1. INTRODUCTION

The National Inventory of Clinical Laboratory Testing Services (NICLTS) is a statistically rigorous inventory of laboratory testing services conducted for patient care in the United States in calendar year 1996. The inventory was produced by drawing a national probability sample of CLIA-certified clinical laboratories in the Health Care Financing Administration's (HCFA) July 1996 Online Survey, Certification, and Reporting (OSCAR) database. In each sampled laboratory, all tests performed for patient care in calendar year 1996 were enumerated and counted.

This Chapter of the NICLTS final report describes the background for NICLTS and provides an overview of the project. Chapter 2 provides a detailed description of the sample design. Chapter 3 describes the major computer systems developed for the project. Chapter 4 describes project operations. Chapter 5 describes the statistical issues encountered in each phase of the study and provides an overall summary of project results. Chapter 6 describes quality assurance measures utilized during the study.

1.1 Background

In 1967, Congress passed the Clinical Laboratory Improvement Act of 1967 (42 USC§263A). The law (CLIA 67) was passed on the theory that laboratories accepting specimens across state lines were engaged in "interstate commerce" and therefore subject to Federal regulation. The law stipulated that all such laboratories be licensed by the Federal government. The responsibility for writing, implementing, and enforcing the regulations was initially delegated to the Centers for Disease Control and Prevention (CDC). The law brought approximately 13,000 laboratories, mostly hospital and independent laboratories, under Federal regulation.

Later, as a result of public and congressional concerns about the quality of laboratory testing in the United States, Congress passed the Clinical Laboratory Improvement Amendments of 1988 (Public Law 100-578). CLIA 88 set standards to improve the quality of laboratory testing in all laboratories that conduct testing on human specimens for health assessment or for the prevention, diagnosis, or treatment of disease. The regulations that resulted from CLIA 88 were implemented in 1992 and set minimum standards for the practice and quality of clinical laboratory testing.

With the publication of the final rule implementing CLIA 88, the delivery of laboratory medicine in the United States changed. CLIA 88 extended Federal regulation to approximately 144,000 additional laboratory sites, mostly physician office laboratories (POLs) and other testing sites, including community clinics, home health agencies, blood banks, health maintenance organizations, student health services, hospices, ancillary testing sites, mobile units, and rural and walk-in screening sites.

CLIA 88 and its subsequent regulations provided for specific regulatory language relative to proficiency testing, quality control, patient test management, personnel, quality assurance, certification, and inspections. CLIA 88 was designed to be site neutral. That is, the designers of the law felt that any person having a clinical laboratory test performed had to be assured that the test would be of the same quality regardless of the testing location. The law allowed for changes in technology and recognized that test quality could be controlled, in part, by technology and therefore allowed differing standards based on the complexity of testing methodology.

Complexity is determined by a set of criteria that reflect how difficult it is to test. In determining complexity, criteria include:

- Knowledge needed to perform the test;
- Training and experience required;
- Reagents and preparations used;
- Characteristics of operational steps;
- Calibration, quality control, and proficiency materials characteristics and availability;
- Troubleshooting and maintenance required; and
- Interpretation and judgment required in the testing process.

The default complexity of a laboratory test is referred to as "High Complexity." These tests require proficiency testing (verification of test performance using outside, graded samples sent periodically to the laboratory), strict quality control and quality assurance programs, personnel trained in laboratory medicine at the director and supervisory level, periodic on-site inspections, and other lesser requirements. Most laboratories thought of as traditional testing sites, such as hospitals and commercial independent laboratories, perform high complexity testing and must adhere to these requirements. Many laboratories located in physicians' offices also

qualify for high complexity testing, with the more traditional ones being those that serve multiple practitioners.

At the other extreme of the complexity scale are waived tests. These are tests designated by the Secretary, Department of Health and Human Services (DHHS), as those examinations or procedures that a) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; b) pose no reasonable harm to the patient if the test is performed incorrectly; and c) have been cleared by the Food and Drug Administration for home use. At the time of introduction of the initial regulations implementing CLIA 88, in 1992, eight generic tests were designated as waived. These included dipstick urinalysis, glucose determinations by a glucometer, and spun hematocrit. As of December 1996, 10 additional generic tests were designated as waived tests.

Laboratories performing only waived tests are issued a Certificate of Waiver and are exempt from all CLIA standards. The Health Care Financing Administration may inspect laboratories holding a Certificate of Waiver if a complaint is received about the laboratory or for random compliance checking. Many laboratories performing only waived tests are POLs.

