Red Meat or Processed Meat and Cardiovascular Disease, Is There an Association?

by
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Abstract

Cardiovascular disease (CVD) stands alone as the number one cause of death in the U.S. This proposal is for a retrospective cohort study to assist in quantifying how much red meat and processed meat can be consumed without significantly increasing the risk of CVD for adults aged 40-85 years old in the U.S. Clustered sampling will be utilized in six different areas of the U.S. to ensure all races, genders, socioeconomic levels, and ages are represented. Each subject will be asked to complete a semi-quantitative food frequency questionnaire as well as demographic and health related questions. It is anticipated that Chi-square test will yield a significant relationship between gender and processed meat intake ($P < .01$), race and processed meat intake ($P < 0.1$), smoking usage and processed meat ($P < .01$), waist circumference and processed meat intake ($P < .01$), as well as diabetes and processed meat ($P < .03$). Next, it is anticipated that Chi-Square test will yield a significant relationship between race and red meat intake ($P < .01$). Additionally, it is anticipated that Logistic Regression will show that there is an increased risk for CVD with moderate versus low consumption of red meat (OR: 1.038, 95% CI: 1.009-1.069; $P = .01$), high versus low consumption of red meat (OR: 2.062, 95% CI: 2.021-2.105; $P < .01$), moderate versus low consumption of processed meat (OR: 1.010, 95% CI: 1.005-1.016; $P < .01$), and high versus low consumption of processed meat (OR: 1.950, 95% CI: 1.927-1.974; $P < .01$). If the results of this proposed study are similar to the anticipated results, the author recommends that a prospective cohort study be completed in the same six regions to further advance evidence-based recommendations.

Keywords: cardiovascular disease, red meat, processed meat, heart disease, stroke

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Chapter 1

Cardiovascular disease (CVD) is a universal term that encompasses a collection of blood vessel and heart conditions such as peripheral arterial disease, stroke, heart valve disease, aorta disease, cardiomyopathy disease, congenital heart disease, abnormal heart rhythms, heart failure, vascular disease, high blood pressure, heart attack, and coronary artery disease (Cleveland Clinic, 2019). Worldwide, CVD is attributed to roughly 31% of all deaths, making it the current number one cause of death; this is projected to continue for the next decade (Pinaire, Azé, Bringay, Cayla, & Landais, 2019). In 2019, the American Heart Association reported that 121.5 million adults in the United States of America (or 48% of the population) have CVD (Benjamin, et al., 2019). They also estimate that roughly 80% of CVDs could be prevented by eating a healthy diet; maintaining a healthy weight; being physically active; not smoking; and managing lipid levels, blood pressure, and diabetes mellitus (Benjamin et al., 2019).

In October 2019, Zeraatker, et al. (2019) published a study concluding "the evidence implicating red and processed meat in adverse cardiometabolic outcomes is of low quality…even if a causal relationship exists, the magnitude of association between red and processed meat consumption and cardiometabolic outcomes is very small" (p. 709). This study was met with much criticism (Aubrey, 2019; "Getting to the Meat of the Matter," 2019; Paul, 2020; True Health Initiative, 2019), leading to the results and its controversy making national news (Narula, 2019). It has been specifically noted that the Zeraatker et al. study utilized a method that is typically used in randomized clinical trials for drugs, which is rarely viable in nutritional studies (Harvard Health Publishing, 2020). Hazen (as cited in Cleveland Clinic Vascular Team, 2019) and Rosenbloom (2019) both commented that it was not a novel study, as an alternative, the authors arrived at their conclusion by reviewing observational studies and saying that observational studies are not robust enough to make nutritional recommendations from the results.

Background

Poor diet quality is a modifiable lifestyle factor for CVD (Mahan, Escott-Stump, & Raymond, 2011). It was estimated in 2012 that 45.4% of cardiometabolic deaths were related to unhealthy diets (Benjamin, et al., 2019). Some diet-related factors that may contribute to CVD risk are the amount of sodium and saturated fat consumed as well as the production of trimethylamine-N-oxide (TMAO). "TMAO is a molecule generated from choline, betaine, and carnitine via the gut microbial metabolism" (Janeiro, Ramírez, Milagro, Martínez, & Solas, 2018, p. 1). Researchers have found that the more red meat that is consumed by an individual, the greater the number of meat-eating bacteria produced in the gut, yielding more microbes to metabolize meat (Harvard Health Publishing, 2019). According to Hazen (as cited in Cleveland Clinic Vascular Team, 2019), this leads to elevated levels of TMAO in the blood, which will raise a person's chances of developing a myocardial infarction, stroke, and atherosclerosis. Next, it is recognized that saturated fat elevates low-density lipoprotein (LDL) cholesterol, a substantial risk factor for CVD (Briggs, Petersen, & Kris-Etherton, 2017). The preponderance of saturated fat originates from animal sources, including beef, lamb, and pork (American Heart Association, n.d.).

While TMAO and saturated fat pertain to both red meat and processed meat, one possible risk factor that separates the two is sodium. The totality of data credits salt (or sodium) restriction (not adding salt and not consuming high salted foods) as a significant practice to impede coronary artery disease and stroke (Piepoli et al., 2017). Most sodium in the American diet is already in the meals people buy and cannot be taken out (Cogswell, Mugavero, Bowman, & Frieden, 2016). Typically, in western countries, 80% of salt consumed derives from processed foods and only 20% is added thereafter (Piepoli et al., 2017). While the sodium content may not be concerning for all red meat, “most processed meats are high in sodium” (Zeratsky, 2018, p. 1).

Hu (as cited in Harvard Health Publishing, 2020) states that data from studies demonstrate that people with a comparably low consumption of red and processed meat have decreased risk factors, but that specific amounts of safe intake are open to debate. Additionally, Kopecky (as cited in Williams, 2019) reports that consuming a small amount of red meat likely would not get one in trouble but consuming as much as desired will have negative effects. Kopecky (as cited in Williams, 2019) and Hu (as cited in Harvard Health Publishing, 2020) agree that there is likely an amount of red meat and processed meat that can be safely consumed, but there is still a question: How much? The leading data indicates that reducing red meat to two to three servings per week is a favorable pattern (Aubrey, 2012); however, Johnston (as cited in Rosenbloom, 2019) disclosed that there is not sufficient evidence to provide guidance on the correct amount of red meat to consume.

Problem Statement

Recognized as a leading source of medical information for the cardiovascular system in the United States, the American Heart Association recommends that people limit the amount of all meat to 5.5 ounces per day and choose healthier types of meat (i.e. lean cuts), plus minimize intake of processed meats (2017b). The words “limit” and “minimize” are relative terms. In America, where the average daily total meat consumption is 128 grams (Daniel, Cross, Koebnick, & Sinha, 2011), and Canada, where the average daily total meat consumption is 69 grams (Ksabharwal, 2018), limiting or minimizing would likely be interpreted differently. What we do not know is what quantifies as limiting and minimizing intake of red meat and processed meat.

Purpose of the Study

The purpose of the proposed study is to test if there is a quantity of red meat or processed meat intake that is not associated with an increased risk of CVD by comparing red meat and processed meat intake to the development of CVD for 40 to 85 year olds living in the United States.

Research Question(s) and Hypotheses

This proposal contains two research questions.

- *Research question* – Is there a higher prevalence of CVD among people age 40 to 85 years old who consume greater than or equal to 45 grams of red meat daily?
    - *Null hypothesis I* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and moderate intake of red meat and the prevalence of CVD.
    - *Null hypothesis II* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and high intake of red meat and the prevalence of CVD.
    - *Research hypothesis I* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a moderate red meat intake as

compared to those who consume a low red meat intake, due to a positive relationship between red meat intake and prevalence of CVD.

- *Research hypothesis II* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a high red meat intake as compared to those who consume a low red meat intake, due to a positive relationship between red meat intake and prevalence of CVD.

Table 1

Categorization of Variables for Red Meat and CVD Relationship

Type of Variable	Variable
Independent Variable	Red Meat intake
Dependent Variable	CVD diagnosis
Mediating Variables	Saturated Fat intake and TMAO production
Confounding Variables	Dyslipidemia, hypertension, metabolic syndrome, poor diet quality, stress and depression
Controlled Variables	Age and gender, family history and genetics, diabetes mellitus, obesity (determined by waist circumference), tobacco use, physical inactivity, race, and low socioeconomic status

- *Research question* – Is there a higher prevalence of CVD among people age 40 to 85 years old who consume greater than or equal to 10 grams of processed meat daily?
    - *Null hypothesis I* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and moderate intake of processed meat and the prevalence of CVD.
    - *Null hypothesis II* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and high intake of processed meat and the prevalence of CVD.
    - *Research hypothesis I* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a moderate processed meat intake as compared to those who consume a low processed meat intake, due to a positive relationship between processed meat intake and prevalence of CVD.
    - *Research hypothesis II* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a high processed meat intake as compared to those who consume a low processed meat intake, due to a positive relationship between processed meat intake and prevalence of CVD.

Table 2

Categorization of Variables for Processed Meat and CVD Relationship

Type of Variable	Variable
Independent Variable	Processed Meat intake
Dependent Variable	CVD diagnosis
Mediating Variables	Saturated Fat intake, Sodium intake, and TMAO production
Confounding Variables	Dyslipidemia, hypertension, metabolic syndrome, poor diet quality, stress and depression
Controlled Variables	Age and gender, family history and genetics, diabetes mellitus, obesity (determined by waist circumference), tobacco use, physical inactivity, race, and low socioeconomic status

Nature of the Study

This proposed research study will survey male and female subjects between 40 and 85 years old. Clustered sampling will be utilized in six different areas of the United States to ensure all races, genders, socioeconomic levels, and ages are represented. The six geographical areas will include Chicago, Illinois; Gaithersburg, Maryland; Houston, Texas; Jersey City, New Jersey; Los Angeles, California; and Sandy Springs, Georgia. It is anticipated that 384 total subjects will be needed to yield results with a 95% confidence interval of +/- 5 from using a sample size calculator (Creative Research Systems, 2012). In order to achieve said results, 107 subjects will be included from each of the six cities to allow for up to 40% of subjects to not respond, which was considered reasonable by Fincham (2008), or be excluded from the study for not completely filling out the questionnaires. Each subject will be asked to complete a semi-quantitative food frequency questionnaire (Appendix A). Questionnaire mailings will include a postage paid return envelope and a LimeSurvey link in case the subject prefers to submit data electronically. Additionally, each subject will be asked demographic and health related questions (Appendix B).

Descriptive statistics ……..Comparative analysis with Chi-Square will be conducted to assess whether red meat or processed meat intake was associated with any of the controlled variables (see Table 1 and Table 2). Relational analysis with Logistic Regression will be conducted to assess total red meat intake with diagnosis of CVD and total processed meat intake with the diagnosis of CVD.

Definitions

- Age and Gender Controlled Variable - men age greater than 45 years old and women age greater than 55 years old (Mahan, Escott-Stump, & Raymond, 2011)
- Diabetes Mellitus Controlled Variable – self reported
- Family History and Genetics Controlled Variable - when a first-degree relative has a history of premature (male < 45 years old or female < 55 years old) CVD (Mahan, Escott-Stump, & Raymond, 2011)

- High Consumption of Processed Meat - based on previous research is defined as greater than an average of 35 grams daily (Haring, et al., 2014; Nagao, Iso, Yamagishi, Date, Tamakoshi, 2012; Wang, Campos, & Baylin, 2017)
- High Consumption of Red Meat – based on previous research is defined as greater than an average of 110 grams daily (Haring, et al., 2014; Nagao, Iso, Yamagishi, Date, Tamakoshi, 2012; Wang, Campos, & Baylin, 2017)
- High Socioeconomic Status Variable - based on a combination of education, income, and occupation calculated as a score of 6-7 using a system based on Berzofsky, Smiley-McDonald, Moore, & Krebs (2014)
- Low Consumption of Processed Meat - based on previous research is defined as less than an average of 10 grams per day (Haring, et al., 2014; Nagao, Iso, Yamagishi, Date, Tamakoshi, 2012; Wang, Campos, & Baylin, 2017)
- Low Consumption of Red Meat - based on previous research is defined as less than an average of 45 grams per day (Haring, et al., 2014; Nagao, Iso, Yamagishi, Date, Tamakoshi, 2012; Wang, Campos, & Baylin, 2017)
- Low Socioeconomic Status Controlled Variable – based on a combination of education, income, and occupation calculated as a score of 0-2 using a system based on Berzofsky, Smiley-McDonald, Moore, & Krebs (2014)
- Middle Socioeconomic Status Variable - based on a combination of education, income, and occupation calculated as a score of 3-5 using a system based on Berzofsky, Smiley-McDonald, Moore, & Krebs (2014)

- Moderate Consumption of Processed Meat - based on previous research is defined as an average of 10 to 35 grams daily (Haring, et al., 2014; Nagao, Iso, Yamagishi, Date, Tamakoshi, 2012; Wang, Campos, & Baylin, 2017)
- Moderate Consumption of Red Meat - based on previous research is defined as an average of 45 to 110 grams daily (Haring, et al., 2014; Nagao, Iso, Yamagishi, Date, Tamakoshi, 2012; Wang, Campos, & Baylin, 2017)
- Non-modifiable Risk Factors – age, gender, ethnicity, and family history (Mahan, Escott-Stump, & Raymond, 2011)
- Obesity Controlled Variable - waist circumference greater than 40 inches for men and greater than 35 inches for women (Mahan, Escott-Stump, & Raymond, 2011)
- Physical Inactivity Controlled Variable – self reported as less than 150 minutes of moderate or vigorous physical activity per week
- Poor Diet Quality Confounding Variable – '*Pertaining to CVD'* low intake of whole grains, nuts, seeds, legumes, fish, fruit, and vegetables with high intake sugar-sweetened beverages, sodium, processed meat, and saturated fat (Benjamin et al., 2019). Can be quantified by utilizing the Diet Quality Index – International (Kim, Haines, Siega-Riz, & Popkin, 2003).
- Processed Meat - meat that has been preserved or flavor enhanced such as cured, smoked and salted meats like bacon, hot dogs, and salami
- Race Controlled Variable - Blacks, American Indians, native Alaskans, Caucasian Hispanic (American Heart Association/American Stroke Association, 2009)
- Red Meat - meat from mammals such as hamburger, beef, pork, lamb, ham, pork chops, or liver (from beef, calf, or pork)

- Tobacco Use Controlled Variable – self reported based on frequency over the past one year (categories include no; more than once a month, but not weekly; more than once a week, but not daily; daily)

Assumptions

This proposed study, as with all studies that use food frequency questionnaires, assumes that subjects will provide an accurate evaluation of their food intake, especially their red meat and processed meat intake. Additionally, this proposal, as with all retrospective nutritional studies, assumes that food intake over the past year for the subjects with CVD was similar to their intake prior to CVD diagnosis.

Limitations

Limitations of this proposal include the inability to be able to demonstrate causation or eliminate bias due to the design being observational and will not be able to control for all modifiable risk factors of CVD since this would require more financial resources to track a larger number of subjects in order to find subjects with identical modifiable CVD risk factors. Additionally, due to limited resources, this study will not assess subjects for undiagnosed CVD. Lastly, subjects who do not return or complete the questionnaire are likely unavoidable and may lead to response bias, which is why the study will start with more subjects than required to allow for up to a 40% non-completion rate.

Delimitations

First, this proposal does not address if red meat or processed meat intake as a minor or young adult (less than 40 years old) has a greater impact on CVD risk than intake as an adult. Since CVD is a progressive disease, the subject's red meat and processed meat intake as a minor or young adult could affect each subject's risk for CVD. Second, this study will only include 40 to 85-year-old residents in the United States. Third, this proposal will not differentiate between different types of red meat. All meat that comes from mammals will be grouped together so if there is a specific mammal whose biological components lead to a larger increase in CVD risk than other red meat, this proposed study will not be able to detect it. Lastly, this proposal will not address any effects that non-CVDs have on altering the digestion of red meat or processed meat.

Significance

The data collected from observing the relationship between the development of CVD and the amount of red meat and processed meat consumed by adults will help to guide a more specific recommendation than to *limit* red meat and *minimize* processed meat. It is projected that close to 50% of the United States population will have some type of CVD and the annual cost to Americans will increase to 1.1 trillion dollars by 2035 (RTI International, 2017). Having evidence-based information to provide an objective measure for red meat and processed meat consumption has the potential to yield more consistent results in preventing the development of CVD than the current method of providing a subjective measure. This proposed study has the potential to help people prevent CVD by providing a measurable guideline for red meat and processed meat daily consumption. Additionally, this proposed study may help mitigate the confusion from conflicting headlines regarding the relationship between red meat and processed meat with CVD.

Summary

Cardiovascular disease is the number one cause of death worldwide. It is projected that over 3 out of every 4 of those deaths could have been prevented by making lifestyle changes, which include diet (Benjamin, et al., 2019). Despite a recent and controversial study that concluded there was no association between red meat and processed meat intake with CVD, leading authorities have summarized that if red meat intake is limited and processed meat intake is minimized, they can be part of a cardiovascular friendly diet (Aubrey, 2019; "Getting to the Meat of the Matter," 2019; Harvard Health Publishing, 2020; Paul, 2020; True Health Initiative, 2019; Williams, 2019; Zeraatker, et al., 2019). This proposed study will be a retrospective cohort study to assist in determining a limit for the amount of red meat intake and the maximum amount of processed meat in order to avoid significantly increasing the risk of CVD for adults aged 40-85 years old in the United States.

The following chapters will review the current literature on CVD, red meat, processed meat and their relationship to one another; the methodology of the proposed project; the anticipated results; and a discussion about the anticipated results. Chapter two will provide a more thorough introduction of CVD, including its pathophysiology, etiology, and risk factors. Also, it will include a more comprehensive review of red meat and processed meat's benefits, and general nutritional recommendations for intake. Chapter two will conclude with recent and peer reviewed original research on the relationship between red meat and processed meat with CVD. Next, chapter three will provide a more in-depth description of the methodology, including the proposed research design, setting and sample, instrumentation, data analysis plan, threats to validity, and ethical procedures. Then, chapter four will present the anticipated results for both the descriptive and inferential statistics. Lastly, chapter five will discuss the anticipated results, how results would compare to results from other studies, the strengths and limitations, suggestions for future studies, and the overall message.

