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The Prevalence of Dietary Supplement Use Among Older Adult Population Using National Health And Nutrition Examination Survey (NHANES) 2009-2012

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A thesis submitted in partial fulfillment of the requirements for the degree of Master of Pharmaceutical Science at Virginia Commonwealth University

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Table of Content

Abbreviations

ADRs	Adverse Drug Reactions
BMI	Body Mass Index
DLA	Daily Living Activity
DS	Dietary Supplement
DSA	Dietary Supplement Act
DSHEA	Dietary Supplement Health and Education Act
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
GAO	Government Accountability Office
GEM	Ginkgo Evaluation Memory
IADL	Instrumental Activities of Daily Living
IRB	Institutional Review Board
MEC	Mobile Examination Center
MVMM	Multivitamin-Multimineral
NHANES	National Health and Nutrition Examination Survey
NHIS	National Health Interview Survey
NSHAP	National Social life, Health and Aging Project
NVDS	Non-Vitamin Dietary Supplement
OTC	Over The Counter
RTCs	Randomized Controlled Trial
USA	United State of America

Abstract

THE PREVALENCE OF DIETARY SUPPLEMENT USE AMONG OLDER ADULT POPULATION USING NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 2009-2012

By Fawaz Mutlaq Alotaibi, MS.

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Background: Dietary supplements (DS) use has increased in the U.S. in the past 20 years. More than half of the U.S. population reported using DS. There are few studies to our knowledge that have assessed DS use specifically for older adults. In this study we purposed to evaluate the trend of using DS among older adults and to test the association between using DS and several demographics, socioeconomics and health characteristics. The second objective was to evaluate the reasons behind using DS among older adults using a nationally representative database.

Methods: This is a cross sectional study using the most recent National Health and Nutrition Examination Survey (NHANES) database 2009-2012. It is a nationally representative sample of noninstitutionalized adults in the U.S. Frequency and weighted percentage (standard error) were

reported for dichotomous variables. Multiple logistic regressions model analyses were used to evaluate the predictors of DS use after testing model assumptions, multicollinearity, and outliers. P values 0.05 were considered significant. All the statistical analyses were conducted using SAS software version 9.4.

Results: Out of 2625 older adult participants (65 years and older) 70.5% of them reported using DS in the past 30 days. Female, non-hispanic white, obese, overweight and excellent and very good self-reported health status participants were more likely to use DS. Multivitamin-multiminerals (MVMM), calcium and vitamin D were the most commonly reported supplements among older adults. 71% of oldest old (80≥ years) reported taking DS and prescription medication in the past 30 days concomitantly and 73% of polypharmacy users reported using DS. To stay healthy, to improve overall health and for bone health were the most commonly reported reasons behind using DS.

Conclusion: majority of older adult participants reported using DS in the past 30 days. Health care professionals need to evaluate the dietary supplement information from older adults in order to improve health care.

CHAPTER 1 INTRODUCTION

This chapter explains the trend of DS use in the past 20 years among U.S. adults, DS regulation in the U.S., brief background about older adults in the U.S., polypharmacy related issues, and study significance. Chapter 2 reviews the recent studies (2004-2014) that have focused on prevalence of DS among U.S. adults. Chapter 3 provides study design, and inclusion/exclusion criteria for the study population and statistical analysis methods. Chapter 4 presents the results of each specific aim. Finally, Chapter 5 provides discussion, strengths, limitations, future direction, and conclusion for this project.

The 1994 United States Dietary Supplement Health and Education Act (DSHEA) defines the term dietary supplement (DS) as "a product taken by mouth that contains a dietary ingredient to supplement the diet"("Q&A on Dietary Supplements," 2014). Dietary ingredients may include vitamins, minerals, herbs or other botanicals, amino acids, enzymes, organ tissue, glandulars, and metabolites. Before DSHEA 1994, DS were subject to the same regulatory requirements as other foods, but now, under DSHEA 1994, the manufacturer has full responsibility for the safety and labeling of DS. The prevalence of DS use in the United States has increased over the years since DSHEA 1994 was enacted (Gahche et al., 2011).

DS use is common among the U.S. adult population. In the National Health and Nutrition Examination Survey NHANES 1988-1994, approximately 44% of the U.S. population reported taking DS in the past 30 days (Gahche et al., 2011). In the same study approximately 30% of the U.S. population reported taking multivitamins/multiminerals in the past 30 days (Gahche et al., 2011). After 18 years the percentage has increased to 53% reporting taking DS and 39% reporting taking multivitamins/multiminerals in NHANES 2003-2006 (Bailey et al., 2011). According to the U.S Government Accountability Office GAO report 2009, the total sales of DS

has increased from 14$ billion in 1997 to 22$ billion in 2007 as shown in **figure 1-1** (States & Accountability, 2009).

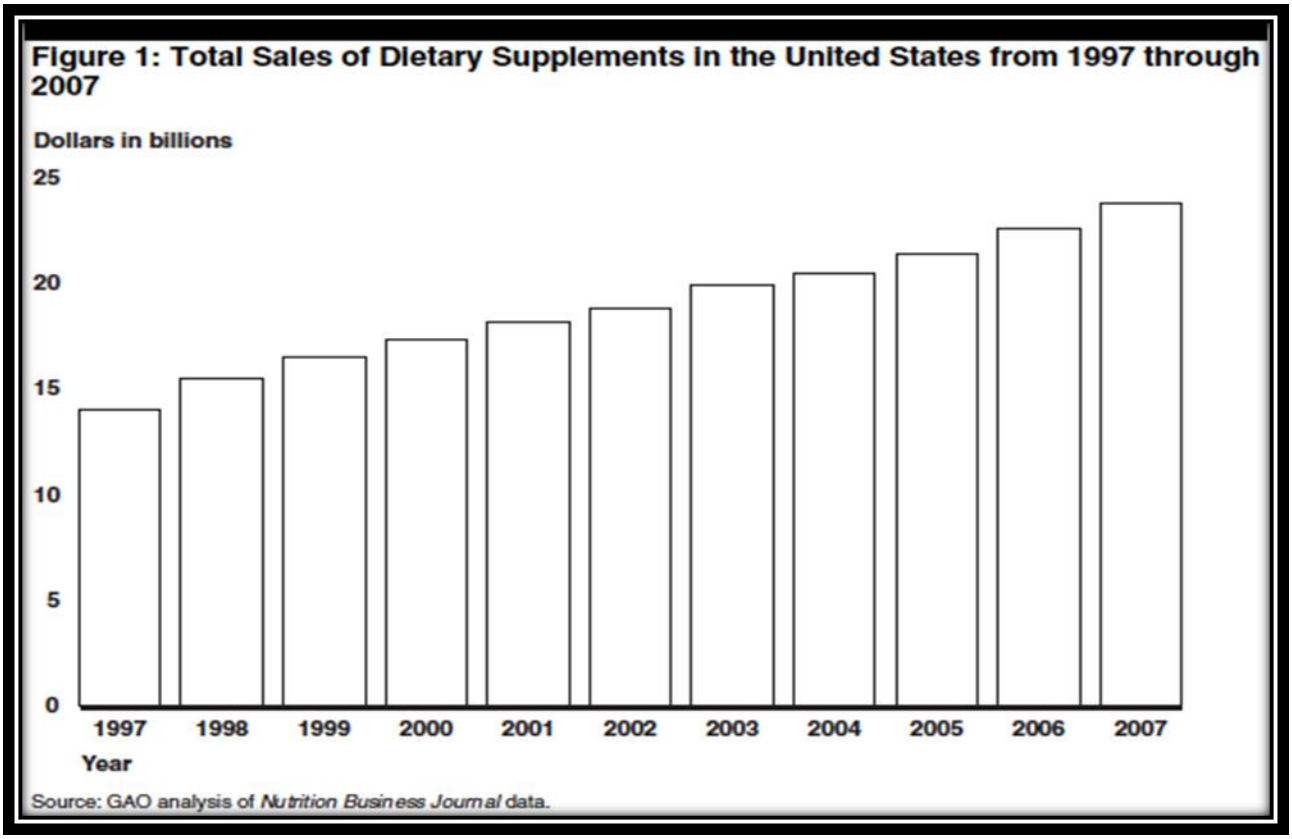

Figure 1-1 Total sales of Dietary supplement in the United States from 1997 through 2007 according to GAO report.

United States Regulation of Dietary Supplements:

There are several pieces of legislation that have been enacted to regulate DS use and safety in the USA. The major legislation addressing DS use before DSHEA-1994 were the Food, Drug, and Cosmetic Act of 1938 (FDCA), the Proxmire Amendment, and the Dietary Supplement Act of 1992 (DSA). As DSHEA 1994 is the most recent DS regulation in the USA, a brief review of this regulation is discussed below.

According to DSHEA-1994, DS have a separate new category of regulation for safety and labelling issues, unlike before DSHEA-1994 when DS were subject to the same regulatory requirements as other foods. Under DSHEA-1994, a manufacture has the full responsibility to make ensure that the DS is safe and properly labeled. The manufacturer is only required to notify FDA if it intends to market a DS that contains a new "dietary ingredient". In addition, FDA requires certain information has to be in the label such as the name of the product, a statement that it is a supplement, the name of the manufacturer, a complete list of ingredients, a declaration that the supplement does not require FDA review or approval, and the disclaimer statement "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease". By DSHEA low, the manufacturer and distributer are responsible for investigating and reporting to FDA any report they receive of a serious adverse event within 15 days. FDA has the responsibility to show that the DS is unsafe after the product is released to the market. That means there are no studies required to be done on the product efficacy or safety before introduction to the market.

More than half of U.S. adults reported using DS in the past 30 days (Eileen T. Kennedy, Hanqi Luo, 2013) and this study shows that reporting using DS increases with age. 42% of U.S. older adults (57-85 years old) reported using Over The Counter (OTC) medication in the past 6 months (Qato et al., 2014). In addition, 48% of older adults form the same study reported using DS in the

past 6 months (Qato et al., 2014). DS prevalence is increasing among older adults due to the misperception that DS are safer than OTC or prescription medications, while still the safety and efficacy of DS is not well established (Nahin et al., 2009). Cultural, philosophical, and religious beliefs play an important role in increasing DS use among U.S adults (Nahin et al., 2009).

Older Adults in the USA:

Older adult is a term referring to a person who is 65 years or older. Today, there are almost 40 millions persons aged 65 years and older living in the United States and this number is expected to increase to 89 millions persons in the next 40 years (Jacobsen, Kent, Lee, & Mather, 2011). This rapid change in population characteristics can lead to economic, social, and health care consequences, especially if the healthcare system does not prepare for this change (Jacobsen et al., 2011). Many older adults have several comorbidities and receive more than one prescription medication, which may lead to difficulty managing their health and maintaining their quality of life. Also, older adults experience physiologic changes associated with aging affecting their liver and kidney function, which make taking DS that have been never tested on this specific population potentially more risky and more likely to result in an adverse outcome.

Polypharmacy:

Polypharmacy is also a concern for older adults. The pattern of polypharmacy is expected to increase in the next few years among the older adult population. Kaufman et al. found that more than half of US older women use more than 5 prescription medications and 12% of them take more than 10 medications per day (Hajjar, Cafiero, & Hanlon, 2007). There are several definitions of polypharmacy proposed in the literature. Use of six or more medications or using at least one potentially inappropriate medication listed on the Beers list (2012) indicating that the risk generally outweighs the benefit for most older adults are the most common definitions of

polypharmacy. (Riker & Setter, 2012). Polypharmacy is a very important issue among older adults because it increases the risk of adverse drug reactions (ADRs) and drug-drug interactions (Mallet, Spinewine, & Huang, 2007). Using DS by patients taking prescribed medications will increase the risk of DS-drug interactions and ADRs, which may lead to increased rates of hospitalization, mortality and morbidity of older adults.

Specific Aims and Significance:

The main objectives of this project are to document the prevalence of DS use among the U.S. adult population and older adults specifically, and to identify demographic and socioeconomic predictors of DS use by analyzing data available from the National Health and Nutrition Examination Survey NHANES 2009-2012.

The specific aims for this study are:

1) To determine the prevalence of DS use among older adults 65 years and older using NHANES 2009-2012 data.

Previous studies have shown that the prevalence of DS use is increased among older adults, although those over the age of 71 years have not been included in previous analyses. Older adults are at high risk of polypharmacy and comorbidities, increasing their risk of supplement-drug interactions or disease-supplement interactions.

2) To assess the relationship between DS use and demographic and socioeconomic characteristics.

Identifying characteristics with a significant association with DS use may be helpful to improve patient health and patient care by facilitating targeting of health care interventions to patients at greatest risk for using DS.

3) To evaluate the reported reasons for using dietary supplements among older adults.

Knowing the reasons for DS use in this population may help health care professionals better understand why older adults may use DS and identify opportunities to improve the use of DS in this population.

Several studies have reported the prevalence of DS among all ages in the U.S. adult population. However, lack of consistency of defining older adults age interval in those studies make it difficult to provide a conclusion specifically for older adults. Most of our objectives in this study were focused on older adults (65 years and older). This is the common age interval for older adults that has used in the previous studies in the health care field. This study will be the first study to evaluate the use of DS specifically among older adults in the U.S. using the most recent cohort available from NHANES. The results of the study will contribute to understand the most common reported reasons for using DS that have used in the past 30 days. Knowing the prevalence and the reasons of DS use may overcome some of the challenges related to DS-drug interaction, DS-disease interactions, or unknown side effects that may appear on older adults due to DS use. The results of the study will document the extent of use of DS among older adults and serve as the basis for further research on the impact of DS use on the health of older Americans.

