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A Comparison of Daily Consumption of Artificial Dye-containing Foods by American Children and Adults

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A comparison of daily consumption of artificial dye-containing foods by American children and adults

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Abstract

Children with developing nervous systems might be at greater risk for any potential neurobehavioral effects of color additives widespread in many foods. This study thus examined whether children consumed foods containing color additives more frequently than adults. Twenty-one adults (aged 18-60) and parents of 14 children (aged 4-7) with regular eating patterns kept detailed food records for five days. Diets were analyzed for foods containing the dyes Red #3, Red #40, Yellow #5, Yellow #6, Blue #1, Blue #2 and Green #3 by comparing ingredient labels found in grocery stores and online. The number of daily dye exposures was significantly ($P<0.001$) greater for children (2.43 ± 0.35 exposures) than for adults (0.76 ± 0.15 exposures). Fruit and vegetable consumption was inversely correlated (-0.63) to the number of dye exposures per day in children but not in adults (0.18). Children habitually consume more brightly colored foods with additives in lieu of nutrient dense foods.

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Chapter 1: Introduction

Synthetic food dyes have been in use in the United States for over 150 years (Food and Drug Administration 2012*a*). During that time, the Food and Drug Administration (FDA) worked to establish safety guidelines for the widely used food dyes as an important part of consumer protection. However, that protection is currently limited in that there must be proof of harm before the FDA can remove the dyes from the food supply. Over the last 40 years, there have been numerous consumer and physician reports of a variety of neurobehavioral effects from the consumption of color additives (Feingold, 1975; Weiss et al., 1980; McCann et al., 2007). Scientific evidence has yet to clearly explain the impact of food dyes on health. If these neurobehavioral effects are influenced by the consumption of color additives, it is important to look at which populations consume these substances most frequently. The purpose of this study is to examine whether children have more frequent daily exposures to artificial food colors than adults.

Currently, the seven most widely used artificial colors approved for use in food by the FDA are Red #3, Red #40, Blue #1, Blue #2, Green #3, Yellow #5, and Yellow #6 (see Table 1). Three of these – Red #40, Yellow #5 and Yellow #6 – account for over 90% of all dyes used (Food and Drug Administration, 2012*b*). One can find food colors not only in brightly colored candies or cupcakes, but also in a variety of foods: cereals, salty snacks, barbecue sauce, dried papaya, salad dressing, pickles, cheese sauce, yogurt, chocolate milkshakes, white marshmallows, or even certain brands of fresh shelled peas. Color additives make the product appear to have higher quality or greater nutritional value than it actually does. In nature, bright colors in fruits and vegetables are indicators of freshness and phytonutrients. Consumers generally won't buy foods that look splotchy, gray, or dull in appearance, so food producers use

color additives to correct the variations in color in processed foods. The foods then look brighter and more attractive.

Color manufacturers must see to it that each batch of dye produced completes a certification process outlined by the FDA in order to be granted GRAS status or to be "Generally Recognized as Safe." While the FDA must certify that each batch of dye meets identity requirements, it may still contain impurities of toxicological concern up to a specified amount for every impurity (Food and Drug Administration, 2012*c*). For example, Yellow #5 (Tartrazine) may contain up to 13% of non-color impurities (Code of Federal Regulations, 2012*a*). Some of these are known carcinogens, such as 4-aminoazobenzene, 4-aminobiphenyl, aniline, azobenzene, benzidine, and 1, 3 diphenyltriazene (Code of Federal Regulations, 2012*a*). Other impurities found in color additives include arsenic, lead, and mercury (Food and Drug Administration 2010). The manufacturer must send a sample of any newly-made batch to the FDA Color Certification Branch for testing and approval. The Code of Federal Regulations parts 70-82 provide specifications of each color's identity, uses and restrictions, and labeling requirements (Code of Federal Regulations, 2012*a*). The composition of each batch needs to be controlled to assure that levels of known carcinogens and toxicological impurities are within the specified limits. While the FDA requires proof of reasonable safety from an additive, it does not require proof beyond any doubt that harm will result under any circumstances (Food and Drug Administration, 2011*a).*

In the past century, safety concerns about the effects of color additives on human physiology have emerged many times. Since 1960, about 100 various color additives have been removed from use due to safety concerns or industry disinterest (Food and Drug Administration 2012*a*). The FDA terminated some of these for having exceeded regulated levels of impurities

or for demonstrating carcinogenicity or liver damage in laboratory animals (Code of Federal Regulations, 2012*b*). For example, Red #4 was restricted from use in foods and ingested drugs or cosmetics due to a high incidence of tissue abnormalities in the adrenal glands and bladder of dogs. However, it is still permitted for use in externally applied drugs and cosmetics (Code of Federal Regulations, 2012*b*). In the early 1970s, physician Ben Feingold began to publish his clinical observations of how food additives such as artificial colors or preservatives and foods containing natural salicylates affected behavioral disorders in children and adults (Feingold, 1975). He observed less restlessness, sleeplessness, inattention, and aggression when children and adults followed a diet free from artificial additives. This spurred much interest from other researchers who tried to test his theories in controlled trials. In 1982, the Consensus Development Panel of the National Institute of Health concluded from examining the studies available that while a diet free from additives and salicylates appeared to show beneficial effects on behavior, it was not clear which substances were clearly responsible for the adverse behavioral effects (Food and Drug Administration, 2011*a*). Food, Drug and Cosmetic (FD&C) Yellow #5, among other food ingredients, was reviewed by the FDA's Ad Hoc Advisory Committee on Hypersensitivity to Food Constituents in 1986 (Food and Drug Administration, 2011*a*) and it was concluded that there was no evidence of behavioral disorders associated with the food components. In 2007, a study from the University of Southampton in the United Kingdom demonstrated that certain color additives along with the preservative sodium benzoate had the capacity to induce hyperactive behaviors in 3-year-old and 8/9-year-old children (McCann et al., 2007). While the FDA decided that this study showed a possible link between the test mixtures and hyperactivity, the results were not thought to be applicable to the general population due to limitations in study design. The European Food Safety Authority (EFSA)

came to a similar conclusion in that the evidence was limited to a small segment of specific children, but nonetheless, the European Union (EU) began to require warning labels on foods with color additives in 2010. Manufacturers in the EU must include the statement: "Name or E number of the colour(s): May have an adverse effect on activity and attention in children" on food products containing one or more of the six colors tested in the Southampton study (Food and Drug Administration, 2011*a*). These include Yellow #5, Yellow #6, Red #40, ponceau 4R, carmoisine, and quinoline yellow (the latter three not approved for use in the United States).

In 2008 the Center for Science in the Public Interest (CSPI) petitioned the FDA to ban eight of the nine color additives used in foods in the United States (Citrus Red #2 was excluded as it was only used on citrus rinds). As a result of this petition, the question of color additive safety was again put before the FDA in March 2011. An advisory committee hearing was held on the possible connection between artificial food dyes and behavior disorders in children. The advisory committee concluded that it was not appropriate at this time to mandate either a ban on food colorings or warning labels on foods containing them. Evidence reviewed by this committee suggested that there was reason to believe that food colors affected specific populations of sensitive individuals and that the mechanism for these reactions is unknown. Only limited data currently indicate that these reactions may affect all members of a general population, so the committee concluded that the "generally recognized as safe" (GRAS) status still applies to the certified additives. Accurate consumption data for different populations is not known. It is also unknown whether there is a dose-response relationship found between the amounts of color additives consumed and behavioral effects.

Production of food colors has increased steadily over the past several decades. Certification of the seven colors listed in this study plus Citrus Red #2 (used on fresh orange

peels), has increased steadily from 9.9 million pounds in 1999 to 17.2 million pounds in 2012 (Food and Drug Administration, 2012*b*). A trip to any supermarket in the United States will reflect the increasing variety of foods containing color additives.

The United States determines consumption by "disappearance data" which measures the disappearance of food (or its ingredients) into the marketing system (Food and Drug Administration, 2012*c*). Total amounts of dyes consumed are estimated by monitoring these data and dividing it by the number of people in the population and by 365 days per year. The FDA calculated estimated daily intake (EDI) of the dyes in 2010 to be roughly 45mg per person, per day, excluding the amounts used in pharmaceuticals and cosmetics (Food and Drug Administration, 2011*a*). This amount was considered to be an "overestimate" due to food waste and spoilage that might reduce the amounts of food consumed. However, the FDA calculated the amounts using only color additives in food and did not include exposure or ingestion of FD&C colors through pharmaceuticals or cosmetics. It did not consider medications taken by mouth or cosmetics and creams rubbed into the skin as a means of exposure to dyes. This EDI amount also did not include the additional D&C colors (Drug and Cosmetic) that are approved only for use in pharmaceuticals and cosmetics and not for food. There is a long list of additional color additives that are ingested through medications or absorbed via topical applications that are never considered to be part of the total exposure to dyes such as Red #33 found in lipsticks, mouthwashes, and soap products. The disappearance data method for determining daily exposure is likely to provide inaccurate and misleading information and most likely does not apply to special populations like young children.

Food products aimed at children are typically brightly colored cereals, baked goods, candy, and snacks, so it is possible that their levels of consumption might be greater than adult

populations. Also considering that Halloween, Christmas, Valentine's Day, Easter, and birthday parties expose children to higher levels of color additives, it is reasonable to anticipate that children consume more foods with dyes than most adults.

It is conceivable that one could obtain a large-scale estimation of intake by analyzing data from the National Health and Nutrition Examination Survey (NHANES) if amounts of color additives found in food items became available. This federally-funded health monitoring program obtains samples of health data from about 5,000 participants each year, some of whom submit dietary records. A survey customized to accurately collect information on foods that contain color additives could yield a wealth of information on consumption amounts of these substances.

In past years, when a new food color was developed, the FDA would look at available toxicology and safety studies, projected human dietary intake, and published literature for this additive and determine an Acceptable Daily Intake (ADI) level. These amounts listed in Table 1 are based on the body weight for an adult. The ADI for Blue #1, for example, is 12 milligrams per kilogram of body weight per person per day. This would theoretically translate to a maximum acceptable amount of 720 milligrams of Blue #1 for a 60kg adult. However, there is no scientific research done that combines the maximum ADIs together. It is not known whether a combination of over 2000mg of dyes per day could be consumed without evidence of carcinogenicity or other effects. While it is highly unlikely that any one person consumes this much of the dyes, it is hard to estimate what an actual "high user" might consume without information on how much dye is found in common foods.