Chapter 2: Review of Literature

Any nutritional recommendations made without evidence-based information is strictly opinion based. Thus, the first step is to research and review what, if any, peer-reviewed studies have been completed on the relationship between red meat or processed meat and CVD. The next step is to compare the existing data to decipher what, if any, additional scientific studies would help to guide future evidence-based recommendations. The following chapter will lay out how the author conducted the literature research; provide background on red meat, processed meat, and CVD; provide detail on the studies that were included in the literature review; and compare the existing studies.

Literature Search Strategy

In search of original research studies conducted on the relationship between red meat and/or processed meat intake with CVD, both PubMed Central and ProQuest Databases were utilized. To find relevant articles, “cardiovascular disease” or “heart disease” or “stroke” or “myocardial infarction” or “heart failure” and “red meat” or “processed meat” were entered as the search terms. Additionally, all articles published more than ten years prior to the search date were excluded from the results. This search yielded six original research studies that conducted analysis on the relationship between CVD and red meat and/or processed meat consumption.

Pathophysiology and Etiology of CVD

As stated by the Centers for Disease Control and Prevention (CDC), the number one cause of death in both men and women, contributing to 610,000 or one in every four deaths each year in the United States, is heart disease (CDC, 2017). The following will detail different types of CVD. Atherosclerotic heart disease (ASHD) entails narrowing and decreased flexibility in the blood vessel wall generated by a build-up of plaque (Mahan, Escott-Stump, & Raymond, 2011). The plaque is composed of calcium, cholesterol, fibrin, cellular waste products, and fatty substances (American Heart Association, 2017a). Atherosclerosis is a gradual, developing disease that can begin in childhood (American Heart Association, 2017a).

In the coronary arteries, atherosclerosis leads to myocardial infarction, sudden death, and angina. Angina is the result of reduced blood flow to the heart muscle (reduced oxygen supply), causing discomfort or retrosternal chest pain (Escott-Stump, 2015). Myocardial infarction is the result of extended insufficient blood supply or oxygen deficit precipitating necrosis in the myocardium (Escott-Stump, 2015). When a patient has no known history of heart disease, sudden death is frequently caused by acute ischemia for which a fatal ventricular arrhythmia can transpire as the earliest indication of coronary atherosclerosis (Mehta, Curwin, Gomes, & Fuster, 1997).

In the cerebral arteries, atherosclerosis leads to transient ischemic attacks and strokes, and in the peripheral circulation, it leads to limb ischemia, gangrene, and intermittent claudication (Mahan, Escott-Stump, & Raymond, 2011). Stroke is the result of blood supply loss that causes injury to a section of the brain (Escott-Stump, 2015). Transient ischemic attacks, which accounts for 80% of strokes, result from blockages that cause short periods of blood loss to the brain

(Escott-Stump, 2015). The predominant origin of peripheral vascular disease (PVD), a gradual and ongoing circulation disorder, is atherosclerosis (John Hopkins Medicine, n.d.a). This decrease in blood flow to the limbs can lead to intermittent claudication or aching leg cramps that arise in conjunction with physical movement and is alleviated by respite (John Hopkins Medicine, n.d.a); limb ischemia with aching leg cramps at rest (Davies, 2012); or gangrene, the loss of tissue.

While the greatest origin of CVD is atherosclerosis (Mayo Clinic Staff, 2018), a major risk factor is hypertension (World Health Organization, 2017). According to the CDC, nearly one out of every three American adults has prehypertension (CDC, 2016). Additionally, nearly one out of every three American adults has hypertension, the leading-or partial-explanation of death for greater than 410,000 Americans in 2014 (CDC, 2016). Blood pressure is a result of a combination of impedance in blood vessels and cardiac output, so when the width of the blood vessel decreases commonly caused by atherosclerosis, blood pressure can increase (Mahan, Escott-Stump, & Raymond, 2011).

Atherosclerosis and hypertension are major risk factors for heart failure (HF) (American Heart Association, 2017c). The CDC reports, in the United States, close to 5.7 million adults have HF and within 5 years of diagnosis, roughly 50% of HF patients will die ("Heart Failure Fact Sheet|Data & Statistics|DHDSP|CDC", 2019). Heart failure results from damage or too much strain to the heart muscle. This leads to inadequate blood flow throughout the body (Mahan, Escott-Stump, & Raymond, 2011). As a consequence, the heart counteracts the insufficient cardiac output by signaling to the kidneys to minimize the excretion of water and sodium, intensifying the strength of contraction, growing in size, and increasing the frequency of pumping (Mahan, Escott-Stump, & Raymond, 2011).

Risk Factors for CVD

Given the prevalence of CVD, it may not be surprising that there are numerous nonmodifiable and modifiable risk factors. Nonmodifiable risk factors include age and gender, family history and genetics, and menopausal status (Mahan, Escott-Stump, & Raymond (2011). The time upon which age itself comes to be a categorical risk for men is at 45 years old and for women is at 55 years old (Marma & Lloyd-Jones, 2009). Family history and genetics is identified by when a first-degree relative has a history of premature CVD (Mahan, Escott-Stump, & Raymond (2011). Strong family history can be identified as a brother or father who is diagnosed before the age of 55 years old and as a sister or mother who is diagnosed before the age of 65 years old (British Heart Foundation, n.d.a). "Estrogen has significant effects on the modification of circulating lipoproteins, inhibition of lipoprotein oxidation, attenuation of atherosclerotic lesions, favorable modulation of homocysteine, changes in blood coagulation and inhibition of intravascular accumulation of collagen" (Koledova & Khalil, 2007, p. 778).

Modifiable risk factors include diabetes, hypertension, metabolic syndrome, and abdominal fat mass. Cardiovascular disease is the cause of death for most people with any form of diabetes (Leon & Maddox, 2015). As a matter of fact, people with diabetes mellitus have greater than a 2-fold elevated risk for CVD in comparison to people without diabetes and beyond 75% of total mortality for people with diabetes mellitus is from CVD (Selvin et al., 2004). Hyperglycemia, after a period of time, is capable of injuring the blood vessels and the nerves that regulate the heart and blood vessels (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). Amongst the risk factors for CVD, hypertension is linked to the most compelling evidence of causality (Fuchs & Whelton, 2020). It is estimated that globally, 54% of strokes and 47% of CHD are ascribed to hypertension (Wu et al., 2015). The metabolic syndrome is characterized as the coexistence of obesity-related CVD risk factors comprising hypertriglyceridemia, hypertension, decreased HDL cholesterol, impaired glucose tolerance, and/or abdominal obesity (Tune, Goodwill, Sassoon, & Mather, 2017). Individually, every factor of the metabolic syndrome is a separate risk factor for CVD (O'Neill & O'Driscoll, 2014; Sperling et al., 2015), jointly generating an expansive range of CVDs (Berwick, Dick, & Tune, 2012; Galassi, Reynolds, & He, 2006; Grundy et al., 2006; Hunt, Resendez, Williams, Haffner, & Stern, 2004; Knudson et al., 2007; Lakka et al., 2002; Ritchie & Connell, 2007). Overabundance of abdominal fat is correlated with an amplified risk of cardiometabolic disease (Klein et al., 2007). Waist circumferences greater than forty inches for men and thirty-five inches for women are deemed to be at amplified risk for cardiometabolic disease (Heart and Stroke Foundation of Canada, n.d.; Klein et al., 2007; NHS, 2019; Wang, Rimm, Stampfer, Willett, & Hu, 2005).

Modifiable lifestyle factors include tobacco use (the leading source of avoidable death in the United States is smoking), physical inactivity, stress, and poor diet quality (Mahan, Escott-Stump, & Raymond, 2011). According to the U.S. Department of Health and Human Services (2014), one out of every four deaths from CVD was triggered by smoking (Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, 2020). Tobacco use is most avoidable origin of CVD (GBD 2013 Mortality and Causes of Death Collaborators, 2015; Roy, Rawal, Jabbour, & Prabhakaran, 2017) and the top source of premature mortality from CVD (Roth et al., 2015; Roy, Rawal, Jabbour, & Prabhakaran, 2017). Smoking can affect the cardiovascular system by reducing blood flow from the heart, damaging blood vessels, causing an instant and long-term increase in heart rate, increasing risk for blood clots, causing an instant and long-term rise in blood pressure, reducing the amount of oxygen that reaches the body's tissue, and reducing blood flow to the brain (John Hopkins Medicine, n.d.b). Physical inactivity and sedentary behavior are one of the foremost modifiable risk factors for CVD (Lavie, Ozemek, Carbone, Katzmarzyk, & Blair, 2019). Remaining inactive can contribute to fatty material assembling in your arteries (British Heart Foundation, n.d.b). Chronic stress can lead to chronic problems for the heart and blood vessels and amplifies one's risk for hypertension, stroke, or myocardial infarction (American Psychological Association, 2018). Additionally, chronic stress can lead to inflammation in the circulatory system and affect cholesterol levels (American Psychological Association, 2018).

Diet quality risk factor for CVD. Pertaining to CVD, diet quality assesses the amount of whole grain, sugar-sweetened beverage (SSB), nut, seed, legume, fish, sodium, fruit, vegetable, processed meat, and saturated fat consumed (Benjamin et al., 2019). Mellen, Walsh, & Herrington (2008) found that people with a daily diet of 2.5 or more servings of whole grains were 21% less likely to have cardiovascular disease than people with a weekly diet of less than two servings of whole grains. There is readily available and compelling data for an etiological relationship involving the consumption of SSB with coronary heart disease (CHD) risk (Malik & Hu, 2019). Pacheco et al., (2020) found an association with women (this study did not assess this relationship in men) who had one daily serving or more of SSB with greater risk of CVD. The results of the Guasch-Ferré et al., (2017) study found a statistically significant, 13-19% decreased risk of total CVD for subjects (which included both men and women) who ate tree nuts and peanuts, two or more times and walnuts, one or more times per week. There is significant data (related to the general population, not specific to gender) demonstrating the relationship between the decreased risk of CVD or a substantial decrease in CVD risk factors (e.g. blood pressure or serum cholesterol) with a higher intake (no specific quantity has been identified) of seeds (Ros & Hu, 2013). Multiple studies have conclusively associated a decreased risk of developing CVD risk factors (obesity, diabetes, high blood pressure, or high cholesterol) or CVD disease (heart disease or strokes) with a pattern of eating high amounts of legumes (Bazzano, Thompson, Tees, Nguyen, & Winham, 2011; Hosseinpour-Niazi, Mirmiran, Hedayati, & Azizi, 2014; Jayalath et al., 2013; Jenkins et al., 2012; Ley, Hamdy, Mohan, & Hu, 2014; Tello & Polak, 2018; Viguiliouk, Mejia, Kendall, & Sievenpiper, 2017). Kris-Etherton, Harris, & Appel (2002) recommend individuals with no history of CHD consume oily fish two times or more per week and individuals with a history of CHD consume about one gram of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) preferably from oily fish per day. Meta-analyses found that subjects who consumed greater than five servings of vegetables and fruits per day had close to a 20% decreased risk of stroke (He, Nowson, & Macgregor, 2006) and CHD (He, Nowson, Lucas, & Macgregor, 2007) when assessed with subjects who consumed fewer than three servings per day.

TMAO risk factor for CVD. New research continues to find possible links between red meat and CVD. In current clinical studies conducted with human subjects, the evidence shows a positive relationship between high plasma levels of Trimethylamine N-oxide (TMAO) and greater risk for serious CVD events (Geng et al., 2018; Koeth et al., 2013; Koeth et al., 2014; Mohammadi, Najar, Yaghoobi, Jahani, & Vahabzadeh, 2015; Wang et al., 2011; Wang et al., 2015). TMAO "is a molecule generated from choline, betaine, and carnitine via the gut microbial metabolism." (Janeiro, Ramírez, Milagro, Martínez, & Solas, 2018, p. 1) TMAO is assembled after eating foods that contain the nutrient choline, which is a component of red meat, as well as eggs, fish, and poultry (Harvard Health Publishing, 2019). As the bacteria in the gut interacts with the choline, the molecule trimethylamine (TMA) is formed (Harvard Health

Publishing, 2019). Then, the liver converts TMA into TMAO (Harvard Health Publishing, 2019). Researchers have found that the more red meat that is consumed by an individual, the greater the number of meat-eating bacteria produced in the gut which yields microbes to metabolize meat (Harvard Health Publishing, 2019). This leads to the production of elevated levels of TMAO in the blood, which raises a person's chances of having a myocardial infarction, a stroke, and atherosclerosis (Cleveland Clinic Vascular Team, 2019).

Benefits of Red Meat and Processed Meat

When evaluating the potential risks of a specific food, it helps to assess its possible rewards to help guide any risk versus reward recommendations. First, meat has an abundance of all essential amino acids (building blocks of protein that the human body cannot synthesize) and is one of the most bioavailable (highest digestibility) sources of amino acids making it one of the best quality sources of protein (Cedars-Sinai Staff, 2019; Hoffman & Falvo, 2004). Second, meat not only contains heme iron which is more bioavailable than nonheme iron, it also increases the absorption of nonheme iron (Office of Dietary Supplements, 2019). Third, along with poultry, red meat is one of the best sources of zinc (Mahan, Escott-Stump, & Raymond, 2011). Zinc boosts the immune system's ability to oppose infecting viruses and bacteria, construct DNA and proteins, support wound healing, and is imperative for accurate senses of smell and taste (National Institutes of Health Office of Dietary Supplements, 2019). Fourth, while Vitamin B12 is not found in plant foods, it is found in animal foods like red and processed meats. Vitamin B12 supports the health of blood cells and nerves, assists in building DNA, and aids in prohibiting megaloblastic anemia (National Institutes of Health Office of Dietary Supplements, 2020). Lastly, it could be argued that eating foods that an individual likes or dislikes can affect their quality of life (Loves et al., 2019; Schnettler et al., 2017). While this literature review will not attempt to quantify the enjoyment that people receive from eating red and processed meats, it is important to acknowledge that some people enjoy eating red and processed meats.

General Nutrition Recommendations Regarding Red and Processed Meats

General nutrition recommendations relate to the fat profile of the meat, the methods of cooking meat, decreasing overall intake through portion control, and increasing protein intake from plant foods. It is recommended that if someone chooses to consume red meat that they choose leaner cuts of meat and/or trim fat off to reduce saturated fat intake (Mayo Clinic Staff, 2019). Next, cooking meats by baking, stewing, or roasting is recommended (American Heart Association, 2017b) over grilling or frying. When grilling meat, there is a concern for the production of cancer-causing chemicals (Cedars-Sinai Staff, 2018). The reaction from grilling meat at high temperatures yields polycyclic aromatic hydrocarbons and heterocyclic amines which are recognized as cancer-causing (Harvard Health Publishing, 2007; National Cancer Institute, 2017). Research suggests that recurrent intake of fried foods is correlated with an increased risk of developing type two diabetes, heart failure, hypertension, and obesity (Gadiraju, Patel, Gaziano, & Djoussé, 2015). Finally, meat replacements such as beans, peas, lentils, tofu (soy), or peanut butter are recommended to reduce saturated intake (American Heart Association, 2017b).

If red or processed meat is eaten, there is currently no consensus on the amount that can be eaten without increasing the risk of disease for most people. Hu (as cited in Harvard Health Publishing, 2020) advises that studies demonstrate that people with a relatively low consumption of red and processed meat have decreased risk factors, but that specific amounts of safe intake are open to debate. Additionally, Kopecky (as cited in Williams, 2019) reports that consuming a small amount of red and processed meat likely would not result in trouble, but that consuming as much as you desire will. Hu and Kopecky agree that there is likely an amount of red meat and processed meat that can be safely consumed, but the question is how much? Thun (as cited in Aubrey, 2012) states that leading data indicates that reducing red meat to two to three servings per week is a favorable pattern. However, Johnston (as cited in Rosenbloom, 2019) disclosed that there is not sufficient evidence to provide guidance on the correct amount of red meat to consume.

Moderate Meat Consumption and CVD

While studies have shown a positive relationship between CVD and meat intake, those studies focused on high intake versus low intake of meat. Nagao, Iso, Yamagishi, Date, & Tamakoshi (2012) wanted to find out if there is a relationship between CVD and a moderate intake of meat. Researchers completed a population-based study with over 50,000 men and women aged 40-79 throughout Japan. Starting with a pool of over 100,000 people, researchers excluded participants who reported a past medical history of stroke, heart disease, or cancer, in addition to anyone who didn’t answer at least five questions on the food frequency questionnaire, or they left at least one of the five meat items blank.

Researchers followed the participants for an average of 18.4 years and used mortality end points for death, coded as stroke, total CVD, and ischemic heart disease. The authors excluded subjects whose deaths occurred within 8 years were not included in results to decrease the risk of potential bias from preexisting disease. The participant’s diets were surveyed using a 33-item food frequency questionnaire (FFQ). The FFQ, which listed the following as meat: pork, liver, processed meat, beef, and poultry. The researchers elected to use a validation study of 85 participants to estimate daily portion sizes of the meats listed above. The subjects were placed in one of five quintiles based on total estimated daily meat intake. When analyzing the lowest versus highest quintiles, the only association that researchers found for red (beef and pork) and processed meat was an inverse relationship with ischemic heart disease for males.

This study provides a statistically significant reason to believe that there is an amount of red and processed meat that can be consumed without significantly increasing someone's risk of death from CVD as no significant relationship was found between any of the middle and lowest quintiles; however, there is some caution needed with this study. For instance, the end point was mortality from CVD which means there is the potential that some subjects had CVD that would have prematurely caused death, but death occurred sooner due to another cause. While this study did not provide a recommendation for red and processed meat intake, the fifth quintile (the largest consumption of daily meat) had a median red meat intake of 57.8/43.9 grams per day for males/females and a median processed meat intake of 13.9/10.4 grams per day for males/females. Additionally, eating patterns, way of life, and genetic background in Japan is dissimilar from those in Western countries (Wada et al., 2017). Regarding eating patterns, the Japanese population is reported to eat a considerably lower quantity of meat than that of Western populations (Speedy, 2003).