CHAPTER 2 LITERATURE REVIEW

This chapter describes recent research findings regarding DS use in the U.S. There are several studies that have discussed the trends in DS use among the U.S. population with different clinical situations for example, use of DS among cancer patients, use of DS among cardiac disease patients, and use of DS in combination with medications to treat certain medical conditions. In this literature review only the prevalence or trend of using DS among the general U.S. adult population will be discussed, without focusing on a specific disease or population.

Literature Review Objectives:

The objectives of this literature review are to:

- Document the recent prevalence of DS use among the adult U.S. population;
- Identify confounders and predictor variables that affect DS consumption;
- Evaluate previous studies and identify "gaps" in the literature in order to inform the design of a new study focusing on DS use among older adults in the U.S.;

Search Strategy:

Studies were identified using comprehensive English MeSH terms in PubMed and CINHAL. MeSH terms and subheadings used included "*Dietary Supplements/Utilization" AND Aged, OR 80 year and older, OR Frail Elderly*. The titles, abstracts, and relevant citations were reviewed, and inclusion and exclusion criteria were applied to determine which studies to include in the review.

Inclusion Criteria:

- Included older adults (65 years and older)
- Used recent data or recent publications (from 2004 to 2014)

- Used nationally representative databases like NHANES or NSHAP
- Conducted in the U.S. with the U.S. population.

Exclusion Criteria:

- Used specific populations that may limit the generalizability of the results such as focusing on DS use among cancer patients or cardiac patients
- Was conducted outside the U.S. or using non U.S. population
- Excluded the older adult population

The Newcastle-Ottawa Quality Assessment scale was used to critically evaluate the studies. This tool is appropriate to critique cohort, cross-sectional and case control studies.

Results:

Out of 375 unique articles identified and screened from both databases (PubMed and CINHAL), there were six studies that met the inclusion and exclusion criteria. All of them were cross-sectional studies. Three studies used NHANES ("National Health and Nutrition Examination Survey : Plan and Operations , 1999 – 2010," 2010), one study used the National Health Interview Survey (NHIS) (Services, 1997), one study used the National Social Life, Health and Aging Project (NSHAP) ("National Social Life, Health, and Aging Project (NSHAP), NORC.org," 2014), and the last study used data collected for the Ginkgo Evaluation Memory (GEM) study ("Questions and Answers: Ginkgo biloba for the Evaluation of Memory (GEM) Study, NCCIH," 2014). **Table 2-1** summarizes each study that met the inclusion/exclusion criteria.

Review of Methodology Used in the Selected Studies:

Five of the six studies identified were derived from nationally representative survey-based datasets such as NHANES and NHIS. One study used data from a randomized double blind, placebo controlled trial (RTC), a multicenter trial to increase the study internal validity, reliability. Four reviewed studies were conducted based on noninstitutionalized, household population surveys, while two studies were based on community dwelling adults. All of the previous studies were inconsistent with defining the older adult age interval even among those studies that used the same database. For instance, there were three studies from NHANES and the definition of older adult was either from 60-69 years, or greater than 71 years, or greater than 60 years old. In the GEM study, older adult was defined participants greater than 75 years old, while in the NSHAP study, the analysis was based on the older adult population from 56 years old to 85 years old. In the NHIS study, the older adult age interval was defined as greater than 65 years old, which is the same age interval that we used in this study consistent with most of the studies in geriatrics field as well. Thus, variability of defining the older adult age interval makes comparing the results difficult.

DS information is another place that we could see variability between the previous studies. All NHANES based studies have used the short term used of DS, which was reported as the DS use in past 30 days, while the NSHAP study has used daily or weekly use. GEM study reported the DS use within the previous two weeks from the interview day and finally the NHIS study considered the DS use for the previous 12 months period. Most of the reviewed studies defined DS based on DSHEA definition. DS information was collected via home interview and self reported questionnaires among all reviewed studies, which may lead to recall bias or selection

bias and may result in overreporting or underreporting of important information related to DS use.

Table 2-1 Summary of all the previous studies that met the inclusion and exclusion criteria.

Study	Setting and sample size	Data source	Conclusion
Kennedy, et al., 2013	Noninstitutionalized participants, 20-69 years old. Only the population estimate was reported.	NHANES	Half of the U.S. population used DS. The percentage of DS users increased while the participants getting older.
Bailey, et al., 2010	Noninstitutionalized, 37516 participants for all ages older than 1 year	NHANES	70% of older adults aged >71 years used DS in the past 30 days. The most common supplement was a multivitamin/multimineral supplement.
Bailey, et al., 2013	Noninstitutionalized, 11956 adult participants >20 years old	NHANES	49% of U.S. adult reported using DS in the past 30 days. 45% of reported reasons for taking DS was to improve or 33% to maintain health. Older adults were more likely to use DS than younger adults.
Gardiner, et al., 2006	Noninstitutionalized, household population. 31044 participants (includes 18 years and older.	NHIS	21% of those who used prescription medications also used Nonvitamins dietary supplements NVDS in the past 12 months. Being female and younger were the factors most strongly associated with using NVDS.
Qato, et al., 2008	Community dwelling persons 2976 participants (aged 57 to 85 years)	NSHAP	Among prescription users and OTC users, 68% of them also used a DS in the past year.
Nahin, et al., 2009	Community dwelling older adults (>=75 years) 3070 participants	GEM	74% of older adults who used prescription medications also used at least one DS.

Some studies assessed the prevalence of DS use across all ages, but most of them focused on adults over 18 years of age. Two studies were conducted using databases that only included older adults in their database such as NHIS and NSHAP. Few studies have examined concurrent use of medication and DS along with the prevalence of DS use. Only one study evaluated drug-supplement interactions among older adults. This study used Micromedex to define the drug-supplement interactions included in the analysis.

Review of the Prevalence of DS use and the motivation of using DS in the Studies:

Bailey et al. in the most recent study conducted using NHANES (2007-2010) found that 49% of U.S. adults over 20 years old reported using DS in the past 30 days (Bailey, Gahche, Miller, Thomas, & Dwyer, 2013). 67% of older adults (>60 years old) were DS users in Bailey study (Bailey et al., 2013). Female, older adults (>60 years old), non-hispanic white, normal BMI, highly income participants, former smokers, self reported excellent or very good health status were more likely to report using DS than other population (Bailey et al., 2013). Multivitamin-multiminerals (MVMM), calcium, omega-3/fish oil, and botanicals were the top 4 DS reported in the same study by 32%, 11.6%, 10%, and 7.5% respectively. Kennedy et al. found in the second most recent study using (NHANES 2007-2008) that almost 50% of the U.S. population used at least one DS in the past 30 days (Eileen T. Kennedy, Hanqi Luo, 2013). In the same study the percentage of DS use was increasing while the age of the U.S. population is increasing as well. In the same study the authors found that DS use was more likely in females, older adults, highly educated people (having college graduate degree or above), and non-hispanic whites (Eileen T. Kennedy, Hanqi Luo, 2013). Bailey, et al. found similar results using an earlier NHANES cohort (2006); 49% of the U.S population used at least one DS in the past 30 days (Bailey et al., 2011). Eighty percent of those users reported taking the DS every day during

the past 30 days. Females, older adults (greater than 71 years old), highly educated people (having greater than high school degree), and overweight participants were more likely to use DS in this study (Bailey et al., 2011). Multivitamins and multiminerals (MVMM) was the highest reported DS use at 33%, followed by botanical supplements used by 14%. Because there was limited information available regarding DS use and concurrent use of prescription medication among older adults, Qato, et al. conducted a study to determine the prevalence of prescription medication and DS use among older adult in the U.S. and evaluate drug-supplement interactions. This study used the NSHAP database of older adults aged 57 to 85 years. Forty-nine percent of this population was reported using DS (Qato et al., 2008). In this study, 68% of the population was using DS and prescription medication concurrently, which may lead to adverse events due to drug-supplement interactions or disease-supplement interactions especially among older adults who often have more than one medical condition and take multiple prescription medications (Qato et al., 2008). Consistent with this study, Nahin et al. evaluated the concomitant use of prescription drugs and DS in ambulatory older people (≥75 years old) using data collected as part of the GEM study. Nahin et al, found that almost 82.5% of study participants used at least one DS and 55% using three or more DS with an average of three DS per participant (Nahin et al., 2009). Ninety percent of DS users were reported using at least one prescription medication, and among all study participants 75% of them reported using at least one DS and one prescription medication (Richard.L. et al., 2009). Multivitamins, iron, and vitamin E were the most commonly used DS among older adults at 60%, 59%, and 44% respectively (Richard.L. et al., 2009).

From NHIS, Paula, et al. found that 21% of those who used prescription medications also used non-vitamin DS (NVDS) in the past 12 months (P Gardiner, Graham, Legedza, Eisenberg,

& Phillips, 2006). Unlike previous studies, Paula et al. found that younger participants (≤24 years old) were more likely to use NVDS compared to older adults (≥65 years old) or middle aged (45-54 years old) participants. Also Paula found that NVDS use was more common among those with non-life threatening conditions such as menopause, insomnia, and chronic pain (P Gardiner et al., 2006). Among all the previous studies there was only one study that examined the reasons of using DS among >20 years old U.S. population using (NHANES 2007-2010). To improve overall health, to stay healthy, for bone health, to supplement the diet, and to prevent health problems were the top 5 reasons for using DS among U.S. adults by 45%, 33%, 25%, 22%, 20.5% respectively (Bailey et al., 2013).

Factors Associated with DS use:

Table 2-2 shows the list of the factors that have been evaluated with DS users in the previous studies. Only seven factors were significantly associated with DS users among all ages including age, race, education, gender, BMI, family income, and region. The rest of the 22 variables they studied were not significantly associated with DS users.

Most studies agreed that older adults consume more DS and alternative medicine than younger age groups (Bailey et al., 2013) (Eileen T. Kennedy, Hanqi Luo, 2013) (Bailey et al., 2011) (Qato et al., 2008). In addition, females, highly educated participants, non-hispanic whites, and insured participants were more likely to use DS. Gardiner et al. examined the factors associated with DS use only among those who take prescription medications (P Gardiner et al., 2006). Paula et al found that females, cigarette smokers, hispanic or non-hispanic whites, and those living in the West (compared to the Northeast) were more likely to use nonvitamin dietary supplements (NVDS). Surprisingly, in the same study they found that younger participants were more likely to use NVDS compare to older adults or middle aged individuals (P Gardiner et al.,

2006). Also, the study showed that prescription users for menopause, insomnia, chronic pain, and sever headache tend to use NVDS greater than those who used prescription medications for hypertension, hyperlipidemia, or diabetes. (P Gardiner et al., 2006).

Table 2-2 Factors that have been evaluated with DS use in the previous studies.

Factor	Kennedy, 2013	Bailey,2010	Bailey,2013	Gardiner,	Qato,	Nahin,
Age*	✓	✓	✓	✓	✓	✓
Race*	✓	✓	✓	✓	✓	✓
Gender*	✓	✓	✓	✓	✓	✓
Education*	✓	✓		✓	✓	✓
BMI*	✓	✓	✓			✓
Income*			✓	✓	✓	✓
Smoking			✓	✓		✓
Health Insurance			✓	✓	✓	
Exercise			✓	✓		✓
Health status			✓	✓		✓
Chronic condition				✓	✓	
Household food security status	✓					
Household food benefit	✓					
Alcohol use			✓			✓
Region*				✓		
Usual source of medical				✓		
Last visit to health professional				✓		
Church attendance						✓
Club attendance						✓
Reading senior magazine						✓
Reading Bible						✓
Difficulties of DLA or IDLA						✓

***variables were significantly associated with DS in the previous studies at 0.005 level of significant.**

Review of concurrent use of prescription medications with DS:

Three of the studies examined concomitant use of DS with prescription drugs. A study by Qato et al, showed that 68% of older adults used DS in combination with prescription medications (Qato et al., 2008). In the GEM randomized control trial, Nahin et al., found that 83% of older adult medication users also used DS (Richard.L. et al., 2009). Moreover, the same study showed that 90% of DS users have also used prescription medications (Nahin et al., 2009). Aspirin, statin medications, and beta blockers were the most frequent medications that were combined with DS (Richard.L. et al., 2009). The study by Gardiner et al. showed that only 21% of prescription medication users also used NVDS in the past 12 months, but this study only focused on NVDS without examining all DS as considered in the other two studies(P Gardiner et al., 2006). There are few studies examining the concomitant use of prescription medications and DS among older adults, and more work in this area is needed. Possible adverse consequences associated with concomitant use of prescription medications and DS are also poorly understood.

Conclusion:

This review was conducted to assess the current literature evaluating the prevalence of DS among the U.S. older adult population using nationally representatives databases. Twelve studies were identified but only six studies were conducted within the most recent 10 years period (2004-2014). This specific time period was focused on because the current prevalence is most likely to be related to the more recent studies that have been conducted. These previous research studies conducted in the past decade used nationally representative datasets that are well-documented methodologically such as NHANES, and NHIS. Only one study focused exclusively on NVDS (Paula Gardiner et al., 2014). Three articles examined the use of DS

among prescription medication users. One study was focused on the most commonly reported motivations for using DS among U.S. adults population.