Table 1. Artificial color additives in use in the United States in 2012

FD&C* Name of dye	Chemical name Or Trade name	Acceptable daily intake (ADI) ** (mg/kg body weight)	ADI for a 60kg (132lb) adult	ADI for a 30 kg (66lb) child (about age 9)
Blue #1	Brilliant Blue	12.0	720	360
Blue #2	Indigo Carmine	2.5	150	75
Green #3	Fast Green FCF	2.5	150	75
Red #3	Erythrosine B	2.5	150	75
Red#40	Allura Red	7.0	420	210
Yellow #5	Tartrazine	5.0	300	150
Yellow #6	Sunset Yellow	3.75	225	112.5
Total		**35.25**	**2115**	**1057.5**

FD&C stands for "Food, drug and cosmetic"—a name given to dyes that meet FDA certification requirements. **Source: Food and Drug Administration, 2011*a

Studies used to determine the ADIs were performed only on animals and only to determine to what extent these substances may cause cancer (see Table 2). The ADIs do not reflect the extent to which they affect neurological function in humans as this is not part of the chronic toxicity studies that the FDA required for safety testing. Additionally, no studies on humans have ever been done using true consumption data or ADI levels.

In many of the neurobehavioral research studies done on children, researchers based intake estimations on data provided by the Nutrition Foundation (Nutrition Foundation, 1980). This was an industry-supported, non-profit organization that contributed funding and supplies for some of the initial research in food dyes and hyperactivity in the 1970s and 1980s. Companies such as Nabisco, M&M/Mars, Hershey, McCormick, and dye manufacturers including H. Kohnstamm & Company and Stange Company, among many others, provided the funding (Nutrition Foundation, Inc., 1980). The Foundation created its own National Advisory Committee on Hyperkinesis and Food Additives which operated to examine the validity of Feingold's hypothesis. Feingold believed that a relationship existed between hyperactivity and

learning disabilities and artificial food additives. In 1980, the committee submitted a final report to the Nutrition Foundation with its conclusions. They stated that while certain individuals appear to demonstrate adverse behavioral effects, there was no need to continue high priority research in this matter, nor recommend any form of warning labels on food products containing color additives (Nutrition Foundation, Inc., 1980). They did acknowledge, however, a lack of any research on risks from a lifetime of exposure to color additives.

In eighteen different studies on food dyes and their relationship to behavioral or neurological effects in children shown in Table 3, amounts of dyes tested in these studies ranged from 1 mg to 150 mg of dye per child per day. The median amount of food dyes tested on children for hyperactivity was 26.6 mg per day. This is near the amount of 27 mg per day, which the Nutrition Foundation believed to be the average daily intake. Based on the estimated daily intake (EDI) by the FDA, a "high user" in 2010 (a 60 kg adult) might consume up to 450mg per day (Food and Drug Administration, 2011*a*). Even if a 30 kg child consumed half of that amount, he or she would still consume more than 200 mg per day. None of the pivotal studies looking at neurotoxicity in children used more than 150 mg per day. The research done to date thus did not test the theoretical "high user" amounts that some people might actually consume.

Another consideration that the FDA has not addressed in the creation of "safe" levels of consumption is that children are more sensitive to carcinogens from a developmental perspective (Hattis, Goble & Chu, 2005). If one pairs higher exposure with higher sensitivity, then the FDA must evaluate intake in children by different criteria than adults and establish lower ADIs.

Table 2. Studies which formed the basis for Acceptable Daily Intakes of color additives					
Certified color	**Author / year of study**	**Pivotal studies for ADI basis**	**Design**	**Results**	**Dosages**
FD&C Blue #1	Borzelleca, Depukat and Hallagan. 1990	"Lifetime toxicity/ carcinogenicity studies of FD&C blue #1 (Brilliant Blue FCF) in rats and mice."	2 year+ bioassays in rats (with *in utero* exposure) and in mice	Decreased mean terminal weight and survivorship of F_1 female rats in high-dose group. No observable adverse effects for highest dose groups in either species.	0, 0.1%, 1%, 2%, 5% dietary concentration
FD&C Blue #2	Borzelleca, Goldenthal and Wazeter. 1986	"Chronic toxicity/ carcinogenicity study of FD&C Blue #2 in rats."	2 year + bioassays in rats with *in utero* exposure	High dose males showed a trend of transitional cell neoplasms and bladder cancer although not statistically significant; Statistically significant increases in brain gliomas although data did not satisfy the criteria for neurocarcinogenesis by the FDA.	0, 2.5, 25, 75, 250 mg/kg
FD&C Green #3	Knezevich and Hogan 1981 (Bio/Dynamics)	"A long-term oral carcinogenicity study of FD&C green #3 in rats."	2 year+ bioassay in rats with *in utero* exposure	Pup mortality increased in F_1 generation of mid-high dose groups; decrease in survival of F_1 generation in all treated groups but no dose-response trend; significant increase of urinary tumors in high-dose male rats not considered related to treatment by FDA.	0, 1.25%, 2.5%, 5% dietary concentration
FD&C Red #3	Hansen, Zwickey, Brouwer and Fitzhugh 1973 Borzelleca, Capen and Hallagan 1987	"Long term toxicity studies of erythrosine. I. Effects in rats and dogs." "Lifetime toxicity/ carcinogenicity	2 year bioassay in rats and dogs 30 month bioassay in rats with *in utero* exposure.	No significant observable adverse effects. Statistically significant increases in follicular cell adenomas, follicular cell hypertrophy and hyperplasia, and follicular cystic hyperplasia of the thyroid in the high-dose males. 94% of high dose males showed proliferative changes of thyroid follicular cells. No observable adverse	0%. 0.5%, 1%. 2%. 5% dietary concentration 0.3%, 1%, 3%

		study of FD&C red #3 (erythrosine) in rats."		effects at lower levels of exposure.	dietary concentration
FD&C Red #40	Borzelleca, Oleson and Reno 1989	Lifetime toxicity/ carcinogenicity study of FD&C Red # 40 (Allura Red) in Sprague-Dawley rats."	2 year + bioassay in rats with *in utero* exposure	Statistically significant decrease in body weight in high-dose females; No other observable adverse effects.	0%, 0.37%, 1.39%, 5.19% dietary concentration
FD&C Yellow #5	Davis, Fitzhugh, Nelson 1964 Borzelleca and Hallagan 1988	"Chronic rat and dog toxicity studies on Tartrazine" "Chronic toxicity/ carcinogenicity studies of FD&C yellow #5 (Tartrazine) in rats."	2 year bioassay in rats and dogs 2 year + bioassay in rats with *in utero* exposure	In rats, highest dosage levels caused diarrhea and gritty deposits in renal pelvis in some male rats. No other effects were found on growth, survival, hematology, tumors or organ weights. In dogs, no signs of toxicity were noted. No biologically significant effects were found. All treated animals had a slight yellow tint to their fur.	0%, 0.5%, 1%, 2%, 5% dietary concentration 0%, 0.1%, 1%, 2%, 5% dietary concentration
FD&C Yellow #6	1982 Study by Bio/Dynamics Inc. under contract by Certified Color Manuf. Assoc.	"Additional Long-Term In-Utero Study in Rats"	2 year bioassay in rats with *in utero* exposure	Some higher mortality in mid-high dose groups. Statistically significant increases in adrenal adenomas and testicular adenomas but not attributed to yellow #6.	0%, 0.75%, 1.5%, 3% dietary concentration

Table 3. Studies examining the effects of color additives on behavior in children.
Note: Studies are listed in ascending order of the dose of dye used.

Study	Behavioral effects demonstrated	Max amt dye used (mg)	Types of colors used	Number of participants
Levy, et al., 1978	No	1	Yellow 5	22
Rose, 1978	Yes	1.2	Yellow 5	2
Sarantinos , Rowe, & Briggs, 1990	Yes	10	Yellow 5 &6	13
Goyette, et al., 1978	Yes	13	Mixture of colors	16
Conners, Goyette, & Newman, 1980	No	15	Mixture of colors	9
Bateman , et al., 2004	Yes	20	Mixture + sodium benzoate	277
Carter et al., 1993	Yes	26	Mixture of colors	19
Spring, Vermeersch, Blunden & Sterling, 1981	No	26	Mixture of colors	6
Adams, 1981	No	26.3	Mixture of colors	18
Harley, Matthews & Eichman, 1978	No	27	Mixture of colors	9
Weiss et al., 1980	Yes	35.3	Mixture of colors	22
Rowe & Rowe, 1994	Yes	50	Yellow 5	54
Rowe, 1988	Yes	50	Yellow 5 or Carmoisine	8
McCann et al., 2007	Yes	62	Two Mixtures	297
Mattes & Gittelman, 1981	No	78	Mixture of colors	14
Boris & Mandel, 1994	Yes	100	Mixture of colors	4
Pollock, 1990	Yes	125	Mixture of colors	19
Swanson & Kinsbourne, 1980	Yes	150	Mixture of colors	40

Rationale for Study

The notion of artificial colors having a relationship to behavioral disorders has been an issue of concern for over 37 years and will likely not go away. The FDA acknowledged that certain individuals who exhibit behavioral disorders may be sensitive to the additives but that this is due to a unique intolerance to the colors. In other words, because scientists have not yet identified the exact chemical mechanism by which the sensitivity occurs, the additives were not considered neurotoxic. The ADI levels that are currently considered "safe" have not been tested on humans, and the endpoints for the safety evaluations have been carcinogenicity and not neurobehavioral toxicity.

Examining whether children consume more dyes than adults is important because there may be risks other than cancer associated with the consumption of the dyes. Children stand to bear a greater share of the risks of high user consumption given that they are developmentally more vulnerable than adults. If they are exposed to dyes more frequently, then this underscores the need for further research for two reasons. First, we do not fully understand the metabolism of these substances. All of the ways these compounds affect human functioning is still being explored. Second, the food industry is using dyes in foods that are American favorites like macaroni and cheese, salad dressings, cereal and salty snacks. Due to the lack of known amounts of dyes in these foods, amounts consumed cannot be calculated. Americans may be encountering the dyes and other impurities frequently from multiple sources, and the effect of this cumulative exposure is unknown. The FDA hearings in 2011 made it clear that they would not force the food industry to provide warning labels or remove food colorings until research could demonstrate proof of *harm* from these substances (Food and Drug Administration, 2011*b*).

The participant ages selected for this study were chosen to provide a simple comparison between one age group of the children's population versus an adult population.

