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NINCDS COLLABORATIVE
PERINATAL PROJECT
A User's Guide to the Project and Data

Volume I
An Introduction to the History, Scope and Methodology of the Project

L. E. Sever
A. R. Olsen
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J. S. Littlefield

December 1983

Prepared for
the National Institute of Neurological
and Communicative Disorders and Stroke
under Contract 2311105150

Battelle
Pacific Northwest Laboratories

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NINCDS COLLABORATIVE PERINATAL PROJECT: A USER'S GUIDE TO THE PROJECT AND DATA

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ABSTRACT

The purpose of this user's guide is to provide researchers with complete documentation of data gathered during the course of the NINCDS Collaborative Perinatal Project (NCPP). The NCPP lasted sixteen years and included approximately 58,000 study pregnancies. Data on the women and their pregnancies and study children are included in the NCPP data base, which is made up of three separate computerized files. The user's guide consists of seven separate volumes. Volume I provides background on the study and detailed procedures for requesting and obtaining data. Volumes II, III and IV provide complete documentation for data items contained in the master, variable and work files, respectively. Volume V, the master index to data items, is a computerized compilation of all data items included in the project. Volumes VI and VII are computerized indexes that allow a researcher to scan for data items in an alphabetical glossary (Volume VI) or to find data items arranged according to person, time of collection or measurement and general subject categories (mother, delivery, medication, etc.; see Volume VII).

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PREFACE

INTRODUCTION

The data from the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) Collaborative Perinatal Project are an important resource for biomedical and behavioral research in many areas of obstetrics, perinatology, pediatrics and developmental psychology. The data were collected as part of a prospective study, unique in its design and magnitude. The data constitute a repository of information of great value. Books and monographs based on analyses of these data and other publications number in the hundreds. Even so, the possibilities for the development of further knowledge based on this study are immense. It is unlikely that such a study will be undertaken again and it is thus of particular importance that the data be utilized as fully as possible.

OBJECTIVES AND READER ASSUMPTIONS

This User's Guide, NINCDS COLLABORATIVE PERINATAL PROJECT: A USER'S GUIDE TO THE PROJECT AND DATA, describes the NINCDS Collaborative Perinatal Project (NCPP) and the data base resulting from that project. The User's Guide objectives are (1) to provide comprehensive documentation of the NCPP, with information regarding the design and conduct of the study, and (2) to allow effective and efficient independent use of the NCPP data by researchers previously unfamiliar with the data. Documentation of the study and methods employed in data collection and processing will help researchers clearly understand the strengths and limitations of the data set.

The reader is assumed to be either a researcher (probably a Ph.D., M.D. or advanced graduate student) or a computer programmer associated with such a researcher. The NCPP data are most appropriate for epidemiological studies and hence the reader is assumed to have general interest in such studies.

DOCUMENT STRUCTURE

This document, NINCDS COLLABORATIVE PERINATAL PROJECT: A USER'S GUIDE TO THE PROJECT AND DATA, is divided into seven volumes. The volumes are:

- Volume I, AN INTRODUCTION TO THE HISTORY, SCOPE AND METHODOLOGY OF THE PROJECT

  provides an overview and should be read prior to acquisition of any other volumes.

- Volume II, PROJECT STUDY FORMS AND DOCUMENTATION OF TRANSFER TO COMPUTERIZED DATA ITEMS IN MASTER FILE

  is an exhaustive compilation of forms, instructions for completing the forms, definition of codes, punched card descriptions, and tabulation of data items related to each form. Over 5000 data items are defined in the 2000 pages of this volume.

- Volume III, VARIABLE FILE,

  describes the major summary file, which contains 1200 data items.

- Volume IV, SELECTED NCPP WORK FILES,

  describes 18 computer tapes related to specific research areas within the study.

- Volume V, MASTER INDEX TO THE NCPP COMPUTERIZED DATA ITEMS,

  tabulates all data items in the order they appear on the various computer data files and assigns unique identification numbers to each item.

- Volume VI, ALPHABETICAL PERMUTED GLOSSARY OF NCPP COMPUTERIZED DATA ITEMS,

  tabulates the data items in alphabetic order with multiple entries for selected words within the data item names.

- Volume VII, CATEGORIZATION OF DATA ITEMS, BY PERSON, TIME OF COLLECTION OR MEASUREMENT, AND GENERAL SUBJECT AREA,

  presents the data item names and identification numbers in three separate orderings based on person, time, and general subject area.

The structure of Volume I is described in this preface; that of Volumes II through VII in Chapter 6 of Volume I.

Chapter 1 begins with a review of the history of the Collaborative Perinatal Project and its goals and objectives. Key to the study was its collaborative nature and the selection of the participating centers. The study sample selection process is discussed and resulting characteristics of each sample presented. This provides the researcher with an understanding of the composition of the NCPP subject population on which the data were obtained.

Chapter 2 includes a discussion of the data collection methodology for the study. Development of forms and manuals used to collect data in a standard format is described, as are the forms themselves and the data collection process. Because of the multicenter nature of the project, standardization of data collection and consistency and accuracy of the data across centers are important considerations.

Chapter 3 describes procedures used for processing the data. This includes consideration of the activities carried out at both the collaborating institutions and at the Perinatal Research Branch of NINCDS. The data are organized into various computer data files and these files are described.

Chapter 4 of the guide presents an overview of the data collected classified by categories. Because of the breadth and diversity of the data, the data items included in the study have been organized according to bio-behavioral category. A hierarchical system of classification that allows a researcher to determine the substantive areas included in the study is also included.

Chapter 5 presents the information needed by a researcher to generate a request for access to data from the NCPP. Included here is a discussion of the policies and procedures to be followed in requesting data. General information on the structure of the individual computer files is included to guide the researcher in assessing the utility of each computer file for specific research requirements.

Chapter 6 describes the contents and use of Volumes II to VII. In these volumes, data collection forms and manuals are described and reproduced; documentation of the transfer of data from the forms to computerized data items is provided as well (Volume II). The three types of computer files are documented and the individual data items contained in the files identified (Volumes III and IV). Also included are a master index (Volume V), an alphabetical permuted glossary of the computerized data items (Volume VI) and categorization of data items by person, time of collection or measurement, and general subject area (Volume VII).

A bibliography that lists all publications based on data from the NCPP is available from the Developmental Neurology Branch of NINCDS. We recommend that a prospective researcher review the bibliography to identify pertinent research that may have been conducted using this data set.

REQUIREMENTS FOR RESEARCHERS

To use data from the NCPP, the researcher must first satisfy the requirements for data access, as established by the NINCDS. These requirements are outlined in Chapter 5 of Volume I of the User's Guide.

Prior to initiating a data request, however, it is recommended that the researcher determine if his computing resources are adequate to process any NCPP data tapes requested. Depending on the data request, substantial resources may be required. We recommend that the discussion of data files in Chapter 3 be reviewed carefully by an individual with computer programming proficiency.