Total, Processed, and Unprocessed Red Meat and Non-fatal Acute Myocardial Infarction

Studies from high-income countries, such as some European countries and the United States of America, have shown a positive relationship between CVD incidence and red meat consumption (Pan et al., 2012; Rohrmann et al., 2013; Sinha, Cross, Graubard, Leitzmann, &

Schatzkin, 2009; Wang, Campos, & Baylin, 2017). Wang, Campos, & Baylin (2017) conducted a population-based case-control study to assess if the move towards an increasingly Western diet within developing Hispanic/Latino countries is partially the cause for a rise in CVD incidences. Specifically, researchers compared over 2,000 case-control pairs of Hispanic/Latino subjects to assess for any relationship between non-fatal acute myocardial infarction (MI) and total, processed and unprocessed red meat consumption. Potential case subjects were identified by two autonomous cardiologists at one of the six recruiting hospitals as being survivors of an acute MI with no past medical history for a MI. Then control subjects were randomly chosen and paired with case subjects within five years of age, same gender, as well as residents of the same county.

To gather details on subjects, staff administered a closed-ended survey on cigarette smoking, physical activity, medical history, demographic characteristics, alcohol intake, and socioeconomic status. Staff also recorded blood pressure and anthropometric assessments. Finally, they used a semi-quantitative food, to record dietary intake.

After modifying for possible confounders, greater consumption of total and processed red meat was correlated with increased risk of an acute MI. This positive correlation is especially powerful when the aggregate amount of red meat consumption surpasses 110 grams per day or when processed red meat surpasses 36 grams per day. Moreover, these positive correlations were found to be greater in women than in men. There was, however, no statistically significant correlation found with the risk of acute MI and unprocessed red meat consumption. In conclusion, this study demonstrates a need to continue researching the relationship between red meat, especially processed red meat, and CVD as this adds to the mounting evidence that there is a good reason to think that there is a positive relationship between the two.

Comparing Different Food Sources of Protein on Risk for CHD

"The relationship of dietary protein distinguished by animal versus vegetable origin with risk of CHD has shown conflicting results" (Haring, et al., 2014, p. 1). Haring, et al. (2014) conducted a community-based cohort study to research the correlation between CHD and total, animal, and plant-based dietary protein. Over 12,000 white and black subjects, aged 45-64 years old, from one of four U.S. communities, were visited roughly once every three years for a total of 4 visits over a period of about 12 years. Among surviving subjects, a fifth visit occurred about 15 years after the fourth visit. Each visit included a comprehensive examination with a compilation of social, demographic, and medical details. Participants were excluded if they had a reported history of certain CVDs or operations, or diabetes, or had omitted details on covariates of concern, or non-fasting blood glucose of greater than 199 mg/dL, using diabetic medication, or fasting blood glucose of greater than 125 mg/dL.

Haring, et al. (2014) estimated protein consumption twice by utilizing an interviewer administered FFQ adapted from Willet, et al. (1985) at visit one and three. The authors concluded there was no statistically significant correlation between the total or sources (including red or processed meat) of animal or vegetable protein intake and the risk for CHD. This study appears to demonstrate a different conclusion than most studies conducted on the relationship between red and (especially) processed meat intake with CVD in the western diet. It is important to note that these researchers grouped the participants into five quintiles by total protein intake, with the highest quintile reporting an average daily protein intake of 93.5 grams. This is notable because the average total meat intake in the U.S. is 128 grams (Daniel, Cross, Koebnick, & Sinha, 2011) so the participants in this study were consuming less total protein than the average American consumes in meat each day.

Red Meat Intake and Ischemic Heart Disease Mortality or Hemorrhagic Stroke Mortality

"It has been hypothesized that the positive association of red meat intake with the risk of chronic diseases may be attributed to high saturated fatty acid and heme iron content or carcinogens, including heterocyclic amines and *N*-nitroso compounds" (Takata, et al., 2013, p. 1). Contrary to North American and European countries, in Shanghai, China, eating processed meats and grilled meats is rare, and pork is the main segment of overall red meat consumption in lieu of beef. Plus, in China, meats are usually stir-fried or stewed with vegetables, and blood is frequently drained from meat prior to eating (Takata, et al., 2013). Thus, researchers conducted two prospective cohort studies, Shanghai Women's Health Study and Shanghai Men's Health Study (Takata, et al., 2013), to assess if there is a difference in meat consumption and cardiovascular mortality outcomes compared to those observed in European and North American countries.

Takata, et al. (2013) evaluated consumption of red meat (along with other foods) by utilizing a quantitative FFQ that was created and validated independently for men and women. In the study, researchers considered cause of death to be the primary explanation of death disclosed on the death certificate. Subjects were excluded if they had a prior history of cancer, daily caloric intake was out of a 500 to 4,000 calorie range, had no follow up, passed away within the first year of observation, or did not respond to all the questions about smoking history. Over 70,000 females and 60,000 males were analyzed as separate cohorts based on gender and grouped into one of five quintiles corresponding to red meat consumption after adapting for age at baseline of survey.

As expected in the Takata, et al. (2013) study, the vast majority of red meat intake was from pork, 97% for women and 95% for men, with very small intake from beef or lamb. Researchers found no statistically significant correlation between red meat or pork intake and all-CVD mortality for both females and males. However, for specific CVD mortality, researchers found a positive correlation with ischemic heart disease and red meat consumption which was a greater correlation with men than women. In addition, researchers found an inverse correlation with the risk of hemorrhagic stroke mortality and both red meat and pork consumption, meaning as intake went up risk went down. There was a greater correlation with women than men. Notably, authors reported that processed meat was not quantitatively evaluated because the consumption of processed meat was very minimal.

This study, by Takata et al. (2013), provides a contrast to the previous studies completed in countries with a predominately western diet because of the stark differences in consumption of various types of red meat. These results demonstrate that there is a need for further research on not just total red meat intake, but also sources of red meat. The median red meat consumption of the participants in the study was 54 grams and 43 grams per day for men and women, respectively, while the highest quintile for this study consumed an average of 126.0 grams and 103.4 grams per day for men and women, respectively.

Consumption of Red and Processed Meat and Risk of Ischemic Heart Disease

In Europe, the most widespread disease and cause of mortality is ischemic heart disease (Key, et al., 2019). While there is some doubt regarding the importance of the consumption of foods from animals in relation to the risk of ischemic heart disease, meat is a large source of dietary saturated fat intake in the United Kingdom, accounting for twenty-four percent of saturated fat intake (Key, et al., 2019). This is noteworthy because significant consumption of saturated fats has been shown to increase circulating low-density lipoprotein cholesterol, which is a known risk factor of ischemic heart disease (Key, et al., 2019). Key, et al. (2019) analyzed the association of foods from animals and the risk of ischemic heart disease using European Prospective Investigation Into Cancer and Nutrition (EPIC), a prospective European cohort of about half a million men and women from ten different countries in Europe.

The subjects in EPIC filled out both lifestyle and dietary questionnaires. Dietary assessments were completed via food frequency questionnaires and were validated by randomly collecting a twenty-four-hour recall from eight percent of the subjects. Lifestyle assessments, established with baseline questionnaires, gathered information about the number of cigarettes smoked per day, alcohol consumed per day, current physical activity level, the highest education achieved, state of employment, and past medical history of hypertension, hyperlipidemia, and diabetes mellitus. Additionally, most of the EPIC subjects had their blood pressure taken and gave blood samples. Subjects were excluded if there was no lifestyle or diet information documented, in the highest or lowest one percent of the energy intake-to-energy requirement ratios, reported or had an unknown medical history of stroke or myocardial infarction at baseline, missing follow-up information, or had unknown data for any of the foods from animals.

The analysis found that EPIC subjects who experienced a myocardial infarction or death caused by ischemic heart disease were six to ten years older than the mean for their cohort, had above average BMI and below average alcohol consumption; were more likely to smoke, be sedentary, not be employed; or have diabetes mellitus, high blood pressure, high proatherogenic lipid levels, and below average detected vegetable and fruit consumption. This analysis revealed a positive relationship for red and processed meat consumption with the risk of ischemic heart disease. However, there was not a statistically significant positive relationship between any other types of animal food with ischemic heart disease, meaning there could be a difference between the particular sources of saturated fats or unique measurements of individual saturated fatty acids found in different sources of food from animals. This study demonstrates that the totality of the different components of red and processed meat could have an effect on CVD beyond just the saturated fat since other large sources of saturated fat from animal foods did not result in a positive association with ischemic heart disease.

Consumption of Red Meat and Risk of Stroke in Men

Studies have suggested that a high intake of red meat, especially processed meat, could be a risk factor for CHD (Bernstein et al., 2010; Micha, Wallace, & Mozaffarian, 2010; Sinha, Cross, Graubard, Leitzmann, & Schatzkin, 2009). While red meat intake may be a risk factor for stroke, research on the association of red meat intake to stroke occurrence or mortality is scarce and findings are varying (Fung et al., 2004; He et al., 2003; Larsson, Virtamo, & Wolk, 2011a; Sauvaget, Nagano, Allen, Grant, & Beral, 2003). Larsson, Virtamo, & Wolk (2011a) had previously concluded that there was a positive relationship between high processed meat intake and greater risk for of stroke in cohort of Swedish women. To the researcher's awareness just two prior studies had inspected the association between red meat intake and stroke occurrence or mortality in men (Larsson, Virtamo, & Wolk, 2011b). Thus, Larsson, Virtamo, & Wolk (2011b) conducted a study to research the relationship of fresh red meat and processed meat intake with occurrence of stroke in a prospective cohort of Swedish men.

Researchers surveyed 45 to 79-year-old men residing in two counties of central Sweden (Larsson, Virtamo, & Wolk, 2011b). The survey included roughly 350 items regarding dietary intake and lifestyle factors. Every subject was followed until date of first stroke or death for up to ten years. When comparing the highest quintile of total red meat intake, fresh red meat intake, and processed meat intake with the lowest quintile, the results yielded positive relationship with (high intake of meat connected to high intake of the following) total energy, alcohol, monounsaturated fat, polyunsaturated fat, fish, fruit, vegetable, whole grain, and dairy food intake. Additionally, when comparing the quintiles, the highest quintile was less likely to possess a university education and had a larger BMI. While the researchers found no statistically suggestive data yielding a dose-response relationship between total red meat intake and the risk of cerebral infarction, hemorrhagic stroke, or total stroke; when comparing the highest quintile of red meat to the lowest quintile, there was statistically suggestive data yielding a greater risk for hemorrhagic stroke and total stroke. Furthermore, the authors found no relationship with fresh red meat intake and any stroke subtype or total stroke but found a positive relationship with processed meat intake and cerebral infarction and total stroke (Larsson, Virtamo, & Wolk, 2011b).

Authors found that for every fifty-gram increase of daily processed meat intake, that there was an eight percent increase in risk for stroke (Larsson, Virtamo, & Wolk, 2011b). Moreover the authors surmised that since there was a positive relationship for the risk of stroke and processed meat, but not with fresh meat, that the cause is probably linked to the sodium and/or nitrite found in processed meat versus the heme iron and cholesterol found in both fresh and processed meat. As previously noted, different populations may generally consume different amounts of red or processed meats. In this study, the highest quintile for fresh meat was greater than 83.1 grams daily. While there was no statistically significant relationship found, the highest quintile in this study was less than the average daily consumption of 99.8 grams for people living in the U.S. (Daniel, Cross, Koebnick, & Sinha, 2011). Regarding processed meat, the highest quintile was greater than 57.1 grams daily (Larsson, Virtamo, & Wolk, 2011b), which is higher than the average daily consumption of 28.2 grams for people living in the U.S. (Daniel, Cross, Koebnick, & Sinha, 2011).

Conclusion

As mentioned previously, CVD is a major inhibiting factor to the overall health of humans. While there is an abundance of research demonstrating a link between red meat and processed meat to CVD, there is also contradictory research showing no statistically significant relationship. The plausible explanation between the different results in the Nagao, Iso, Yamagishi, Date, Tamakoshi (2012), Wang, Campos, & Baylin (2017), and Haring, et al. (2014) studies are that the total consumption of red meat and processed meat of the participants matter. Specifically, Nagao, Iso, Date, Tamakoshi (2012) and Haring, et al. (2014) results may not have been founded to be a statistically significant correlation due to the lower red and processed meat intake reported by their subjects compared to Wang, Campos, & Baylin (2017) finding a statistically significant correlation with a higher red and processed meat intake reported. Given the analysis of these studies, it is possible that the daily recommendation for red meat is in between 44/58 grams (female/male) and 110 grams or for processed meat is in between 10/14 grams (female/male) and 36 grams to avoid a statistically significant increase in risk of CVD. Also, Key, et al. (2019) showed that red and processed meats resulted in increased risk while other sources of animal foods did not, thus providing some evidence that different types of animal foods can have different risk factors. Specifically, Takata, et al. (2013) showed evidence that perhaps more research is warranted in comparing different sources of red meat, in addition to different cooking and preserving methods as this was the only study reviewed in this paper that established a lower percentage of red meat coming from beef or lamb than pork.

This literature review can be used in practice to establish an amount of red or processed meat intake that is acceptable, based on some research, in regard to not increasing the risk of CVD. Additionally, this information can be used to demonstrate guidance for future research that can help answer the question of what amount of red or processed meat consumption is not correlated with CVD, statistically. Finally, this current research can aid dietitians in putting the focus on moderate consumption of red and processed meat, versus elimination of it, for patients or clients who are looking for science-based evidence to answer this question.

Chapter 3: Methodology

There is currently no consensus on how much red meat and processed meat can be consumed each day without significantly increasing the risk of CVD in adults. A 2019 study concluded that there is no association between red meat and processed meat with CVD (Zeraatker, et al., 2019). The leading authorities on CVD, like the American Heart Association, who recommend that people *limit* red meat and *minimize* processed meat, do not quantify how much is safe to consume without increasing the risk of developing CVD. This chapter will cover the methodology of a proposed retrospective cohort study to help assess what quantifies as *limited* and *minimized* intake. Specifically, the following chapter will provide a thorough description of the proposed research design, setting and sample, instrumentation, data analysis plan, threats to validity, and ethical procedures.

Research Design

This proposed retrospective cohort study is designed to examine two research questions.

- *Research question* – Is there a higher prevalence of CVD among people age 40 to 85 years old who consume greater than or equal to 45 grams of red meat daily?
    - *Null hypothesis I* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and moderate intake of red meat and the prevalence of CVD.
    - *Null hypothesis II* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and high intake of red meat and the prevalence of CVD.
    - *Research hypothesis I* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a moderate red meat intake as compared to those who consume a low red meat intake, due to a positive relationship between red meat intake and prevalence of CVD.
    - *Research hypothesis II* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a high red meat intake as compared to those who consume a low red meat intake, due to a positive relationship between red meat intake and prevalence of CVD.

Table 1

Categorization of Variables for Red Meat and CVD Relationship

Type of Variable	Variable
Independent Variable	Red Meat intake
Dependent Variable	CVD diagnosis
Mediating Variables	Saturated Fat intake and TMAO production
Confounding Variables	Dyslipidemia, hypertension, metabolic syndrome, poor diet quality, stress and depression
Controlled Variables	Age and gender, family history and genetics, diabetes mellitus, obesity (determined by waist circumference), tobacco use, physical inactivity, race, and low socioeconomic status

- *Research question* – Is there a higher prevalence of CVD among people age 40 to 85 years old who consume greater than or equal to 10 grams of processed meat daily?
    - *Null hypothesis I* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and moderate intake of processed meat and the prevalence of CVD.
    - *Null hypothesis II* – In individuals age 40 to 85 years old, there is no relationship between the consumption of low and high intake of processed meat and the prevalence of CVD.
    - *Research hypothesis I* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a moderate processed meat intake as compared to those who consume a low processed meat intake, due to a positive relationship between processed meat intake and prevalence of CVD.
    - *Research hypothesis II* – There is a greater incidence of CVD among people between 40 and 85 years old who consume a high processed meat intake as compared to those who consume a low processed meat intake, due to a positive relationship between processed meat intake and prevalence of CVD.

Table 2

Categorization of Variables for Processed Meat and CVD Relationship

Type of Variable	Variable
Independent Variable	Processed Meat intake
Dependent Variable	CVD diagnosis
Mediating Variables	Saturated Fat intake, Sodium intake, and TMAO production
Confounding Variables	Dyslipidemia, hypertension, metabolic syndrome, poor diet quality, stress and depression
Controlled Variables	Age and gender, family history and genetics, diabetes mellitus, obesity (determined by waist circumference), tobacco use, physical inactivity, race, and low socioeconomic status

Setting and Sample

Sample size. A sample of 384 total subjects will be required to yield results with a 95% confidence interval of +/- 5 according to the Creative Research Systems (2012) sample size calculator. With initial enrollment of 642 subjects (107 subjects from each of six unique locations), only 60% of the subjects (Fincham, 2008) will need to reach an endpoint in order to have at least 384 subjects complete this study.

Population. Clustered sampling will be utilized to increase efficiency of obtaining requested information. The clusters will include six different geographical areas chosen to represent all races, genders, socioeconomic levels, and ages. By sampling this way, most data can be obtained in only six locations. In 2019, Wallet Hub ranked the 501 most populated cities in the United States by diversity (McCann, 2019). The finance website analyzed household, religious, socioeconomic, cultural, and economic diversity to rank the cities. First, this list was utilized to choose Houston, Texas (ranked #1 overall) due to being the most diverse large city and a southern city. Second, Jersey City, New Jersey (ranked #2 overall) was chosen due to being the most diverse midsize city and a northeastern city. Third, Gaithersburg, Maryland (ranked #4 overall) was chosen due to being the most diverse small city. Fourth, Los Angeles, California (ranked #8 overall) was chosen due to being the most diverse western city. Fifth, Sandy Springs, Georgia (ranked #12 overall) was chosen due to being the most diverse southeastern city. Sixth, Chicago, Illinois (ranked #13 overall) was chosen for being the most diverse midwestern city. By focusing on cities with diverse locations, it is not a guarantee a diverse population will be reached. However, the probability of reaching a diverse population is increased by this method over focusing on less diverse locations.

Recruitment. Recruitment will include randomly selecting five zip codes for each chosen city, sending mass mailing explaining the purpose of the study, and requesting that everyone between 45 and 85 years old respond by returning the postage paid response card, or visiting SurveyMonkey (2020) website link provided in the mailing, to express interest in participating in the study. Recruitment will end three weeks after the recruitment message is delivered to each zip code. If at the end of three weeks, any chosen city has less than 107 subjects, then another recruitment mass mailing will be sent to five randomly selected zip codes in that corresponding city. This process will continue until each city has at least 107 subjects who express interest in participating in this study.