Two categories of tests are subject to CLIA standards: moderate complexity and high complexity. Laboratories performing moderate complexity tests are required to perform proficiency testing and have periodic on-site inspections. Moderate complexity laboratories have less restrictive personnel requirements at the director and supervisory level but maintain most of the other attributes of laboratories performing high complexity tests. Many smaller, modern automated clinical laboratory tests fall into this classification. Most POLs can qualify as a laboratory performing moderate complexity testing with little or no change in personnel. Many are thought not to perform moderate complexity testing because of perceived cost issues, regulatory oversight implied by an on-site inspection, and especially managed care restrictions on laboratory testing reimbursement.

Soon after the 1992 regulations were implemented, DHHS introduced a subset of moderate complexity testing called Provider Performed Microscopy (PPM). These are tests that must be performed by a physician, a midlevel practitioner under the supervision of a physician, or a dentist. Laboratories may perform PPM testing if they meet certain requirements under the law and if they restrict PPM examinations to a predetermined list of tests. Examples of PPM tests include direct wet mounts, potassium hydroxide preparations, pinworm examinations, fern tests, direct post-coital qualitative examinations of vaginal or cervical mucus, urine sediment examinations, nasal smears for granulocytes, fecal leukocyte examinations and qualitative semen analysis

(Federal Register, Volume 60, Number 78, Monday, April 24, 1995, Rules and Regulations, p.20044).

Under CLIA, the DHHS has the responsibility for developing standards, implementation through the issuance of certificates based on complexity testing, and for both on-site inspection and enforcement. The Public Health Practice Program Office (PHPPO) of the Centers for Disease Control and Prevention (CDC), Division of Laboratory Systems (DLS) has the responsibility for CLIA program and policy evaluation, and oversight to review clinical laboratory testing systems in order to categorize testing into one of the complexity testing categories. The default for an unreviewed or laboratory modified test system is high complexity. A laboratory certified to perform high complexity testing may perform any test within its certified specialty or specialties (chemistry, microbiology, cytology, etc.), including both moderate and waived complexity tests. Laboratories certified to perform only moderate complexity tests may not perform high complexity tests but may perform waived tests. Laboratories certified to perform PPM tests may also perform waived tests. Laboratories having only a Certificate of Waiver may perform only waived tests.

1.2 Justification

With the passage of CLIA 88, the delivery of laboratory medicine in the United States changed. The intent of Congress in passing CLIA was to ensure the safety and accuracy of all clinical laboratory testing regardless of where the testing was performed. Although there is general agreement about the need and importance of the Clinical Laboratory Improvements Amendments, the regulations resulting from CLIA 88 have caused many changes in the way laboratories function, especially among those that are under Federal regulation for the first time. Extending Federal regulation to all laboratories has created a concern that access to needed clinical laboratory testing services, particularly in smaller laboratories and in rural areas, may be jeopardized.

In 1990, the CDC was assigned responsibility for the development of CLIA regulations, for monitoring the impact of the regulations on the nation's laboratories, and for assessing the potential impact of any proposed changes in these regulations on the practice of laboratory medicine in the United States. In this capacity, CDC is required to respond to Congress, the DHHS, and the public in reference to questions concerning the impact of both regulatory and nonregulatory changes in the delivery of laboratory medicine. However, CLIA 88 was passed without a clear understanding of the extent of laboratory testing being performed, especially at locations other

than hospitals and independent laboratories engaged in interstate commerce (Federal Register, Volume 57, Number 40, Friday, February 28, 1992, Rules and Regulations pp. 7106 and 7139-7144). The CDC lacked validated, site-specific information on analytes, test systems, specimen types, and volumes of laboratory testing being performed at laboratories of all sizes and types.

The DLS requires information on analytes, test systems, specimen types, and standardized test volumes to respond to questions concerning the impact of both regulatory and nonregulatory changes in the delivery of laboratory medicine. Assessing the impact of regulatory changes on the delivery of laboratory testing is especially important as the health care delivery system moves toward managed care.

The need for a statistically valid inventory of laboratory services, and the need to produce a model to test proposed regulatory changes from that data, formed the basis for the National Inventory of Clinical Laboratory Testing Services Survey (NICLTS). Conducting this and future periodic inventories of laboratory testing services will allow the government to track changes in access to laboratory tests, to determine what and where tests are available, and to better understand and predict the impact of policy decisions and proposed regulatory changes on laboratory services. Both the development and implementation of national policies will be guided by the results of NICLTS.

Prior to NICLTS, no scientifically valid inventory of laboratory testing existed believed that at least 4 billion laboratory tests are performed annually in the United States.