SUGGESTED RESEARCH PLAN

Based on our experience in developing this document, we suggest an approach to determining if the NCPP data files are of potential use in a research study. While alternative approaches or modifications to the following are possible, we feel that the proposed approach will be the most economical one, both in terms of time and other resources, particularly for the individual who has not used NCPP data before.

We suggest that the researcher first study this volume (Volume I) to develop an understanding of the design of the study and the methods by which the data were collected, processed and stored. This will provide an indication of the potential usefulness of the data. At the same time, the categories of data available should be reviewed to determine if general areas of interest to the researcher are included in the NCPP.

If this review indicates that NCPP data are relevant to the researcher's needs, a copy of the current NINCDS Collaborative Perinatal Project Bibliography and the remaining volumes of the User's Guide appropriate to the researcher's project should be obtained. The bibliography will enable the researcher to determine the previously published work that is relevant. The other volumes of the User's Guide, described in Chapter 6, provide the researcher with specific information on the data collection forms, data items available, coding of data items, and location of data items on the various tape files. Using these volumes, the researcher will be able to generate a request to obtain specific data of interest.

When specific data items of interest are determined and known to be available, a formal request for the data should be submitted, following the procedures described in Chapter 5. Copies of computer data files will be provided to the investigator after approval of the request. Special tapes will not be created for researchers. If the researcher is interested in variables or data that are not computerized, access to the microfilmed copy of the original study forms may be requested. Microfilmed study forms are available for viewing at NINCDS only.

The researcher is expected to conduct analyses of the data requested independent of the Developmental Neurology Branch of NINCDS. The information provided in this guide regarding tape characteristics, field locations, and variable coding is designed to provide the researcher with the knowledge needed for independent use of these data.

In summary, by developing a thorough familiarity with this guide and the descriptions of the NCPP data, the investigator can address questions of research interest. We hope this guide meets its goals of allowing effective and efficient independent use of these data by researchers previously unfamiliar with the NINCDS Collaborative Perinatal Project.

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CHAPTER 1. THE NINCDS COLLABORATIVE PERINATAL PROJECT: AN INTRODUCTION*

BACKGROUND OF THE STUDY

Plans for the NINCDS Collaborative Perinatal Project or NCPP, originally named the Collaborative Study of Cerebral Palsy, Mental Retardation, and other Neurological and Sensory Disorders of Infancy and Childhood, were initiated at the National Institute of Neurological Diseases and Blindness (NINDB) shortly after the Institute's founding in 1950. The general goal of the study was to investigate the relationship between perinatal complications and abnormal outcomes of pregnancy, since by the 1950s many such relationships had been reported in the literature. The factors which gave rise to the support for the investigation are summarized in the following quotation from the introduction to The Women and Their Pregnancies (Niswander and Gordon, 1972):

> "There is an increasing emphasis today in the United States on improving the health of American citizens. One aspect of this endeavor is to improve reproductive efficiency in order to increase the likelihood of the birth of healthy babies free from disease and impairment, and capable of optimal physical and intellectual development. The achievement of this goal depends upon the enlightened and widespread application of measures to prevent perinatal mortality and the continuum of reproductive wastage, which includes mental retardation, congenital malformation, cerebral palsy, and handicapping neurosensory defect.
>
> During the past half century, in many countries including the United States, maternal mortality has declined dramatically; the risk of death associated with pregnancy has, to a large extent, been eliminated. A sharp reduction in infant deaths from 28 days to the end of the first year of life has also occurred during the same period. However, the number of deaths occurring during the perinatal period has declined more slowly. In this Study, perinatal deaths include those fetal deaths occurring between the 20th week of gestation and the time of delivery, and deaths of liveborn infants during the neonatal period (to 28 days). It is the custom to report fetal and neonatal deaths separately, but frequently it is useful in some circumstances to combine them and to consider perinatal deaths as a unit.
>
> The magnitude of the problem of perinatal death comes sharply into focus with the realization that until old age

*Much of the material for this introduction is taken from Broman et al. (1975) and Niswander and Gordon (1972).

> the risk of dying is highest during the perinatal period. While the general mortality rate for the country approximates 9 per 1000 individuals in the population during the period 1955-65, the perinatal death rate is almost four times as great, approximately 35 per 1000 livebirths. The age specific risk of dying does not again approach a rate of 35 per 1000 until the 64th year is reached. Moreover, even at this rate the risks are not comparable because the age specific risk extends over a one-year time span while the risk of dying during the perinatal period is limited to about one-half, from 20 weeks gestation until 28 days after birth."

The high perinatal mortality rates and the associated human suffering were not the only causes for concern. Of far more importance to the individual, the family, and the community was the "continuum of fetal insult" which includes congenital malformations, cerebral palsy, mental retardation, deafness, blindness, and other neurosensory defects. Estimates of the numbers of people with such conditions are very large; when the NCPP was established it was estimated that approximately 20 million individuals in the United States had handicaps or defects which fell within this general category. Their special care, rehabilitation, and education paid for by family, community, and government cost billions of dollars each year. Effective means of preventing these defects were, and are, urgently needed.

HISTORY OF THE COLLABORATIVE PERINATAL PROJECT

It was against this background that plans for the NCPP were developed (Broman et al. 1975). After the establishment of the National Institute of Neurological Diseases and Blindness (NINDB) in 1950, concern about the etiology of cerebral palsy and other forms of neurological, sensory, and intellectual deficits led to the planning of a comprehensive study of pregnancy and its outcome, the outgrowth of which was the Collaborative Study of Cerebral Palsy, Mental Retardation, and Other Neurological and Sensory Disorders of Infancy and Childhood. NINDB, under the directorship of Dr. Pearce Bailey, became the focal point for the planning of research into the etiology of brain damage in childhood. Numerous organizations participated, including voluntary health agencies such as United Cerebral Palsy, the National Association for Retarded Children, and the Association for the Aid of Crippled Children, as well as professional organizations such as the Academy of Neurology and the Academy of Cerebral Palsy.

The Appropriations Subcommittee of the House of Representatives heard testimony from Dr. Bailey and other experts in 1953. These professionals emphasized that maternal infections, toxins, nutritional deficiencies, anoxia and blood incompatibilities between mother and infant may account for certain forms of cerebral palsy and malformations in the offspring. In 1954, the NINDB developed a coordinated system of brain registries for cerebral palsy and other disorders resulting from brain injury. By making postmortem material from all areas of the United States available, the registries aided research on the brain and the development of improved methods of diagnosis and treatment of neurological diseases.