Instrumentation

Each subject will be sent the Harvard T.H. Chan School of Public Health semi-quantitative food frequency questionnaire. The adult general version was designed for self-administration (see Appendix A). This questionnaire has been validated multiple times (Harvard T. H. Chan School of Public Health. Department of Nutrition, 2015). Additionally, a non-validated form will be included to gather information about age, gender, weight, height, race, ethnicity, education level, income level, occupation, family size/household composition (to calculate federal poverty level for determining socioeconomic levels), physical activity level, smoking usage, waist circumference, if respondents have a first -degree relative who has been diagnosed with CVD (and at what age), and if they have been diagnosed with CVD or diabetes (see Appendix B). LimeSurvey will be utilized for subjects who prefer to complete their survey online (Schmitz, 2020). Lastly, every subject will receive a soft tape measure for use in measuring waist circumference and the option to have a pictorial handout or access a video online to help guide the measuring process. For every subject who does not choose an option, the default will be to send a pictorial handout for those who chose to fill out the paper survey and send the link to the online video for those who chose to fill out the online survey.

Data Collection

Every submitted questionnaire will be reviewed by the author for completeness. If any questions are left blank regarding independent, dependent, or controlled variables, the questionnaire will be deemed incomplete and the corresponding subject will be excluded from the study. All completed FFQs will be sent to Harvard University for nutrient analysis of the questionnaires in Excel format. The author will create Excel spreadsheets for each subject and input all the information from the demographic questionnaire (see Appendix B). Additionally, the author will keep a separate list that connects the identifying number in excel with the actual personal identifying information of the subjects. After the author combines the demographic/health history information with the FFQ analysis for each subject, the author will use the combined Excel spreadsheets for final analysis. The author will utilize the help of a local statistician to aid in running statistical analysis.

Data Analysis Plan

Descriptive statistics. The demographics of the subjects in this study will be compared to that of the 40 to 85-year olds living throughout the United States to assess how reflective these subjects are to the general population. This information will be used to assess whether there are any significant differences ($p < 0.05$) between the characteristics of each red and processed meat intake group (low, middle, and high). If there are any significant differences, the data will be used in the inferential statistics to control for those variables as they are known to be CVD risk factors since they could, in part, explain some differences in CVD diagnosis for each group. The controlled risk factors, as seen in table 1 and table 2, will include age, gender, race, ethnicity, education level, socioeconomic level (see table 3), physical activity level, smoking usage, waist circumference, first degree relative with premature cardiovascular disease, and diagnosis of diabetes. Each of the forementioned controlled risk factors will be grouped as seen in table 4 for data analysis.

Table 3

Scoring for Socioeconomic Level

Measure	Index
Education	0: Less than high school
	1: High school, some college, associate's degree
	2: Bachelor's degree
	3: Master's professional, doctorate degree
	Possible range: 0-3
Income (percentage of Federal poverty level)	0: 100% or less
	1: 101%-200%
	2: 201%-400%
	3: 401% or greater
	Possible range: 0-3
Employment	0: Unemployed past 6 months
	1: Employed past 6 months
	Possible range: 0-1

*Score of 0-2 represents low socioeconomic level, 3-5 represents middle socioeconomic level, 6-7 represents high socioeconomic level

Table 4

Controlled Variables for Analysis of Red Meat and Processed Meat Intake Related to CVD Diagnosis

Variable	Categories for Each Variable
Age	40-54
	55-69
	70-85
Gender	Male
	Female
Race	American Indian or Alaska Native
	Asian
	Black
	Native Hawaiian or other Pacific Islander
	White
	2 or more races
Ethnicity	Hispanic or Latino
	Not Hispanic or Latino
Education Level	< High School Diploma or Equivalent
	High School Diploma or Equivalent
	> High School Diploma or Equivalent
Socioeconomic Level	Low
	Middle
	High
Physical Activity Level	</= 150 Minutes of Moderate or Vigorous Physical Activity per Week
	> 150 Minutes of Moderate or Vigorous Physical Activity per Week
Smoking Usage	< Once per Month
	>/= Once per Month and < Once per day
	>/= Once per Day
Waist Circumference	Men < 40”
	Men >/= 40”
	Women < 35”
	Women >/= 35”
1st Degree Relative with Premature CVD	Yes
	No
Has Diabetes	Yes
	No

Inferential statistics. Comparative analysis with Chi-Square will be conducted to assess whether any characteristics were related to red meat or processed meat intake. All characteristics will be compared to red meat (low, moderate, high intake) and processed meat (low, moderate, high intake). Relational analysis with Logistic Regression (odds ratio) will be completed to assess total red meat intake with diagnosis of CVD and total processed meat intake with the diagnosis of CVD (see Table 5). If any controlled risk factors (see Table 4) are found to be statistically significant ($P < 0.05$) it will be added to the logistic regression to adjust the odds ratio to eliminate the effects of that confounding risk factor.

Table 5

Relational Analysis of Red Meat and Processed Meat Intake with Diagnosis of CVD

Dependent Variable (Responses)	Independent Variable (Responses)	Statistical Test	Level of Measurement*
CVD (Yes, No)	Red Meat (Low, Moderate, or High Consumption)	Logistic Regression Test	Ordinal
CVD (Yes, No)	Processed Meat (Low, Moderate, or High Consumption)	Logistic Regression Test	Ordinal

*$P < 0.05$

Threats to Validity

- Selection of study subjects will not be free from bias: Since subjects are not randomly selected, there may be selection bias related to who volunteers for this study.
- Study groups may not be comparable: Authors will not know before recruitment of subjects if groups are comparable on important confounding factors.
- Measurements may not be reliable: Since the study will apply food intake over the past year to the subject's intake over previous years as well, changes over time will not be reflected. Next, subjects may experience fatigue with filling out the long questionnaire which may lead to less thoughtful responses in an effort to complete the questionnaire quicker. Additionally, all information will rely on the subject's memory which can result in recency bias. Finally, subjects are asked to measure their waist circumference with a non-validated tool and with no prior training may result in inaccurate reported measurements.

Ethical Procedures

In order to protect the privacy of the subjects, a few protocols will be established. First, all protected health information will be required to be electronically stored on a secure computer (provided by the study so no information is ever on personal computers) or physically stored in a locked cabinet or drawer designated only for this study. Additionally, all subjects will be assigned an ID number so all data can be transmitted without the inclusion of the subject's name. This will reduce exposure of personal identifying information. Finally, an IRB application (see Appendix C) will be approved prior to starting the study and each subject will be required to complete an informed consent (see Appendix D).

Summary

To help quantify how much red meat and processed meat can be consumed without significantly increasing the risk of CVD, male and female subjects between 40 and 85 years old will be observed in a retrospective cohort study. Clustered sampling will be utilized in six different areas of the United States to attempt to have all races, genders, socioeconomic levels, and ages represented. It is anticipated that 384 total subjects will be needed to yield results with a 95% confidence interval of +/- 5. In order to achieve said results, 107 subjects will be included from each of the six cities to allow for up to a 40% nonresponse rate. The author will obtain and assess the semi-quantitative food frequency questionnaire, physical activity levels, smoking usage, demographics, and waist circumference for completeness.

Comparative analysis with Chi-Square will be conducted to assess if any controlled variables were associated with the independent variable, red meat intake or processed meat. Relational analysis with Logistic Regression (odds ratio) will be conducted to compare total red meat intake with diagnosis of CVD and total processed meat intake with the diagnosis of CVD.

Chapter 4: Anticipated Results

Demographics

Predicted results of the demographics of the study subjects and the general United States population are displayed in Table 6. It is anticipated that by targeting diverse cities, Hispanics or Latinos will represent a portion of the participants that is eleven percent greater than their portion of the United States (U.S.) population ($P = 0.02$). Additionally, it is anticipated that the participants of this study will represent 14.6% more individuals with high school diploma or equivalent education as compared to the U.S. population ($P = 0.03$).

Table 6

Demographics of Study Participants Compared with United States of America's 40-85-Year-Old Population

Demographic	% Participants	% U.S. Population	Difference	P value*
Gender				0.97
Male	47.7	47.9[a]	-0.2	
Female	52.3	52.1[a]	+0.2	
Race				0.60
American Indian or Alaska Native	0.9	0.7[b]	+0.2	
Asian	5.5	3.9[b]	+1.6	
Black	13.5	9.0[b]	+4.5	
Native Hawaiian or Other Pacific Islander	0.2	0.1[b]	+0.1	
White	76.1	85.5[b]	-9.4	
Two or More Races	3.7	0.8[b]	+2.9	
Ethnicity				0.02
Hispanic or Latino	18.6	7.6[b]	+11.0	
Not Hispanic or Latino	81.4	92.4[b]	-11.0	
Education Level				0.03
< High School Diploma or Equivalent	7.1	16.5[c]	-9.4	
High School Diploma or Equivalent	46.1	31.5[c]	+14.6	
> High School Diploma or Equivalent	46.8	52.0[c]	-5.2	

[*] P-values were derived from Chi-square test
[a](Howden & Meyer, 2011)
[b]65-84 years old (Ortman, Velkoff, & Hogan, 2014)
[c]65 years old and older (Roberts, Ogunwole, Blakeslee, & Rabe, 2018)

Red Meat Intake and Controlled Variables

Predicted results between risk factors and red meat intake are displayed in Table 7 and Table 8. It is anticipated that this study will demonstrate a significant relationship between race and red meat intake ($P < .01$).

Table 7

Demographic Characteristics of Subjects with Red Meat Intake

	Total n = 436	Low consumption n = 37	Moderate consumption n = 171	High consumption n = 228	P-value*
Age					0.740
40-54	113 (25.9)	8 (21.6)	47 (27.5)	58 (25.4)	
55-69	173 (39.7)	13 (35.1)	70 (40.9)	90 (39.5)	
70-85	150 (34.4)	16 (43.2)	54 (31.6)	80 (35.1)	
Gender					0.825
Male	208 (47.7)	17 (45.9)	79 (46.2)	112 (49.1)	
Female	228 (52.3)	20 (54.1)	92 (53.8)	116 (50.9)	
Race					< 0.001
American Indian or Alaska Native	4 (0.9)	0 (0.0)	1 (0.6)	3 (1.3)	
Asian	24 (5.5)	3 (8.1)	11 (6.4)	10 (4.4)	
Black or African American	59 (13.5)	5 (13.5)	32 (18.7)	22 (9.6)	
Native Hawaiian or Other Pacific Islander	1 (0.2)	1 (2.7)	0 (0.0)	0 (0.0)	
White	332 (76.1)	26 (70.3)	126 (73.7)	180 (78.9)	
2 or more races	16 (3.7)	2 (5.4)	1 (0.6)	13 (5.7)	
Ethnicity					0.665
Hispanic or Latino	81 (18.6)	6 (16.2)	29 (17.0)	46 (20.2)	
Not Hispanic or Latino	355 (81.4)	31 (83.8)	142 (83.0)	182 (79.8)	
Education Level					0.107
< High School Diploma or Equivalent	31 (7.1)	4 (10.8)	15 (8.8)	12 (5.3)	
High School Diploma or Equivalent	201 (46.1)	16 (43.2)	67 (39.2)	118 (51.8)	
> High School Diploma or Equivalent	204 (46.8)	17 (45.9)	89 (52.0)	98 (43.0)	
Socioeconomic Level					0.942
Low	126 (28.9)	10 (27.0)	47 (27.5)	69 (30.3)	
Middle	228 (52.3)	19 (51.4)	90 (52.6)	119 (52.2)	
High	82 (18.8)	8 (21.6)	34 (19.9)	40 (17.5)	

Values in this table represent n (%)
*P-values were derived from Chi-square test

Table 8

Health Related Characteristics of Subjects with Red Meat Intake

	Total n = 436	Low consumption n = 37	Moderate consumption n = 171	High consumption n = 228	P-value*
Physically Activity Level					0.133
</= 150 Minutes of Moderate or Vigorous Physical Activity per Week	260 (59.6)	21 (56.8)	112 (65.5)	127 (55.7)	
> 150 Minutes of Moderate or Vigorous Physical Activity per Week	176 (40.3)	16 (43.2)	59 (34.5)	101 (44.3)	
Smoking Usage					0.996
< Once per Month	382 (87.6)	32 (86.5)	150 (87.7)	200 (87.7)	
>/= Once per Month and < Once per Day	18 (4.1)	2 (5.4)	7 (4.1)	9 (3.9)	
>/= Once per Day	36 (8.3)	3 (8.1)	14 (8.2)	19 (8.3)	
Waist Circumference					1.000
Men < 40”	117 (26.8)	10 (27.0)	46 (26.9)	61 (26.8)	
Men >/= 40”	91 (20.9)	7 (18.9)	36 (21.1)	48 (21.1)	
Women < 35”	128 (29.4)	12 (32.4)	49 (28.7)	67 (29.4)	
Women >/= 35”	100 (22.9)	8 (21.6)	40 (23.4)	52 (22.8)	
1st Degree Relative with Premature CVD					0.797
Yes	37 (8.5)	4 (10.8)	13 (7.6)	20 (8.8)	
No	399 (91.5)	33 (89.2)	158 (92.4)	208 (91.2)	
Has Diabetes					0.999
Yes	46 (10.6)	4 (10.8)	18 (10.5)	24 (10.5)	
No	390 (89.4)	33 (89.2)	153 (89.5)	204 (89.5)	

Values in this table represent n (%)
*P-values were derived from Chi-square test

Processed Meat Intake and Controlled Variables

Predicted results between risk factors and processed meat intake are displayed in Table 9 and Table 10. It is anticipated that this study will yield a significant relationship between gender and processed meat intake ($P < .01$), race and processed meat intake ($P < 0.1$), smoking usage and processed meat ($P < .01$), waist circumference and processed meat intake ($P < .01$), as well as diabetes and processed meat ($P < .03$).

Table 9

Demographic Characteristics of Subjects with Processed Meat Intake

	Total n = 436	Low consumption n = 109	Moderate consumption n = 196	High consumption n = 131	P-value*
Age					0.563
40-54	113 (25.9)	23 (21.1)	51 (26.0)	39 (29.8)	
55-69	173 (39.7)	43 (39.4)	80 (40.8)	50 (38.2)	
70-85	150 (34.4)	43 (39.4)	65 (33.2)	42 (32.1)	
Gender					< 0.001
Male	208 (47.7)	34 (31.2)	102 (52.0)	72 (55.1)	
Female	228 (52.3)	75 (68.8)	94 (48.0)	59 (44.9)	
Race					< 0.001
American Indian or Alaska Native	4 (0.9)	1 (0.9)	2 (1.0)	1 (0.8)	
Asian	24 (5.5)	11 (10.0)	10 (5.1)	3 (2.2)	
Black or African American	59 (13.5)	10 (9.2)	29 (14.8)	20 (15.3)	
Native Hawaiian or Other Pacific Islander	1 (0.2)	0 (0.0)	1 (0.5)	0 (0.0)	
White	332 (76.1)	78 (71.6)	148 (75.5)	106 (80.9)	
2 or more races	16 (3.7)	9 (8.3)	6 (3.1)	1 (0.8)	
Ethnicity					0.165
Hispanic or Latino	81 (18.6)	16 (14.7)	44 (22.4)	21 (16.0)	
Not Hispanic or Latino	355 (81.4)	93 (85.3)	152 (77.6)	110 (84.0)	
Education Level					0.294
< High School Diploma or Equivalent	31 (7.1)	10 (9.2)	15 (7.7)	6 (4.6)	
High School Diploma or Equivalent	201 (46.1)	42 (38.5)	96 (49.0)	63 (48.1)	
> High School Diploma or Equivalent	204 (46.8)	57 (52.3)	85 (43.4)	62 (47.3)	
Socioeconomic Level					0.794
Low	126 (28.9)	29 (26.6)	58 (29.6)	39 (29.8)	
Middle	228 (52.3)	55 (50.5)	104 (53.1)	69 (52.7)	
High	82 (18.8)	25 (22.9)	34 (17.3)	23 (17.6)	

Values in this table represent n (%)
*P-values were derived from Chi-square test

Table 10

Health Related Characteristics of Subjects with Processed Meat Intake

	Total n = 436	Low consumption n = 109	Moderate consumption n = 196	High consumption n = 131	P-value*
Physically Activity Level					0.194
</= 150 Minutes of Moderate or Vigorous Physical Activity per Week	260 (59.6)	57 (52.3)	121 (61.7)	82 (62.6)	
> 150 Minutes of Moderate or Vigorous Physical Activity per Week	176 (40.3)	52 (47.8)	75 (38.3)	49 (37.4)	
Smoking Usage					0.002
< Once per Month	382 (87.6)	101 (92.7)	178 (90.8)	103 (78.6)	
>/= Once per Month and < Once per Day	18 (4.1)	3 (2.8)	8 (4.1)	7 (5.3)	
>/= Once per Day	36 (8.3)	5 (4.6)	10 (5.1)	21 (16.0)	
Waist Circumference					< 0.001
Men < 40”	117 (26.8)	31 (28.4)	55 (28.1)	31 (23.7)	
Men >/= 40”	91 (20.9)	21 (19.3)	38 (19.4)	32 (24.4)	
Women < 35”	128 (29.4)	46 (41.9)	60 (30.6)	22 (16.8)	
Women >/= 35”	100 (22.9)	11 (10.4)	43 (21.9)	46 (35.1)	
1st Degree Relative with Premature CVD					0.399
Yes	37 (8.5)	12 (10.8)	13 (6.6)	12 (8.8)	
No	399 (91.5)	97 (89.2)	183 (93.4)	119 (91.2)	
Has Diabetes					0.026
Yes	46 (10.6)	6 (5.5)	19 (9.7)	21 (16.0)	
No	390 (89.4)	103 (94.5)	177 (90.3)	110 (84.0)	

Values in this table represent n (%)
*P-values were derived from Chi-square test

Independent and Dependent Variables

Predicted results between red meat and processed meat consumption with diagnoses of CVD are displayed in Table 11. Predicted results showed that there would be an increased risk for CVD with moderate versus low consumption of red meat (OR: 1.038, 95% CI: 1.009-1.069; $P = .01$), high versus low consumption of red meat (OR: 2.062, 95% CI: 2.021-2.105; $P < .01$), moderate versus low consumption of processed meat (OR: 1.010, 95% CI: 1.005-1.016; $P < .01$), and high versus low consumption of processed meat (OR: 1.950, 95% CI: 1.927-1.974; $P < .01$).

