phase 2 personal interview session with the self-administered Medical Outcomes Study 36-Item Short Form (MOS SF-36) Health Survey (Ware et al. 1993) (Appendix E) which has been extensively researched and validated (McHorney et al. 1992), including its use with older adults (Weinberger et al. 1991). Norms for MOS SF-36 summary scores have been established for various age groups based on representative national samples (Ware, Kosinski, and Keller 1994). Pretesting of the MOS SF-36 survey was part of the pilot of the entire computer-assisted personal interview session.

Phase 2 1-day Food and Medication Record

A 1-day, non-quantitative, large-type (6 characters per inch) food and medication record with instructions for completion (Appendix F) was developed to assess dietary adherence. Since most dietary modifications were to be

followed on a daily basis and involved absolute inclusion or exclusion of specific foods or modified eating patterns (Pronsky 1993), a 1-day food record could assess adherence without concern for inadequate reflection of "usual" intake (Hankin 1989). The instructions did, however, specify that the record be kept for a weekday to try to avoid unusual complications which special occasions might impose on food and beverage consumption and drug regimens.

The short record form with instructions addressed information of interest in assessing adherence to dietary instructions. It was pretested during the pilot computer-assisted personal interview session. Pilot respondents were provided with copies of the instructions and form 2 to 4 days in advance. They were asked to complete the record according to the instructions and bring it to the personal interview. None of the respondents reported having trouble following the instructions and completed the record properly, although minor revisions were made to the record instructions as a result of their comments offered for improvements.

Phase 2 Consent Forms

Two consent forms (Appendix G) were developed for Phase 2 and pretested by the focus group and in the pilot personal

interview session. One was for informed consent; the other for the respondent's permission to contact her physician(s) if that was necessary. No revisions were needed.

Phase 2 Drug Container Labels Reading Test

To assess the ability of respondents to read the information on drug container labels, a reading test was developed using copies of two actual drug container labels (Appendix H)--one with black letters on a white background and another with black letters on a red background. The reading test was added to the end of the personal interview questionaire and pretested along it.

Phase 2 Assessment of Respondent Cognitive Ability

Respondent cognitive reliability was assessed after the personal interview session by consistency of answers to duplicate questions, count of "don't know/remember" answers per respondent and by interviewer assessment of confusion or memory problems and level of confidence in information received (Wallace 1991; Gibson and Aitkenhead 1983). All respondents were considered cognitively reliable. This assessment was consistent with the independent living capability required for apartment dwellers in the complex.

Data Collection

Data were collected in two phases, illustrated in Figure 1.

Phase 1

In cooperation with the resident advisory council, the questionnaires were delivered to women residents along with instructions to return completed questionnaires to the Resident Manager's office by a specified day. Although an incentive had been considered for questionnaire return, the council advised against it in the belief that incentives had been ineffective in previous surveys and that residents participated in such activities for the reward of helping other people. Communications to residents about the study were designed with this participation motive in mind.

The questionnaire included a cover letter explaining the purpose of the study and advising that the results would provide confidential background information for a later study. No reference was made to diet or drug regimens.

Announcements concerning the survey were made by the resident council president at in-house meals during the week the questionnaire was distributed and the week the completed

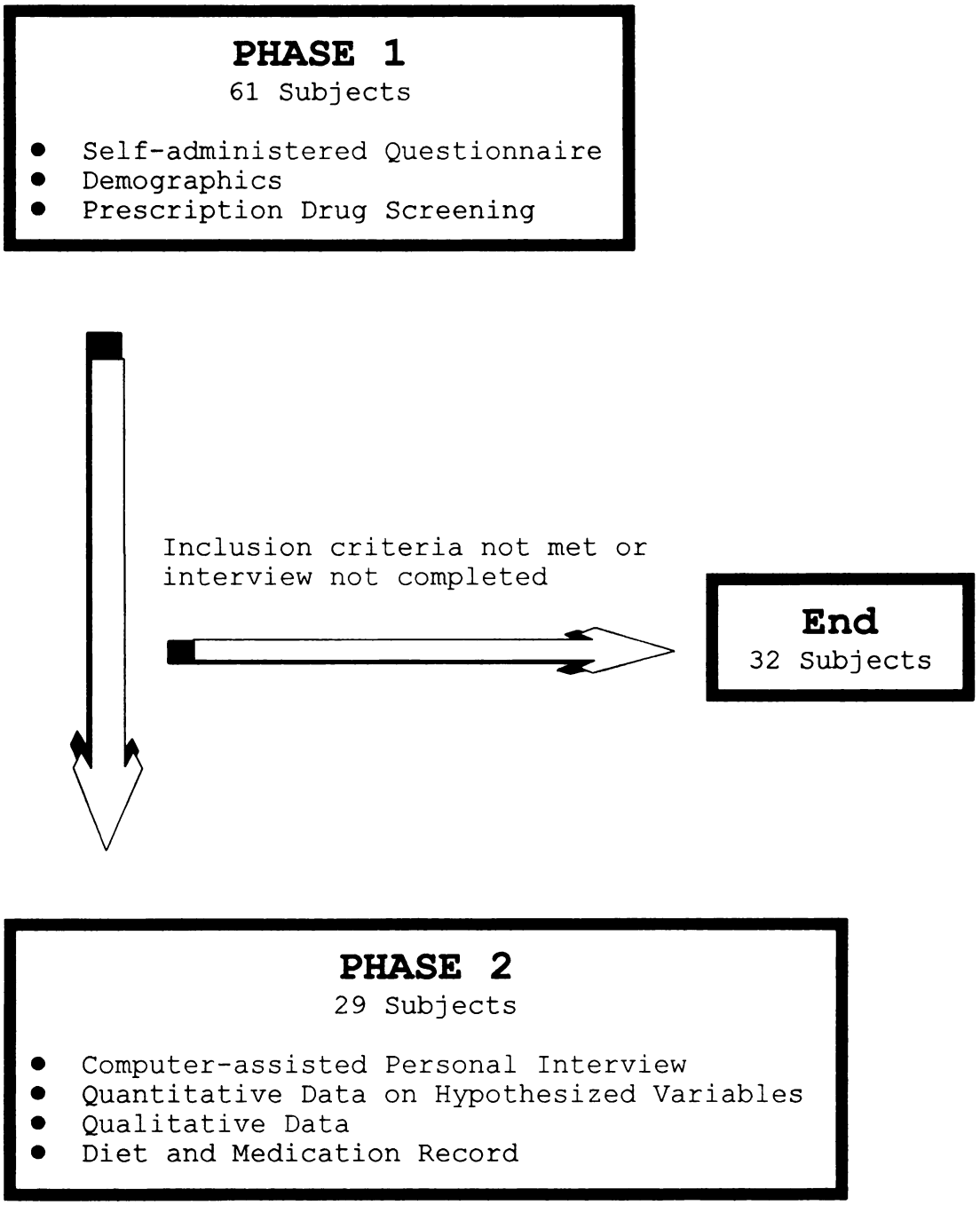
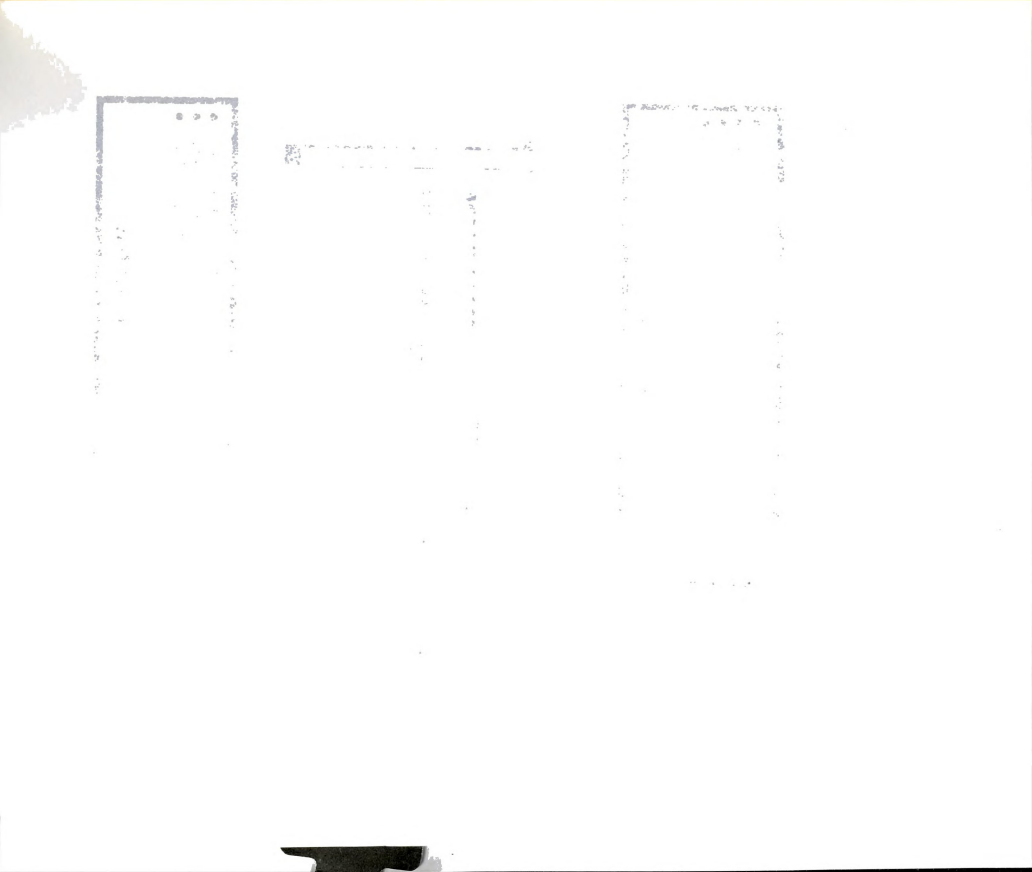


Figure 1: Data Collection Phases



Sixty-one women returned completed surveys by the original return due date, a response rate of 39.6%. Reminder notices were delivered to each apartment two weeks after the original return due date, but no additional surveys were returned. Residents who returned questionnaires with "Don't Know" or blank answers were contacted by phone or in person to attempt to determine the correct response.

A microcomputer database form was prepared so that the data from the self-administered questionnaire could be entered into Epi Info (1994), Version 6: a word processing, database and statistics software program for epidemiology on microcomputers. A rigorous checking system was programmed for the database entry to provide error checking, mathematical operations, rejection of illegal response values, automatic skip/jump patterns, and autosearching for duplication of data which should have been unique. All data were entered a second time by another trained person and the two data files were processed through the software's data entry validation feature. Inconsistent entries were referenced to the written response and corrected.

Prescription drug information from the self-administered survey was also entered into PharmAssist software (1993) to

estimate the number of potential drug-drug interactions for each Phase 1 participant.

Phase 2

Women who listed prescription drugs with indicated dietary instructions on their Phase 1 questionnaire and who met one or more of the following inclusion criteria comprised the population for this phase. The inclusion criteria were:

- Took one or more of the most frequently listed drugs
- Took one or more drugs in drug categories listed seven or more times in the Phase 1 responses (representing more than 10% of respondents)
- Took drugs with serious consequences for nonadherence to dietary regimen

Women meeting these criteria were contacted by telephone and asked to participate in an interviewer-administered computer-assisted personal interview. Specific appointments were made for interviews to be conducted in the individual apartments or in an assigned room in the apartment complex. All but one participant chose to be interviewed in their apartments. Many indicated that they found it difficult to get around the building and an interview at home would be more convenient.