Objective

This is a pilot study to compare the daily number of exposures to artificially colored foods consumed each day by young children aged 4-7 versus adults aged 18-60. An exposure is defined as the event of consuming any food, beverage, medicine, supplement or candy containing one or more of the seven certified food color additives: Red #3, Red #40, Blue #1, Blue #2, Green #3, Yellow #5, Yellow #6. The hypothesis that was tested is that children aged 4-7 regularly have a greater number of daily exposures to artificial colors in foods, medicines, and supplements than adults.

Chapter 2: Review of Literature

The two types of studies most relevant to this research are those that support what the FDA deems is a safe maximum Acceptable Daily Intake (ADI), and assess different effects of color additive intake on human behavior and neurological functioning. The ADI studies provide a rationale for the FDA to claim that the dyes are not carcinogenic. The behavioral studies question whether there are other effects on human physiology. While no single study can tell the whole story, examining the progression of these studies over the past five decades can provide evidence on whether the dyes affect human health. Given the increased amounts of dye in our food supply, this issue warrants further study.

In creating the ADIs for each of the dyes, the FDA examined long-term animal studies for carcinogenicity and set limits on the amounts of carcinogens allowed in the dyes. The FDA intended these measures to ensure that a dye would not cause a lifetime risk greater than one cancer in one million people. However, the FDA established these limits over 24 years ago. Since then, the average daily dye production, the numbers of colored food choices, and colored food consumption have all increased (Food and Drug Administration, 1999-2012).

The studies the FDA considered pivotal in the development of the ADIs (see Table 3) began more than 50 years ago and continued over many decades. The studies examined chronic toxicity and carcinogenicity from feeding the test animals varying levels of the specified color over a period of two years, and most included an *in utero* phase. The FDA considers the best studies to be the ones that include an *in utero* phase of testing the food additives (Food and Drug Administration, 2007) because this ensures that exposure to a tested substance spans the full length of a laboratory test animal's lifetime from conception until termination. The animals were typically rats and mice, with a few studies done on beagles. The FDA requires that the

manufacturer bear the burden of proof that an additive being used in food meets the safety standards set forth for that substance, so many of these studies were conducted by the Certified Color Manufacturers Association.

The need for testing of food additives became apparent in 1950 after a diarrhea outbreak that was related to excessive dye amounts in orange-colored Halloween candy (Food and Drug Administration, 2012*a*). Questions began to arise about whether color additives might cause more serious health problems. United States House Representative James Delaney began hearings on the potential for carcinogenicity of food additives. The outcome of these hearings was that over the next ten years, the FDA re-examined toxicity of each of the dyes in use and terminated any that were shown to have adverse side effects such as the Orange #1 used in the Halloween candy. The Color Additive Amendment of 1960 specified factors that must be evaluated in order to determine if a color is safe and could be added to a provisional list. The "Delaney Clause" of that amendment required that manufacturers not use a color additive if research shows it to be a carcinogen. Since that time, the FDA has removed over 100 dyes from the provisional list and manufacturers no longer use them. For instance, the FDA removed colors such as Red #19 and #37 due to carcinogenic effects in test animals. The FDA removed other colors, such as Red #4 from use in foods, drugs and ingested cosmetics (like lipstick) due to bladder and adrenal damage in dogs, but still allow their use in externally applied cosmetics (Code of Federal Regulations, 2012*b*).

In the 1960s and 1970s, when manufacturers began to use colors more widely, the processed food industry saw tremendous growth, and one physician wondered if there was a connection between these foods and neurobehavioral disorders. Dr. Ben Feingold was the Chief Emeritus in the Department of Allergy at the Kaiser-Permanente Medical Center in San

Francisco, California, from 1969 until his death in 1982. He studied and observed in his practice how diet affected behavioral disorders in children and adults. His basic hypothesis stated that "Any compound in existence, either natural or synthetic, has the capacity to induce an adverse reaction in any individual with the appropriate genetic profile" (Feingold, 1977). He observed that food substances including artificial colors, preservatives, and foods containing natural salicylates had the capacity to induce behavioral disturbances such as Attention Deficit Hyperactivity Disorder (ADHD). He developed a protocol known as the "Feingold Diet" that was free from all of these components and noted improvements in behavioral, psychological, and intellectual measures (Feingold, 1982) in children. Dr. Feingold's studies prompted much interest from other researchers from the 1970s onward. These researchers would use the Feingold diet to eliminate symptoms of hyperactivity, irritability, or inattention and then reintroduce color additives to see if these substances alone could provoke reactions in children with ADHD or in general populations.

While most of Feingold's observations were in a clinical setting, other scientists wanted to see the relationship between behavior and dyes in a controlled trial. The first study, done by Conners, Goyette, Southwick, Lees and Andrulonis (1976), was a crossover trial on fifteen children that used an elimination diet and compared it to a placebo diet over eight weeks. Baseline data for behavioral activity was monitored for four weeks and was followed up by four weeks on each of the diets given in random order. There was no washout period between diets. The elimination diet restricted all artificial colors, flavors, and foods high in salicylates. The placebo diet allowed all of these foods. Foods allowed on each diet were non-overlapping, but the diets were similar in that they each restricted a unique grouping of foods so that the time for shopping, preparation, and planning was the same. The average response was a 15% reduction in

hyperactive behavioral symptoms in children while on the elimination diet. However, this effect was only seen when the placebo diet was given first and then subsequently followed by the elimination diet.

In 1978, J. Preston Harley and a group at the University of Wisconsin (Harley Matthews & Eichmann, 1978) tested nine children who were "responders" to the Feingold diet from a previous study they conducted. They had parents and teachers monitor the children's responses to an "on and off" pattern of dye-containing foods or a placebo over a period of 13 weeks and no significant effects were observed on behavioral measures. These measures included deviant behavior, gross motor activities, non-work behaviors, isolation, disturbing behavior, and attention span. These early studies aimed to prove or disprove Feingold's methods but made some important observations about examining food dyes independently of other dietary factors such as preservatives, flavorings, or salicylates. Eliminating all of these food ingredients simultaneously created the question of which elements were responsible for the behavioral effects. This is what many subsequent research studies tried to examine.

Levy and colleagues (1978) challenged 22 children diagnosed with hyperactivity with tartrazine (yellow #5). Children were evaluated by teachers, parents, a psychiatrist, and psychologist using the Conners scale and also given a series of tests for cognitive and motor skills and memory. They were tested six times: a pretest before the study; at the beginning of a diet that eliminated foods containing salicylates and all artificial flavors and colors; after 4 weeks on the elimination diet when a tartrazine or placebo challenge was given; after the challenge or placebo treatments were reversed; at the beginning of a four week washout period; and after the end of a four-week washout period. The challenge amount used in this study was a mere 1 mg of the dye, and observations were made the day *after* the challenge food was given. No correlation

was found between the dye challenge and behavior or objective tests. Interestingly, however, a small subgroup of participants showed a 25% reduction in behavioral symptoms on the Conners scale (Conners, Sitarenios, Parker, Epstein, 1998) according to mothers' ratings during the placebo phase. When the placebo phase followed the challenge phase, the mothers observed fewer symptoms, which indicated a significant challenge effect. This study is notable in that an unusually small amount of dye was used and that the behavioral effects were not usually apparent the day following the dye challenge. Even though effects from a small amount of dye were not detected in most subjects, another researcher (Rose, 1978) found contradictory results.

A small, but well-designed double-blind, placebo-controlled study by Rose (1978) tested one single dye, tartrazine (Yellow #5). He selected two children who were diagnosed with hyperactivity and were behaviorally responsive to the Feingold diet for the previous eleven months. The children were given 1.2 mg of Tartrazine in the form of a cookie on various challenge days that spanned a 6-week period. Data were obtained by blinded, trained observers 3 hours following the administration of the challenge food where "Out of Seat," "On Task," and "Aggression" behaviors were recorded. These tests indicate whether specific behaviors associated with hyperactivity were observed. In the children, a functional relationship was reported between ingestion of food colors and the increase in frequencies and duration of "Out of Seat" behaviors and a decrease in "On Task" behaviors.

In 1980, Weiss and colleagues conducted a similar study to demonstrate that food dyes alone could elicit direct behavioral disturbances in some sensitive children and that controlled studies could be done to show this relationship. The purpose of this study was to show that a reaction to dyes was possible and not to show prevalence or incidence of behavioral responses in a given population. Children received an artificially colored soft drink (containing a mixture of

dyes) on eight days over an eleven-week period. After an elimination diet for three months preceding the study, two out of 22 children responded with an increase of aversive behaviors to the 35.3 mg mixed dye challenge; one of these children had very dramatic reactions. The mother of this child was able to accurately identify five of the eight days that her child received the challenge drink.

Conners and colleagues (1980) conducted a study to determine whether hyperactive children who appear to react to artificial colors showed a pharmacologic dose-time effect by using more sensitive laboratory tests. The challenge food, supplied by the Nutrition Foundation, was two chocolate cookies each with or without 15 mg of a mix of artificial colors. Researchers tested nine diagnosed hyperkinetic children who were showing notable improvement on the Feingold diet under double-blind conditions in two sessions at 1-2 week intervals. Tests consisted of two types: electronic movement detectors attached to the child's ankle and wrist to assign counts of movements per minute; and behavioral ratings by the experimenter. No significant adverse effects were found for the color challenge for either of the outcome measures. The researchers concluded that an adverse effect may have been obscured by the chocolate in the placebo cookie or possibly by a connection between a hyperglycemic hyperactivity that is reduced by the digestion of a cookie. It was not clear whether the challenge cookie itself was free from other artificial additives that were not allowed in the Feingold diet (flavors or preservatives, for example).

In an Australian study, Rowe (1988) designed a two-phase, double blind crossover project to test the relationship between certain behavioral characteristics and two artificial colors (Yellow #5 and Carmoisine [not approved in the US]). In phase one, 55 children with and without hyperactivity were tested in an open trial of the Feingold diet. The diet was free from all

additives, preservatives, and salicylates. While 40 of these children showed some behavioral improvement on the diet, only fourteen were suspected of reacting to color additives. From this latter group, the researchers challenged eight children in phase two with 50 mg of the color additives or a placebo. The researchers first maintained the children on a placebo lead-in period for 3, 4, or 5 weeks. Then the researchers administered 50 mg of either tartrazine or carmoisine daily for one week on two separate weeks of the study period with a 2-3 week washout period between challenges. Parents measured behavioral outcomes by filling out a behavioral checklist of frequent symptoms (inattention, insomnia, irritability, restlessness, aggression, etc). Two children showed consistent, clear reactions to the dye challenges. What was notable about this study is that the researcher commented that one of the responders did not have typical "attention deficit" symptoms but responded with irritability, restlessness, and sleep disturbances. This suggested that the sensitive individuals who react to the dyes are not always those who are diagnosed with a hyperactivity disorder. Also interesting was that the duration of the reactions differed between the two reactive children. After returning to the Feingold diet, one child returned to baseline behavior within about four days while the other child, who reacted more severely to the color challenges, took 3 ½ weeks to return to baseline behavior.