In 1955, at the hearings of the Appropriations Committee of the House of Representatives, Dr. Bailey announced plans to set up a collaborative study involving various institutions throughout the United States. The purpose of the proposed study was to provide an opportunity to correlate the clinical manifestations of different types of cerebral palsy with the underlying neuroanatomical damage in the brain. In March of 1955, a panel of experts was convened by Bailey to draw up a protocol for a collaborative study of cerebral palsy. The objectives were: (1) to make a more precise determination of fetal, environmental, and medical factors leading to the various forms of human cerebral palsy, and (2) to link the symptoms of this group of disorders to the causative brain damage.

In 1957, Bailey proposed that in addition to the clinical-pathological study of cerebral palsy, a longitudinal investigation of pregnant women and their children be conducted in various medical centers throughout the country by obstetricians, pediatricians, neurologists, neuropathologists, and other specialists. Early in the planning of the collaborative clinical-pathological study of pregnancy and its outcome, the inadequacy of hospital records was recognized. Standardization of records between hospitals and expansion of the information normally recorded was required for a study of this scope. Furthermore, in previous studies, information about pregnancy and perinatal events had been collected retrospectively from parents of children with defects. To offset this problem, the prospective approach was chosen for the NCPP. Data would be collected on pregnancy and perinatal events as they occurred, eliminating biases due to knowledge of pregnancy outcomes.

The need for detailed prospective data, systematically recorded, coupled with the rarity of neurological deficits in childhood, made the availability of a large group of pregnant women imperative. A population of 40,000 pregnancies was projected. From a population this size, approximately 80 cases of Down's syndrome, 200 cases of cerebral palsy, 640 stillbirths, 680 neonatal deaths, 2,800 premature infants, and 3,000 congenital malformations could be expected, the minimum numbers necessary to answer the projected questions. The crux of the research effort was to study a large number of cases in great detail in order to evaluate the effects of perinatal factors on the health of the individual child.

In the offspring, disorders of the nervous system and abnormalities of any other body systems appearing at the time of delivery, during infancy, or in early childhood were to be evaluated. Included were cerebral palsy, mental subnormality, behavioral disorders, and other specific neurological or sensory defects. Related areas of investigation included identification of: (1) factors operative in early and late fetal loss, prematurity, and infant and early childhood mortality; (2) the relationship of physical and mental development in early childhood to genetic, biological, and environmental factors; (3) events in the postnatal environment related to the later development of disturbances of structure and function in the nervous system; and (4) more precise definitions of the events of the reproductive process and the nature of its outcome.

The investigation of relationships between factors and conditions affecting parents and the occurrence and course of abnormalities in offspring was to be accomplished by analysis of pooled information. Data were to be

collected uniformly in the collaborating medical centers on women studied during pregnancy and from their offspring followed from infancy through early childhood. The research effort was directed toward the reevaluation of the effects of factors already suspected in the etiology of abnormal outcomes of pregnancy. In addition, the research sought to clarify mechanisms through which these factors were operative, and the discovery of factors not presently known or suspected.

Areas to be investigated in the parents included: (1) the conditions and complications of pregnancy, the normal and abnormal physiology of pregnancy, labor, and delivery; (2) environmental factors influencing the mother, including social and economic conditions, emotional stress, and medical care; (3) biological factors, such as age, parity, medical and reproductive history, and immunological characteristics; and (4) the genetic background of the parents.

Many managerial details had to be worked out in an undertaking that would cover a wide geographic area and involve teams of professional men and women working under many different systems of hospital and clinical management. In planning the NCPP, these details had to be considered carefully, and were often revised and then re-revised as efforts were made to gather uniform data across the country.

Collaborating Institutions

In 1956, NINDB personnel visited hospitals across the country to acquaint the hospitals' staffs with the general outline of a prospective study of pregnancy and the children thereof. Interest was generated and numerous applications from a variety of institutions were received.

In 1957, after staff members and consultants from the NINDB visited the major medical schools and centers of the United States and acquainted them with the research plans, the following fourteen institutions were approved to participate in the NCPP: Boston Lying-In Hospital and Children's Medical Center; Buffalo Children's Hospital; Charity Hospital, New Orleans; Children's Hospital, San Francisco; Columbia-Presbyterian Medical Center; Johns Hopkins Hospital; Medical College of Virginia; University of Minnesota; New York Medical College; University of Oregon; Pennsylvania Lying-In Hospital and Children's Hospital (Philadelphia); Providence Lying-In Hospital and Brown University; University of Tennessee; and Yale University.

Data collection for the NCPP was initiated in 1959. During the first three months of that year, nine collaborating institutions began registering obstetrical patients; all institutions had begun patient registration by October of 1960, when Buffalo Children's Hospital entered the study. Table 1.1 lists the collaborating institutions that enrolled subjects, the dates between which the registration of subjects occurred, and the approximate number of subjects enrolled.

Withdrawal of Collaborating Institutions

During the course of the study, four collaborating institutions dropped out for various administrative reasons. In 1959, Children's Hospital in San Francisco withdrew after participating in the pretest phase. In 1961, after registering about 900 pregnancies, Yale withdrew from active participation. In 1963, Columbia Presbyterian Hospital terminated obstetrical intake for the NCPP, but continued to follow the children through eight years of age. On July 1, 1970, New York Medical College, having completed the examination of children at age four, terminated because of insurmountable difficulties in achieving an adequate retention rate for children at age seven. While other institutions had a return rate of over 70%, the rate at New York Medical College was only 45% to 55%, and researchers held little hope of improvement because of the mobility of the Puerto Rican population in the sample.

In summary, twelve medical centers contributed obstetrical patients to the NCPP. All of the centers were in urban areas; six were in the Northeast, four in the South, one in the West, and one in the north-central region of the U.S.

TABLE 1.1. Institutions, Location, and Approximate Number of Core Registrants

NINDB INSTITUTION NUMBER	ABBREVIATION	LOCATION	INSTITUTION	REGISTRATION DATES FROM	TO	THOUSANDS OF SUBJECTS
05	BO	Boston, MA	Lying-In Hospital Children's Medical Center	1/59	12/65	13.2
10	BU	Buffalo, NY	Children's Hospital, SUNY	10/60	12/65	3.0
15	CH	New Orleans, LA	Charity Hospital	3/60	12/65	2.6
31	CO	New York, NY	Columbia-Presbyterian	1/59	4/63	2.2
37	JH	Baltimore, MD	Johns Hopkins Hospital	1/59	12/64	3.8
45	VA	Richmond, VA	Medical College of Virginia	1/59	12/65	3.2
50	MI	Minneapolis, MN	University of Minnesota	1/59	12/65	3.3
55	NY	New York, NY	New York Medical College	2/59	12/65	4.7
60	OR	Portland, OR	University of Oregon Medical School	3/59	12/65	3.3
66	PA	Philadelphia, PA	Pennsylvania Hospital Children's Hospital of Philadelphia	1/59	12/65	10.3
71	PR	Providence, RI	Providence Lying-In	3/60	12/65	2.9
82	TN	Memphis, TN	University of Tennessee College of Medicine	10/59	12/65	3.6
						56.1

COLLABORATIVE PERINATAL PROJECT ADMINISTRATION

A central coordinating staff was established at NINDB and in 1959, when data collection began, its size increased. The Project Services Branch of NINDB provided professional, administrative, and logistic support, and the NINDB Biometrics Branch (later renamed Office of Biometry) was responsible for data management and retrieval, and statistical services. The central staff developed close liaison with the project directors at the participating hospitals.

