Measuring and Coding Exposures to Medicines and Herbal Products: Implications for the National Children's Study

Medicine and Pharmaceuticals Working Group

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Introduction

The Medicine and Pharmaceuticals Working Group of the National Children's Study Federal Advisory Committee held two related workshops to discuss the collection of data on the use of prescription and over-the-counter (OTC) pharmaceuticals, dietary supplements, and herbals during preconception, pregnancy, breastfeeding, and childhood.

- The *Medicines Exposures: Collection, Coding, and Classification Workshop* was held on December 16, 2002, in Baltimore, MD.

The purpose of the medicines workshop was to provide the National Children's Study with an updated understanding of methods for assessing exposure and the current methods available for classifying and coding these products.

- The *Use of Herbal Products in Pregnancy, Breastfeeding, and Childhood Workshop* was held on December 16, 2003 in Atlanta, GA.

The purpose of the herbals workshop was to determine whether the use of these products could be incorporated into the Study.

The development of an entirely new nomenclature for medications was not recommended for the Study, but further investigation of an appropriate nomenclature system for herbals should be conducted.

Possible Methods for Coding and Classification

Coding System	Prescription Drugs	Over-the-Counter Drugs	Supplements	Herbals	Coding Criteria
NDC	✓	✓*	–	–	■ Product labeler/ manufacturer ■ Product formulation and dose size ■ Package size
Slone Epi Drug Dictionary	✓	✓	✓	✓	■ Chemical/biological name ■ Trade name ■ Inert ingredients ■ Plant part utilized for herbals ■ Therapeutic categories ■ "Coalitions" ■ Multi-component products
RxNorm (UMLS)	✓	✓*	✓*	–	■ Terms ■ Concepts ■ Multiple source vocabularies ■ Multiple languages

*limited coverage

Possible Methods for Exposure Assessment

- Patient Questionnaire
- Medical Record Review
- Health Insurance Record Review
- Pharmacy Record Review
- Product Sample Analysis

The patient or parent is the best source of product use and consumption patterns, although other sources of data may supplement or confirm potential exposures to medications and herbals. Medical record review may avoid recall bias, but only includes prescription drugs and may not accurately reflect consumption. Pharmacy record reviews and product sample analysis includes additional information on the product.

Studies Reviewed Measuring Exposure to Medications

- Collaborative Perinatal Project
- Nurses Health Studies
- HMO Research Network
- National Birth Defects Prevention Study
- National Birth Cohort, Denmark
- Pregnancy Health Interview Study (Slone Birth Defects Study)
- Slone Survey

Studies Reviewed Measuring Exposure to Herbals

- National Birth Defects Prevention Study
- Pregnancy Health Interview Study (Slone Birth Defects Study)
- Slone Survey
- Behavioral Risk Factor Surveillance Survey
- National Physical Activity and Weight Loss Survey
- Infant Feeding Practices Survey
- National Health and Nutrition Examination Survey

Issues about Collection of Herbals Data in the National Children's Study

- Increasing exposures
- Use during early life stages
  - Weight loss products are used by many women of reproductive age
  - Herbal products are often used to increase milk quantity or quality, and are also used to decrease milk production for weaning.

- Possible risk of adverse effects
  - Many individuals use more than one product
  - Herbal products do not need to be registered with the FDA, toxic substances have been found in supplements, and formulations may change without label changes.

Recommendations for the National Children's Study

Exposure Assessment

- Herbals must be included in exposure assessment along with medications. While some limited information should be collected on medicines and herbals for all Study subjects, herbals should be more intensively studied for a subset of subjects.
- In querying the Study subjects, the interviewer should be someone other than the patient's healthcare provider.
- A variety of tools should be used to enhance recall (e.g., visual aids, diaries).
- Route, dose, duration, frequency, and timing of use of these products should be collected.
- Product samples, manufacturer information, and ingredient lists from should be collected from Study participants, when available.
- Biologic samples should be collected from Study participants, allowing for possible biomarker identification.
- Information on product use should be collected from Study subjects at regular intervals and when triggered by hospitalizations or other illness.
- Focus groups should examine the use of two groups of herbal products: vasoactive herbals used during pregnancy, and phytoestrogens used during pregnancy and breastfeeding.

Coding System

- Several commercial systems are available for coding and should be compared to determine which are most amenable for use in the Study.
- Nomenclature system criteria should include: relational data; ease of inquiry; inclusion of prescribed, over-the-counter, and herbal products; clarity of codes and their specificity; ease and frequency of updating; ability to capture excipients or preservatives; ability to capture specific data (e.g., manufacturer identification).

Implementing the National Children's Study:
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Study Assembly Meeting

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