NHANES 1999–2000 Data Documentation

February 2005; Revised February 2008

Lab 18t4 – Thyroid-Stimulating Hormone and Thyroxine (TSH & T4)

Description

Serum thyroid-stimulating hormone (TSH) and thyroxine (T4) levels will be used to assess thyroid function and will provide population-based reference information on these hormone levels. Thyroid function will be examined in relation to measures of exposure to endocrine disrupting substances, which are hypothesized to effect thyroid.

Eligible Sample and Component-Specific Exclusions:

Participants aged 12 years and older on a ⅓ sample were tested.

Exclusion Criteria: Hemophiliacs

Participants who received chemotherapy within last 4 weeks.
The presence of the following on both arms: rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms or limbs missing, damaged, sclerosed or occluded veins, allergies to cleansing reagents, burned or scarred tissue, shunt or IV.

Laboratory Protocol

Blood and urine specimens are collected on participants aged one year and older at the mobile examination centers (MECs). Hematological profiles are complete for all participants, and specified laboratory tests are performed upon each specimen based on the participant's age at time of interview and sex.

The laboratory component of NHANES includes the collection, processing, storage, and shipping of blood, urine and other biological and environmental specimens. The blood collection procedure consists of administering a questionnaire to screen for conditions that excludes the participants from the blood draw and determines fasting status, a blood draw, and collecting specimens for special studies. The urine collection procedure consists of urine collection, urine processing, and pregnancy testing. The Coulter MAXM performs a complete blood count on blood specimens to provide a study of blood cells and coagulation for all participants.

Survey Staff

The NHANES 1999–2000 laboratory staff consists of medical technologists and phlebotomists. The medical technologists hold baccalaureates in medical technology. The American Society for Clinical Pathologists or a similar organization certifies the medical technologists and the phlebotomists. All laboratory staff completes comprehensive training

in standardized laboratory procedures before they begin working in the MEC. The MEC phlebotomists complete comprehensive training in pediatric phlebotomy techniques, including instruction by a pediatric nurse practitioner.

Data Collection Forms

Detailed specimen collection and processing instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Each chapter in the LPM specifies the procedure to be used for preparation of the participant, specimen collection, labeling, processing, and preservation, and conditions for specimen transport that are appropriate for that method.

Quality Control Procedures

MECs

Laboratory team performance is monitored using several techniques. NCHS and contract consultants use a structured quality assurance evaluation during unscheduled visits to evaluate both the quality of the laboratory work and the quality-control procedures. Each laboratory staff person is observed for equipment operation, specimen collection and preparation, and testing procedures, and constructive feedback is given to each staff. Formal retraining sessions are conducted annually to ensure that required skill levels were maintained.

The NHANES quality control and quality assurance protocols meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM).

Analytical laboratories

NHANES uses several methods to monitor the quality of the analyses performed by the contract laboratories. In the MEC, these methods include performing second examinations on previously examined participants and blind split samples collected on “dry run” sessions. In addition, contract laboratories randomly perform repeat testing on 2.0 percent of all specimens.

NCHS developed and distributed a quality control protocol for all the Contract laboratories outlining the Westgaard rules used when running NHANES specimens. Progress reports containing any problems encountered during shipping or receipt of specimens, summary statistics for each control pool, QC graphs, instrument calibration, reagents, and any special considerations are submitted to NCHS and Westat quarterly. The reports are reviewed for trends or shifts in the data. The laboratories are required to explain any identified areas of concern. NCHS/Westat are currently reviewing these reports.

Data Processing and Preparation

Automated data collection procedures for the survey were introduced in NHANES 1999-2000. In the mobile examination centers (MECs) and analytical laboratories, data for the laboratory component is recorded directly onto a computerized data collection form. The system is centrally integrated and it allows for ongoing monitoring of much of the data. While the complete blood count and pregnancy analyses are performed in the MEC laboratory, most analyses are conducted elsewhere by approximately 24 laboratories across the United States.

Guidelines are developed that provided standards for naming variables, filling missing values, and handling missing records. NCHS staff, assisted by contract staff, develops data editing specifications that check data sets for valid codes, ranges, and skip pattern consistencies and examine the consistency of values between interrelated variables. Comments are reviewed and recoded. NCHS staff verifies extremely high and low values whenever possible, and numerous consistency checks are performed. Nonetheless, users should examine the range and frequency of values before analyzing data.

For laboratory tests with a lower detection limit, results below the lower detection limit are replaced with a value equal to the detection limit divided by the square root of two. This value is created to help the user distinguish a nondetectable laboratory test result from a measured laboratory test result.

Data Editing

The data editing specifications are as follows:

- Age and gender checks
- Total number of observations complete for each field
- No field overlap, truncated values, or weird results
- Direct data entry (DDE) errors
- Abnormal results confirmed by lab
- Test algorithm performed
- Checked comment codes to resolve missing results and missing records
- All missing results and missing MEC-examined records are accounted
- Duplicate records were verified and deleted
- Apply the SI conversion
- Apply the below detection limit formula.

Analytic Notes

LBXTSH and LBXT4:

These tests are performed only on a one-third sample of examinees 12 years or older.

Special Notes about this Dataset

The analysis of NHANES 1999–2000 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 1999–2000 Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables and sample weights for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

Use the weights that are included in the data file for any analysis of the data.

References

1. N/A