1. INTRODUCTION AND METHODOLOGY

Title X of The Children's Health Act of 2000 authorizes the conduct of a large, prospective cohort study of children, the National Children's Study (NCS), that can offer a comprehensive approach to understanding how the environment, family, and society interact with the genetic constitution of the developing fetus and child. Planning groups, comprised of federal scientists, non-federal organizations with special interest in this project, and other experts defined specific study hypotheses, study design, technology applications, and ethical guidelines. The NCS will include collection of dietary and supplement intake data and exposure susceptibility and outcome data throughout the participants' life span, from preconception to birth and then from infancy through age 18. In addition, biological specimens will be collected from both the parents and the children.

As members of working groups related to nutritional assessment, investigators at the National Institutes of Health (NIH) Office of Dietary Supplements, the National Cancer Institute (NCI) and Johns Hopkins University (JHU) commissioned a literature review sponsored by the NCS Program Office. The intent was to compile a comprehensive review of the scientific literature on dietary and supplement intake assessment methodology, as well as methods of assessing food-born exposure to environmental contaminants in the age groups targeted by the NCS. The specific groups in the target population include pregnant or lactating women, infants (0 to 12 months), toddlers (13 to 24 months), preschoolers (25 months to 5 years), school age children (6 to 12 years), and adolescents (13 to 18 years).

The objectives of this literature review are to:

- Identify and describe validated instruments for assessing usual food and nutrient intake patterns and/or vitamin-mineral or herbal supplement intake patterns in the target population;
- Identify and describe validated instruments for assessing exposure to environmental contaminants from food in the target population;
- Describe the socioeconomic and ethnic/cultural characteristics of the populations in which the instruments were validated;
- Describe dietary and supplement assessment instruments employed in large epidemiological studies conducted on one or more of the target age groups and discuss the rationale for the instrument selection;
- Identify methodological issues inherent in assessing food intake in pregnant or lactating women, infants, children, and adolescents; and

- Describe the weight of evidence for the various methods, key issues that are unresolved, and additional information needed to resolve key issues.

The first chapter of this report describes the search methodology for this comprehensive literature review. Chapters 2 through 6 address the specific age groups. Each chapter begins with an overview of the search results followed by detailed tables summarizing the relevant literature. Chapter 7 presents a short summary of approaches to assessing food-born environmental contaminants. Chapter 8 includes a listing of the literature cited.

Methodology

This review examines studies conducted mainly in industrialized, developed countries and published in English between 1982 and December 2003 for pregnant or lactating women, infants, toddlers, and preschoolers. For school age children and adolescents, our search built on a recent review of the literature through 2000 (1) and focused primarily on literature published since that time. Studies were identified in National Library of Medicine PubMed database and the CABI Publishing Nutrition Abstracts and Reviews database using a number of comprehensive search strings containing relevant key words. Exhibit A-1, Appendix A, documents the key words and search strings used. In addition to the key word search strings, we conducted author searches in both databases to identify relevant publications by key investigators with expertise in maternal and child nutrition. These searches were supplemented by cross-referencing from reference lists from reviewed literature. Appendix A includes a description of the Reference Manager Database developed to manage the search and review process, the citation review relevancy criteria, and the full article review process.

Measurement of Validity

Validity is the ability of an instrument to measure what it is intended to measure. Most dietary assessment methods are intended to measure usual or customary food and/or supplement intake over a defined period of time. Because true usual diet is difficult if not impossible to measure, investigators assess relative or criterion validity. Relative validity compares a new measurement method with one or more established methods believed to have a greater degree of demonstrated or face validity (2). The measurement error in the new instrument or method is examined and calibrated with the reference method. This type of validity assessment will fail to detect systematic reporting error or bias if both the new and reference method have correlated

error (3). Alternatively, the new method or instrument can be validated against an independent, external criterion reference measurement, such as a biomarker of intake. The doubly labeled water (DLW) method to measure total energy expenditure is an example of a biomarker that can be used to independently validate self-reported energy intake. The error in the DLW method is independent of self-reported intake error, thus allowing true reporting bias to be detected (3,4).

