NHANES 1999–2000 Data Release

June 2005

Tuberculosis (TB) Examination Skin Test

Description

TB skin testing was added to the NHANES 1999–2000 examination to provide comprehensive data about the extent of tuberculosis infection in the United States. To determine the prevalence of TB infection, NHANES participants 1 year of age and older who consented to this component were skin tested with a tuberculin-purified protein derivative (PPD) product, PPD S-1, the standard antigen. To help distinguish reactions due to *Mycobacterium tuberculosis* infection from cross reactions due to nontuberculous mycobacterial infection, participants were also skin tested with nontuberculous mycobacterial antigen PPD-B (Battey strain lot 100616, also called the Boone strain of *Mycobacterium intracellulare*). The two products used are not commercially licensed; therefore, CDC received Investigational New Drug (IND) approval (BB-IND-7596) from the Food and Drug Administration.

To aid in the interpretation of skin test results and provide for risk factor analysis, participants were asked questions about TB skin testing, disease, exposure to and treatment for *Mycobacterium tuberculosis*. These questions were asked in the household interview.

Eligible Sample and Component-Specific Exclusions:

Eligibility:

Sample persons aged 1 year and over who do not meet the exclusion criteria were eligible.

Exclusion Criteria:

- Positive response to screening question: "Have you ever had a severe reaction to a TB skin test?".
- Severe skin conditions such as burns or active eczema over both arms.

Survey Staff

The staff was composed of a certified phlebotomist to place the TB antigens and six trained, full-time skin test readers and six part-time readers.

Data Collection Procedures

For each participant, a randomized computer program selected a different forearm for application of each of the two PPDs. Trained NHANES phlebotomists injected 0.1 ml (5

international units) of the designated PPD intradermally to the volar surface of the designated forearm using the Mantoux method. Phlebotomists were blinded to PPD type. Reactions were measured 48–72 hours later by trained NHANES TST readers who had no knowledge of which PPD had been applied to either arm. TB readers were not aware of the participant's medical history or any history of contact with TB. To improve return rates for TST reaction measurement, extra remuneration was offered, and readings were performed offsite, in homes, or workplaces, as necessary.

TST measurements were performed for each participant by at least one trained reader. Training and supervision was conducted by four experienced "gold standard" TST readers. To standardize their own practice, gold standard readers performed quarterly blinded sequential comparison readings of at least 20 TB clinic patients' TST reactions to confirm that they were reading within 2 mm of one another.

Study protocol dictated that two separate readers blinded to one another's measurements would measure TST reactions of > 25% of participants. Readers worked in separate rooms and recorded measurements in a computer database; measurements recorded on the first screen were not accessible to the second reader. The induration, if any, was palpated. Using non-smearing eyebrow pencil, a dot was made on either side of the widest point of the induration border transverse to the long axis of the forearm. Measurements between the dots were made with a transparent ruler. Markings were removed with cotton and hypoallergic makeup remover or baby oil. The forearm was wiped with makeup remover or baby oil by the first reader regardless of whether a palpable reaction was found and marked.

41.2% of participants had measurements recorded separately by at least two readers who remained unaware of one another's measurements.

Inspection of the Volar Surface of Each Forearm for Adverse Reactions

- Note and record the presence or absence of other skin reactions such as vesiculation and bullae or ulceration and necrosis anywhere on the volar surface of the arm being examined.
- Identify and record the presence or absence of vesiculations and/or bullae. Vesiculation refers to small, fluid-filled, blister-like lesions. Bullae are similar to vesiculations but they are larger.

Measurement of Induration

- Record right (or upper) forearm results before reading left (or lower) forearm.
- Record millimeter measurement of skin reactions correctly.
- Record measurements between 0 and 86 millimeters as measured. Record measurements greater than 86 millimeters as 87+ millimeters. No reaction greater than 86 millimeters is expected; if such a reaction is recorded, confirm that this is correct, complete an Adverse Reaction Form, and e-mail the form to Dr. Kathryn Porter on the same day.
- Identify and record the presence or absence of ulceration and/or necrosis.

Ulceration refers to sloughing of damaged skin or a raw, open sore. Necrosis is the death of cells because of damage or disease.

Quality Control Measurement of Skin Reactions

The mean TST reaction and PPD-B reaction were used for the 41.2% of participants who had TST reactions read by two or more readers. Distributions based on the readings of any reader who read more than 300 reactions were similar. TBI prevalence based on the findings of any reader who read more than 300 reactions did not differ statistically from the prevalence based on the mean TST reactions.

Data Processing and Editing

The sequence number links these data to all other data collected during 1999–2000 survey years. The following variables were derived.

1. TBDPPDS: the mm of induration for PPDS. This variable combines the measurement for left and right arms since the antigen was randomly placed to blind the reader to the skin test being read.

2. TBDPPDB: the mm of induration for PPDS. This variable combines the measurement for left and right arms since the antigen was randomly placed to blind the reader to the skin test being read.

3. TBDPPDSV: an indication if vesiculation was present or absent for PPDS.

4. TBDPPDBV: an indication if vesiculation was present or absent for PPDB.

5. TBDPPDSU: an indication if ulceration was present or absent for PPDS.

6. TBDPPDB: an indication if ulceration was present or absent for PPDB.

The following variable, TBQ070 (not derived), is also included in this file:

Have you ever had a severe reaction to a tuberculosis (TB) skin test?

1 = Yes
2 = No

TBABCG BCG scar?

1 = Present
2 = Absent
3 = Refused

NHANES medical examiners were trained to recognize BCG scars and to differentiate them from smallpox vaccination scars through supervised examination of photographs and a small number of human volunteers. Visible scars evaluated by examiners as BCG scars were recorded. No validation of these evaluations was included.

Analytic Notes

The basic definition of TB infection (TBI) used in NHANES is a mean TB skin test (TBS) reaction >10 mm. This is the definition used most frequently in U.S. and international surveys. Alternative definitions of TBI can also be used : (i) mean TST reaction >15 mm (the clinical definition of TBI most commonly used for adults in the US, except for individuals with special risks, e.g. contacts, children, immunosuppressed persons, etc.), or (ii) either a mean TST reaction >15 mm or a mean TST >5 mm and <15 mm that is at least 2 mm greater than the reaction of PPD-B (1), the definition that utilizes reactions to both mycobacterial antigens used in the survey.

Although TB infection is generally divided into latent TB infection (LTBI) and TB (active tuberculosis) in the U.S., this distinction could not be made in NHANES 1999–2000. No chest x-ray component was included to distinguish LTBI from TB; therefore, no evaluation of relevant signs and symptoms was performed.

Special Notes about this Dataset

None

References

1. Edwards LB, Acquavuva FA, Livesay VT. Identification of tuberculosis infection. Dual tests and density reaction. Am Rev Respir Dis. 1973:108(6);1334–1339.