The most recent study that evaluated the patterns of use of DS among the U.S. population used the 2010 NHANES cohort. Most of the studies found that using DS was more likely among older adults, females, highly educated participants, insured individuals, and overweight people. Age, sex, marital status, level of education, annual family income, race/ethnicity, health insurance, smoking status, body mass index, and region of U.S. resident were the most common variables tested in the previous studies. In addition, more predictors were evaluated in our study like polypharmacy, concomitant use of prescription medications and DS, and hypertensive participants. Those three factors were associated in previous studies with an increased rate of drug-drug interactions and adverse drug reactions (Brazier & Levine, 2003). While most of the previous studies agreed that older adults were more likely to use DS, there is need for a study using more recent data conducted specifically in this population. All the reasons and factors associated with reported DS in the previous studies were tested among all ages not only for older adults. For that reasons conducting a specific study in the older adults population is necessary. Older adults are generally at greater risk for drug-drug interactions, drug-supplement interactions, disease-supplement interactions, and polypharmacy due to multiple health conditions (Brazier & Levine, 2003). It is very important to focus on this population to ultimately minimize the risk of ADRs and unnecessary medication use, as well as improve quality of life.

CHAPTER 3 METHODS

This chapter details the study design, population of interest, included variables, and statistical analyses methods used to conduct this study.

Aim of the Study:

There are three main objectives in this project:

1- *To determine the prevalence of dietary supplements use among older adults 65 years and older in the U.S. using NHANES 2009-2012 data.*

2- *To assess the relationship between dietary supplement use and demographic and socioeconomic characteristics among the U.S. older adult population (aged 65 years and older).*

3- *To evaluate the most commonly reported reasons for using dietary supplements among older adults in the U.S.*

Study Design:

A retrospective cross sectional study design was used to conduct this study using NHANES (2009-2010 and 2011-2012) cohorts. These are the most current data available publicly for NHANES and will provide the most up-to-date picture of DS use among the U.S. population in general and older adults specifically using NHANES.

Data Source:

NHANES is a survey that is designed to assess health and nutritional status of adults and children in the United States ("National Health and Nutrition Examination Survey : Plan and Operations , 1999 – 2010," 2010). This data is the only free publicly available data source that contains a separate dietary information file, including DS use and some details about the DS use.

This survey examines a nationally representative sample of approximately 5000 persons each year using a complex, stratified, and non-institutional cluster sample design that allows for generalization to the entire U.S. population ("National Health and Nutrition Examination Survey : Plan and Operations , 1999 – 2010," 2010). NHANES participants were selected randomly using a computerized system following these four stages. First was county selection, second was selection of a block within that county, third was selection of a specific household within that block, last stage was selection of individuals within a household. Computer-assisted personal interview system and Blaise software was used to assess the qualified participants within each household. More detail about sample selection can be find in the NHANES Plan and Operations manual ("National Health and Nutrition Examination Survey : Plan and Operations , 1999 – 2010," 2010). One unique aspect of this data is that it contains both the dietary information collected from household interview and examination information collected via the Mobile Examination Center (MEC). It has five main files, including a demographic file, examination file, laboratory file, questionnaire file, and dietary file. Only four files were used to conduct this study (demographic file, examination file, questionnaire file, and dietary file). The overall unweighted interviewed response rate for NHANES 2009-2010 was 79.4%, while the response rate for NHANES 2011-2012 was 72.6% for all ages.

Study Population:

The study population consisted of non-institutionalized adults who completed the dietary information survey from age 20 years through 80 years old and older. Individuals aged 80 and older are not identified by their specific age to protect their privacy.

Inclusion Criteria:

- All individuals age of 20 years and older

Exclusion Criteria:

- Children 19 years old or younger

Dietary Supplements Information:

The questionnaire survey includes many topics related to health like, DS used, medications used, and medical conditions. The most important file needed to conduct this study was the DS file. NHANES has two DS files, the first one related to the individual DS information, which has the supplement details and the motivations for each supplement. The second file was related to the total DS information, which has the question related to DS use and the frequency of the supplement that has used in the past 30 days. Both files are needed to conduct this study. The DS use information was collected during the household interview process. The interviewer asked the participants "Have you used or taken any vitamins, minerals, or other dietary supplements in the past month?". If the participants answered yes, the interviewer asked to see the DS container (**Figure 3-1)**. If the bottle was not available, participants were asked to recall the name of the DS. Additional questions related to DS use were asked such as "Was the DS recommended by a physician, colleague or friends, or chosen on your own?". Answers to these questions were evaluated as part of this analysis. All of this information was obtained from individual and total DS files (DSQIND, DSQTOT).

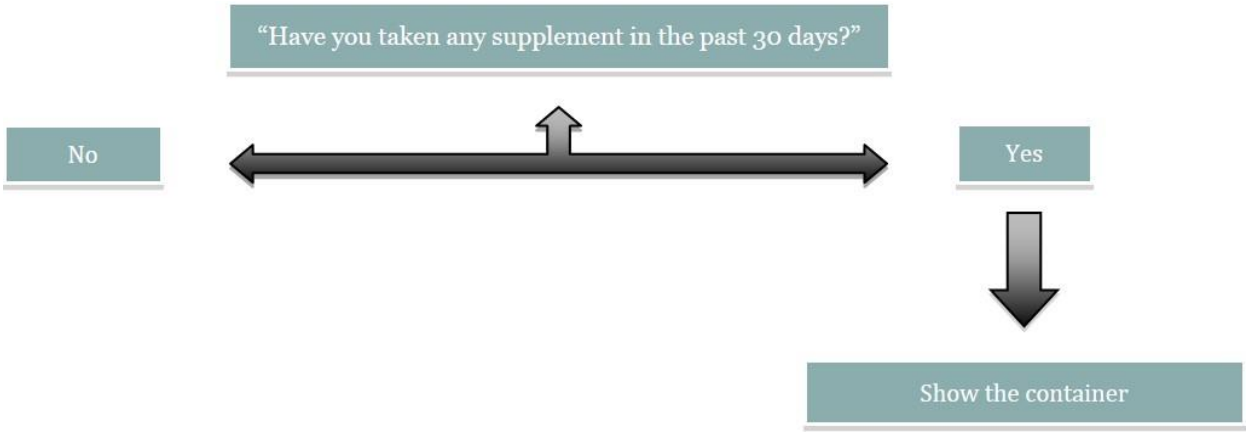

Figure 3-1 The process of how the DS information was collected in NHANES survey 2009-2012.

Reasons for Using Dietary Supplements:

This DS information was collected during the household interview process. In the questionnaire, more than 30 options for reasons for using DS in the past 30 days were provided. In this study, the top reported reason for each individual DS was evaluated. Also, the most common reasons that were reported in general were studied. Any reason that had less than 100 observations was recoded as "other". The Reasons for using DS are listed in **Table 3-1**.

Polypharmacy and Dietary Supplements:

Polypharmacy was defined as using 4 or more prescription medications (Bikowski, Ripsin, & Lorraine, 2001) (Fulton & Allen, 2005). This information on medication use was obtained from the Questionnaire file. Medication file only has prescription medications, which needed a physician to be prescribed. Over the counter medications and DS are listed in separate files. The interviewer asked the participants if they had taken any prescription medication in the past 30 days. The response to this question is dichotomous (yes/no). Another important variable was the number of prescription medications that each participant was using regularly in the past 30 days. Any participants that were using 4 or more prescription medications we categorized as a "polypharmacy" patient. All of this information was obtained from the medication file (RXQ_RX).

Covariates:

All demographic factors were tested in the descriptive and analytical analysis. Demographic characteristics included age, race/ethnicity, gender, marital status, annual family income, and education level. These were the most common variables evaluated in previous studies examining similar objectives as this study. All of these variables were categorized as in previous studies or

according to the number of observations in each group to facilitate comparisons with previous studies. If any category in any variable had a small number of observations, we categorized that group as "other". Age was truncate by NHANES at 80 years and we categorized the age variable into six groups, from 20-39 years, 40-64 years, and older adults as 65 years and older (65-69, 70-74, 75-79, and 80≥). Race/ethnicity was categorized as non-hispanic white, non-hispanic black, Mexican American/other hispanic, and other. Education level was categorized as high school or less, undergraduate degree, and graduate degrees. Other variables included self reported health status (excellent/very good, good, fair/poor), using antihypertensive medication (yes/no), and polypharmacy (yes/no) if the participant was taking 4 or more medications in the past 30 days. Systolic and diastolic blood pressure elevation were assessed by taking the mean of four systolic readings and the mean of diastolic readings. It is considered systolic elevation if the mean four readings was greater than 140, and considered diastolic elevation if the mean four readings was greater than 90. Any responses provided as "Refused", "Don't Know", or "Missing" information were recoded as missing information. All the vitamins and minerals were recoded according to **Table 3-1**. Concatenating each two files was done first then merging all the files under one dataset by the common identifier (SEQN). For example, concatenating two DEMO files (DEMO 2009 and DEMO 2012) then merging the DEMO file with the rest of the files that we cleaned up. We exclude any variable that had large numbers of missing observations like the cholesterol diagnosis variable had more than 3000 missing observation. After completing all the data cleaning and recoding each variable, SAS codes were reviewed by a SAS expert as a second check.

Table 3-1 Variables used in the analyses according to NHANES manual book.

File name	Variable name	Variable description*
1- DEMO[1]	RIDAGEYR	Age at screening
	RIAGENDR	Gender
	RIDRETH1	Race/ethnicity
	DMDMARTL	Marital status
	INDFMIN2	Annual family income
	RIDEXPRG	Pregnancy status at exam
	DMDEDUC2	Education level
2- DSQIDS[2]	DSDSUPP	Supplement name
	DSQ124	Took product on own or doctor advice
	DSQ128A	For good bowel
	DSQ128C	For mental health
	DSQ128D	To prevent health problems
	DSQ128E	To improve overall health
	DSQ128F	For teeth
	DSQ128G	To supplement the diet
	DSQ128H	To maintain health/To stay healthy
	DSQ128I	To prevent cold
	DSQ128J	For heart health
	DSQ128K	For eye health
	DSQ128L	For healthy joints
	DSQ128M	For skin health
	DSQ128N	For weight loss
	DSQ128O	For bone health
	DSQ128P	To get more energy
	DSQ128R	For anemia (low iron)
	DSQ128T	To maintain blood sugar
	DSQ128U	For healthy hair
	DSQ128V	For kidney and bladder health
	DSQ128W	For respiratory health
	DSQ128X	For allergies
	DSQ128Z	Improve digestion
	DSQ128AA	For menopause
	DSQ128BB	For muscle related issues
	DSQ128DD	For stress and relaxation
	DSQ128EE	For CNS health
	DSQ128FF	For liver health
	DSQ128GG	Antioxidants
	DSQ128II	For gout health
	DSQ128S	Other

3-DSQTOT[3]	DSDCOUNT	Total number or DS taken
	DSD010	Any DS taken
4-BMX [4]	BMXBMI	Body mass index
5-BPQ[5]	BPXSY1,BPXSY2, BPXSY3, BPXSY4.	1st Systolic blood pressure reading and 2nd, 3rd, and 4th
	BPXDI1, BPXDI2, BPXDI3, BPXDI4.	1st Diastolic blood pressure reading and 2nd, 3rd, and 4th
	BPQ040A	Taking prescribed medication for hypertension
	BPQ090D	Doctor told you to take prescribed medication for cholesterol
6-HSQ[6]	HSD010	General health condition
7-RXQ_RX[7]	RXDUSE	Taken prescription medication in the past 30 days?
	RXDCOUNT	Number of prescription medications taken?

* According to NHANES manual. [1] Demographic file, [2] Dietary supplement individual file, [3] Dietary supplement total file in the past 30 days, [4] Measurements file, [5] Blood pressure and cholesterol file, [6] Health status file, [7] Prescription medication file.

Statistical Analyses:

All statistical analyses were performed using SAS version 9.4. The combined NHANES databases (2009-2012) were used to determine the weighted trend of DS use among all adult ages and older adults specifically. Weighted frequency and row percentage of demographic and socioeconomics characteristics were reported. In order to assess the association between demographic and socioeconomic variables with DS use, multiple logistic regressions was performed. Bivariate analysis and checking that the assumptions for multiple logistic regression were performed before running the model. Two important assumptions were tested for each variable. The first one was testing if the predictors linearly related to the log of odds of the outcomes by performing the Lemeshow Goodness of fit test. The second test was checking if there are any influential observations in each variable. Multicollinearity and outlier observations were tested. **Table 3-2** details how each supplement was categorized. Because a complex, multistage sampling design was used to determine a representative conclusion about DS use among U.S. population, *PROC SUREVYFREQ* with *STRATA*, *CLUSTER*, and *WIEGHT* for the measurement file were used. DOMAIN statement was used in order to account for the entire sample for variance estimation. The variables included in the model were based on previous studies or theoretical relationships between the outcome and the predictors. Chi-square was calculated to assess the relationship between the outcome variables and the rest of the covariates using p-value 0.05 as the level of significance.