While it became increasingly clear that certain individuals with sensitivity to dyes or additives would react to a dyed food versus a placebo, could this also be true for an ordinary child? Bateman and colleagues (2004) in the United Kingdom conducted a double-blind, placebo-controlled study on 277 preschool children who consumed artificial food colors and the preservative sodium benzoate. The intention was to examine whether these ingredients could induce hyperactive behaviors in the general population. They concluded that the active challenge drink consisting of 20 mg of mixed colors and 45 mg of sodium benzoate could induce

hyperactive behaviors as measured by parental ratings, clinical tests of task performance and tester recordings of behavior. The researchers suggested that this was most likely due to a pharmacological effect of the additives rather than an IgE mediated allergic reaction because the elicited behavioral responses were observed in children with and without previous hyperactivity and atopy. One of the limitations of this study, however, was that it was not known whether the dyes or the preservatives or a mixture of the two caused the behaviors.

A second similar study by McCann and colleagues (2007) also concluded that behavioral effects could be demonstrated in classroom and home observations made independently by teachers and parents by challenging children with dyes and additives. This study was a randomized, double-blinded, placebo-controlled, crossover trial of 153 three-year-old children and 144 eight-to nine-year-old children. Researchers tested two different mixtures of food colors and sodium benzoate on each group. As with the Bateman study, results indicated that although the mixtures could provoke hyperactivity in children, it was still uncertain whether the dyes or the preservative alone or the mixture of both caused the reactions.

One interesting aspect of this study was that the mixtures of dyes consisted primarily of azo dyes. Azo compounds are a specific class of dyes based on their chemical structure and have the potential to be degraded to carcinogenic compounds when exposed to certain bacteria and enzymes. This is a new area of research because although the parent compounds of the azo dyes may not be problematic, once these compounds are exposed to various bacteria on the skin (from cosmetics or tattoos) or in the intestinal tract (from food) they can be reduced to form new compounds that are potentially carcinogenic to humans (Feng, Cerniglia, & Chen, 2012). The azo dyes used in the United States include Red #40, Yellow #5, and Yellow #6 – the top three colors consumed.

In the forty years since Dr. Ben Feingold began to examine a relationship between neurological functioning and food additives, the research demonstrates that food additives trigger reactions in some people but not in others. This might be because there are no reactions to artificial colors or additives, or because science has yet to explain the unique ways in which each individual might be affected. Previous research has shown that reactions to dyes are possible, but that the mechanism for their metabolism is not yet completely understood. The FDA asserts that the amounts consumed by the general population are safe, even though exact amounts consumed by individuals are unknown. Safety for human consumption is based upon rodent carcinogenicity studies done twenty to forty years ago as well as human neurobehavioral studies which have conflicting evidence of effects. Research that tracks true consumption patterns will provide clearer guidelines for designing additional studies. Knowing how much of these substances Americans are actually eating can provide a better estimate for doses of synthetic dyes used in future toxicology studies that test their safety.

Chapter 3: Methods

The researcher recruited 21 adults (ages 18-60) and the parents of 14 children (child ages 4-7). Promotional flyers at local businesses, schools, and youth sporting events were distributed. Public service announcements by local radio stations and newspapers were made. Subjects electing to participate in the study viewed information on a project website: www.FoodSurveyTCkids.com. All participation in this study was conducted anonymously and names, addresses, emails, or other identifying information were not required to participate.

From the main page of the website, participants learned the purpose of the study, the requirements and incentives, and proceeded to the survey at SurveyGizmo.com to determine if they qualified to participate. Participation was limited to one adult or child per family or household. Survey Gizmo automatically blocked multiple responses from the same IP (internet protocol) address. Participants clicked on a tab titled "Survey" from the main website. This presented a simple questionnaire that was designed to determine if a participant met the inclusion criteria for age and health status. Survey Gizmo automatically scored their responses and directed them to the informed consent page if they qualified or to a page that dismissed them from participation if they did not qualify. Inclusion criteria for children were: Ages 4-7 with regular eating patterns. Inclusion criteria for adults were: Ages 18-60 without a history of eating disorders. Exclusion criteria were as follows: Children under age 4 or ages 8-17; adults over age 60; persons with use of medications that significantly increased or decreased the appetite; persons with medical problems that would potentially affect the appetite including: very picky eaters; diabetics; persons with eating disorders such as binge eating, anorexia or bulimia nervosa; persons with Crohn's disease, ulcerative colitis, irritable bowel syndrome, cancer, liver

disease, severe depression, or kidney failure. These criteria were selected to obtain food records that best reflected typical eating patterns of Americans.

Those who did not meet the initial criteria in this questionnaire were prohibited from proceeding further in the selection process. Participants who met the criteria were invited to proceed with the informed consent. If they clicked on "No Thanks", the computer dismissed them from the survey. If they chose to continue, they clicked on "I agree."

The 21 adults and the parents of the 14 children established an anonymous login name and Survey Gizmo assigned them an identification number. Participants used this login process for all access to the record-keeping features of the website. Each adult and parent/caregiver completed a profile that contained demographic and consumer information that the researcher correlated with the diet record data. Data on age, gender, ethnicity, educational, and income levels of the individual or family were included. Once this profile was completed, the participant viewed a brief video training module that explained the procedures for keeping an accurate diet record. Upon completion of the training module, the participant then had full access to their blank online diet record worksheets. All participation took place from November 25, 2012 to January 5, 2013. Participants worked to complete a five-day record over two to four weeks.

Parents/ adults recorded types and amounts of every food, beverage, medicine, vitamin, gum, and candy the child or adult used or consumed for five days. Information obtained was the date of the record, type of food and amount eaten, and brand name and flavor variety (where applicable for packaged foods). They chose any five days over two to four weeks to fill in the record as long as there were at least three week days and two weekend days in the mix. They chose either to take notes throughout the day using paper and pencil, or using their cell phone to

send information to their email. Participants then entered the data from their notes into the database on the website.

To enhance the likelihood of participation, families completing the process had the option to receive a thank you gift of coupons for local businesses and be entered in a drawing for lunch for two at a local restaurant. The coupon packs were available at select businesses for pick up by the participant. Survey Gizmo randomly generated an identification number (1-50) to all participants upon completion of the fifth day of the diet record. The participant randomly receiving the pre-selected winning number went to the winner's page where Survey Gizmo provided instructions on redeeming their grand prize gift certificate.

This study examined the frequency of daily exposures to all seven of the most commonly used color additives: Red #40, Red #3, Yellow #5, Yellow #6, Blue #1, Blue #2, and Green#3. For purposes in this study, the researcher defined an exposure as the event of consuming any food, beverage, medicine, supplement, or candy containing one or more of these color additives. Each time a listed item on a participant's food record contained one or more dyes, the researcher counted it as one exposure.

The researcher exported food records from the database in Survey Gizmo and put them into an Excel format for review. Individual foods were analyzed for dye content by using ingredient labels found online and in grocery stores for specified products and flavors. Manufacturer's websites and FoodFacts.com were used to track ingredients. Each dye found on a food label was recorded to determine which dyes participants consumed most frequently and tallied the average number of dye-containing foods eaten per day per person.

Excel software was used for all statistical analyses including descriptive statistics for the population ages, education and income levels, and two-sample t-tests to compare the mean

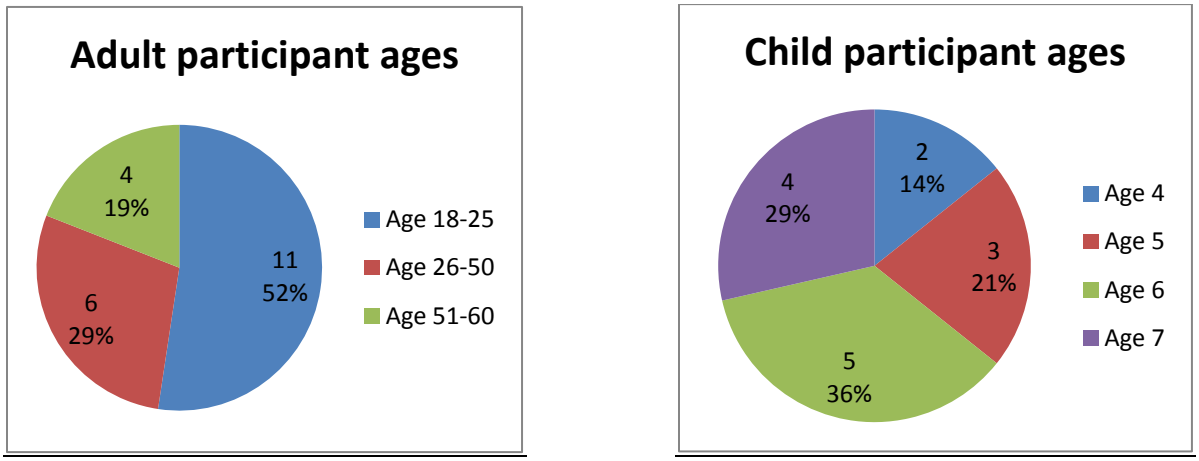
numbers of exposures per person between adults and children for the five days of recorded dietary data. A 95% confidence interval was used for significant differences in consumption patterns between these two age groups.

Also examined were fruit and vegetable consumption as well as average nutrient intakes among the participants in the study. Fruit and vegetable consumption amounts were recorded and compared to the number of dye exposures per day. Dietary records were then analyzed for average daily intake of calories, protein, fat, carbohydrate, sodium, calcium, iron, vitamin C, and vitamin A using the USDA's SuperTracker. These amounts were compared with national averages in the United States for similar gender and age groups from the National Health and Nutrition Examination Survey.