When appointments were made, participants were asked to complete the 1-day food and medication record prior to the interview. Confirming letters were delivered to participants' apartments along with food and medication record forms and instructions. Instructions noted that the records should include all prescription and nonprescription drugs, vitamin and/or mineral supplements, water and alcoholic beverages ingested on the day of record. Participants were asked to have their food and medication records available for the interview to minimize record-keeping bias that might result from the dietary modification questions in the interview. Since the average educational level of the complex's residents was quite high, almost 12 years, this group was likely to be able to keep food records without direct assistance (Elahi et al. 1983; Garry et al. 1982). On the telephone and in the confirming letter, participants were also asked to make all prescription drug containers and any written information they had about their drugs available at the time of the interview.

Food records are one of the screening measures recommended for use with older adults by the Nutrition Screening Initiative (Dwyer 1991). The 24-hour food record is preferable to the 24-hour recall technique since information obtained from the latter is always subject to the ability to

accurately remember foods eaten in the short-term past. Despite a lack of convincing evidence, reviewers have noted that memory deficits may particularly influence 24-hour recall performance by older adults (Krall, Dwyer, and Coleman 1988; Dwyer, Krall, and Coleman 1987; Campbell and Dodds 1967).

In a study of adults aged 60 years and over (Gersovitz, Madden, and Smiciklas-Wright 1978), the internal validity of a 24-hour recall was compared to that of a 7-day food record. Although the study was not directed to individual nutrient intake, results suggested that both methods provide about equally accurate estimates of the mean intake; the recall was subject to flat slope syndrome. The authors also found that 85% of the sample returned usable records for at least two days, but the percentage of usable records declined from the third to seventh days. They suggested that the 1-day food record may provide more accurate information than the 24-hour recall.

Fanelli and Stevenhagen (1986) specifically compared data collected using interviewer administered 24-hour recalls and 1-day food records from 2,667 older adults who participated in the 1977-78 Nationwide Food Consumption Survey. Data were analyzed for energy and 14 nutrients. Both assessment

methods gave similar estimates of intakes for the groups of older adults, even though data were collected on different days, indicating a lack of variability in the diet from day to day.

The interview questionnaire was converted to an Epi Info (1994) database relational file entry form. Programming was completed for the form which allowed conditional switching between three related form levels: the base information form, the drug information form and the dietary instruction form. The hierarchal form levels provided flexible data entry for respondents' records which varied considerably in number of drugs and number of dietary instructions indicated for each drug. A check system was programmed which provided for automatic error checking, mathematical and logical operations, rejection of illegal response values, automatic and conditional skip/jump patterns, autosearching for duplication of entries which should be unique, automatic coding, automatic entry under specified conditions, and pop-up windows to provide data entry coding information for the interviewer.

Based on information reported by respondents in the initial Phase 1 questionnaire, the list of drugs for each respondent participating in a Phase 2 interview was entered by drug

name into Computerized Food-Medication Interactions (FMI) software (1993) to obtain indicated dietary instructions for each drug. Indicated dietary instructions were then entered and coded on each respondent's computer record prior to the interview, along with drug name, drug category code and name of prescribing physician. Dietary modifications listed as "may be needed" (ie. based on lab tests) were not included.

FMI was used in preference to other resources since it provides information obtained from 72 authoritative references, including recent professional journals, in one handbook which is available to health professionals. It is edited by well-known experts in the field: J.P. Crowe, Pharm.D., R.Ph., Director of Pharmacy, Carmilla Hall, Immaculata PA; S. Epstein, M.D., F.R.C.P., F.A.C.P., Head, Endocrinology and Metabolism, Albert Einstein Medical Center and Professor of Medicine, Temple University; and C.H. Smith, Ph.D., R.D., Professor, The Marilyn Magaram Center for Food Science, Nutrition and Dietetics, California State University.

When the interview was conducted, the interviewer followed an introductory, prepared script which was integrated into the interview questionnaire and appeared on the computer monitor screen. Prior to asking any questions, the

interviewer reviewed the general purpose of the study and obtained the informed consent of each participant. Permission to contact the participant's physician, if that should be deemed advisable after analysis of the survey results, was requested at the end of interview. The interviewer advised the participant that her responses to questions would be recorded on the portable computer and explained why the computer was being used.

The interviewer collected the food record and asked to see all prescription drug containers and any additional written information that the respondent had about her drugs.

The Medical Outcomes Study SF-36 Health Survey introduction script (Ware et al. 1993), which was integrated in the computer questionnaire form and visible on the monitor screen, was read to the respondent. She was then given the survey to fill in. While the respondent was taking the survey, the interviewer confirmed the names of the prescription drugs being taken and the name of the prescribing physician(s) and made corrections to the computer record as necessary. At this time, the interviewer also added other information from the drug container label which was required for the questionnaire. When the respondent was finished with the health survey, the

interviewer conducted the personal interview, entering responses to questions directly into the computer program.

At the end of the interview session, the interviewer reviewed the 1-day food and medication record and asked the respondent to clarify information as necessary.

After the interview session was completed, the food and medication record was compared to each of the dietary instructions given and adherence to each instruction was determined. Adherence was scored yes (1) or no (0) and entered into the Epi Info database record. The MOS SF-36 survey responses were also entered into Epi Info by two separate individuals and the two record files were processed and reconciled with the original responses through the program's data entry validation feature.

Information for both over-the-counter drugs (Appendix I) and prescription drugs was entered into PharmAssist software (1993) and the total number of potential drug-drug interactions estimated for each Phase 2 respondent.

Of the 34 women residing in the complex who met the Phase 2 inclusion criteria, interviews were completed and diet records obtained for 29 of them. The length of the

interview sessions ranged from one to two hours. Of the five women who were not interviewed, one was no longer taking prescription drugs so did not qualify for inclusion, two had relocated to Florida, one was in the hospital, and one refused because of illness. The Phase 2 response rate was 87.9%.

Statistical Analysis:

Data were analyzed using Epi Info software (1994), Version 6.0, as noted previously, and SPSS/PC+ (1990) software, Version 4.0. Results were considered significant at the α=.05 level.

Subjects in Phases 1 and 2 were compared to determine if there were any significant differences in their demographic characteristics. Comparisons were done using anova, Satterthwaite's t-tests for samples with unequal variances, and chi square tests for proportions (Dean 1994). Frequencies were determined for all variables; associations were examined using chi square and Fisher exact tests. Further analysis of selected variables was completed to assess the magnitude of their contribution to probability of adherence as predicted by a best fit logistic regression model.

Logistic regression can be used effectively to identify a model which describes the relationship between predictor or independent variables and a dichotomous outcome or dependent variable; for example, adherence or nonadherence (Hosmer and Lemeshow 1989). Logistic regression is the preferable multivariate technique to predict a binary dependent variable from a set of independent variables. If the dependent variable can have only two values, the assumptions necessary for hypothesis testing in multiple regression analysis are violated. Multiple regression analysis also does not allow predicted outcome values to be interpreted as probabilities since they are not constrained to fall in the interval between 0 and 1.

While linear discriminant analysis allows direct prediction of outcome in terms of group membership, it requires the assumption of multivariate normality of the independent variables and equal variance-covariance matrices for its prediction rule to be optimal. Even when the assumptions required for discriminant analysis are satisfied, logistic regression still performs well (Norusis 1990).

In this study, independent variables which were significantly associated with adherence were entered simultaneously to obtain a fully saturated logistic

regression model. A subsequent forward stepwise entry method (with a test for backward elimination) identified variables for inclusion or exclusion from the model based on the significance level of the Wald statistic. This procedure produced a statistically best fitted model with the fewest variables. The final model was compared to the saturated model through goodness-of-fit statistics and by comparing predictions to observed outcomes in a classification table (Hosmer and Lemeshow 1989). The same procedure was followed for other selected variables in domains suggested by the literature review.

The logit (log of the odds of the outcome occurring) of the multiple logistic regression model is given by the equation: $g(\mathbf{x})=B_0+B_1x_1+B_2x_2+\ldots B_px_p$. The logistic coefficient (B) can be interpreted as the change in the log odds associated with a one unit change in the predictor variable (x). The estimated probability of the outcome is $1 / 1 + e^{-g(x)}$ where e is the base of the natural logarithm (approximately 2.718). The probability of the outcome not occurring is 1 minus the probability of the outcome occurring. A probability of 0.5 or greater estimates that the outcome will occur (Hosmer and Lemeshow 1989).

RESULTS AND DISCUSSION

Statistical test results in this section appear either in tables or summary tables. The format for tables not in summary form is shown in Figure 2 on page 50.

Sample Characteristics

There were no significant differences in the demographic characteristics of the subjects in Phases 1 and 2 which are summarized in Table 1.

Table 1: Sample Characteristics Comparisons of Phase 1 and Phase 2

Characteristic	Phase 1 (n=61)	Phase 2 (n=29)	Test	p-Value
Mean Age	76.97	76.03	t-test	.642
% 77 Yrs. or More	52.50	48.30	chi square	.711
% Race = White	83.60	79.30	chi square	.618
Mean Yrs. Education	11.75	11.31	t-test	.427
% Not Married	90.20	89.70	chi square	.810
% Income ≤$11,500*	55.70	62.10	chi square	.570

*Gross income adjusted for Medicare, health insurance and medication expenses.

		B		
		B1	B2	
A	A1	Cell A1/B1	Cell A1/B2	R1
	A2	Cell A2/B1	Cell A2/B2	R2
		C1	C2	Total

[Chi square test statistic or Fisher's Exact test]
[p-Value =]

Legend:

A = Independent variable

A1 and A2 = Independent Variable Categories

B = Dependent variable (potentially influenced by A)

B1 and B2 = Dependent Variable Categories

Cells = Counts of cases with both characteristics

C1 and C2 = Column subtotals

R1 and R2 = Row subtotals

Statistic = Test statistic used for association

p-Value = The probability of a result at least as large as that observed if the null hypothesis is true

Figure 2: Cross-classification Format for Statistical Tests in the Results and Discussion Section

The mean age of subjects was 76.97 years; age range was 54 to 93 years. In Phase 1, 52.5% of respondents were 77 years of age or over; in Phase 2, 48.3%. All subjects tended to be currently unmarried (widowed, divorced or never married) and have an average of somewhat more than 11 years of education. Most were white: 83.6% of Phase 1 respondents, 79.3% of Phase 2. More than half of respondents had incomes equal to or less than $11,500. Maximum household income allowed for apartment residents was $29,650. All but one respondent had known access to health expense coverage: 57 were covered by Medicare, 7 by Medicaid, 43 had private health insurance coverage (some respondents had more than one form of coverage).

Prescription Drug Use

Phase 1

Among Phase 1 respondents (n=61), 53 individuals were taking at least one prescription drug at the time they filled in the questionnaire. The mean number of drugs prescribed for respondents was 3.3. This rate is consistent with a range of mean drug use from 1.5 to 4.5 reported in other studies of community dwelling older women (Chrischilles et al. 1992; Helling et al. 1987; Darnell et al. 1986). The mean number of potential drug-drug interactions estimated by PharmAssist software was 1.7 (Table 2).

An examination of the drug therapeutic categories represented in Phase 1 responses showed that the categories taken most frequently were Hypertension Agents (28.0%), Other Cardiovascular Agents (14.2%), and Arthritis Agents (11.0%) (Table 3). Individual drugs taken by 7 or more respondents, representing more than 10% of respondents, were: digoxin (11), furosemide (9), ranitidine (7) and insulin (7). There were no significant differences in using or not using prescription drugs by age grouping (less than 77 years; 77 years or older) or by race (white or other); comparison chi square test p-values, .095 and .084 respectively.