1.3 Authority and Confidentiality of Data Collection

Data for the NICLTS were collected under the authority of Section 306 of the Public Health Service (PHS) Act (42 USC 242k). Participants were assured that the information they provided would be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m). While many participants were initially hesitant to participate, the strict confidentiality afforded by Section 308(d) clearly contributed to the high response rates obtained for this study.

1.4 Study Overview

The remainder of this chapter presents a summary of the design and conduct of NICLTS. Chapters 2 through 6 provide further details on these topics.

The objective of this research effort was to carry out a statistically valid national inventory of clinical laboratory testing services by analyte, test system, specimen type, and test volume in a stratified random sample of laboratories in the United States. The population consisted of facilities that performed clinical laboratory testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) and who were listed on the Health Care Financing Administration's July 1996 Online Survey, Certification and Reporting (OSCAR) database as certified for performing high, moderate, waived, or PPM testing.

The sampling frame consisted of 157,779 laboratories. Prior to sampling, the frame was stratified by the 10 DHHS designated geographical regions and 6 laboratory groups based on the 23 HCFA clinical laboratory types. Territories and Commonwealths of the United States were excluded. Within each stratum, the frame was further sorted by physician office laboratory category (POL vs. non-POL), certification category (moderate/high complexity vs. waived/PPM), laboratory group (other than POL), and laboratory type. This procedure helped to ensure the selection of laboratories with a variety of characteristics.

The sample was designed to allow determination of the proportion of laboratories performing specific clusters of analytes, test systems, and biological specimens and at what complexity. Given this objective and cost constraints, no attempt was made to ensure that every rare analyte would be included in the sample design. Although test volume was obtained for each cluster, the sample was not optimally designed to provide national estimates of test volume.

The POLs, which comprised about 57 percent of the laboratories holding CLIA certificates, were sampled at one-half the rate of other laboratories. Laboratories holding moderate and high complexity certificates were tabulated on site using a computerized data entry system written in PARADOX for Windows that was developed specifically for the inventory (Phase I). This computerized data entry system, termed the "Tabulation Device," allowed for standardized and structured data collection, utilized the CDC Complexity Model database, and contained a thesaurus of analyte and test system names mapped to their Complexity Model equivalents. Laboratories holding waived/PPM certificates were tabulated using a combined mail-telephone methodology

(Phase II). During Phase I, subsampling was used to reduce costs in three circumstances: (1) when hospitals or health maintenance organization laboratories had nursing stations that performed identical test menus; (2) when daily logbooks were the only source of volume data; and (3) when laboratories with multiple locations with a wide geographic dispersion performed the same tests at all locations.

To meet the desired precision requirements, the study design called for 1,834 participating laboratories. The sample for NICLTS was selected in several stages. After stratification, an initial sample of 6,000 laboratories was systematically selected. A subsample of 2,503 laboratories was then selected for the primary sample. The primary sample was further divided into two parts corresponding to Phase I and Phase II samples. The 3,497 laboratories not in the primary sample were held as a reserve sample, allowing a substantial margin to offset possible losses in the primary sample because of nonresponse or out of business facilities. The reserve sample was sorted by region (10 levels), and laboratory type (23 levels). Within these groups, facilities were randomly divided into four release groups. Each release group constituted a representative subsample so that the addition of a release group did not invalidate the representative nature of the overall sample.

Operationally, the data collection effort consisted of two stages:

- A laboratory enrollment stage in which the sampled laboratories were contacted by telephone to recruit them into the study and
- A tabulation stage in which test data were tabulated through followup contact with the enrolled laboratories on site (Phase I) or by telephone (Phase II).

For Phase I, a primary sample of 820 laboratories and 110 laboratories added from the reserve sample were contacted for enrollment for a total released sample of 930 laboratories. For the Phase I telephone enrollment, the response rate was 85 percent. For field tabulation of Phase I, the response rate was 95 percent.

For Phase II, a primary sample of 1,683 laboratories and 176 laboratories added from the reserve sample was contacted for enrollment for a total released sample of 1,859 laboratories. For the Phase 11 telephone enrollment, the response rate was 86 percent. For telephone tabulation of Phase II, the response rate was 90 percent.

1.5 Design Issues

Three unique design issues had major impacts on the study: laboratory sensitivity regarding reporting of CLIA ID number and the volume of their testing, use of CDC's Complexity Model database, and standardizing the definitions of the concepts "test" and "test volume." Each of these topics is addressed separately below.