Chapter 4: Results

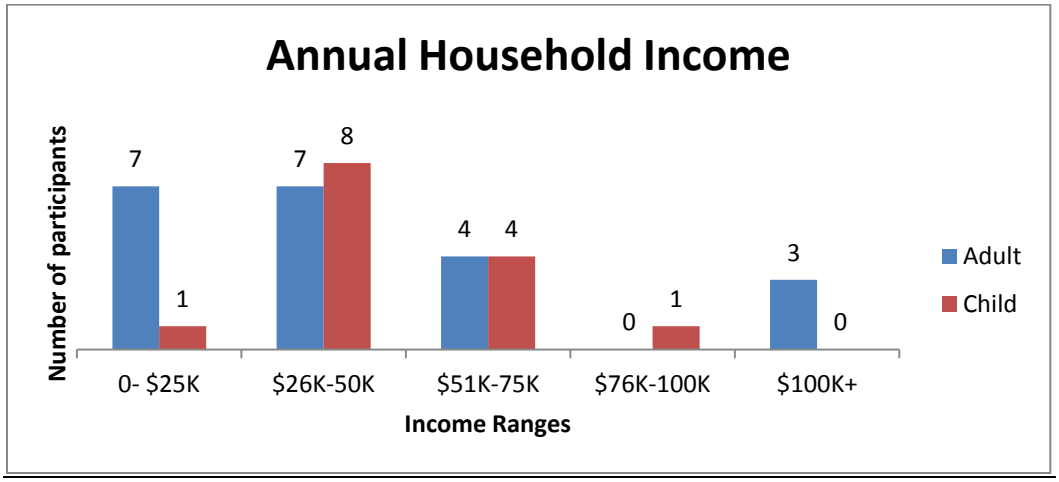
Food records for 21 adults and 14 children were collected. In the adult group, out of the 21 participants, 17 were female and four were male. The children's group had seven girls and seven boys. Figures 1-3 depict demographic characteristics of these populations. In the adult group, approximately half (11 of 35) of the participants were aged 18-25, with the remainder in the 26-50 and 51-60 age groups respectively. The age range of the children was evenly distributed between four and seven years. Given the small geographical area from which they were recruited, nearly all participants identified as white or Caucasian with one participant identifying as Native American (data not depicted in figures below). Household income levels were mainly between $25,000 and $75,000 (Figure 2) annually and educational levels reflected that the respondents nearly all had some college education (Figure 3).

Figure 1. Participant ages



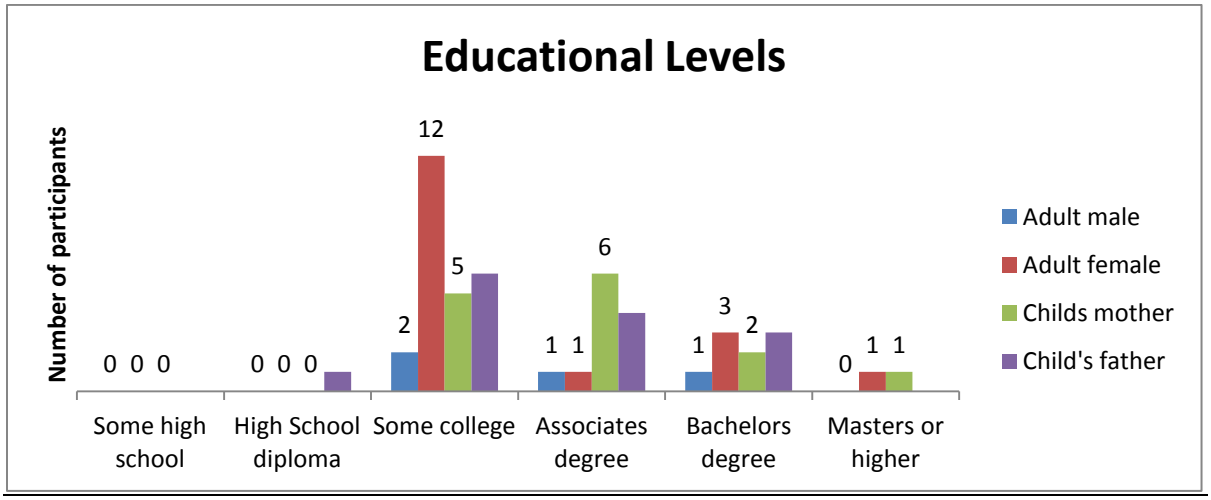
Participant ages for adults (N=21) and children (N=14).

Figure 2. Participant annual household income



Annual income ranges for adult and child households.

Figure 3. Participant educational levels

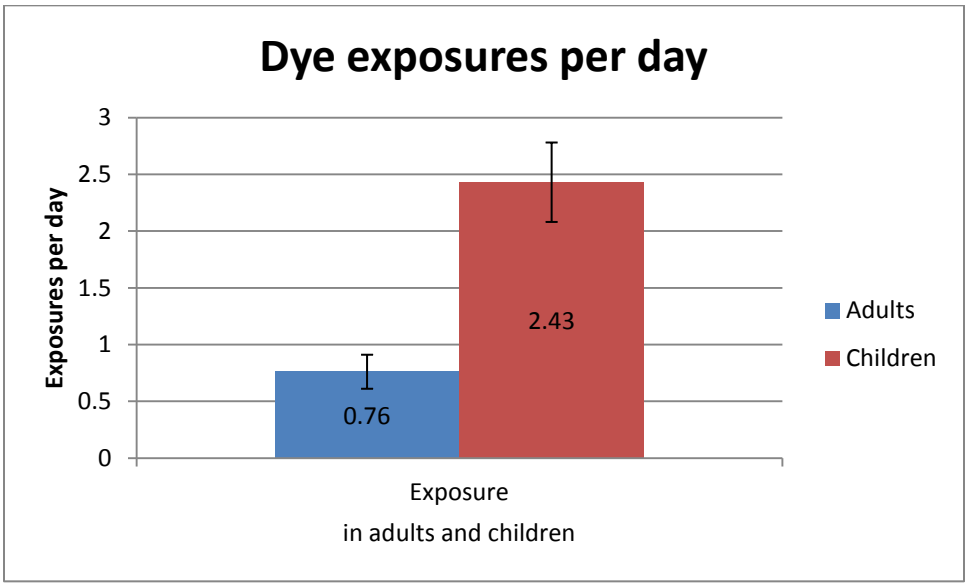


Educational levels for adult participants and parents of the child participants.

In this study, one exposure was defined as any food item, beverage, medicine, gum or candy containing one or more of the seven artificial colors. Adults were exposed to color additives 0.76 ± 0.15 times per day. Children had 2.43 ± 0.35 exposures per day. A two-sample t-test that compared the mean number of dye exposures per day between children and adults determined that the exposures per day were significantly less for adults than children ($P<0.001$).

In the adults, there were two participants (in the 51-60 age range) that had exposures that were 1.5 times more than the others, primarily from dyes in vitamins. Although these outliers were eliminated from the final data, even with their inclusion, mean adult exposures were 0.99 ±0.21 per day and were still significantly less than the children's exposures ($P<0.001$). Children's exposures were still nearly two and a half times greater than the adults when the outliers were included. However, the final data represent the dye exposures for 19 adults and 14 children (see Figure 4).

Figure 4. Dye exposures per day in adults vs. children



Exposures to color additives were 0.76 ± 0.15 per day for adults (n=19) and 2.43 ± 0.35 per day for children (n=14).

There were no correlations between the number of exposures per day and gender, age levels within adult and child groups, income levels, and educational levels. Exposures were fairly consistent across all demographic segments in all categories.

The most frequently consumed color additives among adults in this study were Red #40, Yellow #5 and Yellow #6, in descending order. In the children's group, the top three colors consumed were Red #40, Blue #1, and Yellow #5, in descending order. Overall, the most common foods eaten containing dyes were candy, breakfast foods like cereal, toaster pastries, and cereal bars, macaroni and cheese, cheese flavored salty snacks and

Table 4. Top 3 artificial colors consumed by adults and children

Adults: Top 3 colors				**Children: Top 3 colors**		
Red #40	**Yellow #5**	**Yellow #6**		**Red #40**	**Blue #1**	**Yellow #5**
Snack bar	Candy	Salty snack		Candy	Cereal	Candy
Beverages	Artificial creamer	Artificial creamer		Snack bar	Candy	Cereal
Candy	Beverage	Macaroni & cheese		Cereal	Beverage	Macaroni & cheese
Pastry	Pickles	Candy		Ice cream	Ice cream	Ice cream
Yogurt	Salty snack	Cereal and cookies		Fruit roll up	Fruit roll up	Beverage

Listed above are the top 3 colors consumed by adults and children and the most frequently consumed foods containing these colors.

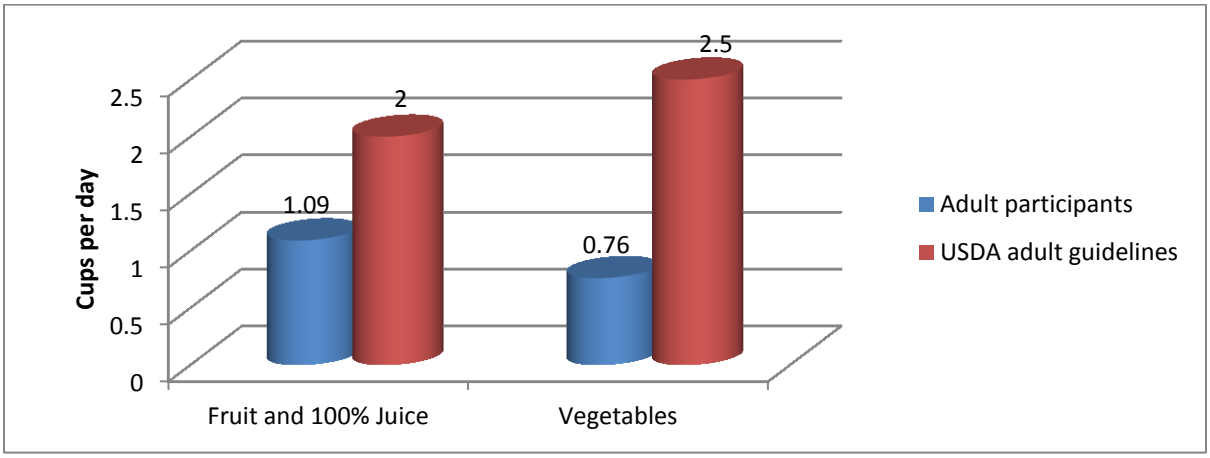
ice cream (see Table 4). The top two dye-containing foods eaten by children were candy and sweetened cereals. Adult exposures to artificial colors were most frequently from snack items and beverages.