Phase 2

Phase 2 respondents, by selection, took at least one prescription drug on a daily or as needed basis. The mean number of prescription drugs was 4.9; the range, 1 to 13. More than half of respondents (18) took 5 drugs or less on a daily or as needed basis; 11 respondents took more than 5 drugs. Less than one quarter (22.6%) of the prescriptions were filled with generic drugs. PharmAssist software (1993) estimated that the mean number of potential drug-drug interactions (DDIs), including both prescription and over-the-counter drugs, was 2.7 (Table 2).

Table 2: Prescription (Rx) Drug Use Characteristics

Characteristic	Phase 1 (n=61)	Phase 2 (n=29)
Subjects Using One or More Rx Drugs	53	29
Mean Number Rx Drugs	3.3	4.9
Potential Drug-Drug Interactions (DDIs)[a]		
Mean	1.7[b]	2.7[c]
Range	0-13	0-13
Std.Dev.	2.919	3.646
DDIs = 0	27	9
DDIs = 1-13	26	20

[a]Estimated with PharmAssist software
[b]Rx drugs only
[c]Rx and over-the-counter drugs

Table 3: Prescription Drug Use by Therapeutic Category

	Phase 1		Phase 2	
Therapeutic Category	Freq	%	Freq	%
Hypertension Agents	53	28.0%	38	26.8%
Other Cardiovascular Agents	27	14.2%	16	11.3%
Arthritis Agents	21	11.0%	21	14.8%
GI Agents	17	9.0%	15	10.6%
Hyperglycemia Agents	12	6.3%	11	7.7%
Other	60	31.5%	41	28.9%
Total	190	100.0%	142	100.0%

There was no significant relationship between the number of prescription drugs used and the number of potential DDIs (comparison Fisher exact test p-value 0.140). As in

Phase 1, the therapeutic categories used most frequently were Hypertension Agents (26.8%), Arthritis Agents (14.8%) and GI Agents (10.6%) (Table 3). There was no significant difference in therapeutic categories used by age group, race, income level or education level (Table 4).

Table 4: Relationship of Phase 2 Demographic Variables to Drug Therapeutic Categories Used

Variable	Chi Square	df	p-Value
Age: < or ≥77	10.14	5	.071
Race: white or other	5.00	5	.416
Income: ≤ or > $11,500	0.65	5	.985
Education: < or ≥ high school	2.41	5	.790

Most drugs were taken once a day (61.3%) or twice a day (20.4%), although some (14.8%) were prescribed on an as needed basis. Respondents reported taking prescription drugs for durations ranging from less than 1 month to 480 months; the mean duration was 65.4 months (Table 5). The length of time a prescription drug had been taken was significantly related to income level, but not to age group or race. Respondents at the lower income level, $11,500 or less, were more likely to take a drug for more than 36 months. This may have been due to the availability of Medicaid and coverage for the costs of prescription drugs.

Table 5: Length of Time of Prescription Drug Use

Months	Number of Drugs	%	Cum.%
<12	36	25.4%	25.4%
13-36	43	30.3%	55.6%
>36	63	44.4%	100.0%
Total	142	100.0%	
Mean Duration	65.39		
Std. Dev.	88.430		

Dietary Instructions

All of the results in this section on dietary instructions were based on interviewer examination of drug container labels and medication fact sheets and on respondent reports. All indications for dietary instructions were according to Computerized Food-Medication Interactions (1993).

Of the 142 drugs taken by Phase 2 respondents, 6 did not have any modification to the diet indicated as part of the drug regimen; 136 drugs did have indicated dietary instructions. More than half (56.3%) of the drugs with indicated dietary instructions had no instructions at all given for them. This was independent of age, race, income level and number of drugs taken; but significantly related to certain drug therapeutic categories (p=.000)(Table 6).

Table 6: No Indicated Dietary Instructions Given by Drug Therapeutic Category

Therapeutic Category	Dietary Instructions Given: No	Yes (Some/All)	Total
Arthritis Agents	3	18	21
GI Agents	11	4	15
Hyperglycemia Agents	4	7	11
Hypertension Agents	27	9	36
Other	18	19	37
Other Cardiovascular Agents	14	2	16
Total	77	59	136

Chi square = 30.99
Degrees of freedom = 5
p-Value = .000

Comparing categories, Arthritis Agents had proportionately fewer drugs with no indicated dietary instructions given. This may have been attributable to the fact that most Arthritis Agents need to be taken with meals or with food or milk. Many respondents said that their doctors told them to take all of their drugs with food or meals.

Individual codes were assigned to each dietary instruction indicated for a drug during data entry (Appendix D). In data analysis, the instruction codes were grouped into one of the six categories listed below. The categories

described the type of potential drug-food or drug-nutrient interaction (DFNI) the instruction was designed to prevent and were similar to those used in a previous research study (Lewis, Frongillo, and Roe 1995).

- Alcohol Incompatibility
- GI-Interference (drug malabsorption when administered with food)
- GI-Meal Omission (reduced drug bioavailability or GI irritation when administered on an empty stomach)
- Inappropriate Supplement or Intake (toxicity and/or reduced drug efficacy with concurrent administration)
- Drug-Induced Nutrient Deficiency
- Reduced Drug Efficacy (drug effect or duration)

The total number of specific dietary instructions indicated for the 142 prescription drugs taken by Phase 2 respondents was 394. According to respondent reports and interviewer examination of drug container labels and medication fact sheets, the total number of instructions actually given was 80 (20.3%). The DFNI category representing the highest number of indicated dietary instructions was Reduced Drug Efficacy (Table 7). The highest percentage of dietary instructions given was in the GI-Meal Omission category.

Table 7: Dietary Instructions Indicated and Given by Drug-food or Drug-nutrient Interaction (DFNI) Category

DFNI Category	Dietary Instructions		
	Indicated	Given	% Given
Alcohol Incompatibility	90	25	27.8%
GI-Interference	10	1	10.0%
GI-Meal Omission	88	37	42.1%
Inappropriate Supplement/Intake	64	5	7.8%
Nutrient Deficiency	26	0	0.0%
Reduced Drug Efficacy	116	12	10.4%
Total	394	80	20.3%

For individual respondents, the mean percent of indicated dietary instructions given was 24.6% with a range from 0% to 100%. Only one individual received 100% of indicated instructions; she was taking one drug which had one instruction indicated. Among multiple drug users (n=27), the two respondents with the highest percentages of dietary instructions given took 4 drugs (69.2% given) and 3 drugs (30.0% given) respectively.

Medical Outcomes Study SF-36 Survey Scores

SF-36 scores were calculated as Physical Component Summary (PCS) scores and Mental Component Summary (MCS) scores. The PCS comprised subscales which addressed respondent assessment of personal physical functioning, physical role,

bodily pain and general health; the MCS subscales addressed vitality, social functioning, emotional role and mental health. The summary scores have been recommended as more reliable measures of individual health status than the subscale scoring system originally applied to SF-36 results for groups (Ware, Kosinski, and Keller 1994).

Phase 2 respondents presented PCS scores which were generally lower than the U.S. general population norms (or averages) for equivalent age and gender (Table 8). This may have been due to the high proportion of respondents who were over 77 years of age (48.3%), and in particular to the 10 respondents who were over 85 years of age. Individuals over 85 years of age are usually under represented in surveys and Ware, Kosinski, and Keller (1994) noted that the oldest old age groups comprising the norms were collapsed into the 65 years and over age group to provide a large enough sample to assure precision. These authors also noted that in the norm population there was an almost linear decline in PCS scores with advancing age beyond 65 years. Given these considerations, the physical health status of Phase 2 respondents probably did not differ greatly from others of the same age. There was no significant relationship between PCS score and demographic variables, number of drugs, any dietary instructions being given or percent of dietary

instructions given (Table 10).

Table 8: Medical Outcomes Study SF-36 Health Survey Physical Component Summary (PCS) Scores and Norm Scores for U.S. Population of Equivalent Age and Gender

PCS	Phase 2	Norm for Women ≥65 Yrs. of Age	Norm for Women 55-64 Yrs. of Age
n	29	413	164
Mean Score	33.64	41.02	45.03
Std.Dev.	11.56	11.52	11.57
Range	16-56	8-59	13-62

MCS scores for Phase 2 respondents were also generally below the norms (Table 9). Ware, Kosinski, and Keller (1994) stated that, unlike PCS scores, MCS scores did not decline for the norm population older old respondents. For Phase 2 respondents, there was a very significant relationship between taking more than 5 prescription drugs and lower MCS score (Table 10). Respondents taking more than 5 drugs had a mean MCS score of 39.70, while those taking 5 or fewer drugs had a mean MCS score of 52.29. These mean scores were below the norm or average score for the U.S. general population of equivalent age and gender.

It is not clear why taking more than 5 drugs might have this effect, but a clue may have been provided by one of the respondents who volunteered the comment that she was upset about having to take so many medicines and sometimes just

didn't take them (Appendix I). Since older adults are the biggest users of prescription drugs, having to take drugs may be an unpleasant reminder of one's advancing age and inevitable mortality. There was no significant relationship found between MCS scores and demographic variables, any dietary instructions being given or percent of dietary instructions given (Table 10).

Table 9: Medical Outcomes Study SF-36 Health Survey Mental Component Summary (MCS) Scores and Norm Scores for U.S. Population of Equivalent Age and Gender

MCS	Phase 2	Norm for Women ≥65 Yrs. of Age	Norm for Women 55-64 Yrs. of Age
n	29	413	164
Mean Score	47.52	51.44	50.56
Std.Dev.	13.09	10.54	10.16
Range	22-71	19-71	13-65

Table 10: Relationship of Selected Variables to Medical Outcomes Study SF-36 Health Survey Summary Scores

Variable	Test	PCS p-Value	MCS p-Value
Age: < or ≥77	anova	.969	.488
Race: white or other	anova	.990	.403
Income: ≤ or > $11,500	anova	.342	.117
Education: < or ≥ high school	anova	.947	.620
Number of Drugs: ≤5 or >5	t-test	.213	**.009**
Diet Instructions: Yes or No	anova	.570	.286
% Instructions Given	t-test	.428	.192

Characteristics of Dietary Instruction Delivery

Dietary instructions were given on drug container labels, in other written forms--most often medication fact sheets--and orally. Instructions were occasionally given more than one way (Table 11).

Table 11: Dietary Instruction Delivery Forms by Potential Drug-food Drug-Nutrient Interaction (DFNI) Category

	Label=1			Other Written=2			Oral=3	
DFNI Category	1	2	3	1&2	1&3	2&3	All	Total
Alcohol Incompatibility	17	8	6	2	3	-	-	36
GI-Interference	-	1	-	-	-	-	-	1
GI-Meal Omission	13	10	18	2	2	1	1	47
Inappropriate Supplement/Intake	-	5	-	-	-	-	-	5
Nutrient Deficiency	-	-	-	-	-	-	-	-
Reduced Efficacy	6	7	6	1	-	-	-	20
Total	36	31	30	5	5	1	1	109

To assess the ability of respondents to read container labels, each was asked to read the information on two real labels obtained from a pharmacy. Label 1 contained alcohol avoidance information in black text on a red background. Of 29 respondents, all but 4 (13.8%) could read the label although some readers had to find a brighter source of light. The 4 respondents who could not read the label knew that it said something about not drinking alcohol.

All could read label 2 which said to take the drug with food or milk and had black text on a white background. Although the different colors of the labels offer some visual association with the instructions themselves, it would probably be helpful for older adults to have the instructions reinforced verbally at the time the prescription is written or filled. More research might determine if the black on red label presents a significant reading difficulty for a larger population of older adults. For the purposes of this study, however, it is unlikely that not being able to read a label seriously impaired the ability of respondents to know what the instructions were.