Ethical Consideration:

Due to using a publicly available de-identified data source this study met the definition of exempt study, which was not necessary to be reviewed by Virginia Commonwealth University, Institutional Review Board.

Table 3-2 Classification created for most of the dietary supplement in NHANES (2009-2012).

Category	Definition	Examples
Multi-vitamin, Multi-mineral (MVMM)	Any product contains both multi-vitamin, and multi-mineral, OR any product has three or more vitamins and one mineral supplement	B-complex, Centrum, and Tri, Vi, Flor
Multi-vitamins (MV)	Any product contains two or more vitamins without containing any mineral supplement	Multi-vitamin, 2 Vitamin C and D
Calcium products	All products that have calcium as a primary supplement.	Calcium, Calcium and magnesium
Fatty acid	All products that contain OMEGA-3 or fatty acids	OMEGA-3
Fiber and colon health	Any laxative product or product that contain fiber supplement	Metamucil Fiber Capsules
Botanicals	Any herbal product or products have botanical ingredient without vitamins or minerals	Garlic, Ginger, Gingko Biloba, Ginseng
Joints supplements	Any product contains joint supplement like glucosamine, MSM, or both	Glucosamine, MSM
Single supplements	Any single supplement without any combination with other vitamins or minerals or botanicals	Vitamin C, B, D, and Iron

CHAPTER 4: RESULTS

This chapter describes the results from the analysis conducted for each aim described previously. All the results were obtained using the most recent NHANES cohorts (2009-2012) available. The purpose of combining two cohorts (2009-10 and 2011-122) was to increase the number of participants, especially the older adult group. NHANES is a complex design cohort for the non-institutionalized U.S. population, which allows our results to be generalized to the U.S. adult population. The data was obtained from the CDC website and is freely available for public use. In this study, the dietary file, demographic file, questionnaire file, and examination file were used for the analysis. The main variables in this study were obtained from the demographic and dietary files. After cleaning and recoding "Unknown" "Refused to answer" or any inappropriate responding in each variable or observation and deleting the missing information, we ended up with n=11,372 participants. **Figure 4-1** and **Figure 4-2** details about the sample size distribution among both younger and older adults. Any variable having more than 5% missing values was deleted according to listwise deletion method.

Overall, out of 11,372 participants approximately half of them used at least one DS in the past 30 days (50.83%) **(Table 4-1)**. In our analyses we focused only on those who were using DS in the past month to evaluate the trend of DS use among the U.S. population.

Table 4-1 Prevalence of DS in the United State among all ages ≥20 years old using NHANES, 2009-2012.

DS use	Frequency	Weighted %
YES	5934	50.83%
NO	5438	49.16%

Prevalence of dietary supplements use among U.S. population ages 20-64 years using NHANES 2009-2012

Table 4-2 shows the descriptive characteristics of those who were using DS among the younger adult population. Of the 11372 participants included in the study, only 8747 fell in the younger population category (20-64 years) and this number were examined for this aim. Sample frequency and weighted percentage were used to present these results. 46.61% of the younger adult population reported taking at least one DS in the past 30 days. 56% of the younger adult population was between 40-64 years of age and was more likely to use DS compared to 40% of those between 20-39 years of age **(Figure:4-1)**. Among this age group females were more likely to report using DS than males (52% vs. 41%). Reported DS use by race is as follows: non-hispanic whites (51%), non-hispanic blacks (38%), Mexican American and other hispanic (32%), and other (49%). Among the younger adult population, normal weight participants were more likely to report using DS than underweight, overweight, and obese, (51%, 39%, 48%, and 42% respectively). Moreover, as the family income increased, the percentage reporting DS use increased from low to middle, and high family income (36%, 46%, 58% respectively). Also, as the participants increased in the level of education, the percentage reporting DS use increased as well (35% high school or less, 48% college degree, 60% graduate degree). The self reported health status distribution was 54% reporting having excellent or very good health, 42% good health and 41% fair or poor health. Half of the married participants reported using DS similarly with divorced participants and 39% of the participants that they never married reported using DS in the past 30 days.

In addition, 49% of the younger adult respondents (20-64 years) having either elevated systolic or diastolic blood pressure also reported using DS. Fifty three percent of those who were

taking antihypertensive medications reported taking DS. The differences between the groups in each variable were statistically significant at 0.05 level of significant except the systolic/diastolic elevation variable and treatment for hypertension, which were not significant.

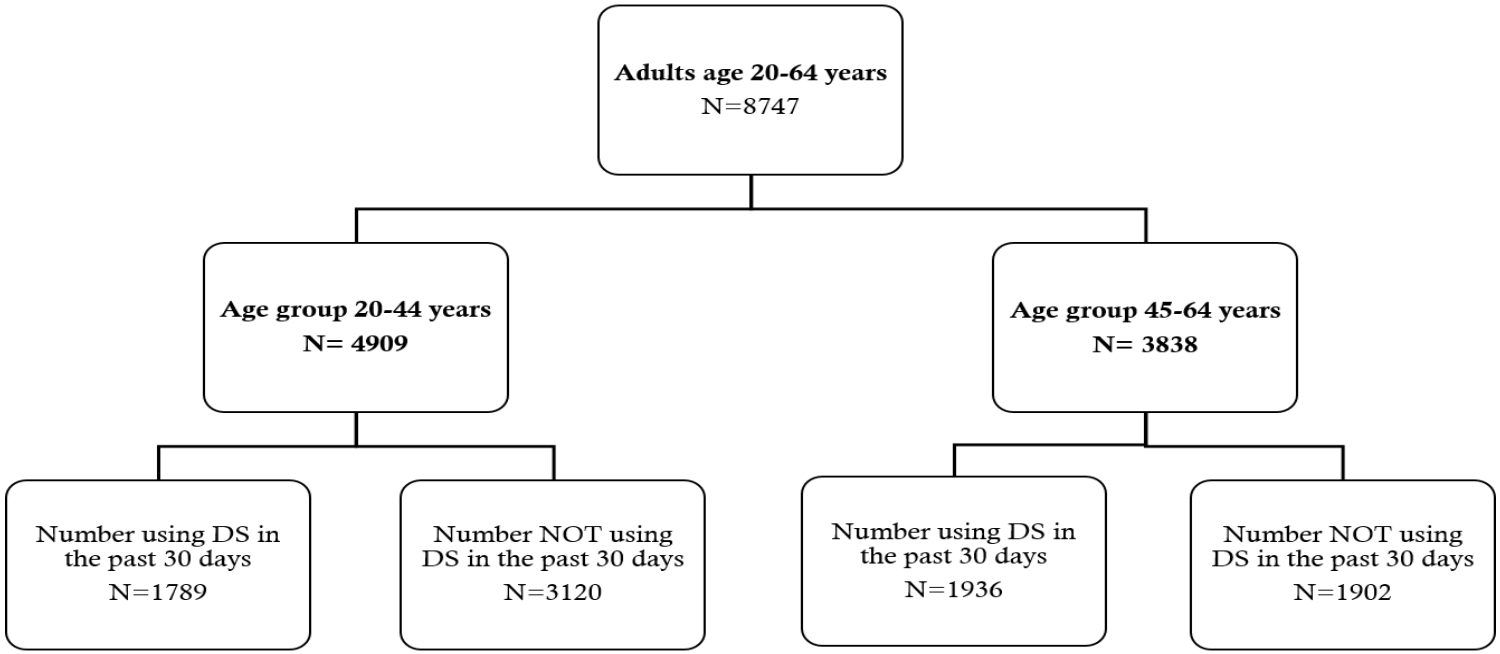

Figure4-1 Flow chart showing the distribution of the younger population (20-64 years old) who reported using DS in NHANES 2009-12

Table 4-2 Prevalence and characteristics of those who reported using DS in the past 30 days among the younger adult population (20-64 years), NHANES 2009-2012.

Characteristic	DS use in the past 30 days			
	Yes		No	
	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]
Age*				
20-39	1789	40 (1.3)	3120	60 (1.3)
40-64	1936	56 (1.3)	1902	44 (1.3)
Sex*				
Male	1571	41 (1.2)	2669	59 (1.2)
Female	2154	52 (1.1)	2353	48 (1.1)
Race*				
Non-Hispanic white	1621	51 (1.1)	1781	48 (1.1)
Non-Hispanic black	773	38 (1.1)	1215	62 (1.1)
Mexican American/other Hispanic	821	32 (1.2)	1497	67 (1.2)
Other	510	49 (2.2)	529	50 (2.2)
BMI*				
Underweight	54	39 (4.6)	90	61 (4.6)
Normal	1112	51 (1.7)	1371	49 (1.7)
Overweight	1216	48 (1.6)	1600	52 (1.6)
Obese	1306	42 (1.1)	1918	58 (1.1)
Family income*				
Low	1378	36 (1.2)	2483	64 (1.2)
Middle	1064	46 (1.5)	1398	53 (1.5)
High	1123	58 (1.6)	909	42 (1.6)
Education*				
High school or less	1299	35 (1.3)	2692	65 (1.3)
College degree	1224	48 (1.4)	1441	52 (1.4)
Graduate degree	1197	60 (1.5)	884	40 (1.5)
Systolic/Diastolic elevation				
Yes	454	49 (2.5)	616	51 (2.5)
No	3108	47 (1.1)	4141	53 (1.1)
Antihypertensive medications				
Yes	932	53 (1.6)	940	47 (1.6)
No	181	45 (3.0)	261	55 (3.0)
Health status*				
Excellent/ very good	1398	54 (1.1)	1461	46 (1.1)
Good	1267	42 (1.6)	1808	57 (1.6)
Fair OR poor	642	41 (1.9)	1078	59 (1.9)
Marital status*				
Married	2245	49 (1.3)	2880	51 (1.3)
Never married	774	39 (1.6)	1325	61 (1.6)
Divorced/widowed/separated	702	50 (1.5)	815	50 (1.5)

*Significant values at 0.05 level of significant using Chi square p-value. [a] sample frequency. [b] weighted percentage and Standard errors.

Prevalence of dietary supplements use among adults 65 years and older using NHANES 2009-2012

For this analysis, only the participants who were 65 years and older at the time of screening and interview were included, and the total sample size was 2625 **(Figure 4-2)**. **Table 4-3** shows the descriptive characteristics of older adults who were using DS in the past 30 days and those who were using prescription medications with DS concurrently. The percentage reporting using DS increased as the participants got older; 66% for 65-69, 42% for 70-74, 70% for 75-79, and 74% for 80≥. Among older females, 74% reported using DS in the past 30 days compared to 65% among male participants. Similar to the younger population, 74% of non-hispanic whites reported using DS. Underweight older participants were more likely to use DS than normal weight individuals. Also, similar to the younger population, as the family income increased the percentage reporting DS use increased (65% for low, 75% for middle, and 74% for high family income). 75% of graduate degree holders reported using DS in the past 30 days compared to 65% among high school degree holders. 74% of older adults who reported excellent or very good health status reported using DS compared to 60% of those who reported fair or poor health status. 70% of married participants and 72% of divorced participants reported using DS in the past 30 days.

Seventy percent of older adults with elevation in systolic or diastolic blood pressure reported using DS and 72% of older adult antihypertensive medication users reported using DS.

Seventy two percent of older adult prescription users reported using at least one DS in the past 30 days. Also, 73% of older adult who were taking four or more medications reported using DS in the past 30 days. 63% of older adults reported deciding to take DS on their own, while 37% of them reported taking DS based on their physician's advice.

In addition, **Table 4-3** shows the characteristics of the older adult participants who reported using at least one prescription medication plus one DS in the past 30 days. The oldest old (80 years old), females, non-hispanic whites, underweight, high family income, reported using antihypertensive medications, and taking four or more prescription medications are more likely to report using prescription medication along with DS in the past 30 days.

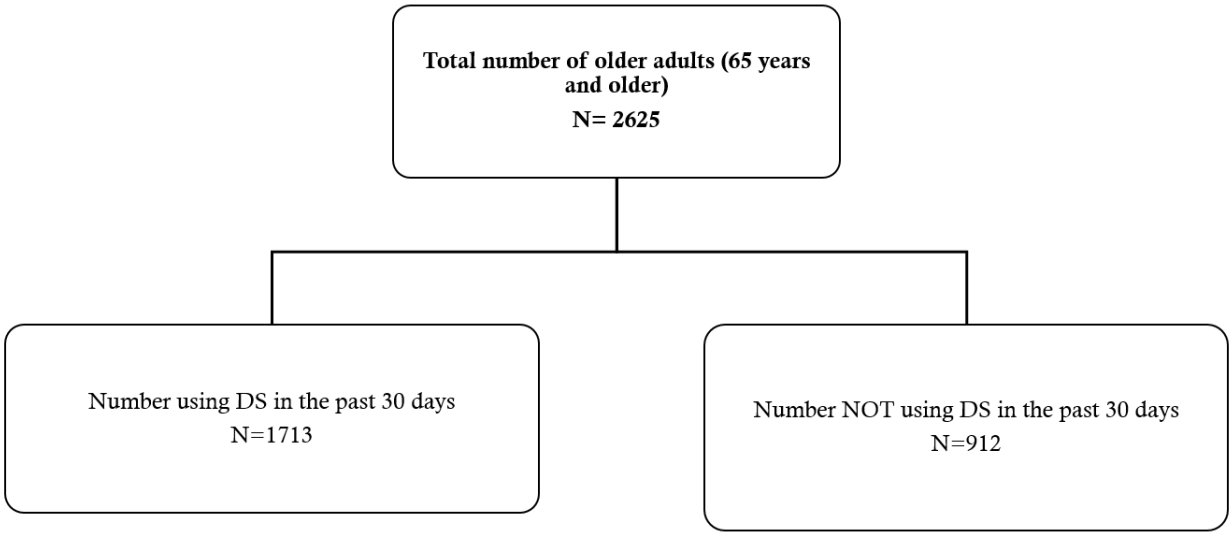

Figure 4-2 Flow chart showing the distribution of the older adult population (65 years old) who reported using DS in NHANES 2009-2012

Table 4-3 The Prevalence and characteristics of those who reported using DS in the past 30 days and those who reported both DS and prescription medications among the population 65 years and older, NHANES 2009-2012.

