

Reporting Examination Findings

NHANES provides health measurement and test results to all participants who have completed at least one component of the health examination. The NHANES program reports individual examination and laboratory test results based on the following criteria:

- The findings are valid and, in the case of laboratory tests, done by a CLIA-certified laboratory;
- The findings may have significant implications for the subjects' health concerns; and
- A course of action to ameliorate, or treat the concerns is readily available.

These criteria are based on guidance from the National Bioethics Advisory Commission (NBAC) in their report, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (Rockville, MD: 1999)

In the process of applying these guidelines, the NHANES Program reviews the current literature or seeks consultation from a variety of sources. Specifically:

- Clinical guidelines set forth by Federal health agencies (NIH, CDC, and AHQR), international health organizations (WHO), national organizations (IOM), other health organizations (National Kidney Foundation, American Social Health Association, etc.), professional societies, and expert committees/panels.
- Existing reporting protocols from clinical research or health surveys using the same or similar components.
- Expert opinion from individuals in academia, governmental organizations, or professional organizations.

When needed, the DHANES Physician Advisory Group (PAG) convenes to make decisions on reporting results. The DHANES PAG consists of four physicians with board certifications in Preventive Medicine, Internal Medicine, Occupational and Environmental Medicine, Rheumatology, and Pathology. When pediatric expertise is required, input is sought from NCHS physicians who are board certified in Pediatrics.

A Preliminary Report of Findings is given to participants at the conclusion of their MEC exam. A Final Report of Findings is sent to participants 12–16 weeks after their exam once the image grading and laboratory testing are completed. Participants are alerted about abnormal findings either during the MEC exam or by letter in the weeks following the exam. The findings are communicated to participants with recommendations for referral. Three levels of referral are based on the urgency of the health finding and are explained below.

A Level I finding is a medical emergency. The MEC physician manages medical emergencies. An emergency medical kit is kept in each MEC so that emergency stabilization can be given when absolutely necessary. However, the preferred manner of handling the medical emergencies is to contact local rescue squads, ambulance services, and hospital emergency rooms, whose

telephone numbers are posted in the examination center. A Level I finding is rare. Persons refusing medical attention for a Level I finding must sign a release form.

A Level II finding is detected either at the MEC or after the exam when laboratory results are sent back from the laboratories. In the MEC, the staff may determine that there is a medical finding that should be evaluated by a health care provider. In this case, the MEC physician initially evaluates the sample participant and the relevant exam finding, and does the following: a) explains the concern to the sample participant; b) provides the sample participant with a written report of the condition; and c) urges the sample participant to make an appointment with their primary care physician within the next two weeks. If the sample participant has no primary care physician, the MEC physician has access to a list of providers or clinics where the sample participant can be evaluated at no charge, or on a sliding scale fee schedule.

Level II findings can also occur when a laboratory or consultant discovers abnormalities based on NHANES early reporting thresholds. Laboratories transmit results—that meet the threshold for early reporting—immediately by uploading results to an FTP site or emailing the results for import into the NHANES database. Once abnormal findings are received, NCHS sends the sample participant (or parent if a minor) an early reporting letter describing the finding and urging the sample participant to see a medical provider for evaluation. The sample participant also has the option to talk with the NCHS medical officer. This type of Level II referral usually occurs within three weeks after the examination.

A Level III finding is the routine Report of Findings provided to all sample participants. Some test results that are immediately available are given to the sample participant before leaving the MEC (i.e., the Preliminary Report of Findings). A complete report, known as the Final Report of Findings is sent to the participants 12–16 weeks after the examination.

Reporting Results for Minors

The procedure to report results to minors is similar to reporting results to adult sample participants. If a parent or guardian accompanies a minor to the MEC, the Preliminary Report of Findings is given to the parent or guardian. Any abnormal findings are communicated to the parent or guardian, and when applicable, NHANES staff requests permission from the parent or guardian to contact the minor's primary care physician.