Table 11

Comparison of Red Meat or Processed Meat to CVD

	Has CVD n = 209	No CVD n = 227	P-value*	Odds ratio**
Red Meat				
Low Consumption n =37	9 (4.3)	28 (12.3)		
Moderate Consumption n = 171	82 (39.2)	89 (39.2)		
High Consumption n = 228	118 (56.5)	110 (48.5)		
Low Consumption vs Moderate Consumption			0.011	1.038 (1.009-1.069)
Low Consumption vs High Consumption			0.002	2.062 (2.021-2.105)
Processed Meat				
Low Consumption n = 109	33 (15.8)	76 (33.5)		
Moderate Consumption n = 196	101 (48.3)	95 (41.9)		
High Consumption n = 131	75 (35.9)	56 (24.7)		
Low Consumption vs Moderate Consumption			< 0.001	1.010 (1.005-1.016)
Low Consumption vs High Consumption			< 0.001	1.950 (1.927-1.974)

Values in this table represent n (%)
*P-values were derived from Logistic regression test
**Odds ratio were derived from Logistic regression test (95% confidence interval)

Chapter 5: Discussion

Based on the anticipated results, both null hypotheses II would be rejected and both null hypotheses I would warrant further investigation. Compared to the low red meat consumption group, the people in the high red meat consumption group had a 106% increased risk (or about twice as likely) of having CVD. Similarly, compared to the low processed meat consumption group, the people in the high processed meat consumption had a 95% increased risk (or about twice as likely) of having CVD. For comparison, it is approximated that smoking raises the risk of CHD and stroke by 100% (World Heart Federation, 2017). In this study, an individual eating a high consumption of red or processed meat increased their risk compared to an individual eating a low consumption of red or processed meat by close to the level that is estimated that smoking increases the risk for CVD.

It is anticipated that this study will not find as large of an increased risk for CVD between the moderate red or processed meat consumption group compared to low red or processed meat consumption group as anticipated between high red or processed meat consumption group compared to low red or processed meat consumption group. Compared to the low red meat consumption group, the people in the moderate red meat consumption group had close to a 4% increased risk of having CVD. Similarly, compared to the low processed meat consumption group, the people in the moderate processed meat consumption had a 1% increased risk of having CVD. While it is anticipated that both moderate consumption groups will demonstrate an increased risk compared to both low consumption groups, with neither anticipated to demonstrate an increased risk above 4%, further research is recommended before advocating a specific range to the U.S. population. Even though it is predicted that this study will not demonstrate the upper range for recommended red and processed meat intake, it is predicted that it will demonstrate that it is unlikely that less than 45 grams of red meat and less than 10 grams of processed meat daily will significantly increase the risk of CVD for Americans between 40 and 85 years old.

Comparisons with Published Studies

The anticipated results align with numerous past studies which show that higher risk of CVD is associated with high intake of red meat or processed meat (Kelemen, 2005; Key, et al., 2019; Larsson, Virtamo, & Wolk, 2011b; Micha, Wallace, & Mozaffarian, 2010; Sinha, Cross, Graubard, Leitzmann, & Schatzkin, 2009; Wang, Campos, & Baylin, 2017), or no association with low intake of red meat or processed meat and CVD (Appleby, Key, Thorogood, Burr, & Mann, 2002; Fraser, 1999; Key et al., 1998; Key et al., 1999; Key et al., 2009). While Nagao, Iso, Yamagishi, Date, & Tamakoshi (2012) found that men with a higher intake of red meat and processed meat had a higher risk for mortality from ischemic heart disease (a type of CVD) than men with lower intake, researchers did not demonstrate this association with females. Haring, et al., (2014) did not find any association between red meat or processed meat with CVD, but the highest quintile of meat consumption would qualify as moderate intake based on this study's definition; therefore, while this differs from this study's anticipated result for moderate intake, there was no comparison of high intake.

Finally, it is anticipated that relationships will be seen between red meat intake and race in addition to processed meat intake and gender, as well as processed meat and race, smoking usage, waist circumference, and diabetes. This is similar with Nagao, et al. (2012) who found a relationship between history of diabetes and total meat consumption. Also, this study agrees with Wang, Campos, & Baylin (2017) who found a relationship between CVD and waist:hip ratio as well as CVD and history of diabetes. They also found a relationship, however, between CVD and physical activity. This differs from Takata et al. (2013), who found an association with red meat intake and age, smoking history, and education. If the actual results mirror the anticipated results, it would be recommended that more research be conducted to assess these relationships. Until these relationships are further investigated, when educating patients who are at risk for CVD, it appears that there may be additional benefit in taking time to discuss reduction of red meat in the diet of white patients and processed meat in the diet of male, currently smoking, history of diabetes, and/or obese (as defined by waist circumference) patients.

Strengths and Weaknesses

The strengths of this study include the use of multiple sample areas throughout the United States and being the first study of its kind. By having multiple sample areas, more people can be included in different regions of the United States. This may account for variables that can be affected by living in different locations. No studies were identified that assessed red meat and processed meat intake with the diagnosis of CVD over the past ten years in diverse areas of the United States. Therefore, there is currently not adequate evidence to provide a recommended intake of red meat or processed meat that people can eat without expecting a significantly increased risk of developing CVD. This study would help expand the research needed to be able to best advise people (using evidence-based methods) on how much red meat or processed meat is likely deemed safe for someone concerned about development of CVD.

The limitations of this study include a non-validated questionnaire, self-selection bias, and recall bias. While the food frequency questionnaire was validated, the demographic questionnaire was not validated so the way the questions were written or the way the form was designed may have led subjects to answer the questions differently than the author intended. Perhaps future work might build upon the questionnaire created for this study to form a validated form for assessing demographics and medical history for upcoming nutritional studies. Next, self-selection bias is possible since subjects "opted-in" to participating in this study. This could have led to an increased number of homogeneous participants while also leading to a decreased number of a different homogeneous non-participants. Thus, the author acknowledges that this study could end up having some selection bias that could limit generalization of the figures to the wide-ranging U.S. population. However, apart from ethnicity and education levels, most of the tracked demographics linked to CVD are anticipated to be similar to the general U.S. population. A retrospective design is susceptible to recall bias since it relies on a subject's memory to provide past dietary intake. It is likely that more recent memory had greater influence on the participants' answers than their more distant memory. While the results from this study have the potential to be exciting in relation to its viable implications, it ought to be regarded with restraint while awaiting a prospective study that reduces recall bias. Further, it is important to keep in mind that an individual's risk for CVD is based on multiple risk factors--both modifiable (i.e. red meat or processed meat intake) and non-modifiable (i.e. genetics) so an individual's actual outcome is dictated by the combination of their total risk factors. This would explain why a person could consume no red or processed meat and still be diagnosed with CVD due to other risk factors. Lastly not all confounding variables were measured. Confounding variables such as TMAO, dyslipidemia, metabolic syndrome, poor diet quality, stress and depression could have accounted for some of the results that this study is attributing to red meat or processed meat intake. Due to financial constraints, not all possible confounding variables could be measured, but it is the hope of the author that the results of this unique study may be used to help raise more funds to allow for completion of a more comprehensive study.

Future Research

If the results of this proposed study are similar to the anticipated results displayed in chapter four, the author recommends that a prospective cohort study be completed in the same six regions to further advance evidence-based recommendations by identifying a causal relationship between CVD and red meat intake, if one truly exists. By following subjects on a yearly basis over a ten-to-twenty-year period, researchers can better track how changes in the quantity consumed are associated (or not associated) with the endpoint of CVD diagnosis. Furthermore, a 24-hour recall could be conducted on a quarterly basis to assess for reproducibility and validity as well as any variability in dietary intake during different seasons. Additionally, the data from the prospective cohort study could be used to further validate or contradict if there is a dependence between race and red meat intake as well as race, smoking usage, history of diabetes, or obesity (based on waist circumference) and processed meat.

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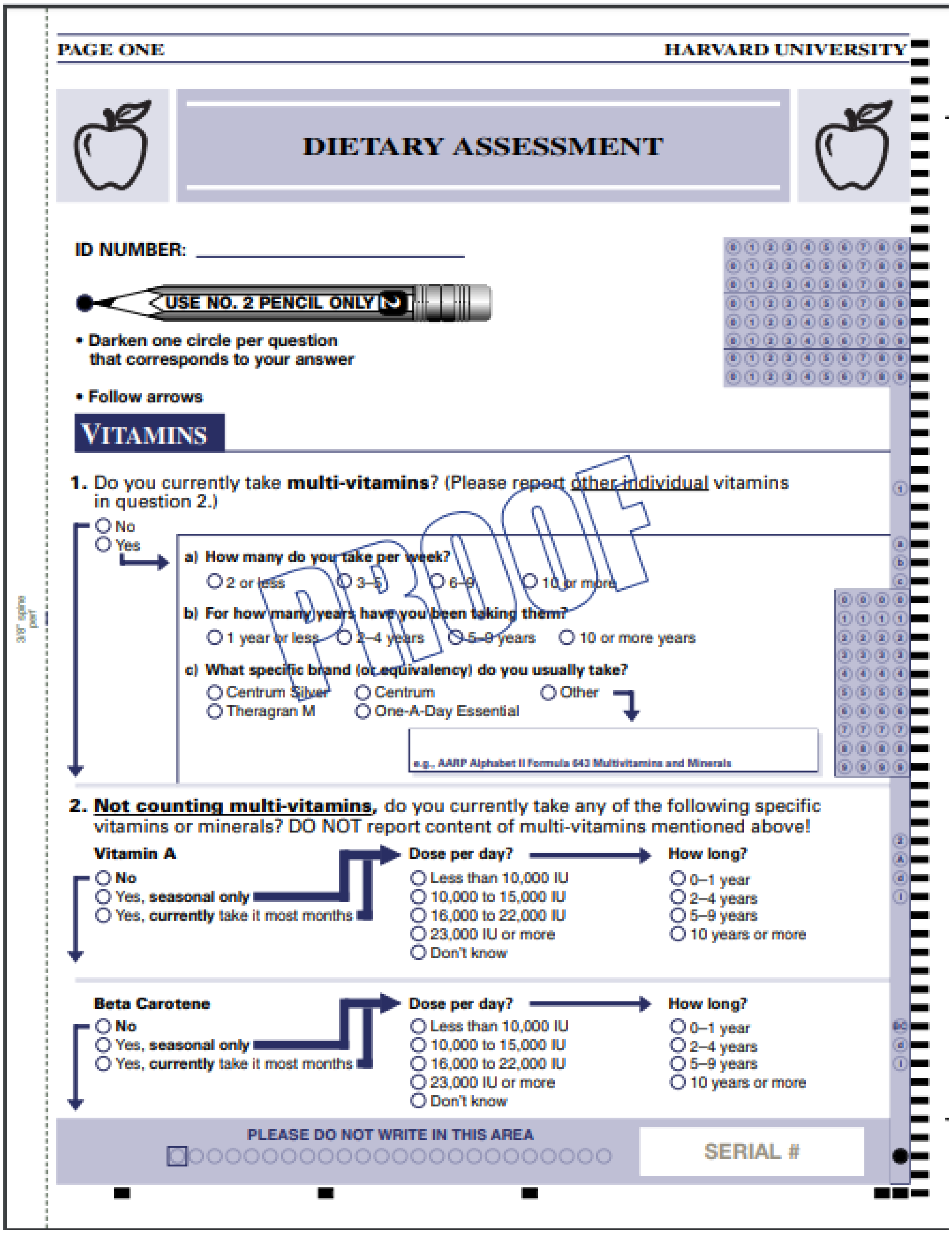
Appendix A

Harvard T.H. Chan School of Public Health semi-quantitative food frequency questionnaire



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DIETARY ASSESSMENT

ID NUMBER: ____________

USE NO. 2 PENCIL ONLY

- Darken one circle per question that corresponds to your answer
- Follow arrows

VITAMINS

1. Do you currently take **multi-vitamins**? (Please report other individual vitamins in question 2.)

- No
- Yes

a) How many do you take per week?
- 2 or less
- 3–5
- 6–9
- 10 or more

b) For how many years have you been taking them?
- 1 year or less
- 2–4 years
- 5–9 years
- 10 or more years

c) What specific brand (or equivalency) do you usually take?
- Centrum Silver
- Theragran M
- Centrum
- One-A-Day Essential
- Other

e.g., AARP Alphabet II Formula 643 Multivitamins and Minerals

PROOF

2. **Not counting multi-vitamins,** do you currently take any of the following specific vitamins or minerals? DO NOT report content of multi-vitamins mentioned above!

Vitamin A
- No
- Yes, **seasonal only**
- Yes, **currently** take it most months

Dose per day?
- Less than 10,000 IU
- 10,000 to 15,000 IU
- 16,000 to 22,000 IU
- 23,000 IU or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

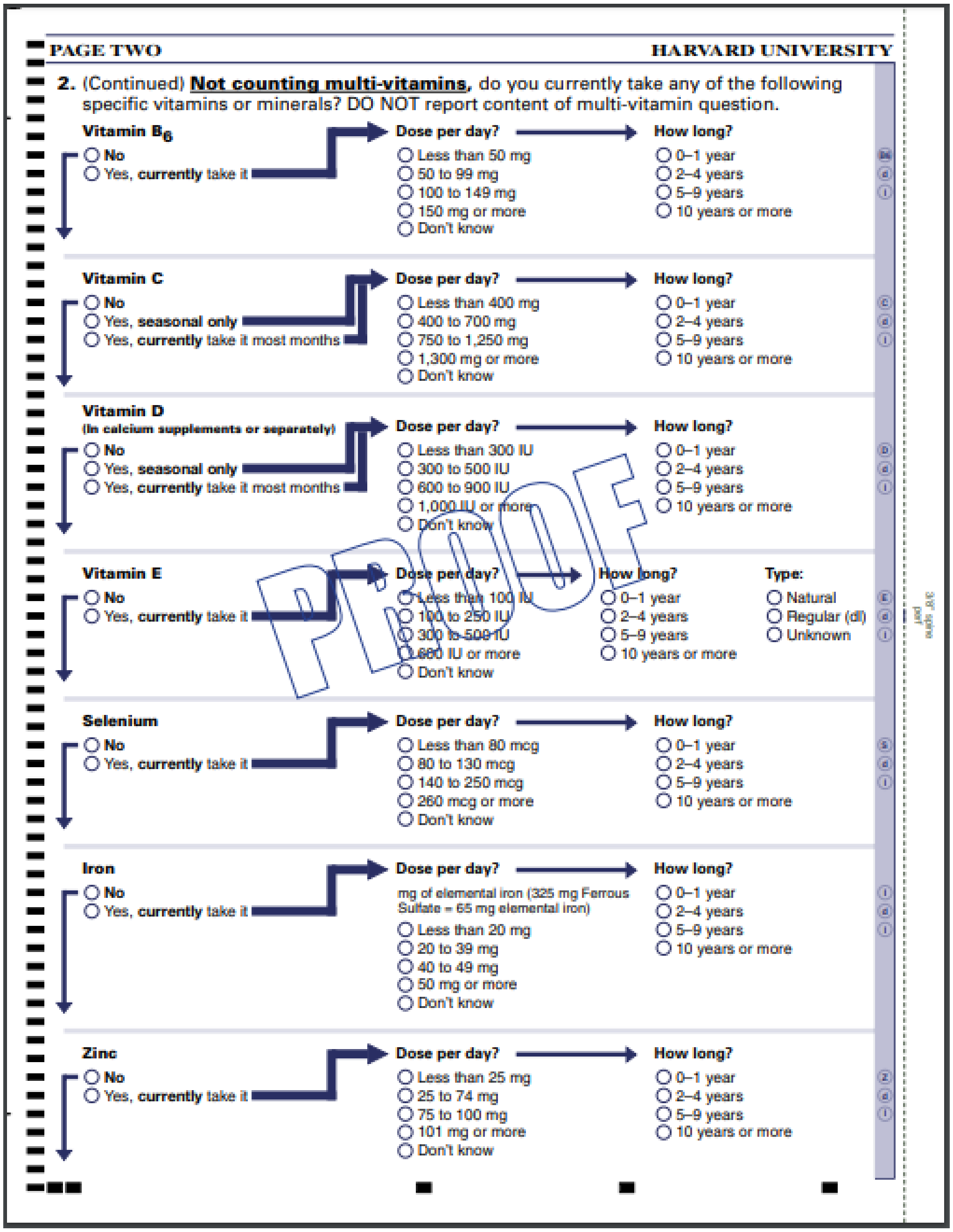
Beta Carotene
- No
- Yes, **seasonal only**
- Yes, **currently** take it most months

Dose per day?
- Less than 10,000 IU
- 10,000 to 15,000 IU
- 16,000 to 22,000 IU
- 23,000 IU or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

PLEASE DO NOT WRITE IN THIS AREA

SERIAL #



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2. (Continued) **Not counting multi-vitamins,** do you currently take any of the following specific vitamins or minerals? DO NOT report content of multi-vitamin question.

Vitamin B_6
- No
- Yes, **currently** take it

Dose per day?
- Less than 50 mg
- 50 to 99 mg
- 100 to 149 mg
- 150 mg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Vitamin C
- No
- Yes, **seasonal only**
- Yes, **currently** take it most months

Dose per day?
- Less than 400 mg
- 400 to 700 mg
- 750 to 1,250 mg
- 1,300 mg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Vitamin D
(In calcium supplements or separately)
- No
- Yes, **seasonal only**
- Yes, **currently** take it most months

Dose per day?
- Less than 300 IU
- 300 to 500 IU
- 600 to 900 IU
- 1,000 IU or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Vitamin E
- No
- Yes, **currently** take it

Dose per day?
- Less than 100 IU
- 100 to 250 IU
- 300 to 500 IU
- 600 IU or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Type:
- Natural
- Regular (dl)
- Unknown

Selenium
- No
- Yes, **currently** take it

Dose per day?
- Less than 80 mcg
- 80 to 130 mcg
- 140 to 250 mcg
- 260 mcg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Iron
- No
- Yes, **currently** take it

Dose per day?
mg of elemental iron (325 mg Ferrous Sulfate = 65 mg elemental iron)
- Less than 20 mg
- 20 to 39 mg
- 40 to 49 mg
- 50 mg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Zinc
- No
- Yes, **currently** take it

Dose per day?
- Less than 25 mg
- 25 to 74 mg
- 75 to 100 mg
- 101 mg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

PROOF

PAGE THREE — HARVARD UNIVERSITY

2. (Continued) **Not counting multi-vitamins,** do you currently take any of the following specific vitamins or minerals? DO NOT report content of multi-vitamin question.