Characteristic	DS use in the past 30 days				Use of Prescription medications with DS in the past 30 days			
	Yes		No		Yes		No	
	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]
Age(years)*								
65-69	443	66 (2.7)	305	34 (2.7)	386	59 (2.3)	361	41 (2.3)
70-74	453	42 (2.0)	227	27 (2.0)	413	66 (2.2)	267	34 (2.2)
75-79	307	70 (2.2)	168	30 (2.2)	285	64 (2.6)	190	36 (2.6)
80≥	510	74 (1.5)	212	25 (1.5)	490	71 (1.8)	230	28 (1.8)
Sex*								
Male	782	65 (1.8)	521	34 (1.8)	704	59 (1.9)	598	41 (1.9)
Female	931	74 (1.2)	391	25 (1.2)	807	70 (1.1)	450	30 (1.1)
Race*								
Non-Hispanic white	1047	74 (1.4)	408	26 (1.4)	965	68 (1.5)	488	32 (1.5)
Non-Hispanic black	294	58 (2.5)	217	42 (2.5)	277	56 (2.7)	234	44 (2.7)
Mexican American/other Hispanic	250	54 (2.4)	208	46 (2.4)	225	50 (2.3)	232	50 (2.3)
Other	122	58 (7.4)	79	42 (7.4)	107	53 (7.2)	94	47 (7.2)
BMI								
Underweight	29	79 (5.2)	17	21 (5.2)	24	67 (7.7)	22	33 (7.7)
Normal	469	73 (1.9)	218	27 (1.9)	411	65 (2.3)	276	35 (2.3)
Overweight	598	70 (2.1)	327	30 (2.1)	552	65 (1.9)	372	35 (1.9)
Obese	574	68 (1.9)	326	32 (1.9)	548	65 (2.3)	351	35 (2.3)
Family income*								
Low	774	65 (1.6)	525	35 (1.6)	711	60 (1.5)	586	40 (1.5)
Middle	574	75 (1.9)	231	25 (1.9)	523	69 (2.0)	282	31 (2.0)
High	278	74 (3.1)	104	26 (3.1)	259	69 (3.3)	122	31 (3.3)
Education*								
High school or less	890	65 (1.5)	610	35 (1.5)	825	61 (1.5)	674	39 (1.5)
College degree	460	75 (2.1)	172	24 (2.1)	429	71 (2.4)	203	29 (2.4)
Graduate degree	358	75 (2.5)	127	24 (2.5)	316	67 (2.8)	167	32 (2.8)
Systolic/Diastolic elevation								
Yes	579	70 (1.7)	328	29 (1.7)	534	65 (2.0)	372	35 (2.0)
No	1059	70 (1.6)	550	29 (1.6)	973	65 (1.6)	633	35 (1.6)
Antihypertensive medications								
Yes	1121	72 (1.7)	546	28 (1.7)	1106	72 (1.7)	559	28 (1.7)
No	33	71 (8.1)	23	29 (8.1)	30	67 (8.1)	26	33 (8.1)
Health status*								
Excellent/ very good	558	74 (1.6)	213	26 (1.6)	492	65 (1.9)	279	34 (1.9)
Good	623	72 (2.0)	304	27 (2.0)	589	70 (2.0)	337	30 (2.0)
Fair OR poor	397	60 (2.1)	301	39 (2.1)	370	57 (2.3)	326	42 (2.3)
Marital status								
Married	960	70 (1.4)	497	30 (1.4)	866	63 (1.6)	589	36 (1.6)
Never married	66	62 (6.1)	39	38 (6.1)	61	57 (7.0)	44	42 (7.0)
Divorced/widowed/separated	685	72 (1.6)	376	27 (1.6)	646	68 (1.4)	414	31 (1.4)
Polypharmacy*								
Yes	988	73 (1.7)	427	26 (1.7)	988	73 (1.7)	427	26 (1.7)
No	725	67 (1.4)	485	33 (1.4)	586	56 (1.6)	621	44 (1.6)
Prescription medications use*								
Yes	1574	72 (1.3)	774	28 (1.3)	1574	72 (1.3)	774	27 (1.3)
No	139	56 (4.8)	135	44 (4.8)	0	0	274	100 (0)

Characteristic	DS use in the past 30 days				Use of Prescription medications with DS in the past 30 days			
	Yes		No		Yes		No	
	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]	Freq[a]	W.%(SE)[b]
Source of DS*								
Decided to take it for reasons of my own	905	63 (2.1)	0	0				
A doctor or other health provider advised me to take it	540	37 (2.1)	0	0				

*Significant values at 0.05 level of significant using Chi square p-value. [a] Sample frequency. [b] Weighted percentage and Standard errors.

Prevalence of use of specific types of dietary supplements and the most commonly reported reason for use of each product among older adults

In this section, the trends in use of each type of DS and the most common reported reason for use of each DS among older adults will be presented. Multi-vitamin and multi-minerals (MVMM) was the most common type of DS use reported by older adults (23.18%) and the primary reason for use was "to maintain health or to stay healthy" (29%). The second most common DS used was calcium (17.05%) which was used mainly for "bone health" (70%). Vitamin D was the third most frequently used (10.30%) and was also used for "bone health" (31%). Vitamin C use was reported by 9.22% to "prevent cold" (45%), followed by Omega-3 (8.44%) used mainly for "heart health and cholesterol" (40%). Vitamin B-12 was reported by 5% and was used mainly to "get more energy" (40%). Joint supplements, iron, botanicals, vitamin E, folic acid, multivitamins, magnesium, potassium, vitamin B-6, vitamin A, niacin, and fiber were the lowest DS reported by older adults used by 5% or less each. The complete list of DS use is reported in **Table 4-5**. Women were more likely to use each of the DS types than men except for niacin, where men reported higher use.

In general, most older adults reported taking DS in the past 30 days in order to maintain their health or to stay healthy (18.15%). The second most commonly reported reason was to improve overall health (17%), and the third most common reason was for bone health 15%. Other reasons for use are reported in **Table 4-4**.

Table 4-4 Prevalence of reported reasons for using DS among older adults in the United States, NHANES 2009-2012.

Reported reason for DS use	Frequency	Weighted %
1-To maintain health (to stay healthy)	779	18.14
2-To improve my overall health	692	16.73
3-For bone health	653	14.96
4-For heart health, cholesterol	337	8.44
5-Other	324	7.76
6-To supplement my diet, food not enough	259	5.73
7-To get more energy	219	4.68
8-For healthy joints, arthritis	202	4.62
9-To prevent colds, boost immune system	186	5.00
10- For eye health	145	3.53
11-For anemia, such as low iron	113	1.98
12-To prevent health problems	106	2.49
13-For good bowel/colon health	74	2.01
14-For skin health, dry skin	70	1.75
15-For muscle related issues	47	1.38
16-For mental health	38	0.60
17-For weight loss	10	0.11
18-For teeth, prevent cavities	1	0.00

Table 4-5 Prevalence of use for each supplement and the most common reason reported for each type of supplement among older adults (65 years and older), NHANES 2009-2012.

Type of Supplement	Overall (N & W.%)¶ n= 2489	Men (N & W.%)¶ n= 1005	Women (N & W.%)¶ n= 1484	Most common reported reason for use	Users reporting this reason W.% ¶
MVMM	574 (23.06)	275 (48)	299 (52)	**To improve my overall health**	31
Calcium	430 (17.27)	117 (27.20)	313 (72.9)	**For bone health**	73
Vitamin D	256 (10.28)	100 (39)	156 (61)	**For bone health**	32
Vitamin C	229 (9.20)	97 (42.35)	132 (57.64)	**To prevent colds, boost immune system**	45
Fiber	209 (8.39)	98 (46.88)	111 (53.11)	**For good bowel/colon health**	64
Vitamin B12	121 (4.86)	52 (43)	69 (57)	**To get more energy**	33
Niacin	116 (4.66)	57 (49.13)	59 (50.86)	**For heart health, cholesterol**	86
Omega-3/Fish oil	106 (4.25)	37 (35)	69 (65)	**For heart health, cholesterol**	45
Multivitamins	85 (3.41)	41 (48.23)	44 (51.76)	**To maintain health (to stay healthy)**	33
Vitamin E	82 (3.29)	22 (26.82)	60 (73.17)	**For heart health, cholesterol**	24
Iron	76 (3.05)	31 (40.78)	45 (59.21)	**For anemia, such as low iron**	63
Joint Supplements	59 (2.37)	23 (39)	36 (61)	**For healthy joints, arthritis**	57
Potassium	40 (1.60)	14 (35)	26 (65)	**For muscle related issues**	29.5
Folic Acid	33 (1.32)	11 (33.33)	22 (66.66)	**To maintain health (to stay healthy)**	26.5
Vitamin B6	31 (1.24)	13 (42)	18 (58)	**To improve my overall health**	19
Vitamin A	18 (0.72)	5 (27.77)	13 (72.22)	**For eye health**	38.5
Magnesium	13 (0.52)	7 (54)	6 (46)	**For bone health**	27
Botanicals	11 (0.44)	5 (45.45)	6 (54.55)	**For heart health, cholesterol**	24

¶ Sample size and weighted percentage.

The relationship between dietary supplement use and demographic and socioeconomic characteristics among older adults

A logistic regression model was built to predict the factors that are associated with DS use among older adults. After reviewing bivariate analyses and checking that model assumptions were met, the final model was selected and is reported in **Table 4-6.** Outliers were assessed and multicollinearity was tested as well and results are shown in the Appendix. Out of 12 predictors evaluated in the logistic regressions model, eight predictors were significantly associated with DS use in the past 30 days among older adults participants. Age, sex, race, annual family income, health status, using medication in the past 30 days, and polypharmacy were significantly associated with using DS among older adults. For every one year increase after 65 years the odds of using DS increased by 1.032 (1.004-1.065). Females were 53% more likely to use DS in the past month compared to male participants OR=1.533 (1.164-2.019). Non-hispanic whites were significantly more likely to report using DS than non-hispanic blacks or Mexican Americans (OR= 0.596 (0.435-0.817) and 0.621 (0.472-0.816) respectively). Those who reported a normal BMI were 32% more likely to report using DS than overweight older participants OR=1.326 (1.037-1.697). Those who reported their health status as fair or poor were significantly less likely to use DS compared to those who reported good health OR=0.576 (0.415-0.801). Using prescription medications in the past 30 days was significantly associated with reporting DS use compared to those not using prescription medications in the past month OR=1.77 (1.146-2.757). This means those who were using prescription medication in the past 30 days were 77% more likely to use DS than those who were not taking prescription medications in the past 30 days. Finally, those who were taking 4 or more prescription medications were 34% more likely to use DS than those who were taking less than 4 prescription medications OR=1.347 (1.012-1.793). All the results were adjusted to age, sex, race,

education, BMI, marital status, family income, hypertension diagnosis, health status, prescription medications use, and polypharmacy.

Table 4-6 Logistic regression model of DS use among older adults, NHANES 2009-2012.

Factors	Adjusted OR (95% CI)¶
Age (continuous)	1.032 (1.004-1.065)*
Sex	
Male	Reference
Female	1.533 (1.164-2.019)*
Race	
Non-Hispanic White	Reference
Non-Hispanic Black	0.596 (0.435-0.817)*
Mexican American & other Hispanic	0.621 (0.472-0.816)*
Other	0.643 (0.322-1.285)
Education	
High school or less	Reference
College degree	1.259 (0.852-1.861)
Higher degree	1.348 (0.988-1.841)
BMI	
Overweight	Reference
Underweight	1.563 (0.634-3.850)
Normal	1.326 (1.037-1.697)*
Obese	0.946 (0.658-1.359)
Marital Status	
Married	Reference
Never married	0.748 (0.441-1.267)
Divorced/Separated/Widowed	1.121 (0.853-1.474)
Family Income	
Low	Reference
Middle	1.452 (1.142-1.846)*
High	1.379 (0.931-2.042)
Systolic/Diastolic Elevation	
No	Reference
Yes	1.028 (0.805-1.312)
Health Status	
Good	Reference
Excellent/very good	1.003 (0.794-1.266)
Fair or poor	0.576 (0.415-0.801)*
Prescription Medication Use	
No	Reference
Yes	1.778 (1.146-2.757)*
Polypharmacy	
No	Reference
Yes	1.347 (1.012-1.793)*

*Significant values at 0.05 level of significance.
¶ Adjusted odds ratio and 95% confident interval.