1.5.1 Laboratory Sensitivity Regarding CLIA ID Number and Volume of Testing

Each laboratory that registers with HCFA is issued an alphanumeric identifier commonly referred to as a CLIA ID number. The CLIA ID number is used in official communications between laboratories and HCFA and is also linked to the OSCAR database containing laboratory attribute information. The survey instrument included a question which asked for CLIA ID number. CLIA ID numbers were sampled from the OSCAR database and the number was used to ensure the statistical integrity of the sample by confirming that the laboratory being inventoried conformed to the corresponding sampled CLIA ID number, that the tabulated tests included only those tested under the sampled CLIA ID number, and that the tabulated tests included all tests conducted under the CLIA ID number. This protocol was a crucial component in compiling a valid national database on the scope and volume of testing in CLIA certified laboratories. Creating such a database is part of the CDC's mandate in implementing the Clinical Laboratory Improvement Amendments of 1988.

Although the CLIA ID number was requested only for record linkage, tracking, and endpoint ascertainment purposes, asking for the number during the inventory was nonetheless a sensitive issue, with some laboratories fearing regulatory implications as a result of their participation. Volume of testing performed under a given CLIA ID number was considered by respondents to be confidential business information. In response to these concerns, study participants were assured that the data for the NICLTS were collected under authority of Section 306 of the Public Health Service (PHS) Act (42 USC 242k), that the information they provided would be held in strict confidence in accordance with Section 308(d) of the PHS Act (42 USC 242m), that no regulatory actions could or would result from their participation, and that inventory data would be aggregated and summarized during the analysis to prevent any link to a particular laboratory. As a result of these assurances, item nonresponse for CLIA ID number was practically nonexistent. All of these factors, including CDC sponsorship, contributed to the high laboratory response rates for this inventory.

1.5.2 Complexity Model Database

In order to collect data in an organized, standardized, and consistent manner, CDCs Complexity Model database of linked analytes and test systems was used to classify all testing. The database contains about 19,000 entries. It is dynamic, changing periodically as new analytes and test systems are approved by the Food and Drug Administration (FDA) and older ones are abandoned. Even though the database is stratified by laboratory specialty (12 levels), data collection proceeded without reference to specialty, since many laboratories test the same analyte in different departments. The inventory employed the Complexity Model database as it existed in February 1997.

Before data collection began, Westat supplemented the Complexity Model database by the addition of analytes and test systems not found in the Complexity Model. Many of these were in the specific specialty areas of anatomic pathology, histology, and microbiology. New entries were assigned temporary codes while awaiting official CDC coding. When additional analytes and test systems were identified in the field, they were forwarded to CDC for coding.

Since the database does not include a separate variable for specimen, and because CDC Complexity Model analyte and test system codes are sometimes confounded by specimen, specimen type was added to the database. A total of 42 biological specimen codes were added to the database. This expanded version of the database is referred to as the "expanded Complexity Model database." The data collected from all laboratories therefore consisted of analyte, test system, biological specimen, and 1996 calendar year volume. The first three elements are referred to as a "cluster."

1.5.3 Definition of Test and Test Volume

Only procedures measuring analytes were considered tests for purposes of NICLTS. Calculated values for patient testing were not tabulated. For example, a CBC consisting of hemoglobin, hematocrit, white blood cell count (WBC), red blood cell count (RBC), mean corpuscular hemoglobin (MCH), mean corpuscular volume (MCV), and mean corpuscular hemoglobin concentration (MCHC) was recorded as four separate tests since hemoglobin, hematocrit, WBC, and RBC are measured and MCH, MCV, and MCHC are calculated.

In order to ensure the comparability of volume data across tabulators and across laboratories, the process of counting volumes of testing was standardized. In general, counting was based on a method developed by HCFA and used by HCFA surveyors. Where counting guidelines did not exist, additional rules were established following the logic of the HCFA method. All measured values for patient testing were counted as tests. Quality control, proficiency testing, method comparison studies, or repeat patient testing were excluded from volume counts. While counting was straightforward for most testing, some specific rules were developed. For example, manual antibiotic susceptibility testing was counted as a single test regardless of the number of disks placed on the agar.

1.6 Phase I Enrollment and Field Procedures

1.6.1 Enrollment

Data were collected on site in moderate and high complexity facilities by trained medical technologists during Phase I of the study. The medical technologists used the Tabulation Device developed specifically for this inventory to record the data. Enrollment of laboratories began on January 6, 1997. Initial contact with the sampled laboratories was by an advance notification letter signed by Edward L. Baker, Jr., Assistant Surgeon General and Director, Public Health Practice Program Office, CDC. The advance letter informed participants about the study and its purpose, gave the authorization for the study, described the random nature of their selection, stressed the importance of their participation, reviewed confidentiality protections afforded participants, and alerted them to expect a telephone call from an enrollment specialist who would address the specifies of their participation.