In the fall of 1960, the Perinatal Research Branch was established to combine the capabilities required to direct and coordinate the NCPP and, at the same time, to explore leads emanating from the study. An infectious diseases laboratory and a pathology laboratory also participated in the NCPP.

During the conduct of the NCPP, a number of committees and task forces were established to provide guidance for the study. A Perinatal Research Committee was established to provide overall outside guidance. This committee was empowered with the authority to advise NINDB on fiscal matters relevant to the NCPP, as well as on research policy and scope. The Perinatal Research Committee also reviewed all NCPP data collection research grant applications and assisted NINDB in evaluating the performance of the NCPP. A Principal Investigators' Committee, consisting of senior professionals from all institutions involved in the project, was responsible for the conduct of the study in the respective institutions and in the project as a whole. The collaborating institutions were also represented by the Project Directors' Committee. This committee was composed of the project directors (managers) from the individual institutions. It decided on the administrative desirability and feasibility of various facets of study design, data collection and data analysis. The project directors were responsible for the managerial aspects of implementing policy decisions made by the Principal Investigators' Committee.

The Perinatal Research Branch and the Project Directors' Committee both set up advisory committees in the disciplines relevant to the project. Advisory subcommittees to the Perinatal Research Branch included obstetrics, pediatrics, psychology, pathology, speech-language-hearing, socioeconomics, sample maintenance, statistics, administration, interviewing, and editing. The Project Directors' Advisory Committees were made up of the senior professional representatives from every institution at the operational level in the disciplines of obstetrics, pediatrics, pathology, psychology, speech-language-hearing, sample maintenance, interviewing, and editing. The committees' functions included advising the Project Directors' Committee on professional issues recommended by the Perinatal Research Branch.

The size and complexity of the NCPP required a highly developed and integrated staff to conduct the research developed and directed by the above referenced committees. The participants at each collaborating institution are included in an appendix of Niswander and Gordon (1972).

A change in organizational structure within NINDB took place in 1967, when the Office of Biometry was established. This office was given responsibility for support in data retrieval and statistical consultation for

the NCPP. At the same time, the support of the collaborating institutions was changed from grants to contracts in response to the criticism that the study lacked strong central direction. This move coincided with the beginning of a formal inter-institutional quality control program to obtain test-retest reliability measures for the examinations given to the children at ages four, seven, and eight.

STUDY SAMPLE SELECTION AND COMPOSITION

The Collaborative Perinatal Project was not intended to develop incidence or prevalence rates of events of pregnancy, or of conditions in the offspring, and was not concerned with the selection of a study sample representative of the population of the United States or of the community in which the study center was located. Instead, the objectives required a broad spectrum of pregnancy conditions, free from biases based on special interests. The samples were chosen so as not to interfere with the routine of the maternity clinic, and so as to promote continuing follow-up of the children. A restriction was the case load a given institution could handle; this ranged from around 300 to 2,000 patients per year, with most institutions providing around 500 to 800 cases annually.

Some participating institutions selected all eligible women; others, only a random sample. Eligibility was defined by the sampling frame (a defined group of patients from which registrants for the study were chosen) for each institution. A common exclusion was "walk-ins" or patients with no prenatal visits prior to the day of delivery. All but one of the 12 sampling frames consisted of clinic patients. The socioeconomic and ethnic composition of the NCPP population was representative of the populations qualifying for medical care at the participating institutions. Detailed information on the selection methods and sampling frame for each institution can be found in Niswander and Gordon (1972) and in Appendix A to this volume.

Selection ratios at the various hospitals ranged from 10 to 100 percent of the sampling frame. This resulted in the creation of 58,760 NINDB case numbers, each uniquely identifying the institution, the type of patient selection, and the gravida or child. Because some institutions used NINDB forms for special concurrent studies, for walk-ins, or for other purposes, several categorizations were developed to identify which cases met the study criteria. These are shown in Table 1.2 and are further described in Appendix A.

Case selection was continuously monitored. The first case was selected on January 2, 1959; the last, on December 31, 1965. The earliest delivery occurred on January 11, 1959; the last, in September of 1966.

Sample sizes by institution and ethnic group are shown in Table 1.3. The largest sample was collected at the Boston Lying-In Hospital, Boston, Massachusetts, where the sampling frame consisted of all clinic patients admitted for prenatal care. Special exclusions were unwed mothers planning to place their babies for adoption. The selection ratio was initially 50%, but was raised to 100% after two months. Nearly 90% of the Boston sample (12,000 cases) were white. Children were followed at the Children's Hospital Medical Center.

TABLE I.2. Categorization of NCPP Cases

CATEGORY	DESCRIPTION	NUMBER OF CASES
Core	Cases Meeting General Study Criteria	56,134
Non-Core	Ancillary Cases Used by Individual Institutions	2,626
		58,760
Walk-In	Cases That Delivered on Same Day Registered	298
Cohort I	Core Cases Excluding Walk-Ins	
Cohort IA	First Study Pregnancy, Single Birth, Registered on or Before 12/31/64	37,998
Cohort IB	All Cases Registered on or Before 12/31/64	48,488
Cohort IC	First Study Pregnancy, Single Birth, Registered at Any Time	43,521
Cohort ID	All Cases Registered at Any Time	55,857 55,908*
Cohort II	Core Cases Excluding Walk-Ins and Lost to Study	
Cohort IIA	Cohort IA Minus Cases Lost to Study	37,579
Cohort IIB	Cohort IB Minus Cases Lost to Study	46,052
Cohort IIC	Cohort IC Minus Cases Lost to Study	43,073
Cohort IID	Cohort ID Minus Cases Lost to Study	53,043
Cohort IID Rev.	Cohort ID Minus Cases Lost to Study	53,039
Basic Document Cohort	Cohort IC Minus Abortions	42,878

*Cohort ID was reported in Women and Their Pregnancies as 55,908 cases; this included 51 registrants who were not pregnant and were subsequently deleted from the data base.