CHAPTER 5: DISCUSSION

This cross sectional study was conducted to determine the trends of DS use among the younger and older adult population in the U.S. using nationally representative data (NHANES 2009-2012). Also, one of the main objectives of this study was to evaluate the most common reasons behind using DS among older adults and the factors associated with DS use in the past 30 days. Moreover, this is the first study to focus specifically on older adults (65 years and older). Main findings, strengths, limitations, future directions, and conclusion will be discussed in this chapter.

Trends in DS use

Out of 14,000 participants in the two NHANES cohorts 2009-2012, 51% of those participants reported using DS in the past 30 days among all ages 20 years and older, an increase of 3% over the previous study using NHANES 2007-2010 (Bailey et al., 2013). Among the younger adult population (20-64 years old), 47% used at least one DS in the past month. The percentage using at least one DS in the past 30 days increased to 70.5% among older adults and this was higher than in the NHANES 2007-2010 cohort where 67% reported DS use in the past 30 days (Bailey et al., 2013). In our study, MVMM was the most common reported DS taken in the past 30 days by the younger adult population (20-64 years of age) and older adults (65 years and older). Thirty percent of the U.S. younger adult population reported using MVMM, while 23% of older adults reported using MVMM. Calcium, vitamin D, vitamin C, and fiber were among the most frequently reported DS used by the older adult population with 17%, 10%, 9%, and 8% of older adults using these supplements respectively. In contrast, MVMM, calcium, omega-3, botanicals, and vitamin C were the top reported DS in the recent study using the 2007-2010 cohort (Bailey et al., 2013). Potassium, folic acid, vitamin B6, vitamin A, magnesium, and botanicals had the

lowest reported use among older adults (1.6%, 1.3%, 1.2%, 0.72%, 0.52%, and 0.44% respectively).

Rationale for using DS among older adults

For this specific aim, only the older adult population (65 years and older) was considered. This is the first study that focused on older adults specifically to determine the most common reasons for using DS. The most common reason reported for using DS in the past 30 days by older adults was to "Maintain their health/to stay healthy" (18.15%), followed by "To improve overall health" (17%). Fifteen percent of older adults reported using DS for "bone health" and 8.5% of them for "heart health and cholesterol". These results are consistent with the recent study that was conducted by Bailey et al., (Bailey et al., 2013) where they evaluated all participants 20 years of age and older in the 2007-2010 NHANES cohort. Also, for each dietary supplement, the most common reasons for use were explored. Niacin had the highest reported percentage (86%) for a single reason for use, which was for "heart health or cholesterol", followed by calcium with 73% for "bone health" and fiber with 64% for bowel health. Taking hypertension as an example to consider the opportunity for drug-supplement interactions or disease-supplement interactions in this study, 96% of older adults were taking antihypertensive medications at the same time there were high percentage of them taking niacin for heart health, which may lead to increase adverse drug reaction if a drug-supplement interaction is present. It is important to consider that DS can enter the market without clinical studies assuring the efficacy or safety of the supplement.

Polypharmacy and prescription medications

70% of older adult DS users consumed at least one prescription medication in the past 30 days. This percentage is lower than the 90% of DS users who reported using prescription medication in the GEM study (Nahin et al., 2009). Seventy one percent of the oldest old (80 years) reported using both prescription medication and DS in the past 30 days. The majority of older participants who used four or more prescription medications reported using DS in the past 30 days. Polypharmacy itself is a major health issue among older adults that may lead to serious health problem like falls, cognitive impairment, increase ER visits, and increased risk of drug-drug interactions (Maher, Hanlon, & Hajjar, 2014). Taking DS concurrently with multiple medications may increase the chance of DS-drug interactions. For instance, in our study the majority of older participants reported using calcium, which may interact with quinolone antibiotic medications, thyroid medications or antiviral medications. Vitamin D was one of the highest reported products in our study, which may interact with steroid medications. Vitamin C may interact with amphetamine products. Moreover, supplements that contain calcium, magnesium, gingko, and iron (Tsai, Lin, Simon Pickard, Tsai, & Mahady, 2012) are particularly associated with a higher risk of DS-drug interactions. Although many older adults choose to use DS because they believe that the DS is safe, there are side effects reported after using DS ranging from severe to moderate (Palmer et al., 2003). It is important to increase patient and health care provider awareness about DS efficacy and safety. Thirty-five percent of DS users were taking supplements based on their physician's advice and this percentage increased by 12% from that reported in the previous study of the 2007-2010 NHANES cohort (Bailey et al., 2013). Also, 63% of DS users reported taking the supplement by their personal choice compared to 77% in the previous study (Bailey et al., 2013). Health care professionals are responsible to ask patients

about their DS and the reason behind using them in order to reduce the risk of adverse events and interactions and potentially to avoid unnecessary costs.

Factors predicting using DS for older adults

In our study we found that being older, female, non hispanic white, normal weight, middle income, having excellent or good reported health status, using at least one prescription medication in the past 30 days, and using 4 or more medications in the past month were significantly associated with using DS among older adult population in the U.S after adjusting for other variables. Most of the previous studies examining predictors of DS using mixed age groups of younger and older adults found similar results. Eileen et al. found in their study using NHANES (2007-08) that there was an association between DS ues and being female, non-hispanic white, and higher educated only (Eileen T. Kennedy, Hanqi Luo, 2013). The more recent study using the NHANES 2010 database by Bailey et al. (Bailey et al., 2013) reported that females, older adults, non-hispanic whites, normal or overweight individuals, and those with good or higher health status were more likely to use DS, which is similar to the findings reported in our study.

Strengths

This study aims to determine the prevalence of DS among adults of all ages and older adults specifically. Also, it aims to understand the rationale for older adults to use DS. Strengths of this study include:

- A nationally representative cohort with large sample size was used, allowing study outcomes to be generalizable to the entire US.
- To our knowledge, this is the first study evaluating the reasons for taking DS among the U.S. older adult population.
- The most recently available NHANES database (2009-2010, 2011-2012) was used to conduct this study, making it the most up-to-date report about DS use in the U.S.
- An analysis of major health problems like hypertension was evaluated for its association with using DS and for this specific predictor a measured variable rather than self reported questionnaire data was used, which increased the reliability of the results. Data that was related to hypertension was taking from MEC.

Limitations

This study has several limitations. First, the analysis is based on data from a self-reported questionnaire, which may lead to overestimated or underestimated the prevalence. Also, different types of bias might be a problem here such as recall bias, behavioral bias, and selection bias. Second, participants in the NHANES study were only asked to report DS use over a short period of time (last 30 days), which makes it difficult to determine if the DS was used for short-term or long-term use, unlike other studies that asked the subjects about DS use in the past 6 or 12 months (Paula Gardiner et al., 2014). Third, reporting using DS or prescription medications does

not guarantee that the subject actually took the DS or medication. Finally, this is a cross-sectional study and can only evaluate associations and the prevalence of DS use rather than any causal relationships.

Future Directions

Future research should focus on DS safety and efficacy to establish whether Food and Drug Administration (FDA) oversight of DS is warranted. It is important to ensure that any product in the market is safe and effective particularly for the older adult population. Randomized controlled trials are expensive, but this is the best way to assess the efficacy and safety of each supplement. In addition, more investigations are needed to understand the healthcare provider knowledge and behavior regarding DS and alternative medicine. NHANES does not ask about pharmacist recommendations regarding DS and this is also an important area of future study. Studying DS use among assisted living facility residents and nursing home residents is also needed area of future study, as these patients are more likely to be frail and have compromised health and functional status.

Conclusion

In conclusion, a high percentage of older adults reported using DS in the past 30 days. Similarly, a high percentage of older adults reported using DS concurrently with prescription medications. Using DS was significantly higher among female, non-hispanic white, normal weight, middle-income, polypharmacy patients, prescription medication users, and self-reported excellent or good health status. Including questions related to DS use in patient medication history in the medical record and carefully evaluating this DS use is important in order to deliver safe and cost effective health care.

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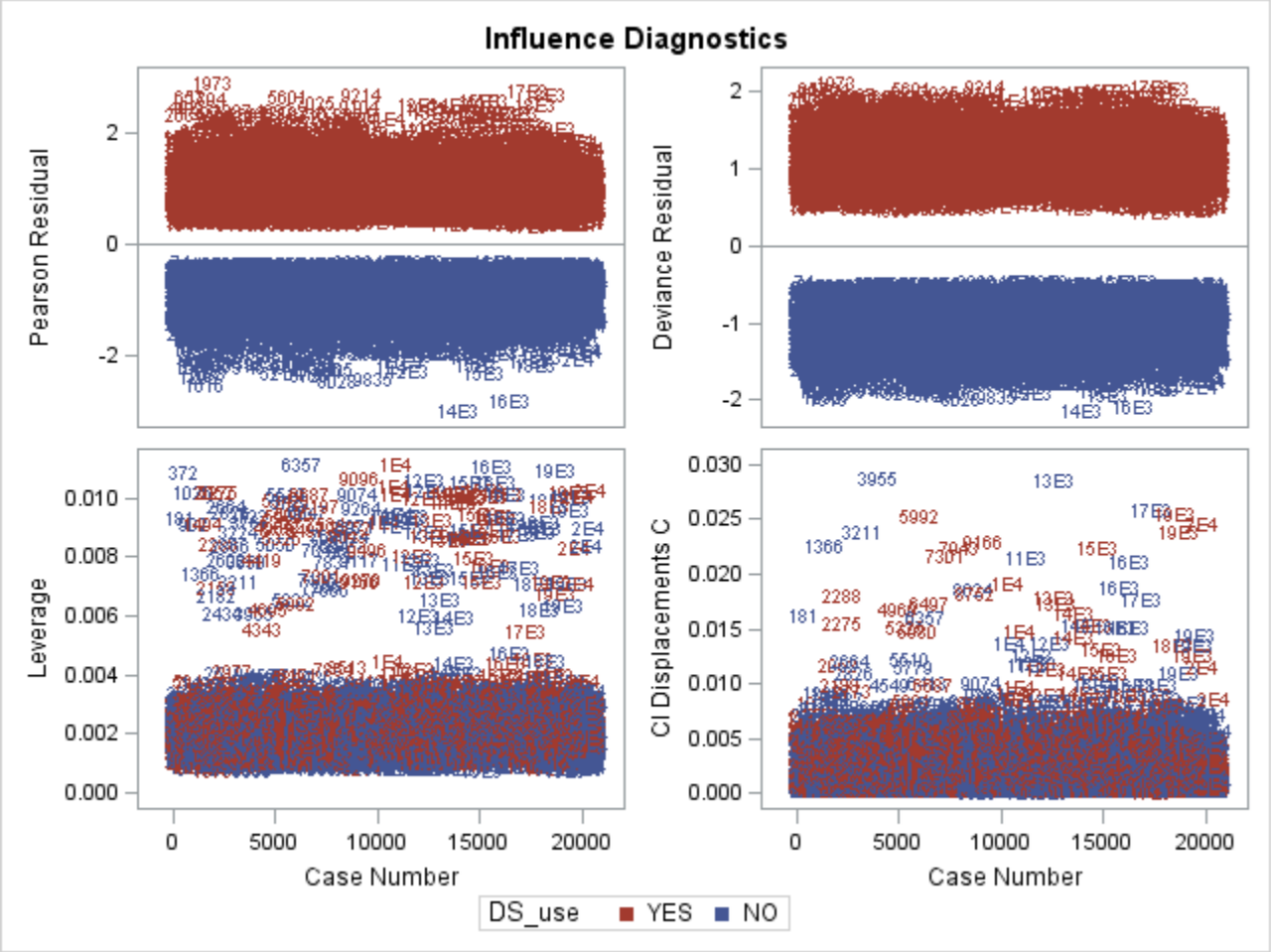
Appendix