Calcium or Dolomite (Include Tums)
- No
- Yes, **currently** take it

Dose per day? (Include elemental Calcium in Tums)
- Less than 600 mg
- 600 to 900 mg
- 901 to 1,500 mg
- 1,501 mg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Fish Oil (Omega 3 fatty acids)
- No
- Yes, **currently** take it

Dose per day?
- Less than 800 mg
- 800 to 1499 mg
- 1500 to 2499 mg
- 2500 mg or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Potassium
- No
- Yes, **currently** take it

Dose per day?
- Less than 2.5 mEq (100 mg)
- 3 to 10 mEq
- 11 to 20 mEq
- 21 mEq or more
- Don't know

How long?
- 0–1 year
- 2–4 years
- 5–9 years
- 10 years or more

Which other supplements are you taking currently on a regular basis (at least once per week)?

- None
- Metamucil
- Cod liver oil
- Brewer's yeast
- Folic acid or folate (B_9)
- Magnesium
- Niacin
- Vitamin B_{12}
- Flaxseed oil
- Flaxseed
- B-complex
- Melatonin
- Chromium
- Lecithin
- CoEnzyme Q_{10}
- Choline
- Evening primrose
- Ginkgo biloba
- Lycopene
- DHEA
- Glucosamine/Chondroitin
- Other Supplements (specify) ______

DAIRY FOODS

In the following section, please describe how often on average you have used the amount specified in the past year. Please indicate your average total use, taking the portion size into account. For example, if you use 1/2 a glass of milk twice a week, mark 1 glass per week to represent your average total intake.

3. For each food listed, fill in the circle indicating your average total use of the amount specified during the past year.

Skim milk (8 oz. glass)	1% or 2% milk (8 oz. glass)	Whole milk (8 oz. glass)
Never	Never	Never
Less than once per month	Less than once per month	Less than once per month
1–3 glasses per month	1–3 glasses per month	1–3 glasses per month
1 glass per week	1 glass per week	1 glass per week
2–4 glasses per week	2–4 glasses per week	2–4 glasses per week
5–6 glasses per week	5–6 glasses per week	5–6 glasses per week
1 glass per day	1 glass per day	1 glass per day
2–3 glasses per day	2–3 glasses per day	2–3 glasses per day
4 or more glasses per day	4 or more glasses per day	4 or more glasses per day

PAGE FOUR — HARVARD UNIVERSITY

3. (Continued) Please fill in your average total use, during the past year, of each specified food.

Soy milk (8 oz. glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2–3 glasses per day
- 4 or more glasses per day

Cream, e.g., in coffee, whipped or sour cream (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

Non-dairy coffee whitener (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

Frozen yogurt, sherbet or low-fat ice cream (1 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Regular ice cream (1 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Flavored yogurt, sweetened with fruit or other flavoring (1 cup)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2 or more servings per day

Yogurt, low carb, artificially sweetened or plain (1 cup)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2 or more servings per day

What type of yogurt do you usually eat?
- None
- Regular
- Low fat
- Nonfat

Cottage or ricotta cheese (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Cream cheese (1 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Other cheese, e.g., American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 slice per day
- 2 or more slices per day

What type of cheese do you usually eat?
- None
- Regular
- Low fat or lite
- Nonfat

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3. (Continued) Please fill in your average total use, during the past year, of each specified food.

Pure butter (small pat or tsp.), added to food or bread; exclude use in cooking

- Never
- Less than once per month
- 1–3 pats per month
- 1 pat per week
- 2–4 pats per week
- 5–6 pats per week
- 1 pat per day
- 2–3 pats per day
- 4 or more pats per day

"Spreadable butter"—butter/oil blend (small pat or tsp.), added to food or bread; exclude use in cooking

- Never
- Less than once per month
- 1–3 pats per month
- 1 pat per week
- 2–4 pats per week
- 5–6 pats per week
- 1 pat per day
- 2–3 pats per day
- 4 or more pats per day

Margarine or spread (small pat or tsp.), added to food or bread; exclude use in cooking

- Never
- Less than once per month
- 1–3 pats per month
- 1 pat per week
- 2–4 pats per week
- 5–6 pats per week
- 1 pat per day
- 2–3 pats per day
- 4 or more pats per day

What form of margarine or spreadable butter do you usually use? (Exclude pure butter)

None

Form? Stick · Tub · Spray · Squeeze (liquid)

Type? Regular · Light spread · Nonfat

What specific brand and type (e.g., Shedd's Spread Country Crock Light Tub)?

FRUITS

4. Please fill in your average total use, during the past year, of each specified food.

Please try to average your seasonal use of foods over the entire year. For example, if a food such as cantaloupe is eaten 4 times a week during the 3 months that it is in season, then the average total use would be once per week over the year.

Raisins (1 oz. or small pack) or grapes (1/2 cup)

- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Prunes or dried plums (6 prunes or 1/4 cup)

- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day

Prune Juice (small glass)

- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Bananas (1)

- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more per day

Cantaloupe (1/4 melon)

- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2–3 times per day
- 4 or more servings per day

Avocado (1/2 fruit or 1/2 cup)

- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- One per day
- Two or more per day

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4. (Continued) Please fill in your average total use, during the past year, of each specified food.

Applesauce (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- One or more per day

Fresh apples or pears (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4 or more per day

Apple juice or cider (small glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Oranges (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4 or more per day

Orange juice—calcium fortified (small glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Orange juice—regular (not calcium fortified) (small glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Grapefruit (1/2)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2–3 times per day
- 4 or more times per day

Grapefruit juice (small glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

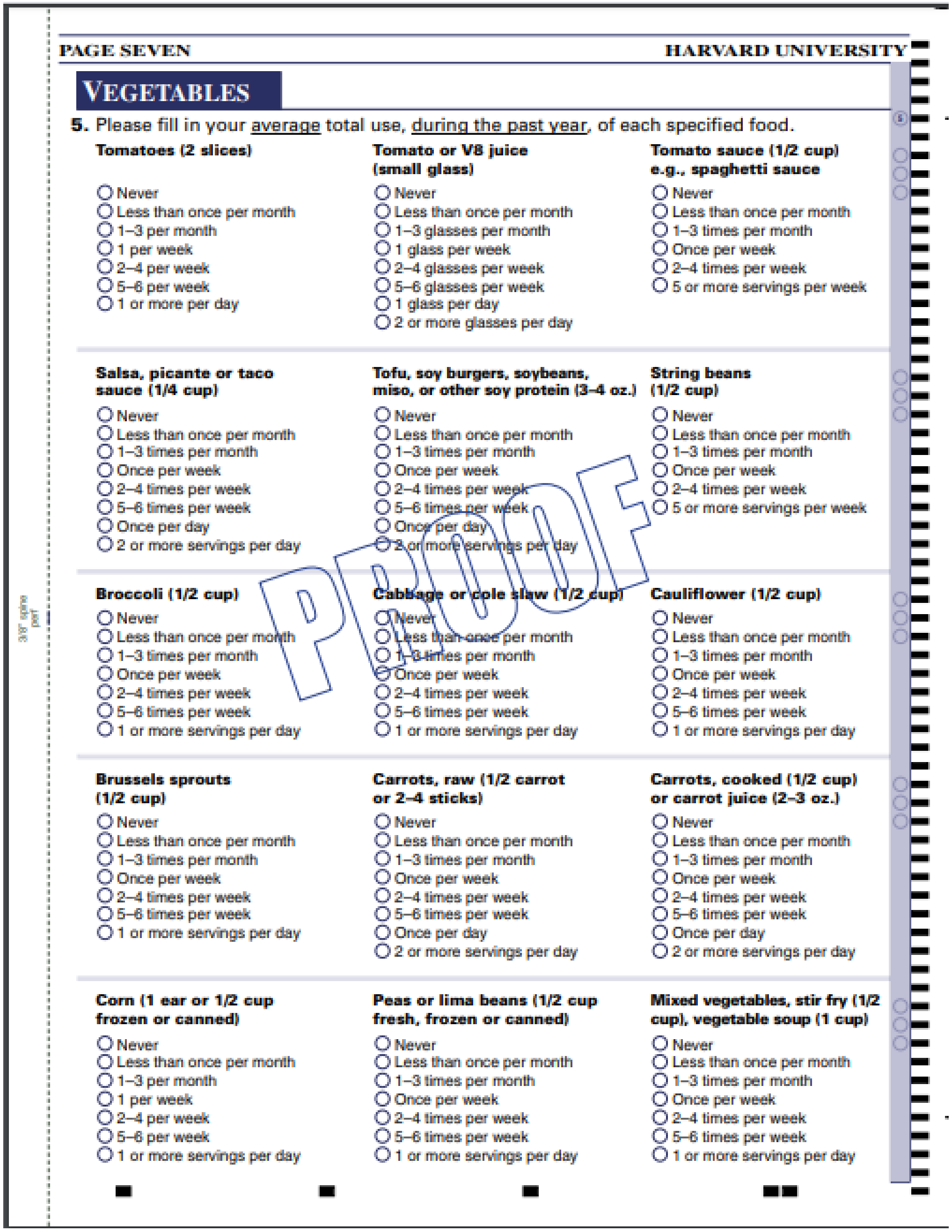
Other fruit juices (small glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Strawberries, fresh, frozen or canned (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once or more per day

Blueberries, fresh, frozen or canned (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5 or more servings per week

Peaches or plums (1 fresh or 1/2 cup canned)
- Never
- Less than once per month
- 1–3 per month
- Once per week
- 2–4 per week
- 5–6 per week
- 1 or more per day

Apricots (1 fresh, 1/2 cup canned or 5 dried)
- Never
- Less than once per month
- 1–3 per month
- Once per week
- 2–4 per week
- 5 or more servings per week



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VEGETABLES

5. Please fill in your average total use, during the past year, of each specified food.

Tomatoes (2 slices)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 or more per day

Tomato or V8 juice (small glass)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2 or more glasses per day

Tomato sauce (1/2 cup) e.g., spaghetti sauce
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5 or more servings per week

Salsa, picante or taco sauce (1/4 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Tofu, soy burgers, soybeans, miso, or other soy protein (3–4 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

String beans (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5 or more servings per week

Broccoli (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Cabbage or cole slaw (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Cauliflower (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Brussels sprouts (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Carrots, raw (1/2 carrot or 2–4 sticks)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Carrots, cooked (1/2 cup) or carrot juice (2–3 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Corn (1 ear or 1/2 cup frozen or canned)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 or more servings per day

Peas or lima beans (1/2 cup fresh, frozen or canned)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Mixed vegetables, stir fry (1/2 cup), vegetable soup (1 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

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5. (Continued) Please fill in your average total use, during the past year, of each specified food.

Beans or lentils, baked, dried or soup (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Dark orange (winter) squash (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Eggplant, zucchini or other summer squash (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Yams or sweet potatoes (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Spinach, cooked (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Spinach, raw as in salad (1 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Kale, mustard, or chard greens (1/2 cup)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Iceberg or head lettuce (serving)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Romaine or leaf lettuce (serving)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Celery (2–3 sticks)
- Never
- Less than once per month
- 1–3 per month
- Once per week
- 2–4 per week
- 5–6 per week
- Once per day
- 2 or more servings per day

Peppers: green, yellow or red (3 slices)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Onions as a garnish or in a salad (1 slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 or more slices per day

Onions as a vegetable, rings or soup (1/2 cup)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 or more per day

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EGGS, MEAT & FISH

6. Please fill in your <u>average</u> total use, <u>during the past year</u>, of each specified food.

Egg Beaters or egg whites only (1/4 cup or 1 egg)
- Never
- Less than once per month
- 1–3 eggs per month
- 1 egg per week
- 2–4 eggs per week
- 5–6 eggs per week
- 1 egg per day
- 2 or more eggs per day

Omega-3 fortified eggs, including yolk (1 egg)
- Never
- Less than once per month
- 1–3 eggs per month
- 1 egg per week
- 2–4 eggs per week
- 5–6 eggs per week
- 1 egg per day
- 2 or more eggs per day

Regular eggs, with yolk (1)
- Never
- Less than once per month
- 1–3 eggs per month
- 1 egg per week
- 2–4 eggs per week
- 5–6 eggs per week
- 1 egg per day
- 2 or more eggs per day

Bacon (2 slices)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Chicken or turkey sandwich or frozen dinner
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5 or more per week

Other chicken or turkey, <u>with</u> skin (3 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Other chicken or turkey, including ground <u>without</u> skin, (3 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Beef or pork hot dogs (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more per day

Chicken or turkey hot dogs or sausages (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more per day

Salami, bologna, or other processed meat sandwiches
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5 or more per week

Other processed meats, e.g., sausage, kielbasa, etc. (2 oz. or 2 small links)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Hamburger, <u>lean or extra lean</u> (1 patty)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 or more per day

6. (Continued) Please fill in your average total use, during the past year, of each specified food.

Hamburger, regular (1 patty)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 or more per day

Beef, pork, or lamb as a sandwich or mixed dish, e.g., stew, casserole, lasagna, frozen dinner, etc.
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more times per day

Pork as a main dish, e.g., ham or chops (4–6 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more times per day

Beef or lamb as a main dish, e.g., steak, roast (4–6 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more times per day

Liver: beef, calf or pork (4 oz.)
- Never
- Less than once per month
- 1 time per month
- 2–3 times per month
- Once per week
- 2 or more servings per week

Liver: chicken or turkey (1 oz.)
- Never
- Less than once per month
- 1 time per month
- 2–3 times per month
- Once per week
- 2 or more servings per week

Canned tuna fish (3–4 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Breaded fish cakes, pieces, or fish sticks (1 serving, store bought)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more per day

Shrimp, lobster, scallops, clams as a main dish (1 serving)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more times per day

Dark meat fish, e.g., tuna steak, mackerel, salmon, sardines, bluefish, swordfish (3–5 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

Other fish, e.g., cod, haddock, halibut (3–5 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- 1 or more servings per day

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CEREALS, BREADS & STARCHES

7. Please fill in your average total use, during the past year, of each specified food.

Cold breakfast cereal (1 serving)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4 or more cups per day

Cooked oatmeal/cooked oat bran (1 cup)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4 or more cups per day

Other cooked breakfast cereal (1 cup)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4 or more cups per day

What brand and type of cold breakfast cereal do you usually eat? → Specify brand & type (e.g., "General Mills Rice Chex")

White bread (slice), including pita bread
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 slice per day
- 2–3 slices per day
- 4–5 slices per day
- 6+ slices per day

Rye or Pumpernickel bread (1 slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 slice per day
- 2–3 slices per day
- 4–5 slices per day
- 6+ slices per day

Whole wheat, oatmeal, other whole grain bread (1 slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 slice per day
- 2–3 slices per day
- 4–5 slices per day
- 6+ slices per day

Bagels, English muffins, or rolls (1 whole)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more per day

Muffins or biscuits (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more per day

Brown rice (1 cup)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2 or more cups per day

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7. (Continued) Please fill in your average total use, during the past year, of each specified food.

White rice (1 cup)
- ○ Never
- ○ Less than once per month
- ○ 1–3 cups per month
- ○ 1 cup per week
- ○ 2–4 cups per week
- ○ 5–6 cups per week
- ○ 1 cup per day
- ○ 2 or more cups per day

Pasta, e.g., spaghetti, noodles, couscous, etc. (1 cup)
- ○ Never
- ○ Less than once per month
- ○ 1–3 cups per month
- ○ 1 cup per week
- ○ 2–4 cups per week
- ○ 5–6 cups per week
- ○ 1 cup per day
- ○ 2 or more cups per day

Tortillas (2)
- ○ Never
- ○ Less than once per month
- ○ 1–3 per month
- ○ 1 per week
- ○ 2–4 per week
- ○ 5–6 per week
- ○ 1 per day
- ○ 2–3 per day
- ○ 4 or more per day

Other grains, e.g., bulgar, kasha, buckwheat, etc. (1 cup)
- ○ Never
- ○ Less than once per month
- ○ 1–3 cups per month
- ○ 1 cup per week
- ○ 2–4 cups per week
- ○ 5–6 cups per week
- ○ 1 cup per day
- ○ 2 or more cups per day

Pancakes or waffles (2 small pieces)
- ○ Never
- ○ Less than once per month
- ○ 1–3 servings per month
- ○ 1 serving per week
- ○ 2–4 servings per week
- ○ 5–6 servings per week
- ○ 1 serving per day
- ○ 2 or more servings per day

French fried potatoes (6 oz. or 1 serving)
- ○ Never
- ○ Less than once per month
- ○ 1–3 times per month
- ○ Once per week
- ○ 2–4 times per week
- ○ 5–6 times per week
- ○ 1 or more servings per day

Potatoes, baked, boiled (1) or mashed (1 cup)
- ○ Never
- ○ Less than once per month
- ○ 1–3 per month
- ○ 1 per week
- ○ 2–4 per week
- ○ 5–6 per week
- ○ 1 per day
- ○ 2 or more servings per day

Potato chips or corn/tortilla chips (small bag or 1 oz.)
- ○ Never
- ○ Less than once per month
- ○ 1–3 per month
- ○ 1 per week
- ○ 2–4 per week
- ○ 5–6 per week
- ○ 1 per day
- ○ 2 or more servings per day

Crackers, regular or low fat, e.g., Triscuits, Ritz (6)
- ○ Never
- ○ Less than once per month
- ○ 1–3 times per month
- ○ Once per week
- ○ 2–4 times per week
- ○ 5–6 times per week
- ○ Once per day
- ○ 2–3 times per day
- ○ 4 or more servings per day

Pizza (2 slices)
- ○ Never
- ○ Less than once per month
- ○ 1–3 times per month
- ○ Once per week
- ○ 2–4 times per week
- ○ 5–6 times per week
- ○ Once per day
- ○ 2 or more servings per day

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BEVERAGES

CARBONATED BEVERAGES—Consider the serving size as one 12 oz. glass, bottle or can for these carbonated beverages.