This review examines studies in which the relative or criterion validity of one diet or supplement assessment method is evaluated by comparisons with measurements obtained from a reference method. The reference methods vary by study and target age group and include established dietary assessment methods, biological markers of habitual intake, and techniques such as direct observation of intake. Exhibit 1.1 presents definitions of and abbreviations for dietary assessment methods and reference methods discussed in this report.

Exhibit 1.1 Definitions and abbreviations (5,6)

Food Record (FR)	Food records are used to record food intake at the time of consumption, over a number of days that are not necessarily sequential. Most studies ask respondents to enter the information on hard copy form, although tape-recording, bar-coding, and electronic weighing also have been used to collect descriptive and quantity information. **Weighed FR:** The respondent weighs on a small scale all food and beverages consumed. **Estimated FR:** The respondent estimates all food consumed using household measures or portion size estimating aides.
Diet History (DH)	Diet History questionnaires are a retrospective assessment method ascertaining a respondent's "usual" food intake by collecting descriptive detail and amount information about each food. DHs may include questions on meal patterns, lists of common foods and groups of generic food. DH questionnaires are typically administered by a trained interviewer either in-person or by telephone, but also can be self-reported.
24-Hour Recall (24HR)	The 24HR is a retrospective assessment method in which an interviewer prompts a respondent to recall and describe all foods and beverages consumed in the preceding 24 hours or the preceding day. The interview may be conducted in-person or by telephone and may be paper and pencil or computer assisted. Portion size estimating aides assist the respondent to recall amounts consumed. The methodology for conducting the 24HR has evolved during the last two decades. Among the methods reported are: 3-pass method, 5-pass method, U.S. Department of Agriculture protocol, University of Minnesota protocol, Bogalusa Heart Study protocol.
Food Frequency Questionnaire (FFQ)	The food frequency questionnaire is a retrospective method asking respondents to report their usual frequency of consumption of each food from a list of foods for a specific period (several months or a year). Food lists vary by the purpose of the study and study population. Frequency of consumption categories also vary by questionnaire but usually include per day, week, or month. **Semi quantitative FFQ:** In this type of FFQ, portion size information is collected; portion sizes are specified as standardized portions or choice (range of portions). **Non-quantitative FFQ**: Portion size information not collected. **NCI Health Habits and History Questionnaire (HHHQ):** Semi-quantitative FFQ developed at the National Cancer Institute under the direction of Gladys Block. **Harvard FFQ (HFFQ):** FFQ developed at Harvard University by Walter Willett and colleagues. Portion size information is included as part of the food item rather than as a separate listing. **NCI Diet History Questionnaire (DHQ):** Semi-quantitative FFQ, using an embedded question approach, developed at the NCI under the direction of Amy Subar and Fran Thompson (7,8).

Exhibit 1.1 Definitions and abbreviations, continued

Propensity Questionnaire	Comprehensive FFQ-type questionnaire designed to supplement other dietary assessment method. Information on portion size information is not collected. May provide information on infrequently consumed foods (9).
Direct Observation (DO)	Intakes are watched and recorded by trained observers.
Doubly Labeled Water Method (DLW) for total energy expenditure (TEE)	The DLW method is used to measure energy expenditure in free-living subjects. This method involves the administration of water containing enriched quantities of the stable isotopes deuterium (^{2}H) and oxygen-18 (^{18}O). The label of "doubly" labeled comes from the fact that both the hydrogen and oxygen are labeled. The oxygen-18 is eliminated from the body in the form of carbon dioxide ($C^{18}O_2$) and water ($H_2{}^{18}O$), and the deuterium is eliminated in water ($^{2}H_2O$). The difference in elimination rate between these two isotopes is a measure of carbon dioxide production. Carbon dioxide production can then be used to calculate energy expenditure by use of standard equations for indirect calorimetry (3). The DLW method has been shown to be accurate to 1%, with within-subject precision of 5 to 8% (10). Because the method is expensive and analysis requires specialized, expensive equipment, it cannot be considered routine. However, the method is widely available and is being applied to dietary assessment validations with sample sizes ranging from 20 to 500 (10).
Test Method (TM)	Dietary assessment method being validated.
Reference Method (RM)	Method against which the TM is being compared and validated.