TABLE 1.3. Sample Size By Institution and Ethnic Group in the NCPP Population (Cohort IID)*

INSTITUTION	ETHNIC GROUP				
	WHITE	BLACK	PUERTO RICAN	OTHERS	TOTAL
Boston Lying-In Hospital	10,803	1,198	25	167	12,193
Children's Hospital, Buffalo	2,383	59	12	15	2,469
Charity Hospital, New Orleans	0	2,582	0	0	2,582
Columbia-Presbyterian Medical Center	633	876	602	27	2,138
Johns Hopkins Hospital	798	2,744	1	6	3,549
Medical College of Virginia	831	2,367	6	6	3,204
Univ. of Minnesota Hospitals	2,986	19	2	140	3,147
New York Medical College	264	1,958	2,610	12	4,874
Univ. of Oregon Medical School	2,976	161	1	12	3,150
Pennsylvania Hospital	887	8,596	116	16	9,792
Providence Lying-In Hospital	2,750	672	2	49	2,872
University of Tennessee College of Medicine	22	3,501	0	0	3,523
Total	43,812	45,017	3,396	513	53,043

*From Broman et al. (1969)

The sample from Children's Hospital of the State University of New York at Buffalo was unique because it consisted of private patients referred by several obstetricians. Women who planned to move out of the area or deliver in another hospital were excluded. More than 95% of the 2500 patients selected were white.

The sampling frame at Charity Hospital, New Orleans, Louisiana, included black patients residing in Orleans Parish and assigned to the Tulane or Louisiana State University medical services in the hospital. The selection ratio varied from one in ten to one in six of the eligible patients and produced a sample of approximately 2500.

All clinic patients admitted to the Columbia-Presbyterian Hospital in New York were included in the sampling frame, selection varied between one in six and one in five patients. After April, 1962, difficulty in follow-up necessitated exclusion of patients residing outside Manhattan or the Bronx. In April of 1963 case selection was terminated. The NCPP sample of 2100, the smallest from any institution, was approximately 30% white, 40% black, and 30% Puerto Rican.

The sampling frame at Johns Hopkins Hospital, Baltimore, Maryland, consisted of all clinic patients living in metropolitan Baltimore; transients and patients referred to county clinics for obstetrical care were excluded. The selection ratio was initially 20% and was raised to 30%, 40%, and finally 100%. Nearly 80% of the 3500 patients selected were black.

Clinic patients residing within a 50 mile radius of the Medical College of Virginia, Richmond, Virginia, were initially included in the sampling frame. Later, the area was reduced to Richmond and three surrounding counties, and still later to the city itself. Excluded were white welfare cases and patients planning to put their children up for adoption. The selection ratio was 100% of the white patients and was increased from 25% to 100% of the black patients. About 75% of the 3200 patients selected were black.

The sampling frame at the University of Minnesota Hospital, Minneapolis, Minnesota, included all clinic patients, although in the first year of registration, women who were divorced, separated, widowed or unmarried before the start of their pregnancy were excluded. The selection ratio was 100% and yielded a sample of 3100. Ninety-five percent of the sample were white.

The sampling frame of all clinic patients was also used at the Metropolitan Hospital of New York Medical College in New York. An initial selection of one in 10 patients chosen from the sampling frame was gradually increased to one in six. The NCPP sample of 4500 was about 60% Puerto Rican and 35% black.

At the University of Oregon Medical School in Portland, the sampling frame again consisted of all clinic patients. Residence requirements were later restricted to certain areas within Multnomah County. Medical students' wives and clients of private adoption agencies were excluded. The sampling ratio varied from one in three to two in three. The sample of 3200 was approximately 70% white.

The second largest sample came from Pennsylvania Hospital in Philadelphia. The sampling frame was the set of all clinic patients except those planning to deliver elsewhere. The selection ratio was 100% and 90% of the nearly 10,000 patients selected were black. Children were followed at the Children's Hospital of Philadelphia.

The sampling frame at Providence Lying-In Hospital, Providence, Rhode Island, was defined as all clinic patients. The NCPP sample of 2800 consisted of about 45% of the sampling frame and was 75% white. Children were followed at the Child Study Center of Brown University.

At the University of Tennessee College of Medicine in Memphis, the sampling frame included all clinic patients living inside the city limits. Initially the patient selection ratio was one in 10, but it was raised to one in seven within six months.

In summary, of the 53,000 pregnant women registered in the NCPP, 95% were clinic patients. All were from urban areas, 64% from cities in the northeastern U.S. Forty-five percent of the women registrants were white, 47% black, 7% Puerto Rican, and 1% from a variety of other ethnic groups. Broman et al. (1975) include an extensive analysis of the demographic characteristics of the NCPP study population which, although too extensive to reproduce here, is of considerable potential value to the researcher.

Women Lost to the Study

The important question of the characteristics of the women who dropped out of the NCPP before completion of their pregnancy is considered as a potential source of bias by Niswander and Gordon (1972). They note that 4.1% of the study registrants were lost to the study before the completion of their pregnancy.

They conclude that on the whole, fewer of the very young white or black women dropped out than might normally be expected. This difference was not consistent by collaborating center.

Among women of both races, the more highly educated mothers were lost to the study more frequently than were those of the lower educational group. Again, the disparity between the two groups was not consistent across the collaborating centers.

An excess of nulliparas and a reduced frequency of grand multiparas occurred in the group lost to study as compared with the study population. Though the trend was reasonably consistent by collaborating center, no consistency was observed in marital status of the women who were nulliparas or grand multiparas.

For the characteristics compared, some disparities were present between the lost-to-study gravidas and those of the study population. With the exception of the number of prior pregnancies, little consistency could be found in the differences by collaborating center.

Niswander and Gordon (1972) also summarize the differences between study women and women lost-to-study, with regard to the distributions of certain characteristics and perinatal mortality rates. These data are presented in Table 1.4.

Perinatal mortality rates among study women age 35 or older, of both races, were higher than rates among women in the intermediate ages. Importantly, the lost-to-study women do not show a disproportionate percent of cases in this age bracket.

Data did not indicate that education of the gravida was related to the perinatal mortality rate. Therefore, the large number of lost-to-study women in the high education group was not thought to be a biasing factor with regard to perinatal death rate.

TABLE 1.4. Comparison of Selected Characteristics of Study and Lost-to-Study Gravidas

ITEM	WHITE			BLACK		
	LOST TO STUDY GRAVIDAS	STUDY GRAVIDAS		LOST TO STUDY GRAVIDAS	STUDY GRAVIDAS	
	PERCENT	PERCENT	PERINATAL MORTALITY RATE*	PERCENT	PERCENT	PERINATAL MORTALITY RATE*
AGE OF GRAVIDA (YRS)						
UNDER 18	3.4	6.3	23.5	9.9	15.9	38.0
18-34	88.2	85.9	33.2	82.0	76.9	40.7
35+	8.4	7.8	63.8	8.1	7.2	63.7
EDUCATION OF GRAVIDA (YRS)						
UNDER 9	10.5	13.1	33.2	8.2	19.0	42.7
9-11	49.8	65.7	33.6	80.7	75.9	41.9
12+	39.7	21.1	32.0	11.1	5.1	38.2
NO. OF PRIOR PREGNANCIES						
0	48.9	40.0	29.1	36.7	34.1	39.2
1-5	48.2	56.0	33.6	58.5	57.3	40.1
6+	2.9	4.0	70.1	4.8	8.6	52.3
MARITAL STATUS						
MARRIED	93.7	86.6	35.5	67.5	60.4	40.1
NOT MARRIED	6.3	13.4	32.5	32.5	39.6	44.7

*Per 1000 births (Niswander and Gordon, 1972)

White and black women having six or more prior pregnancies showed the highest perinatal mortality rates. A smaller percentage of lost-to-study women fell into this category than was the case with study women. If one were willing to assume that the babies of lost-to-study mothers had the same perinatal death rates as babies of study mothers of comparable parity, then the overall perinatal mortality rate would change from 35.1 to 34.9 for whites and would be unchanged for blacks when the lost-to-study cases were included. The impact of these cases lost-to-study would not appear to be very significant.