8. Please fill in your average total use, during the past year, of each specified food.

LOW-CALORIE (Sugar-free types)

Low-calorie beverage with caffeine, e.g., Diet Coke, Diet Mt. Dew (1 glass, bottle or can)
- Never
- Less than once per month
- 1–3 cans per month
- 1 can per week
- 2–4 cans per week
- 5–6 cans per week
- 1 can per day
- 2–3 cans per day
- 4 or more cans per day

Other low-calorie beverage without caffeine, e.g., Diet 7-Up (1 glass, bottle or can)
- Never
- Less than once per month
- 1–3 cans per month
- 1 can per week
- 2–4 cans per week
- 5–6 cans per week
- 1 can per day
- 2–3 cans per day
- 4 or more cans per day

REGULAR TYPES (not sugar-free)

Carbonated beverage with caffeine and sugar, e.g., Coke, Pepsi, Mt. Dew, Dr. Pepper (1 glass, bottle or can)
- Never
- Less than once per month
- 1–3 cans per month
- 1 can per week
- 2–4 cans per week
- 5–6 cans per week
- 1 can per day
- 2–3 cans per day
- 4 or more cans per day

Other carbonated beverage with sugar, e.g., 7-Up, Root Beer, Ginger Ale (1 glass, bottle or can)
- Never
- Less than once per month
- 1–3 cans per month
- 1 can per week
- 2–4 cans per week
- 5–6 cans per week
- 1 can per day
- 2–3 cans per day
- 4 or more cans per day

PROOF

OTHER BEVERAGES

Other sugared beverages: Punch, lemonade, sports drinks, or sugared ice tea (1 glass, bottle, can)
- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2–3 glasses per day
- 4 or more glasses per day

Beer, regular (1 glass, bottle, can)
- Never
- Less than once per month
- 1–3 cans per month
- 1 can per week
- 2–4 cans per week
- 5–6 cans per week
- 1 can per day
- 2–3 cans per day
- 4–5 cans per day
- 6+ cans per day

Light beer, e.g., Bud Light (1 glass, bottle, can)
- Never
- Less than once per month
- 1–3 cans per month
- 1 can per week
- 2–4 cans per week
- 5–6 cans per week
- 1 can per day
- 2–3 cans per day
- 4–5 cans per day
- 6+ cans per day

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8. (Continued) Please fill in your <u>average</u> total use, <u>during the past year</u>, of each specified food.

Red wine (5 oz. glass)

- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2–3 glasses per day
- 4–5 glasses per day
- 6+ glasses per day

White wine (5 oz. glass)

- Never
- Less than once per month
- 1–3 glasses per month
- 1 glass per week
- 2–4 glasses per week
- 5–6 glasses per week
- 1 glass per day
- 2–3 glasses per day
- 4–5 glasses per day
- 6+ glasses per day

Liquor, e.g., whiskey, gin, etc. (1 drink or shot)

- Never
- Less than once per month
- 1–3 drinks per month
- 1 drink per week
- 2–4 drinks per week
- 5–6 drinks per week
- 1 drink per day
- 2–3 drinks per day
- 4–5 drinks per day
- 6+ drinks per day

Water, bottled, sparkling or tap (8 oz. cup)

- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6+ cups per day

Herbal tea or decaffeinated tea (8 oz. cup)

- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6+ cups per day

Tea with caffeine, including green tea (8 oz. cup)

- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6+ cups per day

Decaffeinated coffee (8 oz. cup)

- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6+ cups per day

Coffee with caffeine (8 oz. cup)

- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6+ cups per day

Dairy coffee drink (hot/cold) e.g., cappuccino (16 oz.)

- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 cup per day
- 2–3 cups per day
- 4–5 cups per day
- 6+ cups per day

SWEETS, BAKED GOODS & MISCELLANEOUS

9. Please fill in your <u>average</u> total use, <u>during the past year</u>, of each specified food.

Milk chocolate (bar or packet), (e.g., Hershey's, M&M's)

- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4 or more per day

Dark chocolate e.g., Hershey's, Dark or Dove Dark

- Never
- Less than once per month
- 1–3 candy bars per month
- 1 candy bar per week
- 2–4 candy bars per week
- 5–6 candy bars per week
- 1 candy bar per day
- 2–3 candy bars per day
- 4 or more candy bars per day

Candy bars, (e.g., Snickers, Milky Way, Reeses)

- Never
- Less than once per month
- 1–3 candy bars per month
- 1 candy bar per week
- 2–4 candy bars per week
- 5–6 candy bars per week
- 1 candy bar per day
- 2–3 candy bars per day
- 4 or more candy bars per day

9. (Continued) Please fill in your average total use, during the past year, of each specified food.

Candy without chocolate (e.g., 1 pack mints, Lifesavers) (1 oz.)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2–3 times per day
- 4 or more times per day

Jams, jellies, preserves, syrup, or honey (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2–3 tbs. per day
- 4 or more tbs. per day

Peanut butter (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2–3 tbs. per day
- 4 or more tbs. per day

Fat free or light popcorn (3 cups)
- Never
- Less than once per month
- 1–3 servings per month
- 1 serving per week
- 2–4 servings per week
- 5–6 servings per week
- 1 serving per day
- 2 or more servings per day

Regular popcorn (3 cups)
- Never
- Less than once per month
- 1–3 servings per month
- 1 serving per week
- 2–4 servings per week
- 5–6 servings per week
- 1 serving per day
- 2 or more servings per day

Pretzels (1 small bag or serving)
- Never
- Less than once per month
- 1–3 servings per month
- One serving per week
- 2–4 servings per week
- 5–6 servings per week
- One serving per day
- 2 or more servings per day

Cookies, fat free or reduced fat (1)
- Never
- Less than once per month
- 1–3 cookies per month
- 1 cookie per week
- 2–4 cookies per week
- 5–6 cookies per week
- 1 cookie per day
- 2–3 cookies per day
- 4 or more cookies per day

Cookies, other ready made (1)
- Never
- Less than once per month
- 1–3 cookies per month
- 1 cookie per week
- 2–4 cookies per week
- 5–6 cookies per week
- 1 cookie per day
- 2–3 cookies per day
- 4 or more cookies per day

Cookies, home baked (1)
- Never
- Less than once per month
- 1–3 cookies per month
- 1 cookie per week
- 2–4 cookies per week
- 5–6 cookies per week
- 1 cookie per day
- 2–3 cookies per day
- 4 or more cookies per day

Brownies (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more per day

Doughnuts (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4 or more per day

Cake, home baked (slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 or more slices per day

Cake, ready made (slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 or more slices per day

Pie, homemade (slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 or more slices per day

Pie, ready made (slice)
- Never
- Less than once per month
- 1–3 slices per month
- 1 slice per week
- 2–4 slices per week
- 5–6 slices per week
- 1 or more slices per day

9. (Continued) Please fill in your average total use, during the past year, of each specified food.

Sweet roll, coffee cake or other pastry, fat free or reduced fat (serving)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Sweet roll, coffee cake or other ready made pastry (serving)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Sweet roll, coffee cake or other pastry, home baked (serving)
- Never
- Less than once per month
- 1–3 times per month
- Once per week
- 2–4 times per week
- 5–6 times per week
- Once per day
- 2 or more servings per day

Peanuts (small packet or 1 oz.)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more servings per day

Walnuts (1 oz.)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more servings per day

Other nuts (small packet or 1 oz.)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more servings per day

Breakfast bars, e.g., Nutrigrain, granola, Kashi (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more bars per day

Energy bars, e.g., Clif, Luna, Glucerna, Powerbar (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more bars per day

Low carb bars, e.g., Atkins, Zone, South Beach (1)
- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2 or more bars per day

Oat bran, added to food (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

Other bran (wheat, etc.), added to food (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

Wheat germ (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

Chowder or cream soup (1 cup)
- Never
- Less than once per month
- 1–3 cups per month
- 1 cup per week
- 2–4 cups per week
- 5–6 cups per week
- 1 or more cups per day

Ketchup or red chili sauce (1 tbs.)
- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more servings per day

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9. (Continued) Please fill in your average total use, during the past year, of each specified food.

Salt added at table (1 shake)

- Never
- Less than once per month
- 1–3 shakes per month
- 1 shake per week
- 2–4 shakes per week
- 5–6 shakes per week
- 1 shake per day
- 2–3 shakes per day
- 4–5 shakes per day
- 6+ shakes per day

How many teaspoons of sugar do you add to your beverages or food each day?

Teaspoons

Splenda (1 packet)

- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4–5 per day
- 6+ per day

0 1 2 3 4 5 6 7 8 9

0 1 2 3 4 5 6 7 8 9

Other artificial sweetener (1 packet)

- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4–5 per day
- 6+ per day

Garlic (1 clove or 4 shakes)

- Never
- Less than once per month
- 1–3 per month
- 1 per week
- 2–4 per week
- 5–6 per week
- 1 per day
- 2–3 per day
- 4–5 per day
- 6+ per day

Low fat or fat free mayonnaise (1 tbs.)

- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

PROOF

Regular mayonnaise (1 tbs.)

- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2 or more tbs. per day

Salad dressing (1–2 tbs.) →

- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2–3 tbs. per day
- 4 or more tbs. per day

Type of salad dressing:

- Nonfat
- Low fat
- Olive oil dressing
- Other vegetable oil dressing

Olive oil added to food or bread (1 tbs.); exclude use in cooking

- Never
- Less than once per month
- 1–3 tbs. per month
- 1 tbs. per week
- 2–4 tbs. per week
- 5–6 tbs. per week
- 1 tbs. per day
- 2–3 tbs. per day
- 4–5 tbs. per day
- 6+ tbs. per day

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PAGE EIGHTEEN HARVARD UNIVERSITY

10. What kind of fat is usually used for frying and sautéing at home? (Exclude Pam type spray.)

- ○ Real butter
- ○ Margarine
- ○ Olive oil
- ○ Vegetable oil
- ○ Vegetable shortening
- ○ Lard/bacon fat

11. What kind of fat is usually used for baking at home? (Exclude Pam type spray.)

- ○ Real butter
- ○ Margarine
- ○ Olive oil
- ○ Vegetable oil
- ○ Vegetable shortening
- ○ Lard/bacon fat

12. How often do you eat food fried, stir-fried in oil, or sautéed at home?

- ○ Never
- ○ Less than once a week
- ○ 1–3 times per week
- ○ 4–6 times per week
- ○ Daily

13. How often do you eat deep fried food away from home or as take out (e.g., french fries, fried chicken, fish, clams, shrimp, etc.)?

- ○ Never
- ○ Less than once a week
- ○ 1–3 times per week
- ○ 4–6 times per week
- ○ Daily
- ○ 2 or more times per day

14. How often do you eat <u>toasted</u> breads, bagel or English muffin (e.g., sliced/half bagel)?

- ○ Never
- ○ Less than once a week
- ○ 1–3 times per week
- ○ 4–6 times per week
- ○ Daily
- ○ 2 or more times per day

15. What type of cooking oil is usually used at home (e.g., Mazola Corn Oil)?

(Specify brand and type)

PROOF

16. Are there any other foods not mentioned above that you usually eat at least once per week?

Include for example: Mushrooms, radish, horseradish, dates, figs, rhubarb, mango, mixed dried fruit, papaya, custard, venison, hot peppers, pickles, olives, SlimFast, Ensure (regular or plus), Glucerna shake.

(Do not include dry spices and do not list something that has been listed in the previous sections.)

Other foods that you usually eat at least once per week	Servings per week
(a)	
(b)	
(c)	

DIET CHANGES

17. Do you currently follow a special diet?

- ○ No
- ○ Yes → ○ Physician prescribed ○ Self prescribed

a) **If yes, for how many years?**

(Number of years on diet)

b) **If yes, what kind of diet do you follow? (Select more than one if necessary.)**

- ○ Weight reduction (low calorie)
- ○ Low cholesterol
- ○ Low sodium
- ○ Diabetic
- ○ Low fat
- ○ Low triglyceride
- ○ Ulcer
- ○ High Potassium
- ○ Other → (Specify type of diet) (Exclude weight reduction diets)

18. How has your use of the following foods and beverages <u>changed</u> over the PAST TEN YEARS?

Whole milk
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Butter
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Margarine
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Eggs
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Fish
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Red meat
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Fruits
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Vegetables
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Whole wheat bread
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Whole grains
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Sugar
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Alcohol
- ○ Use has decreased
- ○ Use about the same
- ○ Use has increased

Thank you!

Please check to make sure you have not accidentally skipped any pages.

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PLEASE DO NOT WRITE IN THIS AREA

SERIAL #

Appendix B

Demographic Questionnaire

Tell Us About Yourself

To complete this survey, every question must be answered to the best of your knowledge. If any answer is left blank, it will be assumed that you unintentionally did so and thus your survey is incomplete. Only completed surveys can be included in this study.

(1) How old are you?
  (a) _______ years old
(2) What was your gender listed as at birth?
  (a) _______ (male or female)
  (b) _______ (if you have undergone any physical or hormonal changes to reflect the gender with which you now identify, you may specify here. If you have not undergone any changes or decline to answer, write “n/a”)
(3) How tall are you today?
  (a) ___ feet ___ inches **OR** _______ centimeters
(4) What is your race? (select all that apply)
  (a) ___ White (European, Middle Eastern, North African)
  (b) ___ Black or African American (Africa)
  (c) ___ American Indian or Alaskan Native (North America, South America, Central America)
  (d) ___ Asian (Far Eastern, Southeast Asian, Indian)
  (e) ___ Native Hawaiian or Other Pacific Islander (Hawaii, Guam, Samoa, Pacific Islands)
(5) What is your ethnicity?
  (a) ___ Hispanic or Latino
  (b) ___ Not Hispanic or Latino
(6) What is your highest education level completed?
  (a) ___ No formal education credential
  (b) ___ High school diploma or equivalent
  (c) ___ Some college, no degree
  (d) ___ Postsecondary nondegree award
  (e) ___ Associate’s degree
  (f) ___ Bachelor’s degree
  (g) ___ Master’s degree
  (h) ___ Doctoral or professional degree

Please continue to next page

(7) What was your household income over the past year?
- (a) ___$0-20,000
- (b) ___$20,000-30,000
- (c) ___$30,000-40,000
- (d) ___$40,000-50,000
- (e) ___$50,000-60,000
- (f) ___$60,000-70,000
- (g) ___$70,000-80,000
- (h) ___$80,000 or above

(8) What was your primary occupation over the past 6 months?
- (a) ______________________ (job title, OR retired, student, disabled, unemployed, etc.)

(9) What is your family size/household composition?
- (a) _______ people depend on the income of the head of my household
- (b) _______ people live in my household as their primary residence

(10) How physically active were you over the past year?
- (a) _______ average number of minutes of low intensity exercise per week (continuous movement that has little to no changes on breathing or ability to hold a conversation
- (b) _______ average number of minutes of moderate intensity exercise per week (continuous movement that has noticeable changes to breathing, but still able to hold a conversation)
- (c) _______ average number of minutes of high intensity exercise per week (continuous movement that changes breathing to the point that you are unable to hold a conversation)

(11) Did you smoke over the past year?
- (a) ___ (no)
- (b) ___ (yes, more than once a month, but not weekly)
- (c) ___ (yes, more than once a week, but not daily)
- (d) ___ (yes, daily)

(12) What is your waist circumference? *(First, stand and place a tape measure around your middle, just above your hipbones. Second, make sure tape is horizontal around your waist. Third, keep the tape snug around the waist, but no compressing the skin. Lastly, measure your waist just after you breathe out)*
- (a) _______ inches **OR** _______ centimeters

Please continue to next page

(13) Do you have a first-degree relative *(this does not include step- or adopted-)* who has been diagnosed with cardiovascular disease?
- (a) ___ no
- (b) ___ yes, siblings (write "n/a" if none)
  - (i) *If yes, how old were they at diagnosis?*
    1. _______ years old (*please include ages of all siblings diagnosed*)
- (c) ___ yes, parents (write "n/a" if none)
  - (i) *If yes, how old were they at diagnosis?*
    1. _______ years old (*please include ages of all parents diagnosed*)
- (d) ___ yes, children (write "n/a" if none)
  - (i) *If yes, how old were they at diagnosis?*
    1. _______ years old (*please include ages of all children diagnosed*)

(14) Have you ever been diagnosed with diabetes?
- (a) ___ no
- (b) ___ yes

(15) Have you ever been diagnosed with any form of cardiovascular disease?
- (a) ___ no
- (b) ___ yes

Appendix C

IRB Application

Office use only: IRB Approval #: ________

Mount Mary University

Mount Mary University

Institutional Review Board (IRB)

for the Protection of Human Subjects

Application for IRB Review

DATA COLLECTION CANNOT BEGIN

UNTIL THE IRB HAS APPROVED THIS PROJECT

Directions:

- Faculty and student researchers, as well as student research advisors, should **read all relevant information on the University IRB page in My Mount Mary before initiating an application**. This includes full knowledge of the US Department of Health and Human Services Code of Federal Regulations Title 45 (Public Welfare), Part 46 (Protection of Human Subjects). http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
- All applicants must verify completion of Human Subjects Training. See http://www.citiprogram.org
- The IRB application must be filed and approved by the IRB **prior** to any Mount Mary University faculty, staff, or student (undergraduate or graduate), initiating a research project/study.
- If there is a cooperating institution, attach a copy of their IRB approval.
- In the case of a student research project, the student may complete the IRB application but the student's research advisor must sign and submit the application to the IRB for approval. It is the responsibility of the faculty research advisor to ensure that student applications and all attachments (e.g., informed consent forms and survey instruments) are in their final edited form. Even though a student research project may qualify as **exempt** from full IRB review, the research advisor may request the student to complete and submit a full IRB application.
- Complete this application using your word processing program (ex. Word), then print it out and obtain signatures from all investigators and advisors. (**Handwritten applications will not be**

accepted.) For your benefit, save the completed application on your computer in case it needs to be revised and resubmitted.