Approximately 1 week after the letter was mailed, a trained telephone enrollment specialist initiated telephone contact with each sampled laboratory to request its voluntary participation in the study. Additional objectives of the telephone contact included confirmation of the participant's CLIA ID number with information provided in OSCAR, securing both an enrollment contact person and field contact person, identification of other locations performing testing under the sampled CLIA ID number, and clarification of any laboratory demographic inconsistencies.

An Eligibility Screener Questionnaire, which incorporated a series of structured probes, was implemented whenever a sampled facility claimed that it was not a laboratory or did not perform clinical testing during calendar

year 1996. The screener allowed the enrollment specialist to determine whether or not a facility performed testing during 1996 that was subject to CLIA. For example, if a facility performed occult blood testing on stool specimens, it was classified as a laboratory even though its staff had stated that they did not perform laboratory tests.

Each laboratory agreeing to participate in the study received a personalized confirmation letter from the NICLTS project director. The letter thanked the laboratory for agreeing to participate, referenced the enrollment telephone call, identified the laboratory by name and address, reinforced the information provided in the enrollment call, and specified that a medical technologist would call in the near future to set an appointment to visit the facility. It reaffirmed the confidentiality afforded participating facilities and provided the laboratory with a toll-free number to use if its staff had any questions about the study, the site visit, or specific technical matters.

1.6.2 Field Procedures

Field Tabulator Recruitment and Training

To collect the data, the study required certified medical technologists at the baccalaureate level with at least 2 years of generalist experience, good communications skills, the ability to travel overnight from their home locations, computer skills, and demonstrated interpersonal skills. Since the technologists were needed across the country, advertisements were placed nationwide in three major medical technology journals. Qualified candidates were invited to attend a paid training program in Rockville, Maryland.

The training curriculum was designed to ensure standardized data collection and strict adherence to field, administrative, and operational protocols. A significant proportion of the training time was devoted to learning to use the Tabulation Device and ensuring standardized counting of tests. Toward the end of training, tabulators were sent to laboratories that had been recruited to serve as practice sites. The tabulators carried out the full on-site protocol and data tabulation at their assigned facilities.

Data Tabulation

Phase I data tabulation began at the end of the training session in January and was completed in July 1997. Tabulators followed a standardized on-site protocol that ensured the comparability of data across tabulators and across laboratories. Tabulators called the contact person for participating laboratories and arranged a date and time to visit. Once on site, the tabulator confirmed the CLIA ID number and probed for other possible testing sites under that number. After touring the laboratory and documenting visible test systems, tabulators asked for existing records from which to tabulate. The information was typically provided in the form of computerized annual or fiscal year billing records, annual volume logs, and daily and/or monthly hand-written logs. When existing records were not available, a standardized protocol was used to obtain testers' estimates.

After obtaining the testing records, the tabulator used the Tabulation Device to record the data. The protocol included additional checks at this point to again verify that the site was indeed the one sampled and to ensure that data were being entered for the current location. Data were entered separately for each site at a geographic location. The Tabulation Device included menu-driven algorithms for randomly subsampling nursing stations and daily log books.

Data entry was standardized and consisted primarily of analyte, specimen, test system, and volume. When the analyte or test system names provided by the laboratory differed from those in the expanded Complexity Model, the tabulator used the built-in thesaurus to locate and link the analytes and test systems to the expanded Complexity Model. Analytes and test systems not in the expanded Complexity Model were, after the tabulator obtained confirmation and permission from the technical support line, entered in a standardized format and subsequently forwarded to CDC for coding.

1.7 Phase II

Phase II laboratory enrollment and data collection occurred in the Fall and Winter of 1997-1998. Data were collected in waived and PPM facilities by trained medical technologists. The principal collection method was a telephone interview using standardized telephone survey research telephone protocols.

1.7.1 Advance Letter, Telephone Enrollment, and Data Collection Packet

Initial contact with the sampled laboratories was by an advance notification letter similar to the one used in Phase I. Approximately 1 week after the letter was mailed, a trained telephone enrollment specialist initiated telephone contact with the laboratory to request its participation in the study. The objectives and protocol of the telephone contact were similar to Phase I, the only difference being that laboratories were requested to respond to a mail-telephone data collection rather than to allow a tabulator to visit the laboratory.