The most frequent source of written dietary instructions (Table 12) other than container labels was the pharmacist (64.5%) who used medication facts sheets as the format (Table 13). Oral instructions were most often given by physicians (56.7%) using individual counseling, although dietitians provided group instruction for 7 dietary instructions related to the use of Hyperglycemia Agents. Occasionally, written instructions were obtained by the respondent herself from independent sources. These sources of dietary instruction included a book about prescription drugs (1 instruction), the Physician's Desk Reference (1 instruction), sample package inserts (2 instructions), and a

label about drinking orange juice or eating a banana that was on the container of another, previously prescribed, diuretic drug which the respondent still had in her medicine cabinet (1 instruction).

Table 12: Sources of Dietary Instruction Other Than Labels

Source	Written (not label)	%	Oral	%
Dietitian	6	19.4%	8	26.6%
Doctor	1	3.2%	17	56.7%
Pharmacist	20	64.5%	5	16.7%
Other	4	12.9%	-	-
Total	31	100.0%	30	100.0%

Table 13: Dietary Instruction Formats Used by Health Professionals

Format	Frequency
Label	36
Individual Counseling	23
Medication Fact Sheet	20
Brochure	7
Group Instruction	7
Sample Package Insert	2
Book	2

In addition to dietary instructions indicated for the 142 drugs taken by Phase 2 respondents, other dietary instructions were given for 39 of the drugs (27.5%). In these instances, other instructions were provided by the

doctor (26 drugs), the pharmacist (10 drugs), a container label for an earlier purchase (1 drug), a brochure provided by a nephew (1 drug), and a senior citizen organization's meeting presentation (1 drug). The methods used to provide extra instructions included individual counseling (28), container label (6), fact sheets (4) and group instruction (1).

The extra instructions did not conflict with those indicated for 30 of the drugs, but for 9 drugs conflicting instructions were given. All conflicting instructions would pose a risk for DFNI and were associated with individual counseling by respondents' physicians (p=.018). In five instances, instructions had been given for individuals to take all their medications with food, probably in an effort to avoid gastrointestinal discomfort. Twice instructions were given for individuals to take all medications together in the morning before breakfast, probably to simplify the dosing schedule. One individual was told to take a specific drug with food which was recommended for administration on an empty stomach, again probably in an effort to avoid gastrointestinal distress.

The extra instructions which did not conflict with those indicated were: take all medications with food (11), eat a

banana and/or drink a glass of orange juice every day (6), take all medications together in the morning (4), take with food or milk for GI distress (3), take with a full glass of water (2), do not drink alcoholic beverages (1), take with breakfast (1), general information on how to take medications (1), increase cereal/fiber intake to help control diabetes (1). Many of these instructions were listed as "may be needed," rather than indicated, by Computerized Food-Medication Interactions software (1993) and would be helpful for the respondent in managing her drug regimen. The instruction to take all medications with food was given as a blanket statement and, in the case of these instructions, would not create a potential DFNI.

Attitudes, Beliefs and Knowledge

When respondents were asked if they knew why a drug had been prescribed, they indicated 83.1% of the time that they did (118 of 142 drugs). They further indicated that 78.9% of the prescribed drugs (112) helped them. As expected, there was a strong association between knowing why a drug was prescribed and the belief that it helped (p=.000).

When dietary instructions were given for a drug (59 drugs), most of the time respondents believed that the drug could be taken as directed and that they understood the dietary

instructions for their drugs and followed them. Responses were divided about knowing why dietary instructions were given or what problems could develop if the instructions were not followed, and about having trouble following the instructions (Table 14).

Table 14: Respondents' Beliefs About Dietary Instructions Given for Each Drug

Survey Question	Responses			
	Yes	%	No	%
Do you know why certain eating or drinking habits are included in your instructions?	32	54.3%	27	45.7%
Do you know what problems might develop if you don't follow these instructions?	30	50.8%	29	49.2%
Do you understand the instructions about eating and drinking habits?	59	100.0%	-	-
Do you have any trouble following the instructions?	10	16.9%	49	80.1%
As a general rule, do you follow the instructions?	54	91.5%	5	8.5%

There was no significant relationship between knowing what problems could develop and income level, but there was a significant relationship to education level ($p=.027$). Those respondents who had completed 12 or more years of school were less likely to say that they knew what problems could develop than those who had less education. This was unexpected since education level is often considered a proxy

for income. The relationship may just be an artifact or health care providers may perceive that less educated individuals require more information or that information needs to be presented in a different way to achieve a positive outcome.

Self-efficacy scores were very similar for all of the respondents who received dietary instructions with 93.2% feeling completely confident in their ability to adjust their eating or drinking habits in order to take their prescription drug(s) exactly as instructed. Respondents who needed more help thought that additional written information and someone explaining what they needed to do would make them fully confident.

Seven respondents, taking a total of 10 drugs, gave the following reasons for trouble with dietary instructions:

- can't remember
- can't afford foods specified (diabetic meal plan)
- can't eat all the food listed (diabetic meal plan)
- exchange system is confusing (diabetic meal plan)
- activities interfere (2)
- instructed to take medicine four times a day with meals but only eat 3 meals.

Only 2 respondents indicated that they receive any help in taking their prescription drugs: one regularly from a neighbor, one occasionally from a home health aide.

Respondents believed that they had experienced side effects with 30 of the 142 drugs taken (21.1%), including 8 complaints of GI distress (Table 15). Three complaints of GI distress came from respondents who should have received dietary instructions to help prevent the complaint, but did not.

Table 15: Side Effects Reported by Respondents That They Attributed to One of Their Drugs

Side Effect Reported	Frequency
GI distress	8
Shakes/sweating	5
Fatigue	2
Drowsiness/very dry mouth	2
Puffiness	2
Reduced urine output	2
Colonic hemorrhage	1
Loss of taste sensation	1
Diminished vision	1
Tender breasts	1
Hair thinned/facial hair formed	1
Ringing in ears/heavy head	1
Irritable/can't think	1
Frequent urination (often can't find bathroom)	1
Dizziness	1

Adherence

Adherence was assessed for each dietary instruction which was given, using the completed 1-day diet and medication records. Although 80 instructions were given, 8 instructions were for medications prescribed on an as needed basis and not taken on the record day. Adherence was scored yes or no.

Respondents adhered to 59 (81.9%) of the 72 dietary instructions given. Almost all of the instances of nonadherence involved respondents who believed that they understood their dietary instructions and followed them. These individuals may just have needed further explanation in order to adhere. A glaring exception in nonadherence was the dietary instruction to follow a diabetic meal plan. There was a significant difference (p=.000) between adherence to diabetic meal plans and adherence to all other dietary instructions (Table 16).

Table 16: Adherence to Diabetic Meal Plan Instructions Compared to Adherence to All Other Dietary Instructions

	Adherence		
Dietary Instruction	No	Yes	Total
Diabetic Meal Plan	5	1	6
All Other Instructions	8	58	66
Total	13	59	72

Fisher exact
2-tailed p-value = **.000**

The difference between adherence to instructions given for drugs in the Hyperglycemia Agents category, which included both oral hypoglycemics and insulin, and those in other categories was also significant (p=.0496) (Table 17), but less so because respondents did adhere to instructions for

those drugs other than the diabetic meal plan (ie. in relation to meals, avoid/caution with alcohol).

Table 17: Adherence to Dietary Instructions Given for Hyperglycemia Agents Compared to Adherence to Dietary Instructions Given for All Other Drugs

	Adherence		
Drug Therapeutic Category	No	Yes	Total
Hyperglycemia Agents	5	8	13
All Other	8	51	59
Total	13	59	72

Fisher exact
2-tailed p-value = **.0496**

Six respondents, 4 using insulin and 2 taking oral hypoglycemics, were given diabetic meal plan instructions, but only one adhered. Those who did not adhere said in the interview that they did not follow the instruction. Two also said that they were not completely confident that they could follow the instruction even if they wanted to. One of these indicated that she thought she could become confident if someone explained the meal plan to her again, talked about applying it when eating out, and gave her additional information to refer to at home. The other said that it wouldn't matter how much more help she had, that her 2000 kilocalorie diet was just more than she could eat and she did not intend to give up everything she liked (Appendix I).

Most of those who did not adhere also said that their doctors did not ask them if they followed their meal plans. If their blood sugar levels were high, the doctor just said to stop eating sweets (Appendix I). In one case, however, the doctor had scheduled the respondent to return to diabetic meal plan group instruction with a dietitian.

The one respondent, on an oral hypoglycemic, who followed her meal plan said that she had lots of support. Her doctor always asked about how she was doing with her diet, had her meet with the office nurse to discuss it each time she came in, and went so far as to have her to dinner at his house to show her how to apply the plan to a real meal (Appendix I).

None of the demographic variables were significantly related to adherence (Table 18). Of the variables hypothesized, the only one which proved to have a significant relationship to adherence was the doctor as a source of oral dietary instruction (Table 19). Other variables were also tested for a relationship to adherence revealing only one of significance, the reduced drug efficacy DFNI category (Table 18), which was negatively associated. The methods of instruction used for this category were not significantly related to adherence.

Table 18: Relationship of Adherence to Selected Variables

Variable	Test	p-Value
Assistance with drug regimen	chi square	.406
Belief that drug helps	chi square	.654
DFNI category	chi square	**.002**
Drug therapeutic category	chi square	.932
Hyperglycemia Agents category	Fisher exact	**.0496**
Knowledge of instruction's purpose	chi square	.108
Knowledge of nonadherence consequences	chi square	.229
Length of time drug taken	chi square	.158
Number of drugs	chi square	.932
Doctor as source of oral instruction	Fisher exact	**.044**
PCS score	anova	.831
MCS score	anova	.859
Self-efficacy	Fisher exact	.106
Side effects reported	Fisher exact	.336
Trouble following instruction	chi square	.254

Table 19: Adherence by Source of Oral Dietary Instruction

	Adherence		
Source of Oral Instruction	Yes	No	Total
Doctor	14	2	16
Dietitian or Pharmacist	6	6	12
Total	20	8	28

Fisher exact
2-tailed p-value = **.044**

Reduced efficacy DFNI category, Hyperglycemia Agents therapeutic category, and doctor as source of oral instruction were entered into forward stepwise logistic regression as dichotomous variables to determine their significance as predictor variables in a model for adherence. Reduced efficacy DFNI was the only variable included in the final model (Table 20) where it decreased the probability of adherence:

$$\text{Probability of adherence} = 1 \,/\, 1 + e^{-g(x)}$$

$$g(x) = 2.3224 - 2.3224(\text{reduced drug efficacy DFNI})$$

Table 20: Parameter Estimates for Logistic Regression Model

Variable	β	S.E.	Wald	df	Sig	R	Exp(β)
Reduced Drug Efficacy DFNI	-2.3224	.6853	11.4849	1	.0007	-.3735	.0980
Constant	2.3224	.4686	24.5596	1	.0000		

The final model correctly classified 81.94% of cases.

Groups of other variables in domains suggested by literature review were also entered into logistic regression models but none were significant predictors of adherence.

Summary of Results

All of the results related to dietary instructions were based on interviewer examination of drug container labels and medication fact sheets and on respondent reports. Indications for dietary instructions were according to Computerized Food-Medication Interactions (1993).

Hypotheses I, II and III were accepted:

Hypothesis I: In the majority of cases (51% or more), respondents did not receive instruction for all indicated dietary modifications.

This hypothesis was accepted based on the following results:

- Twenty-eight respondents (96.6%) did not receive all indicated dietary instructions. Only one respondent (3.4%) received all indicated dietary instructions; she was taking one drug with one instruction indicated.
- The mean percent of indicated dietary instructions given per respondent was 24.6% (range 0.0% to 100.0%).

- Of the 394 dietary instructions indicated for 136 drugs, only 80 (20.3%) were actually given.
- Seventy-seven (56.3%) of the 136 drugs which had dietary instruction indicated had no dietary instructions at all given.