Similarly, the perinatal mortality rate for babies born to never-married white women was lower than that for babies born to married white women. The rate of never-married women among the cases lost to study was half the rate of the study women. An adjustment comparable to that described above would not change the overall perinatal mortality rates if the cases lost-to-study were included.

We have included this discussion of differences between the lost-to-study gravidas and study gravidas in relation to perinatal mortality because we believe it illustrates a lack of significant bias resulting from lost-to-study patients. While the results of analyses related to perinatal mortality can

not be generalized to all outcomes of interest, it is reassuring to note that loss of women from the study has apparently not been an important biasing factor with regard to this major outcome variable.

Children Lost to the Study

Problems of follow-up, inherent in all long-term, longitudinal studies, are especially present in multicenter studies conducted in a highly mobile, free society. Throughout the NCPP, a considerable effort was expended to prevent attrition of the study population and reasonable success was achieved. The number and characteristics of children lost to study from the various collaborating centers are discussed in detail in Niswander and Gordon (1972), Broman et al. (1975), and Hardy et al. (1979). Discussion directed specifically to the children included in the speech, language and hearing exams can be found in Lassman et al. (1980).

Follow-up rates for survivors of the total population of 53,042 pregnancies were 85% at one year, 75% at four years and 79% at seven years.* At three and eight years, speech, language and hearing exams were given at selected institutions; follow-up rates were 48% and 47%, respectively. The reduction in subjects for the speech, language and hearing examinations is considered below.

Hardy et al. (1979) note that children who missed one examination did not necessarily miss later ones. They state that a child's missing an evaluation led to intensified efforts to get the child to return for the next examination. While the rates for follow-up were high for the combined institutions, some of the centers were more successful than others (Niswander and Gordon, 1972). As Hardy et al. (1979) point out, however, review of rates of children with major abnormalities by institution shows reasonable consistency, indicating no obvious patterns in the loss of cases.

At Johns Hopkins University in 1962, a study of 50 consecutive infants who missed the one-year examination was conducted (Hardy et al., 1979). A pediatric-neurologist and a nurse examined each infant on a home visit. It was found that most of the children had failed to return because their mothers had other young children to care for, family illness or other problems, rather than for reasons related to the presence or absence of abnormalities of the study child.

Hardy et al. (1979) present data comparing characteristics of the children examined to characteristics of the children from the whole NCPP study population lost to follow-up at age one. This was done to evaluate the introduction of possible bias occurring as a result of loss to follow-up. Variables collected earlier and known to relate to abnormal pregnancy outcome, such as selected maternal characteristics and low birth weight, were compared for those infants receiving the one-year neurological examination and those

*Detailed data on the distributions of infants examined, death and attrition through one year are presented in Niswander and Gordon (1972). Overall, more than 85% of all children were examined at four months and a similar percentage had the neurological examination at age one year (Hardy et al., 1979).

who failed to receive it. If the frequency of these predictive variables in the two groups is similar, then there would be no evidence of bias due to missed examinations.

For the study as a whole, relatively small differences existed between infants examined and not examined at one year. For three maternal characteristics, age, parity and education, differences were slight and inconsistent. For three characteristics of the newborn, sex of the child, birthweight and Apgar score, essentially no difference existed between the groups.

In their discussion of IQ at four years of age, Broman et al. (1975) compare the total NCPP cohort, the sample they studied at the four-year exam, those lost by attrition, and those lost by death. Comparing a number of demographic and neonatal characteristics, they found the groups to be very similar.

In summary, characteristics of the subjects lost to follow-up have been found to be similar to those of the subjects examined at both the one-year and four-year evaluations. Active follow-up methods were employed to keep the loss-to-follow-up percentages low and a concerted effort was put forward to maintain the sample.

Sample Size Reduction at Later Ages:
Attrition of Collaborating Institutions

In the latter part of the study, another type of problem related to the administration of the speech, language, and hearing (SLH) examinations arose.

Most of the collaborating institutions began to perform the three-year SLH tests as the children in their respective samples became of age. Some losses of study data resulted from failures to keep appointments and from uncooperative behavior by the children. The greatest loss of three-year data was caused by difficulties in providing space and staff at Boston and Philadelphia, where the largest numbers of NCPP cases were registered. These two institutions found it necessary to screen their three-year-old children for possible SLH problems and to test only the smaller number who were considered to have SLH deficits. Screening was performed by nonspecialists during home visits. As a result, only 1059 children who were given SLH tests at Boston and 460 who were tested at Philadelphia were available for analysis after culling for correctness of age and NCPP registration and completeness of data. Data from these two subsamples were analyzed by the study staff and were examined by a special group of consultants as part of an inquiry into the quality of the total NCPP data base. These data were judged suitable for inclusion within the larger SLH study subsamples because the prevalence and types of SLH problems in these subsamples did not differ significantly from those at other NCPP institutions.

The eight year SLH examination likewise was routinely scheduled for all children once they reached the prescribed age range. Boston, however, was delayed by problems of space and staff until two years after the first children registered there came of age. At midyear in 1970 the eight year examination was discontinued for administrative reasons at six of the 12

participating centers. Examinations continued at Children's Medical Center in Boston, Children's Hospital at Buffalo, Johns Hopkins Hospital in Baltimore, and the Universities of Tennessee, Minnesota and Oregon. The reduction in the size of the eight-year S.H subsample, as compared with the NCPP population, is mainly a reflection of these events.

THE EXPANDED RESEARCH PROGRAM AND RESEARCH AREA

In 1970 the Perinatal Research Committee established a number of ad hoc task forces. These task forces included the following: Basic Document Task Force; Task Force on Toxemia of Pregnancy; Task Force on Labor and Delivery; Task Force on Speech, Language and Hearing; Task Force on Physical Growth and Development; Task Force on Four and Seven-Year Data; Task Force on Congenital Malformations; and Task Force on Pathology. An Epidemiological and Statistical Advisory Committee was established, as was a Coordinating Committee for Data Analysis. This latter committee developed a master plan for data analysis to insure that the objectives of the NCPP were attained. The master plan established priorities, coordinated task force studies, and contained a consensus on methodologies from the Epidemiological and Statistical Advisory Committee.