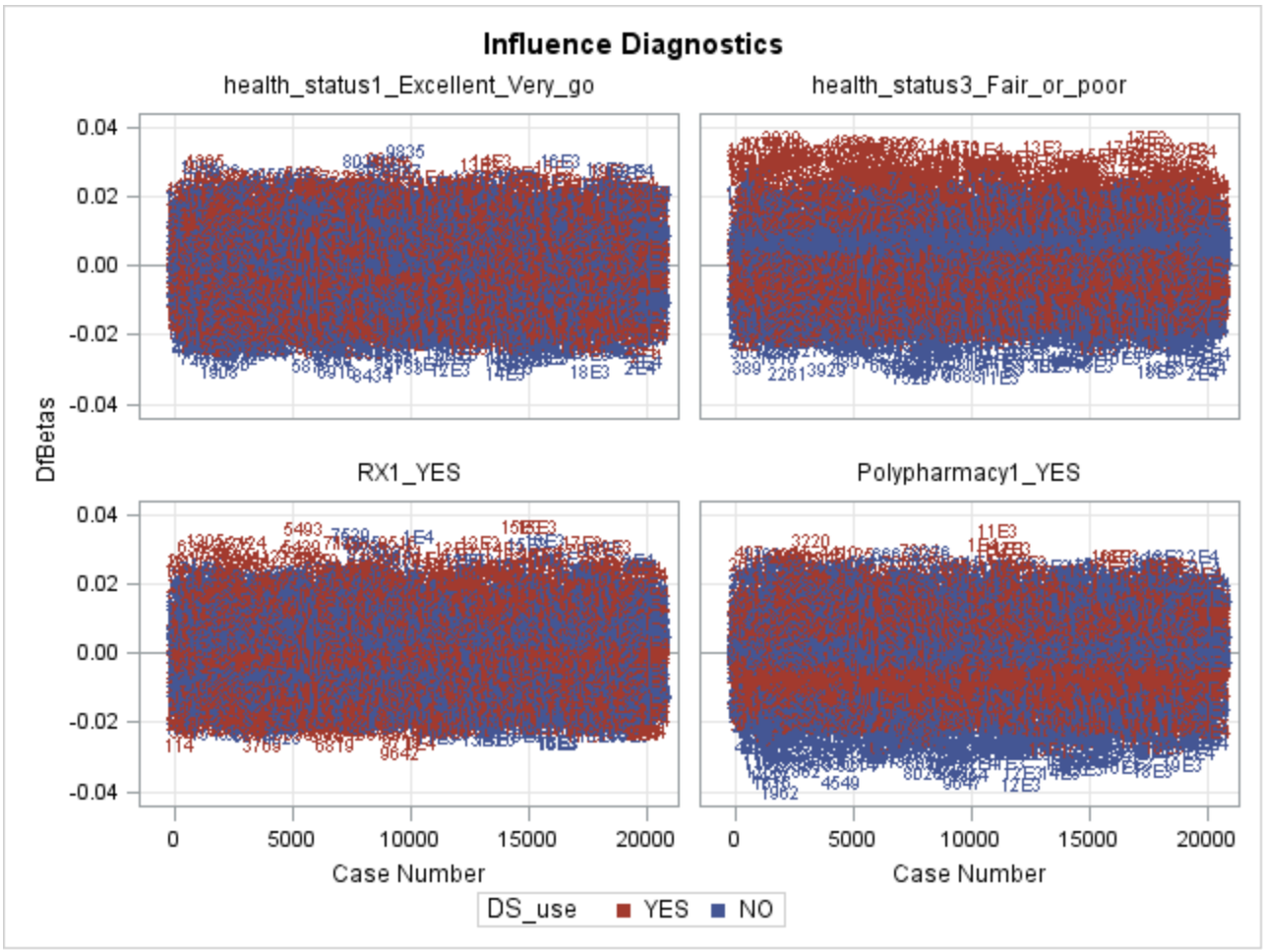
Multicollinearity checking:

Pearson Correlation Coefficients Prob > |r| under H0: Rho=0 Number of Observations										
	SEX	**RACE**	**Education**	**BMI**	**Marital_status**	**Family_income**	**HTN**	**health_status**	**RX**	**Polypharmacy**
SEX	1.00000 20293	0.00616 0.3800 20293	0.02164 0.0190 11758	0.03137 <.0001 18011	0.13513 <.0001 11767	-0.03012 <.0001 19323	0.02544 0.0020 14801	0.04706 <.0001 12449	-0.06777 <.0001 20282	-0.02784 <.0001 20293
RACE	0.00616 0.3800 20293	1.00000 20293	-0.06083 <.0001 11758	-0.10925 <.0001 18011	-0.04368 <.0001 11767	-0.06562 <.0001 19323	0.04479 <.0001 14801	0.10692 <.0001 12449	0.18924 <.0001 20282	0.13004 <.0001 20293
Education	0.02164 0.0190 11758	-0.06083 <.0001 11758	1.00000 11758	-0.09816 <.0001 11214	-0.09551 <.0001 11748	0.38800 <.0001 11176	0.08703 <.0001 10823	-0.31554 <.0001 10039	0.00235 0.7986 11750	0.09395 <.0001 11758
BMI	0.03137 <.0001 18011	-0.10925 <.0001 18011	-0.09816 <.0001 11214	1.00000 18011	0.01077 0.2538 11223	-0.02592 0.0007 17188	-0.15078 <.0001 14652	0.22275 <.0001 12310	-0.28370 <.0001 18002	-0.27617 <.0001 18011
Marital_status	0.13513 <.0001 11767	-0.04368 <.0001 11767	-0.09551 <.0001 11748	0.01077 0.2538 11223	1.00000 11767	-0.25490 <.0001 11184	-0.07950 <.0001 10832	0.09505 <.0001 10046	-0.08220 <.0001 11759	-0.11255 <.0001 11767

Pearson Correlation Coefficients Prob > |r| under H0: Rho=0 Number of Observations										
	SEX	**RACE**	**Education**	**BMI**	**Marital_status**	**Family_income**	**HTN**	**health_status**	**RX**	**Polypharmacy**
Family_income	-0.03012 <.0001 19323	-0.06562 <.0001 19323	0.38800 <.0001 11176	-0.02592 0.0007 17188	-0.25490 <.0001 11184	1.00000 19323	0.05333 <.0001 14151	-0.23525 <.0001 11910	-0.01969 0.0062 19313	0.05813 <.0001 19323
HTN	0.02544 0.0020 14801	0.04479 <.0001 14801	0.08703 <.0001 10823	-0.15078 <.0001 14652	-0.07950 <.0001 10832	0.05333 <.0001 14151	1.00000 14801	-0.11234 <.0001 12145	0.19845 <.0001 14793	0.18790 <.0001 14801
health_status	0.04706 <.0001 12449	0.10692 <.0001 12449	-0.31554 <.0001 10039	0.22275 <.0001 12310	0.09505 <.0001 10046	-0.23525 <.0001 11910	-0.11234 <.0001 12145	1.00000 12449	-0.16008 <.0001 12442	-0.24404 <.0001 12449
RX	-0.06777 <.0001 20282	0.18924 <.0001 20282	0.00235 0.7986 11750	-0.28370 <.0001 18002	-0.08220 <.0001 11759	-0.01969 0.0062 19313	0.19845 <.0001 14793	-0.16008 <.0001 12442	1.00000 20282	0.47547 <.0001 20282
Polypharmacy	-0.02784 <.0001 20293	0.13004 <.0001 20293	0.09395 <.0001 11758	-0.27617 <.0001 18011	-0.11255 <.0001 11767	0.05813 <.0001 19323	0.18790 <.0001 14801	-0.24404 <.0001 12449	0.47547 <.0001 20282	1.00000 20293