An unplanned outcome of this research was the ability to examine fruit and vegetable consumption in this population. The researcher compared participants' daily number of exposures to artificially colored foods with amounts of fruits and vegetables consumed. Adult consumption ranged from a low of 0.7 cups to a high of 5 cups of whole fruits and vegetables per

day with the average at 2.12 ± 0.26 cups. Children's whole fruit and vegetable consumption ranged between a low of 0.2 cups per day and a high of 2.7 cups per day with the average being 0.99± 0.24 cups. This intake was then compared with individual quantities of fruits and vegetables recommended by the United States Department of Agriculture guidelines (United States Department of Agriculture, 2011) in figures 5 and 6. The USDA (ChooseMyPlate.gov) recommends nutrient amounts based on age, gender and caloric intake. Participants consumed less than half of the recommendations for daily vegetable consumption per day. USDA recommendations for most adults aged 18 and over are to consume 2 ½ to 3 cups of vegetables per day and adult participants in this study consumed an average of 0.76 ±0.15 cups per day. Children ages 4-7 are recommended to consume 1 ½ to 2 cups of vegetables per day and those in this study averaged just over 0.39 ±.07 cups per day (Figure 6).

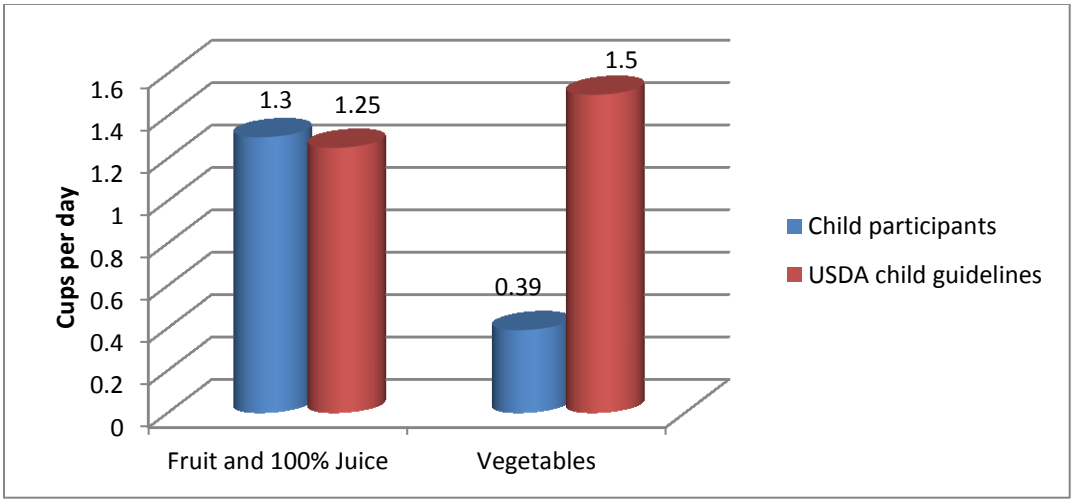
Fruit consumption was nearer the federal guidelines but only with the inclusion of 100% fruit juices which comprised nearly one third to one half of all participant fruit choices. Adults ate an average of 1.09± 0.15 cups of fruit and 100% juice and did not meet the USDA guidelines of two cups per day. Children on the other hand, need about 1 to 1 ½ cups of fruit or 100% fruit juice and those in this study met requirements and consumed an average of 1.3 ± 0.21 cups per day (Figure 6).

Figure 5. Fruit and vegetable consumption in adults



Number of cups per day of fruit and vegetables consumed by survey participants compared to the USDA Choose My Plate recommendations for adults aged 18+ consuming a 2000 calorie a day diet.

Figure 6. Fruit and vegetable consumption in children

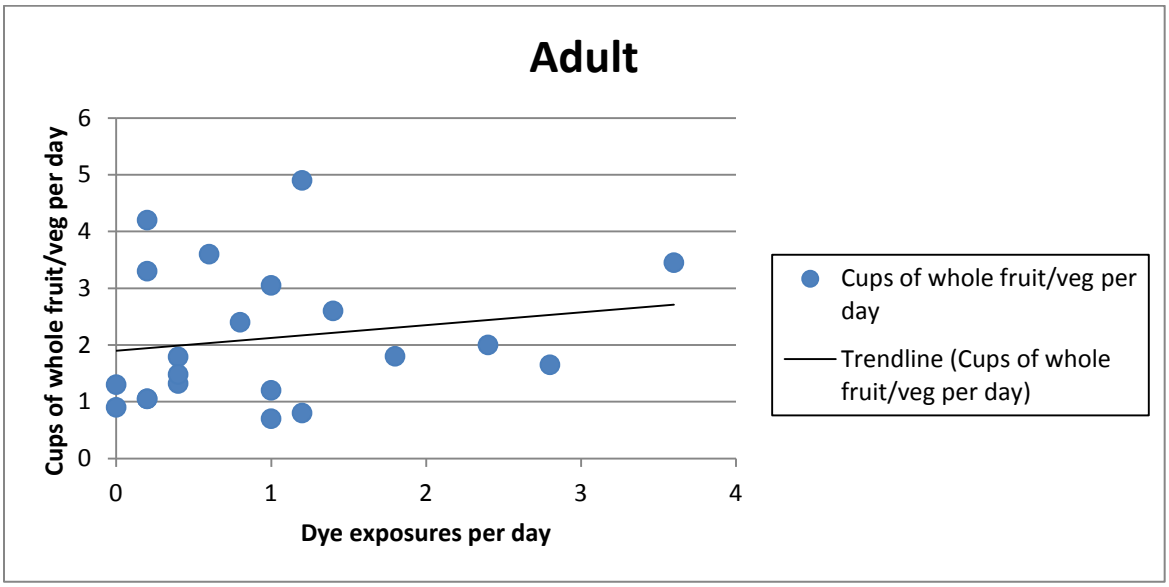


Number of cups per day of fruit and vegetables consumed by survey participants compared to the USDA Choose My Plate recommendations for children aged 4-7 consuming a 1200-1400 calorie a day diet.

In adults, there was a positive relationship between the number of dye exposures and amount of fruits and vegetables consumed (Figure 7). When consumption of fruits and vegetables increased, so did the exposures to processed foods containing artificial food colors.

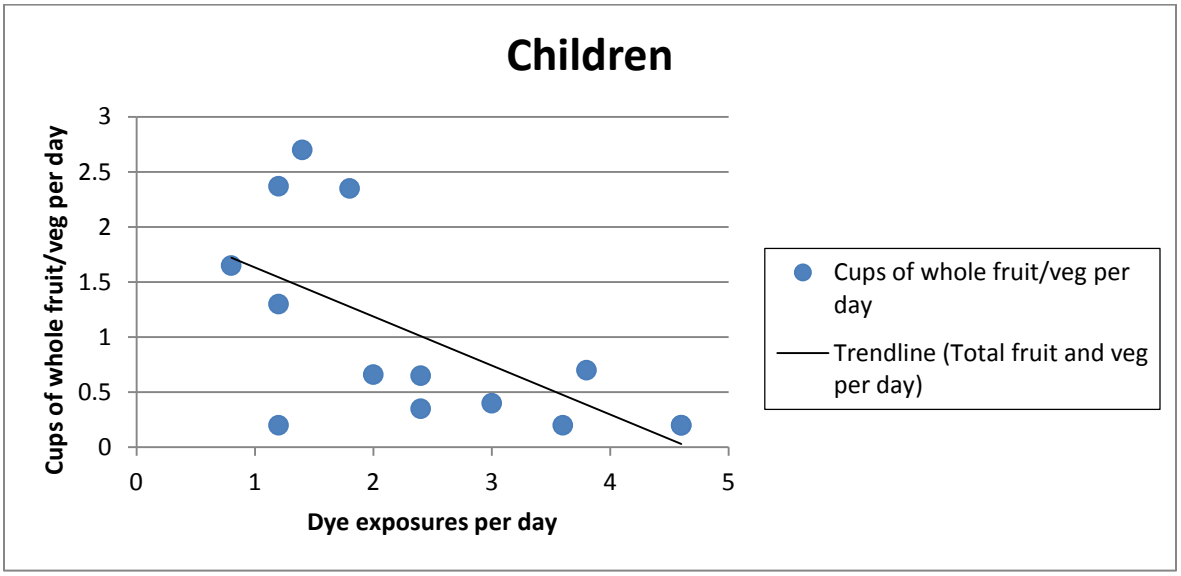
This is likely a reflection of the variable amounts of food eaten by individuals. However, the children showed a very different pattern: there was a strong inverse relationship ($P<0.015$) between whole fruit and vegetable consumption and frequency of exposures to processed foods with color additives. When processed food consumption increased, fruit and vegetable intake decreased. Thus, the children who had more frequent exposures to artificially colored foods ate fewer whole fruits and vegetables than those children with less frequent dye exposures.

Figure 7. Fruit and vegetable correlation with dye exposures in adults



In adults, dye exposure frequency is positively correlated (0.18) to fruit/veg consumption (black line).

Figure 8. Fruit and vegetable correlation with dye exposures in children



In children, dye exposure frequency is inversely correlated (-0.63) to whole fruit and vegetable consumption (black line).

Comparisons of average nutrient intake were made between the dietary records from this study and data from the 2005-2006 National Health and Nutrition Examination Survey (NHANES) which is the most recent version of this information (Centers for Disease Control and Prevention, 1999-2006). Mean intake levels were examined for total daily intake of calories, protein, fat, carbohydrate, sodium, calcium, iron, Vitamin C and Vitamin A (Figures 8-11). Caloric intake among adult females and all children was relatively comparable. The men's caloric intake in this study was slightly lower than the national average. Macronutrient and micronutrient intake levels were also relatively similar for all groups when compared to the NHANES data. Micronutrient data was not available for the children's population in the NHANES database.

Table 5. Nutrient intake for adult males

Adult Male Participant #	Calories	Protein (% of kcal)	Fat (% of kcal)	Carbohydrate (% of kcal)	Sodium (in mg)	Calcium (in mg)	Iron (in mg)	Vitamin C (in mg)	Vitamin A (in ug RAE)
Averages for males	2315 ±508	17% ±1%	30% ±3%	54% ±3%	2880 ±742	1897 ±722	23 ±6.4	95 ±35	914 ±332
NHANES age 20+ average	2638	15.8%	33.7%	47.4%	3466*	966	17.2	103	961

Comparison of the average daily nutrient intake of adult male participants ages 18+ (n=4) vs. adult males 20+ from the 2005-2006 United States National Health and Nutrition Examination Survey.

