

# *SAMPLE PROPOSAL*

*PROVIDED TO ASSIST IN THE DEVELOPMENT OF NEW PROPOSALS*

## **Correlates of serum lycopene in older women (Example of a MS proposal with all the required elements)**

### **INTRODUCTION**

Over the past decade, increasing interest has been focused on the role of antioxidant nutrients in disease prevention. The carotenoid pigments, which number over 500, are well known for their antioxidant properties. Only  $\beta$ -carotene has been studied extensively; the other major carotenoids found in the human body have garnered much less attention. Of this group, lycopene is particularly important because it comprises roughly half the total carotenoid concentration of human serum. Dietary lycopene is primarily derived from tomatoes and tomato products.

Early research found that intraperitoneally injected lycopene improved survival rates of irradiated mice (1). Interest in this nutrient was renewed following the 1989 publication by Di Mascio et al. which reported that lycopene has the greatest ability of all the common carotenoids to quench singlet oxygen, a mechanism by which protection from the damaging effects of reactive oxygen species is thought to occur (2). Recent biologic evidence suggests that lycopene is a more effective inhibitor of human endometrial, mammary, and lung cancer cell proliferation in cell culture than  $\alpha$ - or  $\beta$ -carotene (3). Although there is conflicting evidence, in some observational epidemiologic studies this nutrient has been found to be associated with a decreased risk of prostate cancer (4, 5), cervical intraepithelial neoplasia (6), stomach cancer (7), pancreatic cancer (8), and myocardial infarction (9).

Although research conducted over the past 8 years suggests that lycopene may play an important role in disease prevention, there is little information about predictors of serum lycopene. It is the only major carotenoid found to decrease with age and does not appear to be higher in women than men, as are other carotenoids (10), thus, lycopene status may be particularly important in older women. There are conflicting results regarding the relationship of serum lycopene levels to both cigarette smoking (10-12) and alcohol consumption (10, 13). As lycopene intake among African-American male health professionals was found to be substantially less than among their Caucasian counterparts (4), ethnicity may be an important determinant of serum lycopene. By investigating the factors associated with serum lycopene in a subset of older women, a better understanding of the relationship between this potentially important nutrient and certain disease processes may be gained.

### **OBJECTIVES**

1. To evaluate the relationship of serum lycopene with dietary lycopene intake, foods high in lycopene and other dietary factors as estimated by the baseline FFQ.
2. To assess the relationship of serum lycopene with lifestyle, demographic, and biochemical factors of WHI participants at baseline.

The ethnic diversity of the WHI also offers a unique opportunity to study the determinants of serum lycopene among the various ethnic groups.

## **ANALYSIS PLAN**

### *Statistical Analysis*

We propose to analyze baseline data from CT participants in the 6% serum subsample whose blood samples have been analyzed. Over 1500 such blood samples have been analyzed to date and include a large percentage of minority participants.

We will describe the intake and serum concentration of lycopene and the demographic characteristics of the study population (Table 1).

The relationship between serum lycopene and other factors will be assessed by Pearson correlation coefficients and multiple linear regression. Pearson correlation coefficients will be presented, adjusted for age and other covariates, if appropriate (Table 2). The results of multiple regression analysis of dietary, biochemical, demographic, and lifestyle factors on serum lycopene will be presented in Table 3. Log transformation of lycopene and other variables will be used if distributions are found to be skewed. For factors that are found to be associated with serum lycopene, e.g. lycopene intake, we will test for modification of the effect by age, ethnicity, and smoking status (current, former, or never). If any of the findings differ by these variables, the results will be stratified by these variables.

### *Pertinent variables*

1. Serum lycopene
2. Lycopene intake
3. Total caloric intake
4.  $\beta$ -carotene intake
5.  $\alpha$ -carotene intake
6. Total carotenoid intake
7. Fruit and vegetable intake
8. Fiber intake
9. Intake of specific foods high in lycopene
10. Vitamin supplement intake/use- multivitamins, vitamin C, vitamin E
11. Serum  $\beta$ -carotene
12. HDL
13. LDL
14. Triglycerides
15. HRT use
16. Age
17. Alcohol consumption
18. Cigarette smoking
19. BMI
20. Physical activity
21. Ethnicity



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