Checking Outliers




Influence Diagnostics
health_status1_Excellent_Very_go
health_status3_Fair_or_poor
RX1_YES
Polypharmacy1_YES
DfBetas
0.04
0.02
0.00
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-0.04
0
5000
10000
15000
20000
Case Number
DS_use
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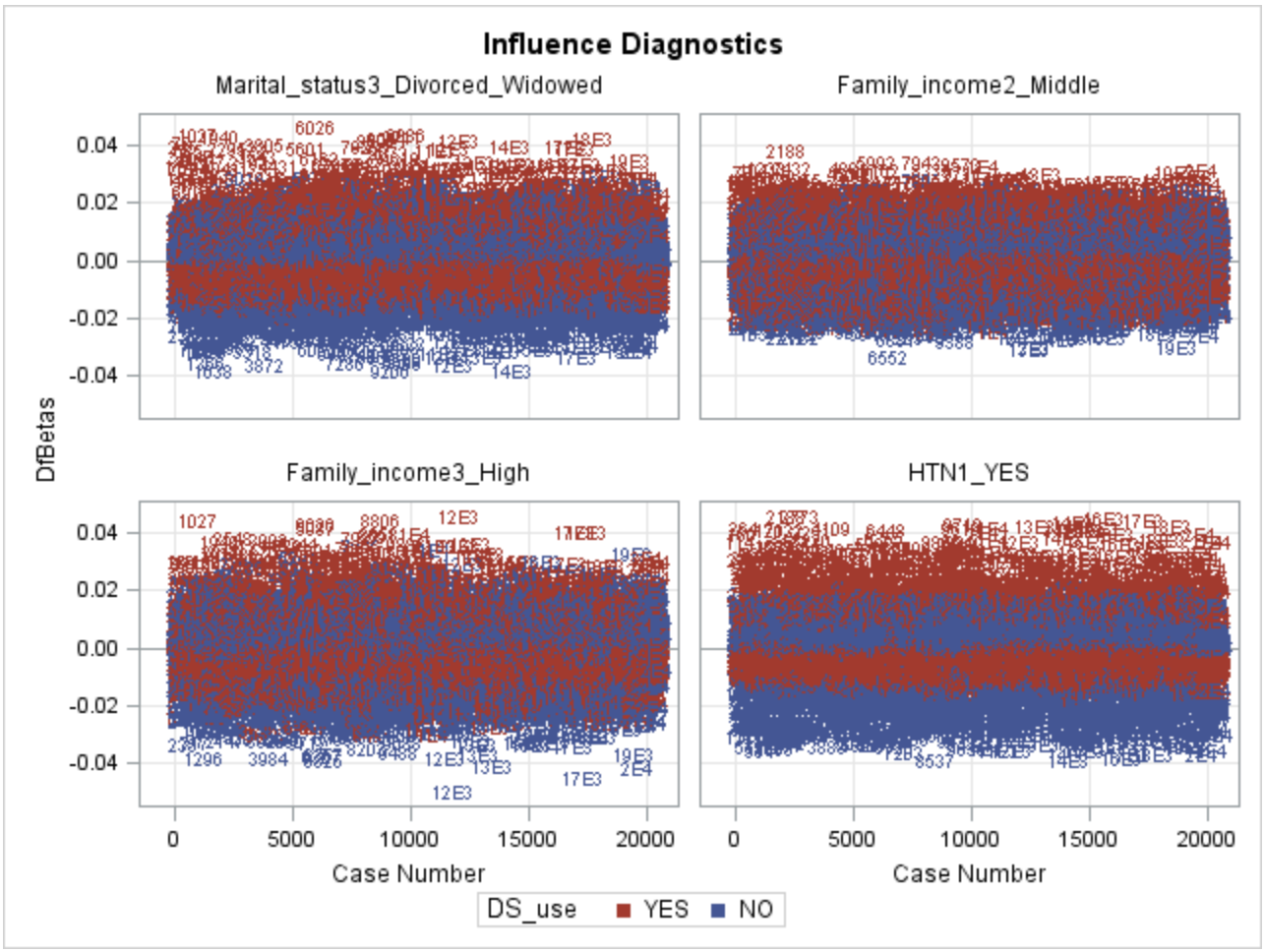
NO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Family_income2_Middle
Family_income3_High
HTN1_YES
DfBetas
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0.02
0.00
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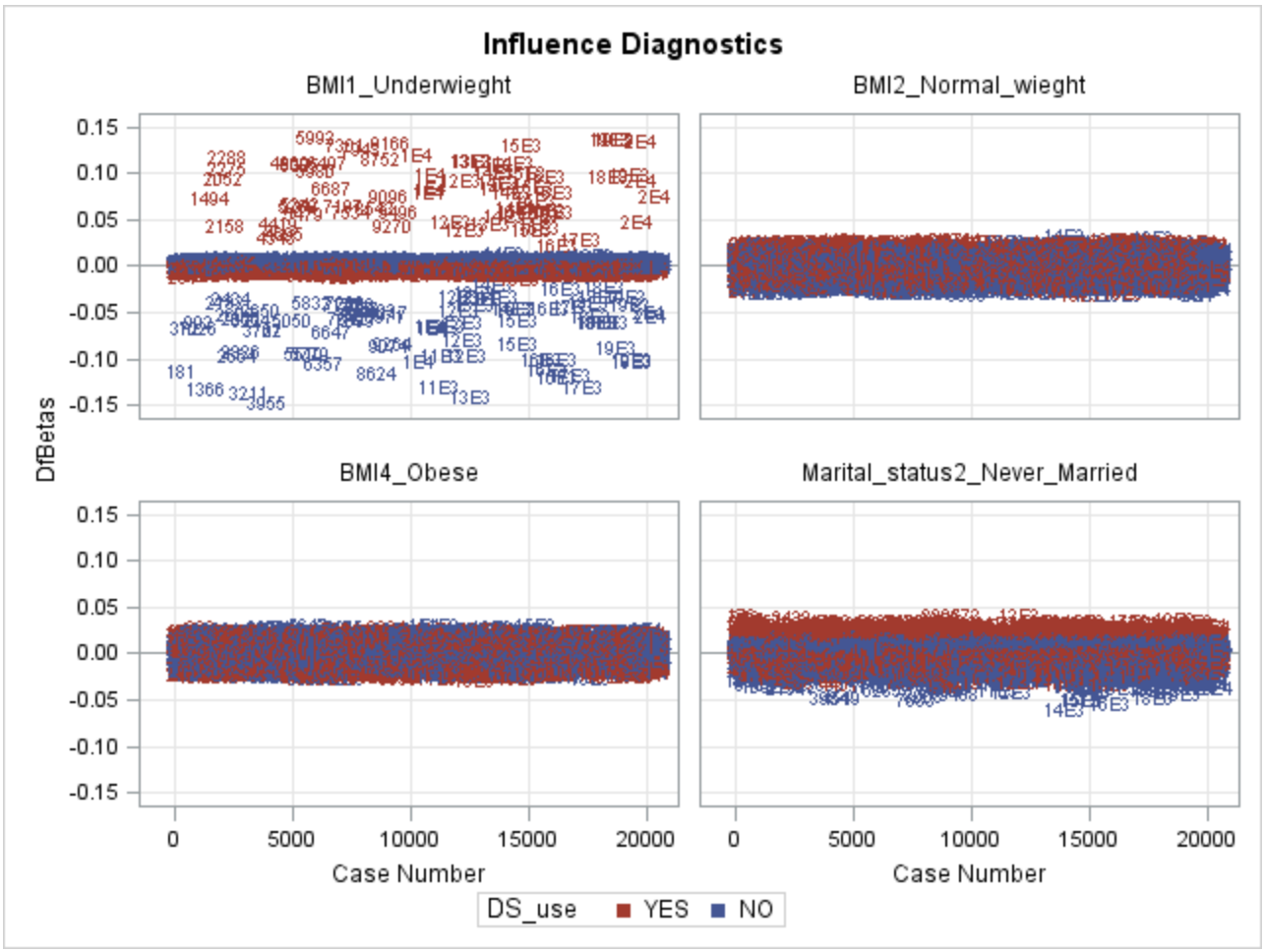
-0.04
0
5000
10000
15000
20000
Case Number
DS_use
YES
NO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BMI4_Obese
Marital_status2_Never_Married
DfBetas
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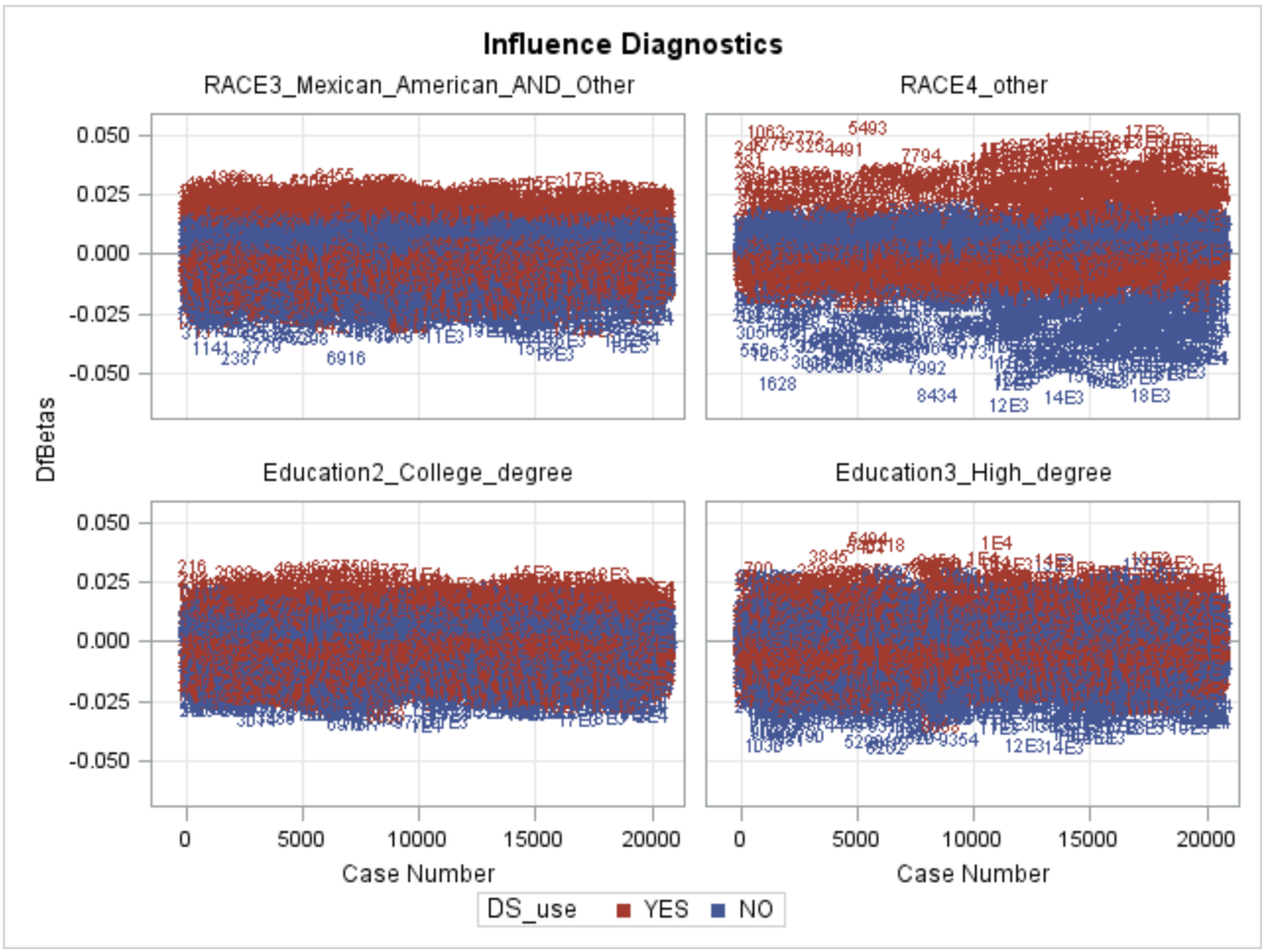
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Education3_High_degree
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Case Number
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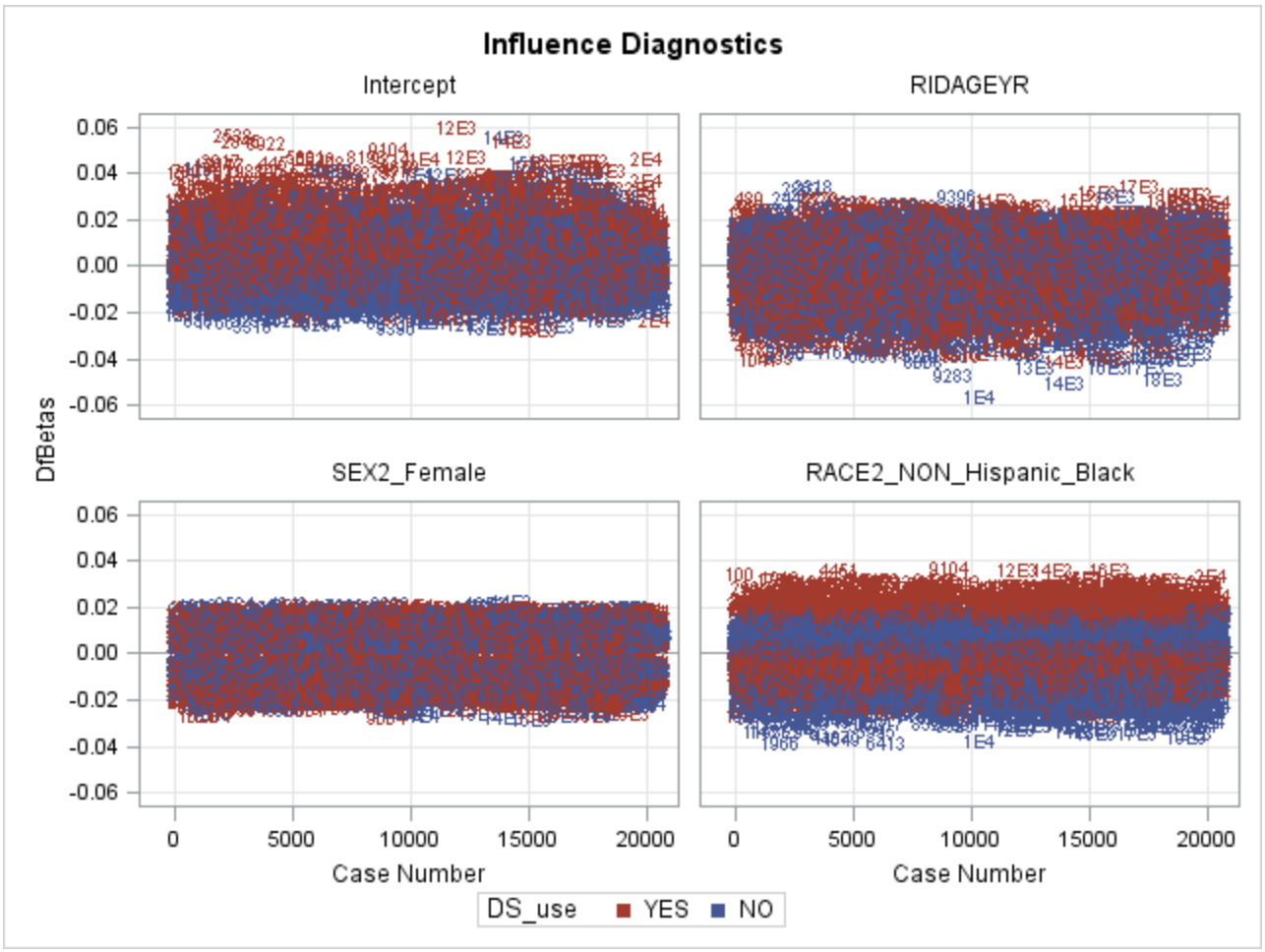
NO


Influence Diagnostics
Intercept
RIDAGEYR
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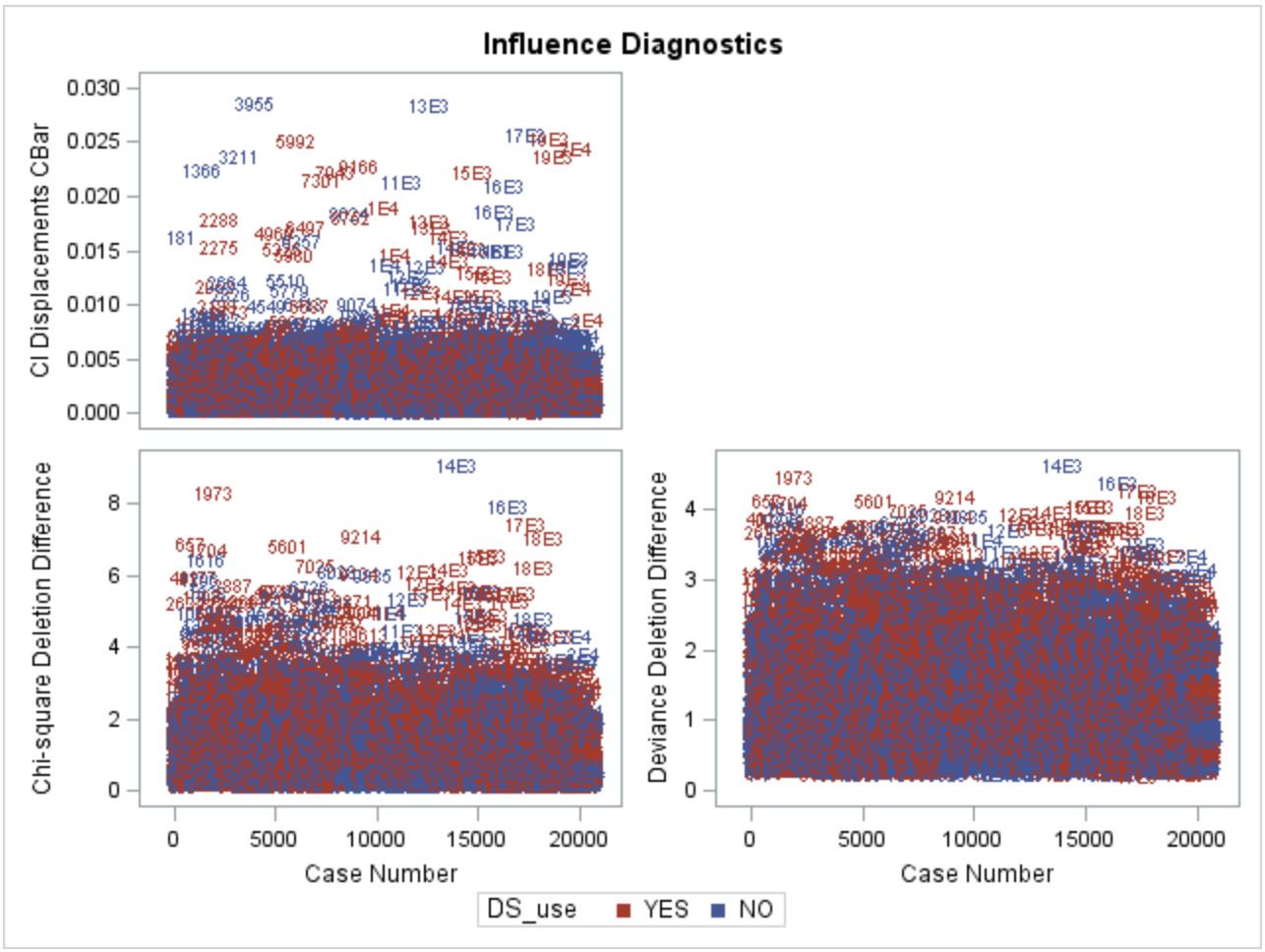
RACE2_NON_Hispanic_Black
DfBetas
0.06
0.04
0.02
0.00
-0.02
-0.04
-0.06
0
5000
10000
15000
20000
Case Number
DS_use
YES
NO


Influence Diagnostics
CI Displacements CBar
Chi-square Deletion Difference
Deviance Deletion Difference
Case Number
Case Number
DS_use YES NO