The eligibility screener developed for Phase I was also used in Phase II. The screener allowed the determination at the telephone enrollment stage of whether or not a facility performed testing during 1996 subject to CLIA. As in Phase I, many waived and PPM facilities holding CLIA certificates did not consider themselves a "laboratory" or claimed not to have performed testing in calendar year 1996. Upon screening, however, many were determined to have performed testing subject to CLIA.

Each laboratory agreeing to participate in the study received an individualized data collection packet. The packet included a personalized confirmation letter from the NICLTS project director, which thanked the laboratory for agreeing to participate, referenced the enrollment telephone call, identified the laboratory by name and address, reinforced the information provided in the enrollment call, reaffirmed the confidentiality afforded participating facilities, and provided the laboratory with a toll-free number to use if there were any questions about the study, the forms, or specific technical matters. The packet also included a set of data inventory forms and instructions for the laboratory to use in assembling and standardizing its recording of the data. These mailed forms were, however, not the ultimate data collection instruments. They served only as an intermediate form used by the sampled facility prior to the actual collection of data by telephone. Sampled laboratories were requested not to mail back completed forms.

1.7.2 Telephone Tabulator Recruitment and Training

Medical technologists with qualifications similar to those in Phase I were recruited to work in the Washington, DC metropolitan area as telephone tabulators. The medical technologists attended a training session in Rockville, Maryland. All candidates successfully completed the training program. The training curriculum was designed to ensure standardized data collection and strict adherence to telephone, administrative, and operational

protocols. A significant amount of the training time was devoted to learning standard telephone data collection techniques and ensuring adherence to the standardized telephone data collection protocol.

1.7.3 Telephone Tabulation

The telephone tabulation protocol standardized all activities associated with the telephone data collection effort. This protocol ensured the comparability of data across tabulators and across laboratories.

In general, telephone tabulators called the laboratory contact person approximately 1 week after the mailing of the confirmation letter and data inventory forms. The primary purposes of this initial phone contact were to confirm that the laboratory had received the packet, to address any technical questions or concerns expressed by respondents, and to prompt laboratories to complete the inventory form in a reasonably short time frame. Many laboratories provided the data during this initial contact. For laboratories that had not yet received the mailing or had misplaced it, the tabulator arranged for a new packet to be mailed. For facilities that had received the packet but had not yet completed the inventory, the tabulator requested a date and time that would be most convenient to the laboratory for collecting the information. This early initial phone contact made operations more efficient and reduced the total time for completing the inventory.

The precoded data collection instrument used by telephone tabulators for collecting waived/PPM data mimicked the mailed inventory form. The tabulators used a scripted protocol that directly referenced the inventory form in the study participant's hands. Because the test menu for waived/PPM facilities was limited, the tabulator explicitly read each of the tests approved for waived/PPM facilities and asked whether the laboratory had performed that test during calendar year 1996. Additional probes were used to elicit any moderate or high complexity testing that might have been performed.

1.7.4 Key Entry

All data were double key entered. Systems staff subsequently reviewed a random subset of entered data by cross-checking the electronic data file with the original data collection instrument. No errors in key entry were found during this check.

1.8 Statistical Issues

The issues discussed in this section apply to the entire sample, both Phase I and Phase II.

1.8.1 CLIA ID Number Verification and Problem Resolution

For purposes of NICLTS, a laboratory was defined as the unit corresponding to a CLIA ID number. It was CLIA ID numbers that were sampled from the OSCAR database and the CLIA ID number was the unit of analysis. Therefore, verification of these numbers was important to the validity of the data collection effort.

During NICLTS, three general types of CLIA ID number verification problems were encountered. These included (1) the CLIA ID number on the laboratory's certificate did not match the sampled number or could not be located; (2) more than one CLIA ID number was found at the sampled location; and (3) more than one location was included under the sampled CLIA ID number. When the CLIA ID number at the laboratory did not match the sampled CLIA ID number, or when it could not be located, a standardized set of rules was used to determine whether or not data collection should proceed. When more than one CLIA ID number was provided at a sampled location, the participant was asked to provide data only for tests performed under the sampled number. If the respondent could not distinguish testing conducted under the sampled number, all data were collected and the information was forwarded to the survey statisticians for review. When more than one geographic location was included under the sampled CLIA ID number (other than multiple sites within a facility), and the number of multiple locations was three or less, and the various facilities were located in the same approximate area, all such facilities were tabulated. For laboratories with more than three widely dispersed locations, the survey statisticians reviewed the situation to determine whether to tabulate all locations or to subsample them.