***2005-2006 average for male and female adults ages 20+.**

Table 6. Nutrient intake for adult females

Adult Female Participants	Calories	Protein (% of kcal)	Fat (% of kcal)	Carbohy-drate (% of kcal)	S0dium (in mg)	Calcium (in mg)	Iron (in mg)	Vitamin C (in mg)	Vitamin A (in ug RAE)
Averages for females	1760 ±127	17% ±0.7%	36% ±1.3%	48% ±1.6%	3108 ±216	823 ±78	14 ±1.4	75 ±8.3	723 ±67
NHANES ages 20+ average	1785	16%	33.8%	49.4%	3466*	765	13.4	91	916

Comparison of the average daily nutrient intake of adult female participants ages 18+ (n=17) vs. adult females 20+ from the 2005-2006 United States National Health and Nutrition Examination Survey.

***2005-2006 average for male and female adults ages 20+.**

Table 7. Nutrient intake for boys

Male Child Participants	Calories	Protein (% of kcal)	Fat (% of kcal)	Carbohydrate (% of kcal)	Sodium (in mg)	Calcium (in mg)	Iron (in mg)	Vitamin C (in mg)	Vitamin A (in ug RAE)
Averages for male children	1672 ±108	15% ±0.7%	25% ±2.9%	59% ±2.4%	2450 ±156	1002 ±88.6	13 ±1.65	162 ±22.7	730 ±83
NHANES ages 2-5 average	1641	13.9%	31.4%	55.9%	NA	NA	NA	NA	NA

Comparison of the average daily nutrient intake of boys ages 4-7 in this study (n=7) vs. boys ages 2-5 from the 2005-2006 United States National Health and Nutrition Examination Survey.

Table 8. Nutrient intake for girls

Female Child Participants	Calories	Protein (% of kcal)	Fat (% of kcal)	Carbohydrate (% of kcal)	Sodium (in mg)	Calcium (in mg)	Iron (in mg)	Vitamin C (in mg)	Vitamin A (in ug RAE)
Averages for female children	1485 ±67	13% ±1.1%	27% ±0.8%	61% ±1.1%	2225 ±157	796 ±86	13 ±1.49	164 ±21	697 ±118
NHANES ages 2-5 average	1486	14.3%	31.1%	56%	NA	NA	NA	NA	NA

Comparison of the average daily nutrient intake of girls ages 4-7 in this study (n=7) vs. girls ages 2-5 from the 2005-2006 United States National Health and Nutrition Examination Survey.

In summary, the children in this study are more frequently exposed to artificial color additives than the adults in their daily diets with Red #40 being consumed most often by both groups. This frequency appears to be inversely related to whole fruit and vegetable consumption in children but not in adults.

Chapter 5: Discussion

Participation

The age groups for this study provided a comparison of frequency of dye exposures between one segment of a children's population versus an adult population. The age group between four to seven years is a school-age developmental period where tremendous physical and neurological growth occurs. If color additives pose any toxicological concern, this would affect children more significantly than adults as their neurological systems are still developing. This age group was thus selected since children at this stage are potentially more vulnerable to the toxic effects of dyes.

Participation was limited to one person per household. Since most families eat a similar variety of foods and share meals, the limit was set to derive the greatest possible number of eating patterns among individuals in a small study.

All participants kept a written food record for five days. The tools provided for training the participants in keeping quality records included a short video, a written instruction sheet and "pop-up" instruction windows on the survey website. The quality of the food record information was excellent based on the amount of detail given for the majority of the records. Most of the participants (28 of 35) recorded three weekdays and two weekend days as requested. The remaining participants recorded four weekdays and one weekend day. This pattern was called for to get the best information on an individual's food selections on different days of the week as activities and eating habits may vary. Food records were well kept and included all meals and snacks, beverages and medicines in a consistent manner as per instructions. Items such as condiments, gum, and candy were included in the food records.

A comparison was made between nutrient averages from the diet records in this study and 2005-2006 US averages from the Centers for Disease Control. The adult age groups were 18 and over for this study and 20 and over for the NHANES data. The children's age group in the national data was slightly lower (ages 2-5) than those in this study (ages 4-7). Although a direct comparison cannot be made, it is useful to examine nutrient intake of the study participants alongside a broader demographic segment of the United States. Daily mean intake of calories, protein, fat, carbohydrate, sodium, calcium, iron, Vitamin C, and Vitamin A was comparable between the participants of this study and the national averages recorded in the NHANES dietary database. While the caloric intake in the adult male participants of this study was slightly lower than the national average, this is likely a reflection of the small number of male participants (n=4) for this study. There was also larger variability in energy consumption by the adult males. The adult female and children's caloric and nutrient averages were similar to national averages indicating that the dietary data in this study may be reflective of larger demographic segments.

Color Additives

The hypothesis that was tested for this study was proven to be true that children have more frequent exposures to artificial food colors than adults. Based on observations from dietary records, children's dye exposures were approximately three times more frequent than adult exposures. Exposures per day were measured because no industry data is available on amounts of dye contained in processed foods. In this study, foods frequently contained several types of dye such as a chocolate ice cream which contained Red #40, Blue #1 and Yellow #5. This was counted as one exposure because it is not yet possible to calculate the amounts of each dye contained in the product. Still, it needs to be stressed that a higher frequency of exposure will not necessarily equate to higher amounts of consumption in milligrams of dye. One exposure to

dye in a piece of gum will not be the same as one exposure in a 20-ounce blue sports drink. True consumption can only be measured when amounts of dye present in foods become known. Currently, there is no requirement to indicate the amount of dye in a food so there is no way of estimating the actual amount therein. The higher frequency means that children (or their parents) are selecting colored, processed foods more often than would adults. For example, children preferred the brightly colored, fruity cereals while most adults tended to choose oatmeal, granola or "flake" type cereals. The implications of such choices may be that the diet lacks necessary nutrients when processed foods are chosen on a regular basis.

Although absolute amounts consumed are unknown at this time, research has shown that even small amounts of color additives affect some children (Levy et al., 1978; Rose, 1978). Higher frequency of dye consumption even in small quantities still raises a concern whether children bear a higher risk of any possible toxicological effects. The human brain and nervous system undergo rapid growth and maturation from the weeks following conception until well into childhood (Lenroot and Giedd, 2006). Billions of neurons are formed during these times that ultimately evolve into the central nervous system which influences a person's ability to learn and function. Tartrazine (Yellow #5) has been shown to have a negative effect on emotional state, learning, memory, and behavior in weanling and adult rats (Gao et al., 2011, Kamel and El-lethey, 2011). Adult rats showed greater impairment in memory tasks when higher dosages of tartrazine were administered (Gao, et al., 2011). Weanling rats demonstrated higher rates of anxiety, depression and social interaction impairment when exposed to tartrazine (Kamel and El-lethey, 2011). These studies have demonstrated that changes in brain tissue due to the formation of reactive oxygen species from the metabolism of tartrazine likely caused these effects. While tartrazine is the most well-studied artificial color additive, it is possible that other colors may

also have deleterious effects on health. Monitoring consumption frequency of the dyes provides valuable information regarding which colors may be of greater concern for a specific population.

In both children and adults, Red #40 was the most frequently consumed color. It was identified 79 times in the aggregate adult food records and 112 times in the aggregate children's records. Its popularity in foods is due to its wide usage for creating colors that mimic strawberries, raspberries, and blueberries in fruit and grain bars, yogurt, beverages, and cereal. Consumers are led to falsely believe that products with Red #40 and Blue #1 contain real fruit because the color is bright and attractive.

Blue #1 was consumed much more often by children (identified 63 times in aggregate records) than adults (identified 31 times). This color additive was found in "fruity" breakfast cereals, hard candy, blue fruit-drink beverages, artificial chocolate colorings in ice cream or candy, and fruit "roll-up"-type snacks. All of these foods are specifically marketed to children through television commercials and other child-centered media (Cairns, Angus and Hastings, 2009; Gambel and Cotugna, 1999).

A potential concern that has not yet been addressed in any of the neurological studies with food colors is the ability for Blue #1 to cross the blood-brain barrier and permeate into the brain and spinal cord tissues (Peng et al., 2009). This study examined Brilliant Blue G, a derivative of Blue #1, as a treatment for traumatic spinal cord injury and could be an appropriate medical intervention in adults, whose blood-brain barrier and nervous system are fully formed. However, this is not the same as to say that Blue #1 is safe for chronic ingestion in pregnancy, infancy and childhood. The implications of long-term ingestion of Blue #1 and its non-color impurities having direct contact with developing neural tissues are unknown.

Yellow #5 and Yellow #6 were also more frequently consumed by the children. Yellow #5 is a bright yellow, and Yellow #6 is more orange-like. These two colors are commonly found together in yellow-colored foods to provide a pleasing hue like those found in artificial cheese flavored products which were favored by the adult participants. Products most frequently found containing these colors were cheese-flavored chips and popcorn, flavored coffee creamers and macaroni and cheese. Yellow #6 by itself was most often found in the coating on adult multivitamin formulas and consumed most frequently by the adults in the highest age group. Children favored cereals, candy, and macaroni and cheese containing these two colors.

Acceptable Daily Intake Levels

Much of the neurobehavioral research to date used far less than the "high user amounts" or Acceptable Daily Intake (ADI) levels established by the FDA. The FDA based the ADI levels on two-year bioassays for chronic toxicity and carcinogenicity done on rodents (see Table 2). Chronic toxicity in humans has not been studied. It has not yet been clearly established whether a dose-response relationship exists between amounts of dyes consumed and behavioral or health effects. There may be some individuals who are more sensitive to the dyes as research studies have shown the effects of synthetic dyes on neurobehavioral reactions are pronounced only in a selected group of individuals. If reactions to these substances are not obvious for the general population, what is it about the "sensitive individuals" that causes them to react to the dyes? Recent studies suggest a link between genetic polymorphisms affecting histamine degradation and might explain a range of behavioral responses to color additives (Stevenson et al., 2010). Children in that study who had a specific genotype for histamine degradation were more likely to show behavioral symptoms of ADHD when exposed to a challenge mix of artificial colors.