Hypothesis II: Respondents adhere to a majority (51%) of dietary instructions.

This hypothesis was accepted since respondents adhered to 81.9% of instructions given.

Hypothesis III: A regression equation can be constructed which will predict dietary instruction adherence.

This hypothesis was accepted since a logistic regression equation was constructed which correctly predicted adherence for 81.94% of the dietary instructions received by respondents in the study. The only predictor variable included in the logistic regression model was Reduced Drug Efficacy DFNI category, a variable not hypothesized. Its inclusion may have been enhanced by the presence of the diabetic meal plan instruction as a category component, since that instruction demonstrated a very high rate of nonadherence.

The inclusion of only one variable in the final logistic regression model does not necessarily indicate that the hypothesized variables do not contribute to adherence or that they are unimportant in practice. In analysis, the doctor as a source of oral instruction was significantly related to adherence. This was consistent with the many respondents who mentioned during interview probing that their doctors told them anything important that they need to know about their prescription drugs. The significant relationship of the Hyperglycemia Agents category to adherence was similarly consistent with the very low rate of adherence to diabetic meal plan instructions. The failure of these variables to enter into the logistic regression model and of other variables to reach the $\alpha=.05$ significance level of relationship may have been attributable to small sample size.

CONCLUSIONS AND IMPLICATIONS

Conclusions

The following conclusions were reached in this study:

- Subjects did not receive most of the dietary instructions indicated for their prescription drugs, putting them at risk for drug-food and/or drug nutrient interactions. This was true despite a conservative approach to tabulating indicated instructions. If preventative measures, like increasing intake of foods high in potassium with use of potassium-depleting diuretics before laboratory tests detect hypokalemia, were added to the tabulation, the percentage of instructions given would have been even lower.
- Although the risk posed by many of the potential drug-food and/or drug-nutrient interactions was not necessarily life-threatening, even small decrements in functioning must be avoided for older adults to attain the highest levels of physical and social functioning.

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- When dietary instructions were given as part of the prescription drug regimen, they tended to be followed, except for diabetic meal plans.
- Even when subjects did not adhere to instructions, they most frequently believed that they understood and followed them.
- The instructions least likely to be followed were those intended to prevent reduced drug efficacy interactions, especially diabetic meal plans.
- Oral instructions from doctors were significantly related to adherence and the doctor was viewed as the ultimate source of drug information.
- Dietary instructions which conflicted with those recommended were most likely to be given by doctors.

Implications

Dietary Instruction Delivery and DFNI Awareness

Since individuals cannot adhere to instructions they never receive, the key issue in reducing risk for drug-food and drug-nutrient interactions is delivery of appropriate dietary instructions. Strategies to assure delivery should focus on increasing awareness of DFNI risk and prevention measures in relevant arenas.

Awareness of DFNIs, the means to prevent them and the ripple

effect of small decrements in functioning, should be defined components of continuing and higher education drug related courses for dietitians, physicians, pharmacists and nurses. This study indicated that the physician is viewed by the patient as the ultimate source of persuasive drug information and can play an effective role in enhancing patient awareness of the importance of dietary instructions. Whether physicians themselves have an adequate awareness is unknown. The evidence presented here suggests that they may not. For the physician who is educated to look for it, there is a wealth of information about DFNIs available in the form of handbooks and computer software like that used in this study. The Working Group on Health Education and High Blood Pressure (1987) has acknowledged the important role of the physician in improving adherence to high blood pressure treatment regimens, including those for drugs and dietary modifications.

Even when the physician relies on other health professionals to communicate DFNI information to the patient, however, it is clear that the physician's persuasive caution to the patient about the importance of following instructions from other sources may improve adherence.

Although the dietitian is responsible for assuring

communications to the patient about DFNIs upon hospital discharge (Joint Commission on Accreditation of Hospitals 1986), pharmacists and nurses frequently assume the role of DFNI educator. Community dwelling individuals who receive outpatient drug prescriptions are unlikely to have the advantage of a dietitian's counsel since health insurance reimbursement is currently not allowed for such service.

The nutrition community may best influence DFNI communications in these circumstances by enhancing awareness of DFNIs in other health professionals with whom they deal and by promoting public education messages through professional organization venues. The Physician Education Project of the American Dietetic Association and the public service announcements produced by The Society for Nutrition Education represent the kind of avenue which might be used.

Like the issue of drug-drug interactions, DFNI awareness and education also need to be widely addressed at the level of the consumer. Older women, and all other consumers, should know enough about the possibility of DFNIs to question the need to modify eating and drinking habits in prescription drug regimens. Many people are now informed consumers who question the combinations of drugs they take. Publications like those from the American Association of Retired Persons,

"The Smart Consumer's Guide to Prescription Drugs" (American Association of Retired Persons 1989a) and "Healthy Questions" (American Association of Retired Persons 1989b), are a step toward DFNI awareness. These publications tell readers to ask pharmacists and doctors about taking drugs with certain food and beverages, but they do not tell them why they should ask or mention that quality of life issues may be involved. Measures being taken by the Food and Drug Administration to mandate readable, understandable information about over-the-counter drugs is another step toward DFNI awareness.

The most effective ways to achieve increased awareness and knowledge of DFNIs among older women need to be identified. As part of this study, the resident advisory council and participants of Phase 2 were questioned informally about their interest in attending a presentation about the relationship of foods to prescription drugs. They were polite, but unanimous in their disinterest. The disinterest may have reflected the views of several Phase 2 respondents who, in response to the interviewer script section suggesting that they might find it helpful to ask the pharmacist or physician about the need for dietary modifications in their prescription drug regimens, said that their doctors tell them everything they need to know about

their medicines. The resident manager said that there are often health related presentations in the complex and that they are generally not well attended.

Diabetic Meal Plans

Results of this study related to diabetic meal plans were very alarming. A low percentage (just more than 50%) of diabetic meal plan instructions were given and there was very poor adherence. This is in direct opposition to the position of the American Diabetes Association (ADA) that medical nutrition therapy is integral to total diabetes care and management (American Diabetes Association 1994). Reasons cited for nonadherence (see p.72) suggested that respondents did not understand how to apply their meal plans, that meal plans had not been individualized and that skills had not been developed in adapting meal plans to special situations. The Food Guide Pyramid has been recommended for use in diabetic meal planning (American Diabetes Association 1994) and could prove to be a simpler, yet effective, approach for the older adult. The one respondent who actually adhered to her diabetic meal plan mentioned that she had been given the Food Guide Pyramid to use and that she liked it (Appendix I).

Four respondents who reported that they received no dietary

instructions were taking oral hypoglycemics; two were using insulin. Although the need for coordinating insulin use with food and beverage intake is generally acknowledged, the inclusion of dietary modifications in oral hypoglycemic regimens may have been viewed as optional. The American Diabetes Association position on medical nutrition therapy (American Diabetes Association, 1994) in non-insulin-dependent (NIDDM) or type II diabetes mellitus is that a nutritionally adequate meal plan with a reduction of total fat, especially saturated fats, and consistent spacing of meals to spread nutrient intake throughout the day can be employed to improve metabolic control.

Individuals on either insulin or oral hypoglycemics are at risk for hypoglycemia or hyperglycemia (American Diabetes Association 1995). Hypoglycemia produced by oral agents may occur more frequently in the elderly than in other age groups. A reduction or increase in caloric consumption can alter insulin or oral agent needs.

A recent study of elderly NIDDM subjects in Finland (Kuusisto et al. 1994) reported that metabolic control and duration of NIDDM are important predictors of coronary heart disease (CHD) in elderly individuals, especially women, and that it is reasonable to assume that achieving good

metabolic control would also reduce risk of CHD events.

Specific attention to treatment of dyslipidemia is important since NIDDM patients have demonstrated a two- to threefold increase in prevalence of dyslipidemia compared to age- and sex-matched nondiabetic individuals, with as many as 40% of those with NIDDM potentially having high risk levels of LDL cholesterol (Stern et al. 1989)

Franz et al. (1994), in a technical review of nutrition principles for the management of diabetes and related complications, noted that nutrition therapy emphasis for NIDDM should be placed on achieving glucose, lipid and blood pressure goals and that a reduction in fat, especially saturated fats, should be implemented. They, in agreement with the American Diabetes Association, also suggested that desirable weight loss to improve diabetes control in NIDDM is best attempted by a moderate decrease in calories and an increase in energy expenditure. If glucose parameters can be sufficiently improved with weight control measures, NIDDM patients may be able to discontinue use of oral hypoglycemic agents. If nutrition strategies to improve unacceptable lipid and blood pressure parameters are not successful, lipid lowering and/or antihypertensive drugs may be required.

The concept that older adults are not interested in or cannot be taught complex diabetic management regimens was dispelled by the Diabetes Care for Older Adults Project (Funnell et al. 1994) which reported that insulin-dependent older adults actively participated in educational sessions, significantly increased their knowledge scores, and regarded the educational and care activities as positively impacting on their control of diabetes. The contrast between the participation of older adults in this project and the disinterest of study respondents in a presentation about DFNI may indicate a difference between the two groups in perceived need for the offered information.

Future Research

Now that the methodology has been successfully applied, funding could be sought to expand this research to see if some of the variables that did not achieve significance do so with a larger sample size.

Other related topics which deserve research consideration are:

- Physicians' level of awareness and knowledge of DFNIs
- Physicians' and pharmacists' practices in communicating information about DFNIs

- Innovative methods to educate health professionals about DFNIs, like the computer-assisted instruction on drug-nutrient interactions developed for long-term caregivers by Magnus and Roe (1991)
- DFNI educational methods preferred by older women
- Development and testing of an intervention to determine if indicated dietary instructions being given and followed actually improves patient status or drug treatment outcome

BENEFITS, STRENGTHS AND LIMITATIONS OF THE STUDY

Benefits

This was the first study to examine the risk of DFNIs among community dwelling older adults. It determined that risk existed within the studied population of older women and that dietary instructions to prevent potential DFNIs were generally not given. This study can serve as a bellwether to alert the health care community to the need to avoid the risks of mortality, morbidity and small decrements in functioning which may be associated with DFNIs. It can also serve as a starting point for study of larger populations.

Strengths

Demographic Characteristics

Although the study population was relatively small, it was controlled for several potential confounding factors--including gender, geographic location, cooking facilities, public transportation and availability of in-house meal service--to reduce the possibility of Type II error. Comparison tests were run to be sure that there were no significant differences in results attributable to age,

race, income level, educational level or marital status.

While the study results cannot strictly be generalized beyond the apartment complex population which yielded the data, many of the characteristics of the study population compared well with those reported in the Michigan Needs Assessment of the 60 and Over Population (Michigan Office of Services to the Aging 1987) (Table 21).

Table 21: Comparison of Selected Demographic Characteristics of Phase 1 Respondents and Michigan Needs Assessment of the 60 and Over Population Respondents

Characteristics	Michigan Needs Assessment	Phase 1	Chi Square p-Value
Race = White	90.9%	83.6%	.056
Less Than High School Education	42.4%	32.8%	.138
Covered by Health Insurance	96.2%	98.4%	.565

Within the study, there was a good distribution of ages, with mean and median ages being within a year of each other. More than half of the data was collected from respondents 77 years of age or older, including 10 over 85 years, 4 of whom were 90 years or more. This was an advantage since individuals over 75 years of age are frequently under represented in surveys. The data collection design which allowed the self-administered questionnaire and the personal

interview to be completed in the home may have enhanced participation of this older old group.

In-home interviews also allowed participants to be comfortably seated, reducing fatigue and allowing the length of interviews to be extended as much as necessary to cover all interview topics in depth.