1.8.2 Clusters within Each Location

In creating volume estimates for distinct sets of clusters of analytes, specimens, and test systems within each location, statistical adjustments were made for subsampling of daily logs and nursing stations, nonresponse among sampled logs and nursing stations, and subsampling of locations. These adjustment are discussed in Chapter 5.

1.8.3 Weighting and Nonresponse Adjustment

As noted already, for definitional and operational purposes, a sampled CLIA ID number (laboratory) could have multiple geographic locations--for example, when a public health laboratory had several clinics with different addresses scattered across the state. A location, in turn, could have multiple sites within it-for example, a hospital with several nursing stations.

For weighting, NICLTS survey statisticians first reviewed the Tabulation Problem Forms[1] to determine if any situations described affected weighting. Next, survey operational result codes for every laboratory location were assigned a response code. Operational result codes for locations were reduced to four response codes for weighting purposes (see Table 5-1). These included respondent, eligible nonrespondent, ineligible, and nonrespondent with unknown eligibility.[2] For laboratories with multiple locations, a single response code was assigned that characterized the final response outcome at the level of the sampled CLIA ID number.

The laboratory base weight was simply the inverse of the probability of selection. As discussed earlier, physician office laboratories were sampled at one-half the rate of other laboratory types. The base weights account for any such differing probabilities of selection. After calculating the base weights, three nonresponse adjustments were calculated. The first adjustment was to account for nonrespondents of unknown eligibility at the enrollment stage, the second was to account for eligible nonrespondents at the enrollment stage, and the third was to account for all nonresponse at the data collection stage.

1. Tabulation Problem Forms were completed by the field staff to describe unusual situations related to multiple locations, multiple CLIA ID numbers, use of billing data, availability of data for only part of 1996, and other unusual situations.

2. To be eligible for the study, a sampled laboratory needed to perform laboratory tests for patient care during calendar year 1996.

1.8.4 Raking and Calculation of Final Laboratory Weights

After completing the nonresponse adjustment, the adjusted weights were raked. Raking is a procedure wherein survey estimates are adjusted to match certain known values. For the NICLTS, the adjusted weights (after nonresponse adjustment) were raked to counts of laboratories by the six laboratory groups and 10 regions. All counts were obtained from the HCFA July 1996 OSCAR database used for the sampling frame. The final laboratory weight was the product of the base weight, nonresponse adjustments, and raking adjustments.

1.9 Phase I Verification and Validation of On-Site Data Collection

The NICLTS Phase I included two mechanisms for verifying that data collection actually occurred on site at the sampled laboratory and according to the standard protocol. These mechanisms included telephone verification with all of the tabulated laboratories and a second site visit to 30 selected facilities.

1.9.1 Phase I Telephone Verification

The telephone verification quality assurance program consisted of a brief followup interview by home office staff with all of the laboratories tabulated during Phase I. The purpose of the interview was to verify that the tabulator had visited the laboratory and performed the data tabulation in conformity with the on-site protocol. Results of the interview were graded and coded according to three criteria: (1) unconditionally verified, (2) verified after specific review, and (3) unable to reach respondent.

The verification process revealed a high degree of conformance with the data collection protocol. It showed that 98.3 percent of field tabulators unconditionally adhered to the protocol (i.e., every protocol-related question was answered with the desired response); 1.2 percent conditionally adhered to the protocol (i.e., one protocol-related question was answered with an unexpected response and, after further review by project staff, the tabulator was determined to have followed the protocol); and0.5 percent were incomplete verifications (project

staff could not reestablish contact with a laboratory contact knowledgeable about the site visit).

In light of these results (99.5% verified, 0.5% no contact), it was not necessary to pursue additional quality assurance checks for verifying site visits. The overall finding of tile verification process was that the tabulators visited every site in person and carried out the study according to the data collection protocol.

1.9.2 Phase I Site Validation Visits

Because this was the first scientifically valid probability sample of clinical laboratory testing conducted in the United States, a validation test of the NICLTS protocol was performed. This involved retabulation in a sample of 30 laboratories that had already been tabulated. A different tabulator was assigned to revisit the laboratory to carry out a duplicate but independent tabulation. The protocol and methodology for the validation retabulations were identical to those used for the original tabulations.

The purpose of the validation study was to evaluate the field protocol and reliability of data tabulated in the field during Phase I of the NICLTS. A comparison of the original field tabulation data (survey data) with data collected during the validation visit (validation data) was performed.