A Comprehensive Plan for Analysis and Interpretation of Collaborative Perinatal Project Data was developed in the early 1970s. After a careful review of the objectives of the NCPP, the data available for analysis and the work in progress, it was recommended that major efforts in analysis and interpretation were needed in ten primary areas to meet the basic objectives of the project. The ten primary areas are: Cerebral Palsy; Mental Retardation; Communicative Disorders; Visual Abnormalities; Convulsive Disorders; Learning Disorders; Minimal Brain Dysfunction; Congenital Malformations; Birthweight - Gestational Age Relationships (Prematurity); Neuropathology, General Pathology and Placentology.

Implementation of the comprehensive plan was through a team of researchers for each of the ten primary areas, each team headed by a member of the professional staff of the Perinatal Research Branch. On each team was a member of the Office of Biometry staff and a member of the Perinatal Research Branch's Section for Production of Data Analysis. In each of the ten primary areas, a program plan was developed to expand on the summary statements in the comprehensive plan and to provide a detailed approach to the major components of the area and required data analysis. Monographs in book form were planned in each of the areas.

In addition to the ten primary areas, ten secondary areas of analytical focus were identified. These secondary areas are: Pregnancy Hypertension; Maternal Infection During Pregnancy; Labor and Delivery; Neonatal Hyperbilirubinemia; Maternal Anesthesia - Analgesia During Labor and Delivery; Intelligence Test Scores at Age Four; Physical Growth and Development (Birth to Seven Years); Multiple Births; Genetic and Socioeconomic Factors; Drugs Taken During Pregnancy.

In August of 1975, the Developmental Neurology Branch was created within the Neurological Disorder's Program of NINCDS. With this organizational change, the Perinatal Research Branch became the Perinatal Research Section

within the newly formed Developmental Neurology Branch. A major objective of the Developmental Neurology Branch was the completion of the Comprehensive Plan for Analysis and Interpretation of Collaborative Perinatal Project Data.

Analysis and reporting of the data from the NCPP have been carried out by a diverse group of investigators. Some have been entirely within the individual collaborative institutions, others within the Perinatal Research Branch; some studies were based on investigator-initiated grants while others were supported by individual contracts for a particular analysis. Analyses and reports in the identified primary and secondary areas were primarily carried out by NINCDS staff or through specific contracts with outside investigators.

Major books and monographs from the study include the following: The Women and Their Pregnancies (Niswander and Gordon, 1972). Blood Pressure, Edema and Proteinuria in Pregnancy (Friedman et al., 1976). Pregnancy Hypertension (Friedman and Neff, 1977), Birth Defects and Drugs in Pregnancy (Heinonen et al., 1977), Congenital Malformations in Singletons (Myrianthopoulos and Chung, 1974), Congenital Malformations in Twins (Myrianthopoulos, 1975), External Ear Malformations: Epidemiology, Genetics, and Natural History (Melnick and Myrianthopoulos, 1979). The First Year of Life (Hardy et al., 1970), Preschool IQ: Prenatal and Early Developmental Correlates (Broman et al., 1975), Minimal Brain Dysfunction: A Prospective Study (Nichols and Chen, 1981), Early Correlates of Speech, Language, and Hearing (Lassman et al., 1980), and The Developing Human Brain. Growth and Epidemiologic Neuropathology (Gilles et al., 1983).

THE NINCDS COLLABORATIVE PERINATAL PROJECT BIBLIOGRAPHY

We have mentioned only briefly the research conducted using the data from the NCPP. For the researcher who is interested in using these data, we strongly recommend obtaining a copy of the NINCDS Collaborative Perinatal Project Bibliography. The bibliography is available from the Developmental Neurology Branch at NINCDS and lists all publications that have included data from the NCPP. Of particular usefulness is the subject index, which readily allows an investigator to identify publications by specific research areas. Over 500 publications have been based, at least in part, on the NCPP; complete citations can be found in the bibliography.

SUMMARY

In this chapter we have provided a discussion of the background, history, organization, subject selection and research areas of the NCPP. We have drawn extensively from the published works of Niswander and Gordon (1972), Broman et al. (1975), and Hardy et al. (1970), as well as from NINCDS publications and documents to provide the researcher with an introductory overview of the study.

CHAPTER 2. DATA COLLECTION METHODOLOGY

THE PRETEST: FORM DESIGN AND DEVELOPMENT

Collection of data for the NINCDS Collaborative Perinatal Project required a well established and reviewed methodology. Because of the prospective nature of the study, data were collected as soon after an event as possible. In addition, they were collected without reference to antecedent events to provide as unbiased a data base as possible.

Hardy et al. (1979) review some of the special challenges involved in NCPP data collection. They identify the following key features: (1) data collection took place over a sixteen-year time span; (2) large amounts of reliable, standardized, highly specific and detailed information on each mother-child pair were required; (3) a very large number of women, and later children, were enrolled; (4) the geographic distribution of the collaborating centers required that special attention be paid to communication; and (5) the study personnel changed over time and varied in their professional orientation.

The collection of study data required that standardized protocols, forms and manuals be developed with the above challenges in mind. In addition, developers of the study instruments sought to: (1) include detailed and comprehensive information required for thorough etiologic studies; (2) reduce ambiguity to a minimum, assuring reproducibility and comparability of information collected over time by different examiners and institutions; and (3) simplify and standardize the processing of information at all stages of data collection and processing.

To meet these requirements, specific forms and manuals were developed through collaboration of staff members from NINDB, the participating institutions, and consultants. The Perinatal Research Committee and a number of ad hoc committees, described in Chapter 1, devoted much time and attention to all aspects of data collection and production. A large number of task forces developed data collection protocols, which, after a series of revisions, resulted in the production of pretest forms in 1957. The design of the study required that all data be collected and recorded in a uniform fashion as quickly as possible after an event. Because most of the data collection forms were structured and precoded, positive findings and responses were described more extensively in a special section of each form. Information was collected and recorded by specially trained and highly skilled interviewers and examiners using detailed instruction manuals. Standardized manuals, available for every form, provided instructions on how the form should be filled out and definitions of specific items of information, such as diseases.

When the pretest forms were introduced for evaluation by the collaborating institutions on January 1, 1958, a number of difficulties were identified. Many pregnant women resented some of the questions asked. Physicians often objected to working with structured forms that took a long time to complete and contained many questions that were thought to have little relevance to patient care. Another problem was duplication of effort; certain

hospitals continued to use their own hospital records in addition to completing the NCPP study forms. In many instances, however, the new forms were adopted by the hospital and became the official hospital record.