At one time in our food history, food colors may have been part of an occasional treat: birthday cake, candy or a small soda. Today, they are more widely used in our food supply. Manufacturers consider food colors an essential element to meet consumer demand for food and products that are visually attractive. Food dyes are found in everyday foods and hoodwink consumers into believing that an enhanced food might contain more nutrition or flavor than it actually does. Children and many adults likely obscure their internal cues for nutritious foods by selecting foods enhanced with dyes. In this study, while adults appeared to eat processed foods with color additives in addition to a variety of fruits and vegetables, the children ate processed foods with color additives *instead* of fruits and vegetables. Children's snacks were often fruit roll-ups instead of whole fruit and orange-flavored drinks were chosen instead of 100% orange juice. In the diet records, processed foods with color additives were not just an occasional extravagance, but a regularly occurring ingredient in meals and snacks.

Limitations of Study

The main limitation of this study relates to its small sample size. The study was conducted on one major ethnic population from a rural community and almost all participants who responded had some college level education. Recruitment from a diverse geographical region more representative of the United States population would have captured a true reflection of the population at large. More importantly, one aspect of demographics that would be immensely useful to examine, would be whether children live in households with one parent or two, and whether one or both parents work outside the home. If processed foods are a matter of convenience for parents who don't have time or the interest to prepare meals, this might explain why dye consumption is consistent across all other demographic segments. While this study saw no difference in dye consumption between levels of income, it would be useful to examine

whether the consumption patterns differ among families when both parents work or when there is a stay-at-home parent.

Examining consumption in multiple age groups would have also been desirable. However, the time required to study these patterns in pregnancy, infancy, and other childhood age groups was outside the scope of this study.

Recommendations for Further Research

Currently there is no way of practically assessing the amount of dye that an adult or child consumes. There is a need for a larger, more demographically diverse study to investigate amounts of these compounds found in common foods and to examine intake of these compounds at different ages, income levels, education levels and by the number of working parents in a household. However, until manufacturers list amounts of dye in a particular food, it is not possible to assess amounts consumed. Additionally, more studies on the mechanisms of dye metabolism in humans is essential to understand effects of the dyes on human physiology.

Conclusion

In this study, children consumed artificial color additives three times more frequently than adults did. Consumption frequency was not related to gender or socioeconomic status in any age group but was inversely related to whole fruit and vegetable consumption in children. This poses a concern whether children with more frequent exposures to food dyes obtain fewer daily nutrients or bear a higher risk of any possible toxicological effects.

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Appendix A: College of Health and Human Services
Human Subjects Review approval letter

From: Gretchen Dahl Reeves [mailto:editor-chhs_hs-1094-1398477@commons.emich.edu]
Sent: Wednesday, October 31, 2012 9:12 AM
To: Carol C Bell Ms.
Cc: The Authors; The Administrators
Subject: MS #1094 - College of Health and Human Services Human Subjects

Dear Carol,

Congratulations! After careful review, your proposal revisions to "A comparison of daily consumption of artificial dye containing foods by American children aged 4-7 with adults age 18-60" have been accepted by the College of Health and Human Services Human Subjects Review committee. Please revise the study approval dates on any consent documents "from 1/31/12 to 10/30/13".

The current version of your paper is available here:
http://commons.emich.edu/cgi/preview.cgi?article=1094&context=chhs_hs

We stress that you do not stray from your proposed plan.

Good luck with your research effort.

Sincerely,

Gretchen Dahl Reeves, PhD
Chair, CHHS-HSRC

Appendix B: How to Keep a Food Record: Written Instructions

1. Write down everything that you eat or drink, including all foods, beverages, medicines, supplements, vitamins, gum, mints, candy, cough drops etc. Include all your meals and between-meal snacks from the time you get up until you go to bed.

2. Please be as honest and accurate as you can. The information gained in this study may help many people who struggle with chronic disease.

3. If you prepare food yourself, please list all ingredients used. For example, if you make chili, your food list would contain fresh ground beef, Hunts tomato sauce, chili powder, onions, garlic, Bushs canned kidney beans, McIlhenney chipotle Tabasco sauce, salt, & pepper.

4. If a food is in its natural form, like a raw carrot or fresh salmon you can use a generic name for it. **If the food comes out of a package, can or bottle, please be sure to include the brand name and flavor variety. This is very, very important so that accurate nutrition information can be obtained from the label**. If the food comes from a restaurant or take-out, please list name of restaurant and include as many ingredient items as possible.

5. You can record the information in different ways:
   a. Keep a paper copy of the form with you all day. Write down the information as soon as you or your child finish eating, since meals are difficult to recall in detail after time has passed.
   b. Use your iPhone to keep a list or send text messages to your email with descriptions and amounts of foods eaten.
   c. Take pictures of your meals and snacks and email them with your phone to your email. Be sure to include any medications, supplements and gum or candy too!

6. Record the amount you or your child ate. Estimate the size in inches, the volume (1/2 cup or 1 tsp), the weight (2 ounces) and/or the number of items (12 French fries) for that food.

Use as many lines/as much space as needed, rather than crowding information.

7. Please choose at least 2 weekend days and 3 week days to record diet info. If you or your child are ill or are not eating normally, skip that day and record on a different day.

If you have any questions, send us an email and we'll be happy to help you out.

FoodSurveyTCkids@hotmail.com

One food or item per line. Also include medications, vitamins, cough drops/syrup, candy, mints, chewing gum, beverages.

Date	Food item, beverage, med, gum, candy, supplement	Brand name and flavor variety	Amount eaten

Appendix C: How to Keep a Food Record: Slides

Thank you for participating!

This nutrition study is a master's degree thesis project for a graduate student through Eastern Michigan University.

The goal is to compare intake between adults and children of a variety of food ingredients to better understand typical eating patterns in average Americans.

Your Information is always anonymous.

- Names, addresses or other identifying information will be not be connected to your record
- You create your own login name
- Participants only have access to their own records and data
- The researcher will see your data as a code number assigned to you when you choose a login name

What is a food record?

- Written record of everything a person eats and drinks through the whole day.
- Is the most accurate way to do research on food intake.

How many days?

- Any 5 days of your choice

This will include

- 3 week days (Monday-Friday)
- 2 weekend days (Saturday or Sunday)

What will it look like?

Date	Food item, med, gum, candy, supplement	Brand name and flavor variety	Amount eaten
9/14 /12	Multi-vitamin	Flintstones Gummi complete	1
	Toasted bagel	Lenders Plain	1 bagel
	Cream cheese	Philadelphia reduced fat	3 TBS
	Pear	Raw	¼ pear
	Chicken flavored Ramen noodles	Top Maruchan	½ cup prepared
	Peanut butter	Jif – Jif to Go	2 TBS
	Pretzel rods	Snyders	½ rod
	Bottled water	Ice Mountain	8 oz bottle
	Orange passionfruit juice	Sunny D	1 cup
	Spearmint candy	Life Saver	1 candy
	Barbeque flavor baked chips	Lays Baked	1 1oz. bag

What things are included?

- Meals
- Snacks
- Beverages
- Candy and gum
- Cough drops
- Medicines
- Vitamins

Everything a person eats or drinks!

What about sick days?

If you or the child are sick and not eating normally, skip that day and choose a different day to record what is eaten.

It is important that the food record reflect a day of normal eating.

What about special days?

- Birthday parties or family gatherings are special days.
- These days are fine to record as long as you or the child are eating normally that day and not skipping meals.

Important things:

1. Please be as accurate as you can
2. Please be honest

The quality of the research depends upon accurate food records. You are helping us understand what real people eat everyday!

How do I fill in the chart?

STEP 1 : Write down what is eaten

Many ways to do this:

- Carry a blank form in your pocket with a small pencil
- Take a picture with your phone of the meal or snack
- Use your phone to send a memo to your email
- Use your phone to access the website directly

Important!

Record what is eaten throughout the day rather than trying to remember it all at the end of the day. Sometimes our memories aren't as accurate as we would like!

Take notes several times a day!

Date	Food item, med, gum, candy, supplement.	Brand name and flavor variety	Amount eaten
6-10-12	2 % Milk	Meijer brand, plain	6 oz
	Mini bagel	Lenders, plain	1 bagel
	Peanut butter	Jif	1 tbsp
	Applesauce	Motts, mixed berry	½ cup
	Lemonade	Capri sun pouch	6 oz
	Mac and cheese	Kraft, original flavor	1/3 cup
	Baked chicken	homemade	1 drumstick
	Canola oil	Meijer brand	1 tsp
	Old bay seasoning	Old bay	dash
	Barbecue sauce	Open pit, original	1 tsp
	Green beans	Fresh	¼ cup
	Chocolate chip cookies	Rainbow Chips Ahoy	2 cookies
	Cough drop	Halls, cherry	1 piece
	Cold medicine	Childrens Tylenol multisymptom, grape	10 ml (1 dose in am, 1 dose in pm)

How do I fill in the chart?

STEP 2: Use your written page, pictures or notes to fill out the record on the website.

- Go to www.FoodSurveyTCkids.com
- Under the "Survey" tab, click on "Returning visitors"
- Login with your username
- Fill in the chart starting with Day 1

When you are done

Be sure to click the icon "Save" after you have completed each day of the food record so that all of your food data is saved.

Gift coupons

Once you submit all of your completed food records, you will be eligible to receive a thank you gift of some coupons from local businesses.

These can be picked up at designated locations or you can contact us to arrange a more convenient delivery.

You will also be entered in a drawing for lunch for two at Amical Restaurant in Traverse City.

Questions

If you have any further questions about the study or how to complete the food record, please feel free to contact us at the email below. We'll respond promptly!

FoodSurveyTCkids@hotmail.com

THANK YOU!

Please go to the "Sample Food Record" tab on our home page to print blank food record forms or to the "Survey" tab login to the database.

www.FoodSurveyTCkids.com

Appendix D: List of Abbreviations

ADHD – Attention Deficit Hyperactivity Disorder

ADI – Acceptable Daily Intake

CFR – Code of Federal Regulations

CSPI – Center for Science in the Public Interest

D&C – Drug and Cosmetic

EDI – Estimated Daily Intake

EFSA – European Food Safety Authority

EU – European Union

FD&C – Food, Drug and Cosmetic

FDA – Food and Drug Administration

GRAS – Generally Recognized As Safe

IP – Internet Protocol

NHANES – National Health and Nutrition Examination Survey

RDA – Recommended Daily Allowance

USDA – United States Department of Agriculture