Regression analyses showed that differences between survey data and validation data were not significant enough to make adjustments to the survey data. The validation study did not reveal any constant or systematic errors in the tabulation of analytes, triples (clusters), or volume.

1.10 Phase II Verification and Validation

Since Phase II used a mail-telephone methodology, no telephone verification was performed with participating laboratories. However, the telephone tabulation supervisor silently monitored the telephone data collection performed by tabulators daily to ensure adherence to the standardized telephone data collection protocol, to check progress and problem reporting, and to ensure efficient and proper utilization of tabulator time. No problems were encountered of an individual or collective nature that had any implications for the validity of the NICLTS protocol or the resulting data.

The Phase II data collection was validated by collecting data on site from a sample of responding laboratories. A nationally distributed team of validation field tabulators was selected from among those who had worked on Phase I. The team members were individually assigned to visit the Phase II validation sample in their geographic areas to carry out a duplicate but independent on-site tabulation. The protocol for the validation site visits was similar to that used for the Phase I tabulations, with the exception of enrollment and the use of paper and pencil methodology rather than laptop computers.

Validation enrollment operations were similar to those used in the Phase II main study with the exception that laboratories which had already participated by telephone were now asked to allow a site visit by a different data tabulator to repeat the tabulation process in person. Laboratories were purposively chosen from a two-way grid of telephone data tabulator by laboratory type (waived, PPM). All telephone tabulators who participated in the mail-telephone data collection effort were represented in the sample. The data tabulators completed retabulations in a total of 110 locations.

The purpose of the Phase II validation study was to evaluate the reliability of mail-telephone data collection versus on-site data collection in waived/PPM laboratories. A comparison of the original mail-telephone data (survey data) with data collected during the validation site visit (validation data) was performed. The analysis was broken down by number of analytes recorded, number of clusters (analyte, test system, specimen) recorded, and estimated total volume for each location. The Phase II validation analysis showed consistent differences between survey data and validation data, though they were not significant enough to require adjustments. Specifically, the validation study indicated consistent underreporting in the mail-telephone modality by about 10 percent. This amount is, however, well within the sampling error of the overall estimates.

1.11 Overall Survey Estimates of Laboratory Volume

The NICLTS found that hospital laboratories collectively tested 8,164 distinct clusters (i.e., analyte, test system, specimen), while POLs collectively tested 1,604. The POLs in Region 1 (Northeast) tested 148 distinct clusters. The average number of distinct clusters per laboratory type varied by region. For example, POLs as a whole tested an average of nine distinct clusters, though this was somewhat higher for POLs in the Northwest (about 15 distinct clusters). Nationally, the estimated mean distinct clusters tested per laboratory was 15.2, and the

95 percent confidence interval around this point estimate was 13.9 to 16.4.

Based on NICLTS data, the estimated total national volume of testing performed in calendar year 1996 was 7,250,519,342 (7.25 billion) tests and the 95 percent confidence interval around this point estimate was 5.12 to 9.38 billion tests. Chapter 5 gives more detailed information of volume of testing by region and laboratory group and type.

1.12 Issues to be Considered when Interpreting NICLTS Data

Depending on the types of analysis being undertaken, there are several issues which should be kept in mind when analyzing NICLTS data. First, there is a small degree of underestimation in collection of waived/PPM data (see Chapter 6). Second, the regional estimates obtained in the NICLTS represent the region where tests were performed, not where they were ordered. Finally, the survey was designed as an exploratory study to estimate the prevalence of analyte, test system, and specimen combinations in laboratories, not to generate test volume estimates.

Chapter 6 discusses in detail the design, implementation, and results of the Phase I and II validation studies. While the Phase I results showed close correlations between the initial and retabulated data, the Phase II validation study indicated a consistent tendency for the field tabulators to undercount tests. This point should be considered when analyzing data from laboratories performing waived and PPM testing. The contribution of these laboratories to overall test volume and to the number of unique triples was relatively small (about 4%), however, so this issue is not important when considering overall estimates.

When evaluating regional estimates obtained in the NICLTS, it should be remembered that specimens may be shipped to a laboratory from anywhere in the United States. While it is likely that tests performed in a given region are associated with patients residing in that region, it is not known to what extent this assumption is true.

Finally, except for undersampling POLs, the survey was designed with proportional representation. While this design gives a broad representation of different types of laboratories, it is not the most efficient design for generating estimates of test volume. Volume could have been estimated more efficiently with a design that

oversampled large laboratories to a greater extent. Such a design would, however, have been less efficient as an exploratory survey.