Measures and Data Collection Procedures

Measures for this study were, or were drawn from, previously validated and recognized instruments. Reliability of data was improved by 1) double entry and validation of responses provided on the self-administered questionnaire and the MOS SF-36 survey; 2) rigorous data entry programming of the computer-assisted interview questionnaire to provide error checking, mathematical and logical operations, rejection of illegal response values, automatic skip/jump patterns, autosearching for duplication of unique data, automatic coding, and automatic entry when specified conditions were met; and 3) completion of all personal interviews by a single interviewer. There were no missing data.

Hypothesis Testing

Research hypotheses were tested at the α=.05 level of significance to reduce the probability of Type I error.

Nonparametric statistical inference procedures were used for categorical data and for nonnormal distributions.

Limitations

Sample Size

The most serious limitation of this study is that the small sample size may have increased the probability of Type II error, although efforts were made to compensate for small sample size by controlling for population characteristics and specifying stringent respondent inclusion criteria. The magnitude of statistical evidence leading to acceptance of research Hypotheses I and II also reduced the probability of Type II error in testing those hypotheses.

Nonresponse Bias

Nonresponse bias, particularly in Phase 1 which had a 39.6% response rate, is a matter of concern. The very high 87.9% response rate in Phase 2, however, makes it likely that sample estimates were very good even if the nonrespondents differed from respondents and that the results are applicable to the apartment complex population as a whole (Fowler 1988). In addition, data provided by the apartment complex manager covering age, race and marital status for each resident made it possible to show that respondents in both data collection phases did not differ

significantly on the basis of these key characteristics from other residents of the complex (Table 22).

Table 22: Comparison of Study Respondents to All Women in the Apartment Complex by Three Key Characteristics

Characteristics	All Women	Phase 1	Phase 2	Chi Square p-Value
% 77 Yrs. or More	55.84%	52.50%	48.30%	.722
% Race = White	80.50%	83.60%	79.30%	.842
% Not Married	90.90%	90.20%	89.70%	.970

Nonresponse to the Phase 1 self-administered questionnaire was followed up during the two-week period before the due date with announcements by the resident advisory council at meals and events and by posters at elevator banks; during the one-week extension, with reminder notices placed under apartment doors. Since appointments for personal interviews were set by telephone, reasons for nonresponse in Phase 2 were obtained. Nonrespondents also had previously filled in baseline demographic and drug screening information on the self-administered questionnaire; their responses were very similar to those of residents who did participate in Phase 2.

Selection Bias

A disadvantage of mailed surveys is that the people most interested in the topics addressed tend to be the people who

fill them in and return them. Although the Phase 1 survey was placed under apartment doors, not mailed, this bias of mail surveys probably still applies. The design of Phase 1 instructions and the survey itself addressed part of this concern by avoiding any reference to diet or drug regimen, but the information requested from drug containers made it obvious that prescription drugs were a focus of the survey. This may have stimulated the interest of residents who took prescription drugs and wanted to express their views or had problems or concerns related to their drugs.

Early returns of self-administered surveys are also frequently biased toward respondents with greater interest and higher levels of education. An effort to assess this bias aspect was made by numbering returns in the order in which they were put in the return box and then examining early responses to see if they differed from those of later returns; they did not.

APPENDICES

APPENDIX A

APPROVAL TO CONDUCT STUDY

Approval to Conduct Study

MICHIGAN STATE
UNIVERSITY

June 1, 1994

TO: Donna F. Mclean
236 Trout Food Science Building

RE: IRB#: 94-242
TITLE: ADHERENCE TO DIETARY MODIFICATIONS IN PRESCRIPTION DRUG REGIMENS: A PREDICTIVE MODEL FOR OLDER WOMEN
REVISION REQUESTED: N/A
CATEGORY: 1-C
APPROVAL DATE: 06/01/94

The University Committee on Research Involving Human Subjects'(UCRIHS) review of this project is complete. I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the UCRIHS approved this project including any revision listed above.

RENEWAL: UCRIHS approval is valid for one calendar year, beginning with the approval date shown above. Investigators planning to continue a project beyond one year must use the green renewal form (enclosed with the original approval letter or when a project is renewed) to seek updated certification. There is a maximum of four such expedited renewals possible. Investigators wishing to continue a project beyond that time need to submit it again for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please use the green renewal form. To revise an approved protocol at any other time during the year, send your written request to the UCRIHS Chair, requesting revised approval and referencing the project's IRB # and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/ CHANGES: Should either of the following arise during the course of the work, investigators must notify UCRIHS promptly: (1) problems (unexpected side effects, complaints, etc.) involving human subjects or (2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of any future help, please do not hesitate to contact us at (517)355-2180 or FAX (517)336-1171.

Sincerely,

David E. Wright, Ph.D.
UCRIHS Chair

DEW:pjm

cc: Jenny Bond

OFFICE OF
RESEARCH
AND
GRADUATE
STUDIES

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APPENDIX B

PHASE 1 SELF-ADMINISTERED SURVEY

Phase 1 Self-administered Survey

To the Ladies of Friendship Manor:

This survey has been sent to you by a health research team at Michigan State University. If you decide to fill it in, your answers will provide important background information for a larger research study to be conducted a little later. Answering the survey questions is completely voluntary and does not obligate you in any way to participate in the later study, although you may be asked to do so.

The survey asks for your name, telephone number and apartment number just in case we need to contact you again. No one except the Michigan State University research team will ever know the names or addresses of people who provided answers to the survey or be able to connect your name to your answers. Your name will never be used in any written materials about the survey. Your name, address or telephone number will never be given out.

You indicate your voluntary agreement to participate in this survey by completing the questionnaire and returning it in the original sealed envelope to your apartment manager's office by Friday, June 17. If you were away from home when this survey arrived and unable to return the questionnaire by June 17, please return it as soon as possible but definitely before Monday, June 27.

If you have any questions or concerns about the survey, please contact one of the following Michigan State researchers: Jenny Bond at (517) 355-1756 or Donna McLean at (810) 632-7246.

Name _____

Apartment No. _____ Phone No. _____

When were you born? _____
month day year

Race: [ ] Black [ ] White [ ] Other

Circle the highest grade or year of regular school you have completed:

Elementary	1	2	3	4	5	6	7	8
High School	9	10	11	12				
College/Training	13	14	15	16	17	18	19	

Current Marital Status:

[ ] Married [ ] Separated
[ ] Widowed [ ] Never married
[ ] Divorced

What is your current living arrangement?

[ ] Alone
[ ] With your husband
[ ] With someone not your husband

Do you have (check all that apply):

[ ] Medicare (for senior citizens)
[ ] Medicaid (based on income)
[ ] Private health insurance
[ ] None of the above
[ ] Don't know

Is your apartment at Friendship Manor

[ ] Rent subsidized
[ ] Rent based on sliding scale

Do you have any medicines prescribed by a doctor that you have taken or were supposed to take regularly in the past two weeks?

[ ] Yes
[ ] No

Do you have any medicines prescribed by a doctor that you are supposed to take only when you need them?

[ ] Yes
[ ] No

If you do not take any medicines prescribed by a doctor and answered "No" to the last two questions, you have finished the survey. Thank you for helping the research team!

If you do take medicine(s) prescribed by a doctor and answered "Yes" to either of the last two questions, please continue...

Does anyone help you take your medicine(s)?

[ ] Yes
[ ] No

If "Yes," who helps you? (Check all that apply)

[ ] Husband
[ ] Other relative
[ ] Friend
[ ] Neighbor
[ ] Visiting nurse
[ ] Home health aide
[ ] Other: _____

Please use the labels on your prescription medicine containers to fill in the following information.

Name of Medicine	Name of Prescribing Doctor
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

Name of Medicine	Name of Prescribing Doctor
11.	
12.	
13.	
14.	
15.	

Thank you for taking the time to fill in the complete survey!

APPENDIX C

PHASE 2 COMPUTER-ASSISTED PERSONAL INTERVIEW QUESTIONNAIRE AND INTERVIEWER INSTRUCTIONS

Phase 2 Computer-assisted Personal Interview Questionnaire and Interviewer Instructions

Interviewer:
A separate medication record is required for each medication. Participant name/ID #, medication name and physician (as listed on the self-administered questionnaire) and recommended dietary modifications should be recorded prior to the interview. Fill in the remaining information in Section 2 using medication containers and instruction materials provided by the participant and by probing as needed.

Greet participant cordially and thank her for coming. Begin interview after obtaining study participation consent signature.

Explain the reason for the survey being done on computer:

> During the interview, I'll be recording information on this computer. I use the computer because it allows the interview to move along more quickly and because it makes it less likely that I'll make mistakes in recording any information you give me.

Ask participant to complete SF-36 Health Survey while Section 2 information is being added:

> We would like to better understand how you and other women in this study feel, how well you are able to do your usual activities, and how you rate your own health. To help us understand these things, we'd like to ask you to complete this questionnaire about your general health.
>
> The questionnaire is simple to fill out. Be sure to read the instructions on the top of the first page. *[point to them]* Remember, this is not a test and there are no right or wrong answers. Choose the response that best represents the way you feel. If there are things you don't understand, please be sure to ask me about them. I will quickly review the questionnaire when you are done to make sure that you haven't missed any questions. *[If necessary:]* You should answer these questions by yourself without help from anyone else.
>
> While you are filling in the questionnaire, I'll be adding some information from your medicine bottle(s) to the computer record.

When the participant has finished, check to see that all questions were answered. If not, ask if she had any difficulty completing the questionnaire. Note that some answers are missing. If she indicates that she meant to answer them or had a question about them, let her complete them. Otherwise, list reasons for non-completion on the back of the questionnaire.

Section 1

Name _____ Participant ID #:

Number of medications taken: __ [Autojump to Section 2 then back.]

Interviewer [at the end of the last Section 2 record]:

Give the respondent the Medication Labels sample and ask her to read the instructions to you.

Did she read label 1 correctly? _ *Yes=1 No=0*
Did she read label 2 correctly? _ *Yes=1 No=0*

If indicated dietary modification instructions were not given for any of the medications discussed, advise the participant that she may find it helpful to ask her pharmacist or physician about the need for dietary modifications in her prescription drug regimen .

Ask respondent to sign the Permission to Contact Physician and thank her again for being helpful and participating.

Did she sign the form? _ Yes=1 No=0

Section 2

Participant ID: __ MedID: ___

Drug name: (generic) _____
(brand) _____

Recorded accurately by participant? __ Yes=1 No=0
If no, correct: _____/_____
(generic) (brand
Drug category (see code sheet): _____ Rx date __/__/__

Dosage Directions: _____

Prescribing Physician: _____

Recorded accurately by participant? __ Yes=1 No=0
If no, correct:_____

Were any dietary instructions given? _ Yes=1 No=0
[If yes, autojump to Section 3 and then back.]

Other Recommendations:

Did the participant receive drug regimen dietary instructions other than those recommended? Yes=1 No=0 __

What other instructions? _____

What was the source of the instructions? __
1=doctor 2=pharmacist 3=nurse 4=dietitian/nutritionist
5=radio/TV 7=relative/friend 8=don't know
6=other _____

What method of instruction was used? __
1=individual counseling 2=group instruction 3=videotape
4=telephone contact 6=other_____

Did the instructions conflict with those recommended? __
Yes=1 No=0

Interviewer: Address the following questions directly to the participant and record responses as indicated.

How many months have you been taking this medicine? ___

How many times did you take it yesterday? ___

If you did not take it yesterday, have you taken it in the past 2 weeks? __ Yes=1 No=0 Don't Know=8

Do you think that this medicine helps you? __
Yes=1 No=0 Don't Know=8

Interviewer: If dietary modification instructions were given in Section 3, ask the following questions.