- This is a professional document; please check spelling, grammar and punctuation.
- Submit an electronic copy, via email, of the completed application with required signatures and attachments, **in a single pdf**, to Tammy Scheidegger, IRB Chair, scheidet@mtmary.edu . You will receive an email verifying receipt of the application from the IRB Board Chair.
- Allow a **minimum of 30 working days** to process your application. Make sure this timeframe is accounted for when considering initiation of data collection and due dates for student projects. Please be aware that if, upon completion of the application, you find that ***no exemptions apply to your research, your application will need to go through a full IRB Committee review which can take as many as 60 days to be completed.***
- For class projects you must submit IRB applications to the IRB Chair by October 31st of the fall semester and March 31st for the spring semester. For summer classes, please consult with the IRB Chair.
- Upon receipt of the IRB letter of approval, data collection may begin.

I. Required Documentation - No action will be taken without these attachments.

Are the following attached to the IRB application?

Informed Consent Document	☒ Yes	Informed Consent Documents should include an explanation of procedures, risk, safeguards, freedom to withdraw, confidentiality, offer to answer inquiries, third party referral for concerns, signature and date. See Appendix. A and use the **MMU Informed Consent Template** to avoid delays in the process.
Questionnaire/Survey Instrument(s)	☒ Yes	If a survey is being administered in any written format (e.g., survey monkey, qualtrics), a copy of that survey must accompany this application. If a survey is being conducted verbally, a copy of the introductory comments and survey questions being asked must be attached to this application. If survey includes focus group questions, a complete list of the question must be attached. For research using a

		published/purchased instrument, a photocopy of the instrument will suffice.
Verification of Human Subjects Training	☒ Yes	Copy of transcript, certificate or other evidence that ALL members of the research team have completed the required training. .
Copy of cooperating institution's IRB approval.	☐ Yes	Not required if there is no cooperating institution. .

II. Investigator(s):

Name: Andrew Mirviss

Phone: 414-930-3000

Affiliation with Mount Mary University (e.g. faculty, student, etc.): Student

Email: mirvissa@mtmary.edu

Signature: ___________________________________

Date:

Name:

Phone:

Affiliation with Mount Mary University:

Email:

Signature: ___________________________________

Date:

If student, list Research Advisor and complete the application. Research Advisor must provide requested information and verify.

Department: Dietetics

Research Advisor's Name: Dr. Dana Scheunemann

Email: scheuned@mtmary.edu

Phone: 414-930-3658

Research Advisor: Have you completed Human Subject's Training? ☒ Yes ☐ No

Research advisor's signature indicates responsibility for student compliance with all IRB requirements.

Signature: ____ Date:

Research Advisor

III. Project Description – Required by all applicants

Instructions: Briefly describe the proposed project including the sample and methodology (e.g. human subjects, data collection, data analysis and instruments).

1) Objectives (purpose of project):

The purpose of this study is to test if there is a quantity of red meat or processed meat intake that is not associated with an increased risk of CVD by comparing red meat and processed meat intake to the development of CVD for 40 to 85 year olds living in the United States.

2) Relevance to practice/body of knowledge:

The data collected from observing the relationship between the development of CVD and the amount of red meat and processed meat consumed by adults will help to guide a more specific recommendation than to *limit* red meat and *minimize* processed meat.

3) Describe the research design (e.g. subject/participant selection and assignment, design, intervention, data analysis):

Subject selection- Clustered sampling will be utilized in six different areas of the United States to attempt to have all races, genders, socioeconomic levels, and ages represented. It is anticipated that 384 total subjects will be needed to yield results with a confidence interval of 95% +/- 5. In order to achieve said results, 107 subjects will be included from each of the six cities to allow for up to a 40% nonresponse rate.

Design- retrospective cohort study

Intervention-none

Data analysis- The demographics of the subjects in this study will be compared to that of the 40 to 85-year olds living throughout the United States to assess how reflective these subjects are to the general population. Comparative analysis with Chi-Square will be conducted to assess whether any characteristics were related to red meat or processed meat intake (i.e. if there is relationship between males and red meat intake compared to females and red meat intake). Relational analysis with Logistic Regression (odd ratio) will be completed to assess total red meat intake with diagnosis of CVD and total processed meat intake with the diagnosis of CVD.

4) What measurement/data collection tools are being used?

Tools-Each subject will be sent the Harvard T.H. Chan School of Public Health semi-quantitative food frequency questionnaire. The adult general version was designed for self-administration. Additionally, a non-validated form will be included to gather information about age, gender, weight, height, race, ethnicity, education level, income level, occupation, family size/household composition (to calculate federal poverty level for determining socioeconomic levels), physical activity level, smoking usage, waist circumference, if respondents have a first -degree relative who has been diagnosed with CVD (and at what age), and diagnosed with diabetes or CVD. LimeSurvey will be utilized for subjects who prefer to complete their survey online. Lastly, every subject will receive a soft tape measure for use in measuring waist circumference and the option to have a pictorial handout or access a video online to help guide the measuring process.

Data collection-Every submitted questionnaire will be reviewed by the author for completeness. All completed FFQs will be sent to Harvard University for nutrient analysis of the questionnaires in Excel format. The author will create Excel spreadsheets for each subject and input all the information from the demographic questionnaire. Additionally, the author will keep a separate list that connects the identifying number in excel with the actual personal identifying information of the subjects. After the author combines the demographic/health history information with the FFQ analysis for each subject, the author will use the combined excel spreadsheets for final analysis. The author will utilize the help of a local statistician to aid in running statistical analysis

IV. Additional Project Information – Required by all applicants

1) What human subjects training has the researcher completed (e.g. course work, online certification)?

CITI Training

2) What process is used for obtaining informed consent (attach the informed consent application)? See Appendix for consent application.

All subjects will be required to complete the written informed consent before being able to participate in this study.

3) Does the research include special populations?

Minors under 18 years of age?	☐ Yes	☒ No
Persons legally incompetent?	☐ Yes	☒ No
Prisoners?	☐ Yes	☒ No
Pregnant women, if affected by research?	☐ Yes	☒ No
Persons institutionalized?	☐ Yes	☒ No
Persons mentally incapacitated?	☐ Yes	☒ No

4) If **YES,** describe additional precautions included in the research procedures.

5) Does the research involve any of the following procedures?

False or misleading information to subjects?	☐ Yes	☒ No
Withholds information such that their informed consent might be questioned?	☐ Yes	☒ No
Uses procedures designed to modify the thinking, attitudes, feelings, or other aspects of the behavior of the subjects?	☐ Yes	☒ No

6) If **<u>YES</u>**, describe the rationale for using procedures, how the human subjects will be protected and what debriefing procedures are used.

7) Does the research involve measurement in any of the following areas?

Sexual behaviors?	☐ Yes	☒ No
Drug use?	☐ Yes	☒ No
Illegal conduct?	☐ Yes	☒ No
Use of alcohol?	☐ Yes	☒ No

8) If **<u>YES</u>**, describe additional precautions included in the research procedures.

9) Are any portions of the research being conducted online?

Survey posted on a website?	☒ Yes	☐ No	If yes, assure anonymity
URL for survey includes information that could identify participants?	☐ Yes	☒ No	If yes, assure anonymity

Invitation to participate sent by email?	☐ Yes	☒ No	If yes, assure anonymity
Items use drop-down box?	☐ Yes	☒ No	If yes, assure that items allow choice of "no response"

10) If **YES**, describe additional procedures.

All personal identifying information will be located solely on the survey. All other information will be extracted from the survey and entered into excel spreadsheet where an unique identification number will replace all personal identifying information.

11) Describe the methods used to ensure confidentiality of data obtained.

All personal identifying information will be utilized on a designated school computer (never on a personal device) for questionnaires completed online or kept in a locked cabinet designated solely for this study on school grounds for questionnaires completed on paper.

Risks and Benefits

1) Describe risks to the subjects and the precautions that will be taken to minimize them. (Risk includes any potential or actual physical risk of discomfort, harassment, invasion of privacy, risk of physical activity, risk to dignity and self-respect, and psychological, emotional or behavioral risk.)

Risks to the subjects are limited to their personal identifying information being exposed. The precautions listed above will be taken to minimize this risk by limited access to a school computer with cyber security and a locked cabinet within the school.

2) Describe the benefits to subjects and/or society. (These will be balanced against risk.)

This proposed study has the potential to help people prevent CVD by providing a measurable guideline for red meat and processed meat daily consumption. Additionally, this proposed study may help mitigate the confusion from conflicting headlines regarding the relationship between red meat and processed meat with CVD.

V. Is the proposed project "research" as defined by Institutional Review Board requirements? - Required by all applicants

- Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- A human subject is defined as a living individual about whom an investigator obtains either 1) data through intervention or interaction with the individual; or 2) identifiable private information.

Does the research involve human subjects or official records about human subjects?

☒ Yes

☐ No

***If NO STOP here, and SUBMIT application*.**

If the results will be available in the library, presented at a professional conference (includes any presentation to group(s) outside of the classroom), or published, please check the Yes box:

☒ Yes

☐ No

If the YES box is CHECKED, proceed to SECTION VI.

***If the NO box is CHECKED, STOP here, and SUBMIT application*.**

VI. Exemptions - Required by all applicants

Are you requesting exemption from IRB review in one of the federally approved categories?

If yes, please reference OHRP website http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html and continue with application.

1) Does the research meet the criteria for exempt category 1 (education)? [45 CFR 46.101 (b) (1)]

Is the research conducted in established or commonly accepted educational settings (e.g. schools, Universities or other sites where educational activities regularly occur)?

☒ Yes

☐ No

Does the research study involve only normal education practices (e.g. instructional strategies, techniques, curricula, or classroom management techniques)?

☐ Yes

☒ No

*If **both** questions are answered **"yes"**, stop here, and **submit** application.*

2) Does the research meet the criteria for exempt category 2 (specific procedures)? [45 CFR 46.101 (b) (2)]

Does the research involve only the use of educational tests, survey procedures, interview procedures or observation of public behavior?

☒ Yes

☐ No

Is the information obtained recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects? (See Appendix B)

☐ Yes

☒ No

*If **both** questions are answered **"yes"**, stop here, and **submit** application.*

3) Does the research meet the criteria for exempt category 3 (public officials)? [45 CFR 46.101 (b) (3)]

Does the research involve only the use of educational tests, survey procedures, interview procedures or observation of public behavior?

☒ Yes

☐ No

Are the human subjects elected or appointed public officials or candidates for public office? **If no, proceed to Category 4.**

☐ Yes

☒ No

Does any federal statute require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? (See Appendix B)

☐ Yes

☒ No

*If **all** questions are answered **"yes"**, stop here, and **submit** application.*

4) Does the research meet the criteria for exempt category 4 (existing data/specimens)? [45 CFR 46.101 (b) (4)]

Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens?

☐ Yes

☒ No

Will the information be recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects? (See Appendix B)

☐ Yes

☒ No

*If **both** questions are answered **"yes"**, stop here, and **submit** application.*

5) Does the research meet the criteria for exempt category 5 (federal program research)? [45 CFR 46.101 (b) (5)]

Does the research involve studying, evaluating or examining federal public benefit or service programs?

☐ Yes

☒ No

Is the research conducted through a federal agency?

☐ Yes

☒ No

*If **both** questions are answered **"yes"**, stop here, and **submit** application.*

6) Does the research meet the criteria for exempt category 6 (taste and food quality)?

[45 CFR 46.101 (b) (6)]

Does the research involve a taste and food quality evaluation or consumer acceptance study?	☐ Yes ☒ No
Does the food consumed contain no additives, or a limited amount of food additives at or below a level approved by the FDA or EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture?	☐ Yes ☒ No

*If **both** questions are answered **"yes"**, stop here, **submit** application.*

If no exemptions apply, your application will need to go through a full IRB Committee review. Be advised that this process can take as many as 60 days to be completed.

Appendix A: Required Elements of Informed Consent

Please use the template provided on the MMU IRB website for constructing your Informed Consent Document

Informed consent is the process of communicating to a prospective participant, in easy-to-understand language (usually sixth- to eighth-grade level), all that he or she needs to know about participating in a research project, and then obtaining the prospective participant's agreement to participate. The following ten elements of consent are widely recognized and, except under certain specific conditions, **must be included in all consent processes and forms**:

1. An explanation of the study, including goals, procedure, and a statement that the study is research.

2. A description of what participants are expected to do and expected length of participation.
3. A description of any likely risks or discomforts for the participants. Potential harm should be explained in language that participants can understand and that relate to everyday life.
4. A description of any likely benefits to the participant or to others.
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
6. A statement describing the level of privacy assured for collected information (anonymous, confidential) and how private information and information security will be managed.
7. An explanation of whom to contact for answers to questions about the research. When a Mount Mary student is the principal investigator, the name and phone number of a supervising faculty member is required.
8. An explanation of whom to contact for concerns about the participant's privacy and rights, which for Mount Mary University is its IRB Chair.
9. For research involving more than minimal risk, a statement describing any compensation for injuries and contact information. (Minimal risk is a risk of harm to the participant that is no greater than the risk encountered in normal, day-to-day activities or during routine physical or psychological examinations.)
10. A statement that research participation is voluntary and the participant may withdraw from participation at any time, without penalty or loss of benefits to which the participant is otherwise entitled. If the participant is a patient or client receiving medical, psychological, counseling, or other treatment services, there should be a statement that withdrawal from the study will not jeopardize or otherwise affect any treatment or services the participant is currently receiving or may receive in the future. Participants also should be told whether their data will be destroyed should they withdraw from the study. If a survey instrument or interview questions are used and some questions deal with sensitive issues, the participants should be told they may refuse to answer individual questions.

Appendix B: IRB De-Identification Standard for Information

Protecting the privacy of research participants is a general concern in the vast majority of research projects. The degree to which privacy needs to be ensured or maintained depends on the nature of the particular research, its setting, and the research participants. Researchers share a general obligation to design their research to reduce the risks of disclosure of collected information about individual research participants. Thus, the present standard for de-identification of information is useful as a guide to protecting privacy even when it is not required or fully required. In this regard, the researcher should consider the following question when collecting and handling data.

Does the information I am accessing, recording, and/or disclosing contain identifiers? Simple access to information may be without concern, for example when the researcher is an employee who routinely handles the records in carrying out his or her position. <u>But, the presence of identifiers in any **recorded or disclosed** information in the research means the information is not anonymous and so does not meet the IRB de-identification standard, which in some cases may also disqualify the research from exemption from IRB review.</u>

The IRB de-identification standard includes all 18 direct identifiers specified in the HIPAA Privacy Rule de-identification standard—*45 CFR 164.514(b)*. Below are listed specific direct and indirect identifiers that lead to information not being anonymous.

Identifiers: Direct; Indirect

One way to distinguish between information that is truly anonymous and information that is simply being kept confidential is to determine whether the data set contains direct or indirect identifiers. Information in a data set with either direct or indirect identifiers is not anonymous.

Direct Identifiers include:

- Names
- Addresses
- Telephone and fax numbers
- Email addresses, IP addresses, and URLs
- Social Security numbers
- Medical record numbers
- Account numbers, such as those associated with bank accounts or health plans
- License or certificate numbers, including driver's license numbers
- License plate numbers and other vehicle identifiers
- Fingerprints, voiceprints, or full-face photographic images
- Other unique characteristics or identification numbers (example student ID numbers)

Indirect Identifiers can be combined with publicly available information to identify individuals. The determination of indirect identifiers depends on the nature of the research participants. For example, in a study of residents of the state of Wisconsin, the information that someone graduated from one of the UW system schools probably would not be a unique identifier. However, in a study of small business leaders in Racine, WI, the same information might well apply to only one individual. In general, if any single variable in a data set applies to fewer than five participants, it is considered a potential indirect identifier.

Examples of indirect identifiers include:

- Detailed geographical information, such as state, county, or census tract of residence
- Organizations to which participants belong
- Educational institutions from which participants graduated
- Exact occupations
- Places where participants grew up
- Many dates, e.g. birth dates, hospital admission dates, high school or University graduation dates, etc.
- Detailed income information
- Offices or posts held by participants.

Appendix D

Informed Consent

Research Participant Information and Consent Form
Mount Mary University

Title of Study: Red Meat or Processed Meat and Cardiovascular Disease, Is There an Association?

Invitation to Participate and Purpose of the Research

You are invited to participate in a research study that seeks to test if there is a quantity of red meat or processed meat intake that is not associated with an increased risk of CVD by comparing red meat and processed meat intake to the development of CVD for 40 to 85 year olds living in the United States. Participants will be asked to complete two questionnaires. Data will be de-identified and analyzed by researchers. Participants must be 40 to 85 years of age or older.

Benefits and Risks

This research is designed to benefit the healthcare profession, by helping to guide a more specific recommendation than to *limit* red meat and *minimize* processed meat for cardiovascular health. Although participants may not benefit personally from being in this research study, findings generated by this research may add new knowledge to the dietetic field in general. There will be no monetary compensation. There are no known potential risks associated with participating in this study. Please address any questions or issues of concern to the researchers using the contact information provided above.

Confidentiality

All information obtained will be kept confidential by the researchers who will be the only people with access to the data. Information obtained will be stored electronically and will be password protected. Per the U.S. Office of Human Research Protections (code §46.115), all data will be destroyed 3 years after the end of data collection. Paper files will be shredded, and electronic files will be deleted. Individual participants will not be identified in any report or publication about this study.

Contact Information

If you have questions about this research study, your rights as a research subject, or would like to know the outcome of the research, please contact Andrew Mirviss (investigator), 414-930-3000, mirvissa@mtmary.edu or Dr. Dana Scheunemann (supervising faculty member), 414-930-3658, scheuned@mtmary.edu. If you have any questions regarding your rights or privacy as a participant in this study, please contact Dr. Tammy Scheidegger, Mount Mary University Institutional Review Board Chair, 2900 North Menomonee River Parkway, Milwaukee, Wisconsin, 53222-4597, telephone (414) 930-3434 or email schediet@mtmary.edu.

Consent

By signing below, you are indicating that you have read this consent form, have been given the opportunity to ask questions, and have agreed to voluntarily participate. You may withdraw from participation at any time, or refuse to answer any question herein, without penalty or loss of benefits to which other participants are entitled.

You may request a copy of this page for your records. Thank you for your participation.

Signature of participant____ Date ______________