If the minor is not accompanied by a parent or guardian (allowable for minors 12 years and older) or if the minor is accompanied by an adult other than the parent or guardian, then the minor receives the Preliminary Report of Findings in a folder labeled "For the attention of the child's parent or guardian." If there are any abnormal results, NHANES notifies the parent or guardian. If there is a Level I finding, the MEC physician immediately calls the parent or guardian. If there is a Level II referral, the MEC physician calls the parent or guardian to get consent to notify the minor's primary care physician. The MEC physician can also give the parent or guardian a list of providers in the area that can assist in evaluation and treatment.

Participant Inquiries

NCHS has an in-house survey response team available to answer calls from sample participants regarding questions about results from the Report of Finding System. The response team effort

works as a triage mechanism. Sample participants call a toll-free telephone number during regular scheduled business hours. The response team members include a physician and other personnel (including bilingual staff) who are trained to answer specific questions.

STD/HIV Reporting Procedures

The reporting of STD/HIV test results is handled differently from other NHANES exam findings. STD/HIV results are provided to persons tested by telephone. Because of the medical, social, and emotional consequences of positive STD and HIV tests, disclosure of results must be handled such that counseling can be provided at the time results are given.

At the time of the MEC examination, the physician provides STD/HIV pre-test counseling. Physicians explain the purpose of the testing, the reporting procedures and the confidentiality assurances. The participant may opt out of having STD and/or HIV testing at this point. The physician then asks the participant to provide a password to be used when the results are given at a later date. This password is entered into the database. Before leaving the mobile examination center (MEC), examinees are given a sheet with a toll-free number, their password, and the dates when test results are available (approximately 3–4 weeks after the exam). The examinee is instructed not to share the information with anyone and to call for the test results after the stated date. Participants who are monolingual Chinese, Vietnamese or Korean will have an instruction sheet printed in their native language stating the NHANES Program will call them with their results after a date specified. The NHANES Program will use a telephone interpretation service.

Adolescents 14–17 years are instructed to call for their results in the same fashion as adults 18 years and over. An important principal that guides the reporting of STD test results to adolescents participating in NHANES is the fact that all adolescents in the United States can consent to the confidential diagnosis and treatment of STDs. Medical care for these conditions can be provided to adolescents without parental consent or knowledge. Therefore, there is no legal obligation to disclose findings to anyone other than the participant (CDC, 1993 Sexually Transmitted Diseases Treatment Guideline, MMWR 42 RR-14). Results, whether they are positive or negative, will be given to the examinee over the phone after they have provided NCHS with their password. Adolescents who have not called for their findings within a ten-day period of the designated dates will be notified by telephone by NCHS. There will be a total of three attempts within a one-month period to contact the adolescent. Adults who have not called for their findings within a ten-day period of the designated dates will be sent a reminder by letter from NCHS. If the adult examinees do not call within a two-week period after the reminder letter was sent, a second notification letter will be sent reminding them to call NCHS to get their test results. If there is still no response after a two-week period from the second mailing, a third and final letter is sent.

Results of STD or HIV tests will **not** be put in writing with the respondent's name or any other personal identifiers, **unless** the respondent verbally requests that the findings be sent to their own address, or that of a designated health care provider or clinic.

The toll-free STD results line is manned Monday from 8:30am—7:00pm when the survey is operating in the Eastern Time zone and Central time zones, 8:30pm—8:00pm when the survey is in the Mountain Time zone, and 8:30pm—9:00pm when the survey is in the Pacific Time zone.

Tuesday through Friday, the hours are 8:30am to 6:00pm. After hours and weekends there is a two-minute tape recording giving callers basic information about business hours and asking them to call back the next business day. Staff answering the STD line receive 25 hours of STD training and are HIV Counseling certified. Spanish-speaking staff is available. Prior to reporting results to participants a health educator compiles a list of local STD clinics where participants testing positive can be referred as needed.