Please tell me if you agree with the following statements:

"With the information I have, I am confident in my ability to adjust my eating or drinking habits in order to take this medicine exactly as instructed, if I want to." __ Yes=1 No=0

How would you rank your level of confidence on a scale of 0 to 10, with 0 being not at all confident and 10 being totally confident? __

"I am confident that I could adjust my eating or drinking habits in order to take this medicine as instructed, if I have additional written information about what I need to do." __ Yes=1 No=0

How would you rank your level of confidence on a scale of 0 to 10, with 0 being not at all confident and 10 being totally confident? __

"I am confident that I could adjust my eating or drinking habits in order to take this medicine as instructed, if someone explains exactly what I need to do and I have additional written information to refer to at home." __
Yes=1 No=0

How would you rank your level of confidence on a scale of 0 to 10, with 0 being not at all confident and 10 being totally confident? __

Do you know why certain eating or drinking habits are included in your medicine instructions? __ Yes=1 No=0

Do you know what problems might develop if you don't follow the instructions about eating or drinking habits? __
Yes=1 No=0

Do you understand the instructions? __ Yes=1 No=0 Don't Know=8

Do you have any trouble following the instructions about eating habits? __ Yes=1 No=0 Don't Know=8
What kind of trouble do you have? __
1=forget to follow 2=don't eat meals 3=don't like milk 4=conflict with instructions for other medicine(s) 5=don't like foods specified 7=foods specified cause GI upset 9=foods specified cause constipation 10=uncooperative cook 11=can't afford foods specified 12=can't drink high fluids 13=need drink/beer to be social 14=can't give up coffee 8=don't know 6=other_____

As a general rule, do you follow the eating instructions? __
Yes=1 No=0 Don't Know=8

Does anyone help you take your medicine? __ Yes=1 No=0
Who? __
1=husband 2=daughter 3=son 4=other relative 5=roommate 7=visiting nurse 9=home health aide 10=friend/neighbor 6=other _____

Have you experienced any side effects or physical problems which you believe are related to taking this medicine? __
Yes=1 No=0
What? __
1=GI distress 2=appetite loss 3=extra appetite 4=dry mouth 5=fatigue 7=dizziness 8=confusion 6=other _____

Section 3

Med ID: ___ Diet ID: __

Instructions: _____
Dietary Modification Instruction Code __
Yes=1 No=0 Seen on label __ Other written __ Oral __

If other written instructions were obtained for the recommended modification, what was the source? __
1=doctor 2=pharmacist 3=nurse 4=dietitian/nutritionist
5=book 7=magazine/newspaper 9=relative/friend
8=don't know 6=other source: _____

If other written instructions were provided by a health professional, what format was used? __
1=medication fact sheet 2=brochure 3=handwritten
6=other format _____

If oral instructions were obtained for the recommended modification, what was the oral source? __
1=doctor 2=pharmacist 3=nurse 4=dietitian/nutritionist
5=radio/TV 7=relative/friend 8=don't know
6=other _____

If oral instructions were provided by a health professional, what method of instruction was used?

__
1=individual counseling 2=group instruction
3=videotape 4=telephone contact
6=other method _____

Section 4 *Interviewer Assessment*

1. Factual questions were answered with: _
   No difficulty=1 Some difficulty=2 Great difficulty=3

2. Subjective questions were answered with: _
   No difficulty=1 Some difficulty=2 Great difficulty=3

3. Additional comments or observations about respondent interview or situation: _____

_____

_____

_____

_____

APPENDIX D

DATA ENTRY CODE SHEETS FOR DIETARY INSTRUCTIONS AND DRUG CATEGORIES

Data Entry Code Sheets for Dietary Instructions and Drug Categories

DIETARY INSTRUCTIONS CODE SHEET

Code Number	Dietary Instruction
1	on empty stomach
2	with food
3	with food-relieve GI distress
4	with milk/juice
5	with meal(s)
6	with food or milk
7	with meal(s) or milk
8	with ample water
9	with 8 oz water/juice
10	after meal(s)
11	1 hr after meal(s)
12	2 hr after meal(s)
13	before meal(s)
14	1 hr before meal(s)
15	2 hr before meal(s)
16	1 hr before or 2 after meal(s)
17	no foods high in phytate
18	no food/milk for 1 hr
19	no Ca/Mg supplement for 1-2 hr
20	drink plenty of fluids/water
21	avoid/limit/caution alcohol
22	avoid high pressor amines food
23	avoid natural licorice
24	avoid high intake of caffeine
25	avoid high intake of xanthine
26	avoid high intake of dairy pro
27	avoid high intake of vitamin C
28	avoid high intake phosphorus
29	avoid potassium/salt subs
30	high intake of folate
31	high intake of riboflavin
32	high intake of dietary fiber
33	high intake of potassium
34	high intake of calcium
35	high intake of vitamin D
36	high intake of vitamin K
37	high intake of vitamin B6
38	high intake of vitamin B12

DIETARY INSTRUCTIONS CODE SHEET (cont.)

Code Number	Dietary Instruction
39	high intake of fat soluble vit
40	with low fat food/meal/diet
41	low cholesterol diet
42	diabetic meal plan
43	avoid/caution Ca supplement
44	avoid/caution vit D supplement
45	avoid iron supplements
46	avoid magnesium supplements
47	no iron supplement for 2-4 hrs
48	low sodium intake
49	high protein intake
50	no zinc supplement for 2 hrs
51	not with high fiber/pectin
52	caution with herbal teas
53	full glass org jce/eat banana
54	no tryptophan supplement
55	consistent CHO/protein intake
56	limit charcoal-broiled foods
57	constant potassium in diet
58	not with egg
59	caution w/ folate supplements

DRUG CATEGORIES CODE SHEET

Code Number	Drug Categories
1	diuretic-K depleting
2	calcium channel blocker
3	ACE inhibitor
4	combination diuretic
5	beta blocker
6	adrenergic stimulator
7	ACE inhibitor with diuretic
8	alpha adrenergic blocker
9	rauwolfia combination
10	antianginal
11	cardiotonic
12	antihyperlipidemic
13	antiarrhythmic
14	antiplatelet
15	antiulcer
16	antiinflammatory/antiarthritis
17	antidepressant
18	antidiabetic/insulin
19	bronchodilator
20	potassium preparation
21	thyroid
22	estrogen
23	antineoplastic
24	analgesic
25	oral hypoglycemic
26	muscle relaxant
27	corticosteroid
28	anticonvulsant
29	antianxiety
30	antihistamine
31	prescription vitamin/mineral supplement
32	antispasmodic
33	antibiotic
34	antianemic
35	stool softener/laxative
36	sedative
37	antinauseant
38	antigout
39	antisecretory
40	psoralen
41	opthalmic
42	diuretic-K sparing
43	expectorant

APPENDIX E

PHASE 2 MEDICAL OUTCOMES STUDY SF-36 SURVEY

Phase 2 Medical Outcomes Study SF-36 Survey

THE MOS 36-ITEM SHORT-FORM HEALTH SURVEY (SF-36)

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (circle one)

Excellent 1

Very good 2

Good 3

Fair 4

Poor 5

2. Compared to one year ago, how would you rate your health in general now?

(circle one)

Much better now than one year ago 1

Somewhat better now than one year ago . . 2

About the same as one year ago 3

Somewhat worse now than one year ago . . 4

Much worse now than one year ago 5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

ACTIVITIES	Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking **more than a mile**	1	2	3
h. Walking **several blocks**	1	2	3
i. Walking **one block**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	YES	NO
a. Cut down the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

(circle one number on each line)

	YES	NO
a. Cut down the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

(circle one)

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

7. How much bodily pain have you had during the past 4 weeks? (circle one)

None 1

Very mild 2

Mild 3

Moderate 4

Severe 5

Very severe 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all 1

A little bit 2

Moderately 3

Quite a bit 4

Extremely 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks

(circle one number on each line)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

(circle one)

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

11. How TRUE or FALSE is each of the following statements for you?

(circle one number on each line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

APPENDIX F

1-DAY FOOD AND MEDICATION RECORD INSTRUCTIONS AND FORM

ONE-DAY FOOD AND MEDICINE RECORD

Name _____

Directions: Choose one weekday between now and your interview. On that day, use the following pages to record all foods, beverages, water, prescription medicines and the time of day when they are consumed. Don't forget to include snacks, nibbles, condiments (ie. catsup, salt), alcoholic beverages, liquid diet supplements (ie. Instant Breakfast or Ensure) and foods you eat away from home. If you take vitamin/mineral preparations (ie. One-A-Day, Centrum, calcium, Vitamin E) or non-prescription medicines (ie. aspirin, Tylenol, cough syrup), record them in the medicine column.

Please bring this record with you to your scheduled interview.

Time	Food/Beverage/Water	Name of Medicine

Time	Food/Beverage/Water	Name of Medicine

Time	Food/Beverage/Water	Name of Medicine

APPENDIX G

CONSENT FORMS

Consent Forms

Research Study Participation

This study is being conducted by a health research team from Michigan State University. The information obtained will be used to identify health education needs among older women and to develop materials or programs to meet those needs.

Participation is completely voluntary. Any information you give will be held in strict confidence. No one outside the research team will ever be able to connect your answers with you or your address. You do not have to answer any questions that make you uncomfortable in any way. You can end your participation at any time you wish. The interview you are scheduled for today will take about one hour.

If you understand the explanation on this page and agree to participate in the study, please sign your name below.

NAME: _____

DATE: _____

PERMISSION TO CONTACT PHYSICIAN

During your participation in this research study, we may have obtained information from you which your doctor should know. We will not give that information to him/her unless you agree that it is alright for us to do so.

Please sign your name below if you will allow us to contact the doctor(s) who prescribed your medication.

Name_____

Date_____

APPENDIX H

DRUG CONTAINER LABELS USED FOR THE PHASE 2 READING TEST

Drug Container Labels Used for the Phase 2 Reading Test

Label 1: Black letters on a red background

Label 2: Black letters on a white background

APPENDIX I

ANECDOTAL INFORMATION/INTERVIEWER OBSERVATIONS AND OVER-THE-COUNTER DRUG USE (OTCs) FOR SELECTED RESPONDENTS BY ID

ANECDOTAL INFORMATION/INTERVIEWER OBSERVATIONS AND OVER-THE-COUNTER DRUG USE (OTCs) FOR SELECTED RESPONDENTS BY ID

ID	Information/Observations OTCs
1	She went to the library and read up on HTN and on her medication in the PDR. She is an RN. Doctor said she was more concerned about her watching her fat intake than sodium. She is quite slender and looks much younger than her age. OTCs: calcium & vitamin D (500mg & 200IU X 2) aspirin 10gr Centrum
5	She is a heavy smoker--can't quit. She didn't sign physician consent form. She says the doctor just lectures her about smoking and she can't quit. They had a falling out and she hasn't been back since. She does everything he wants her to do but just can't quit smoking. The doctor said she should eat salt, that her body is low in salt. She runs a test tape on urine am & pm. When she gets the shakes she eats a small candy bar. She had the shakes just before interview, delaying it 20 minutes. She was on insulin years ago and "weaned" herself off. Doctor didn't give her a meal plan this time because he knew she still had one from before (2000 kcal-she can't eat that much now). She eats dinner in the complex dining room every day. OTCs: garlic-parsley pill aspirin
6	She was in the hospital with ulcers last summer--has had ulcer problems for years. She also has had gall bladder attacks, but doctor reluctant to do surgery--said she is high risk because of gastric problems and high blood pressure. Doctor told her to take all meds with food unless otherwise instructed. OTCs: docusate sodium (2) X 2 garlic pill calcium-magnesium-phosphorus-D (650mg-400mg-500mg-200IU X 2) Phillips milk of magnesia Tessalon Perles X 4

She received a meal plan when she started on hypoglycemics about 5 years ago, but never really followed it. When she does follow the plan she finds it discouraging that blood sugar readings don't go down (she uses glucometer). Also she is distressed that even when readings are low at night (94) they are high again by morning (134). Doctor doesn't ask about meal plan adherence and she doesn't tell him that she does not follow. She did not know where the meal plan was for me to see. She says the doctor is pleased with her blood sugar. Monitor readings usually run 120-130 at home--highest about 160.

OTCs: One-a-day vitamin X 2
Fibre-con (2) X 2

She had some medication sheets for some of the meds, she thinks, but she says she always puts those away somewhere where she can't find them.

OTCs: multi-vitamin (100% RDA)

She has emphysema--oxygen tank with her at all times. Doctor not happy with blood sugar. She monitors am & pm--runs low 200s am; about 250 pm. Doctor is sending her to dietitian on Fri. He does not routinely ask about her diet, but she has told him she does not stay on meal plan. She was on an oral hypoglycemic for several years first; insulin later. She says she just gets lonely and food is solace. She said if someone "really leaned on" her she would probably stick to the diet. Meal plan not available to see--didn't know where it was. She takes 2 Slo-bid if she has a cold; extra atarax (total 4) when especially nervous. She drinks herb & regular tea, and takes Lanoxin.

OTCs: aspirin

She seems to have no problem scheduling medicine correctly.

OTCs: 1/2 aspirin
calcium & vitamin D (600mg & 200IU) X 2

19 She worked as a nurse's aide for many years so is familiar with medications. She has some financial problems getting fresh fruit and some medications. Doctor ordered potassium supplement but she has not had prescription filled because she would rather not spend the money. She has had some signs of potassium deficiency though so she guesses she will. Thinks she may be having an allergic reaction to oranges and will have to stop eating them for potassium.

OTCs: none

20 She has her medication fact sheets and she says she refers to them regularly. She took triamterene one time with just water and it bothered her GIT--read fact sheet and makes sure she takes with food now when fact sheet says to. She takes ferrous sulfate 325mg three times per day--after meal with full glass water--per doctor who says she is anemic. She is a very small, thin person.

OTCs: ferrous sulfate 325mg X 3

21 She is upset about having so many medicines so sometimes she just doesn't take them. Potassium supplement bothers her stomach so she only takes it once in a while. There are far too many pills left in her containers for the dates on the labels. She takes Zantac only when her ulcer bothers her and then takes one instead of two as directed. Her daughter-in-law is a doctor and she prescribed the Ambien. It is very hard for her to get around because of arthritis. Used to have help coming in for housework before but not cooking. Apartment was an unbelievable mess, with litter everywhere, every kitchen cupboard/oven door standing open, an old beef roast sitting out with fat congealed.

OTCs: Advil (2) X 3
acetominophen

28 She was hospitalized for "bladder problems" which she says is why she now takes the K-Dur and Demadex. Many years ago she took another kind of thryoid that she says was much stronger. She has talked to the doctor about increasing her dose, but he doesn't think she needs it. She feels very tired all the time and isn't able to do hardly anything around the house. (She is over 90.) She has an aide who comes in every day and helps with her bath, dishes, and whatever she needs. She's not sure what days she should take the K-Dur. She thinks maybe her Meijer medicines came with fact sheets. She's not sure. If so, they were thrown away--but she "knows what they said".

OTCs: docusate sodium
Advil (2)

29 Given 1200 kilocalorie diabetic diet some 30 years ago, but says she couldn't eat that much food. She never has talked to a dietitian or nurse about her diet through the years. Doctors have talked about her diet, but mostly just tell her she has to cut out the sweets when her suger goes up. Sugar only goes up occasionally. Her diet is now limited by availability of congregate meals in the apartment complex-4 or 5 per week. The rest of the time she does pickup food like canned soup. Asked her about meals on wheels --says she gets enough of that kind of food (made a face) in the complex dining room. She says her daughter wants her to move to Burcham Hills where 3 meals/day are provided. She is over 90.

OTCs: Meijer vitamin/mineral supplement for those over 50 years old

31 Very alert and seems to have no problems with her drug regimen. Her granddaughter was there visiting and said she seems to be just fine on her own. Using Ensure once a day. She is over 90.

OTCs: none

33 Takes her Darvocet-N with food because it upsets her stomach otherwise--but was not instructed to do so. Uses Fiber-con to correct constipation. She was in an auto accident 5 years ago and damaged her hip. It still bothers her a lot and she takes Darvocet for pain. Had hysterectomy many years ago.

OTCs: Fibre-con (2) X 2 -- takes with her Lanoxin
iron supplement once a week (not available to see) aspirin

34 She believes that the many supplements she takes keep her healthy. She certainly is very spry. She is a senior companion and keeps very busy. She thinks firmly that her garlic capsules have helped her blood pressure. She has many books on medications and health and says she has read them, but doesn't seem to know anything about potential drug-food or drug-supplement interactions.

OTCs: high potency multi-vitamin/mineral
B-complex pill
antioxidant pill
garlic capsule
calcium-magnesium (500mg-250mg X 4)
vitamin E 400mg
vitamin C 500mg
zinc 50mg
Metamucil

35 She is very systematic with putting pills for each day in little cups to be sure she takes them correctly. She is using mail order pharmacy. She gets medication fact sheets and reads them, but then throws them away. None were available to see. She says she'll keep them from now on, it's just that she seems to collect so much paper and there is no room for it all in her small apartment.

OTCs: aspirin (1)

37 She was given a diabetic diet many years ago, but doesn't follow now. She keeps away from sugar, fat but thinks she eats too much bread--but isn't going to change that. Her doctor thinks she does fine. She does not monitor her sugar, just has lab tests when the doctor orders. She cannot get out of the house much since her husband is housebound, apparently with dementia.

OTCs: Centrum Silver

39 She is very alert and bright. She eats lots of bran flakes and oatmeal, and takes Lanoxin.

OTCs: Centrum Silver
Tums EX with Calcium (Ca=750mg) X 3
vitamin C 250mg
baby aspirin (1)
docusate sodium (1)
Excedrin (1)

41 She says she has a lot of trouble with memory from hardening of brain blood vessels. She could not handle medicines if her friend did not lay them out for her with signs every day. Her diet record is very sparse and she says that she has no appetite at all. I talked to her when the interview appointment was made but she did not remember the date. She wasn't in the building at appointment time, had been to the doctor. She came home later in the day and was willing to do the interview then. She had not been told to avoid alcohol and said it would be difficult for her to do so since she and her gentleman friend like to go out for dinner and drinks.

OTCs: none

43 Almost 90 years old, she is very bright and alert. She moved to assisted living after she fell and needed therapy on her leg. She is eager to get back to her own apartment. Her niece says they want her to stay where she is--that she made a mistake taking her medicine while she was there and now they are worried. She was taking her own drugs, now the nurse dispenses. Her medication containers were not available to see, but medication dosing schedule was available from her chart. There were no diet instructions at all. The only drug she's still taking from her list on the first survey is prednisone--she remembered that she is supposed to take that with food or milk. She said her doctor told her that and she makes sure that if they hand her the pills before there is food on table she waits to take the pills until she has food.

OTCs: baby aspirin (1)
Tylenol (2)

45 When she was found to be diabetic, she was given a diet plan but ever since her doctors have said she's doing ok as she is. She used to monitor her sugar with urine tape, but has not done so in many years. She "can tell" when her sugar gets high. She says it usually is in good control. She tends to get leg cramps. She says she lost 3 pounds over the holidays and that worries her. She is very tiny--says she now weighs 105 lbs, but used to weigh 120. She lost weight after her heart bypass 1.5 years ago. Uses Ensure once a day.

OTCs: Meijer Advanced Formula multi-vitamin/mineral
aspirin (1)

52 Doctor told her to always take all drugs with food and she always does. Aspirin and vitamin/mineral supplement cause GI distress if she doesn't take with food or milk. She was very slow about filling in the MOS survey, but didn't seem to have any trouble answering questions. She says she has a lot of trouble with eyes, and holds papers right up to her nose in order to see. She takes her Lanoxin with bran flakes, drinks herbal tea.

OTCs: Bufferin (1)
Myadec high potency vitamin/mineral supplement

53 Her husband is very ill--home health aide coming in. He has had multi-strokes and cannot be left alone.

OTCs: enteric-coated aspirin (1)

54 She is not taking Norvasc anymore only rarely takes Tylenol #4 (did not have it available for label). She is taking Excedrin PM for sleeplessness and "funny dreams"-- 2 at bedtime. If she does not take it, she has horrible dreams, ie. about dead husband with glowing green eyes. She only has experienced the dreams since first taking Excedrin PM--she didn't have dreams before. Her diet record is very sparse but she is quite heavy-set. She did have Tylenol #4 medication sheet available to see.

OTCs: Excedrin PM (2)

55 Doctor told her to just take all drugs with food as a rule. She also takes Advil as needed for leg cramps--sometimes it helps more than Flexeril. She is not taking peri-colace or colace any more. Neighbor suggested that she eat oatmeal instead and she says that seems to work. Although not instructed to do so, she does take Oxsoralen with food, says it upsets her stomach if she doesn't. She forgot to include insulin on original survey list. She was given a diabetic diet years ago but does not follow it now--in moving she lost it. She monitors blood sugar herself every am. She has been upset that it varies widely. Her doctor is pleased if readings are under 200. She was in the hospital with ketoacidosis when put on insulin.

OTCs: Advil

56 She takes a B12 injection (1000mg) every 2 weeks. She was given a diabetic meal plan initially and she knows what it was, but didn't have it around any more. She monitors her blood sugar every day--usual range 200-270, once in a while up in the 300s. Doctor thinks her meter may not be working right because she has big swings. Last night it read 116. She is not taking Quinamm or Tagamet any more.

OTCs: calcium-vitamin D (600mg-200IU) X 2

57 She believes firmly that her chromium supplement improves blood sugar control. She has a meal plan and full instructions but does not follow it. She says she never has money for groceries--gives money to her daughter who is always in trouble. She used to follow the meal plan carefully and understood it completely. She thinks she should inject insulin twice a day instead of just in the morning because she gets irritated, tired and can't think in afternoon. Doctor said it was ok to do, but she found she couldn't remember to do pm injection, so went back to all in am. She uses a glucometer which she says ranges 130-154 with chromium; 160-214 without.

OTCs: Vitamin C 1000mg
One-a-Day vitamin/mineral supplement
400mcg chromium picolinate
enteric-coated aspirin (2)

60 She continues to go to KMart for prescriptions, even though it's far away, because the pharmacist takes time to talk to her about her drugs. She had knee surgery in 1978 and had to have potassium for 10 days before they could operate. She had been falling a lot before that. Now she always eats a banana or drinks orange juice as her old medicine bottle said many years ago. She used to be diabetic but lost 60 lbs and walked a lot and now is ok without insulin or pills. She is not taking Quinamm or Zantac now since Flexeril and Prilosec work better and doctor said to not take both. Her doctor retired. She was taking Titralac antacid 20 per day until she started the Prilosec.

OTCs: vitamin C 500mg X 2

61 Family history of diabetes--brother especially had it very bad. Knowing that encourages her to follow her diet and be careful. She has difficulty with English but goes to a doctor and nurse who speak Spanish and who help her with her diet. Her doctor asks her on a regular basis about how she is following her diet and even has her over to dinner. When the MSU health fair came to the apartment complex, a woman there talked to her about her diet plan and gave her a copy of the new food guide pyramid which she incorporates into her meal plan. She is not taking Premarin any more and is to have hysterectomy later this month.

OTCs: aspirin (1)

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