In parallel with the development of the forms, procedure manuals were developed to ensure uniformity of data collection. Certain instructions in the use of the protocols seemed too stringent to a few institutions. Adjustments were permitted, which in turn affected the uniformity with which the records were used across institutions.

During the pretest period, the staff of the coordinating unit at NINDB was small and only limited evaluation of the preliminary data was possible. Review at this point included an assessment of the problems encountered in the use of the data collection forms, an examination of the uniformity and adequacy with which the data were collected, and identification of population differences as shown in the reported data (Broman et al., 1975).

While the institutions were evaluating the pretest protocols, the NINDB initiated workshops and training sessions for staff concerned with data collection. Designed to assure accuracy of the examinations and observations, the sessions provided specific instructions in interviewing procedures, examination techniques and other relevant factors.

After two years of protocol development, pretesting and revision, the collection of study data began on January 1, 1959. Because some of the collaborating hospitals continued to have problems with the use of the obstetrical protocols, protocols were revised even after January 1, 1959 so that they could serve as hospital as well as research records. Timing and other aspects of forms revision are considered in the next section.

CATEGORIES OF DATA COLLECTED

Data for the NCPP were collected in a number of major categories, including: obstetrics, pediatrics, pathology, serology, socioeconomics, genetic history, psychology, speech, language, and hearing. A more complete discussion of the data categories may be found in Chapter 4. The data were collected over a 16 year period with final data collection for eight year speech, language and hearing occurring in 1974 (Figure 2.1).

All of the major data categories required multiple forms for the collection of information relevant to research variables of interest. In addition to forms required to collect study data, general and administrative forms were used to maintain subject records and to ensure smooth communication between the collaborating institutions and NINDS. The forms for these areas were developed through the collaborative activities of specialists in the individual fields. In all, 97 different forms were used. Copies of the individual forms, with the exception of a few of the administrative forms, are included as part of Volume II of this guide.

In listing the forms used in the NCPP by major category (Table 2.1), we have included the form identification codes (an abbreviation of the data category and a form number) and the titles of the forms. The major phases of the data collection process, indicated in Table 2.2, also appear in

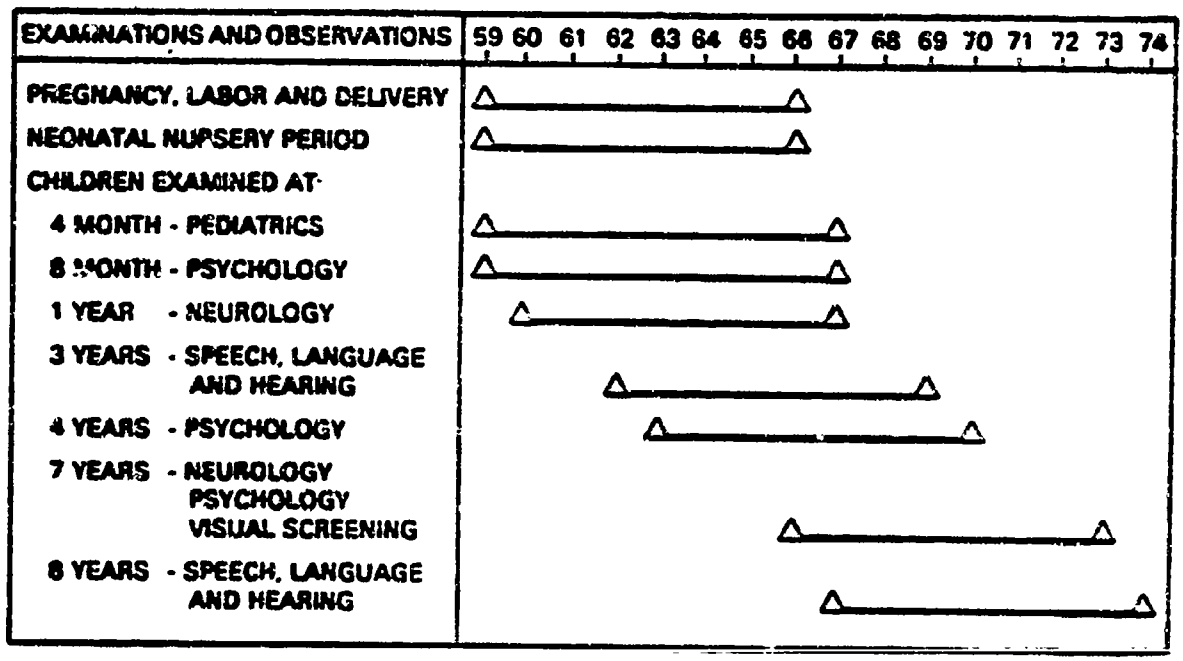


FIGURE 2.1. Data Collection for the NCPP, 1959-1974

Figure 2.1. Included here are the types of information collected at each examination and the relevant data collection forms, identified by form code.

FORM MODIFICATION AND REPLACEMENT

As noted earlier, obstetric protocols were revised because they presented problems at some institutions after the study began. Protocol revision had important implications. The new forms differed substantially from those used initially, and as a result, pregnancies registered from 1959 through the early part of 1962 were recorded on the original OB forms. Beginning in the spring of 1962, however, pregnancies were observed and recorded using the revised protocol. At the beginning of the study, family history information at registration was collected using a series of forms FHH 1-4. Subsequently, these forms were replaced by GEN 5-8 (1961) and SE-1 (1963). Table 2.3 shows a summary of form replacements. Changes in other forms, such as pediatrics and psychology, were of a lesser degree and mostly minor in nature.

All the study forms were printed by NINDB on multicopy NCR paper and distributed to the collaborating institutions. Included on each form is the revision number and the date for the form. Some revisions were cosmetic only. The color of the identification stripe may have changed, for example, or the ordering of the questions may have been changed. Other revisions involved rewording of some questions, while a third type of change involved addition of new data items. Each form and its revisions are included in Volume II. Form revisions were assigned numbers that are included on all punched cards copied onto the master data file.

TABLE 2.1. Forms Used in the NCPP by Subject Area

GENERAL AND ADMINISTRATIVE

AR-2	Administrative report for record inventory and patient followup
AR-3	Notice of identification change
AR-4	Inventory of completed seven-year examinations
AR-5	Sample maintenance data
AR-8	Inventory of completed eight-year examinations
CP-9	Report of transmission of specimen by hospital neuropathologist
CP-S	Continuation sheet for obstetric or pediatric forms

OBSTETRICS

AR-1	Obstetrical administrative record
OB-2	Reproductive history
OB-3	History since last menstrual period
OB-4	Gynecological history
OB-5	Recent medical history
OB-6	Past medical history
OB-7	Infectious disease and system review
OB-8	Repeat prenatal history
OB-9	Prenatal record
OB-10	Return visit and laboratory record
OB-12	Summary of hospitalization
OB-15	Drugs in Pregnancy
OB-30	Admitting record by obstetrician
OB-31	Admitting examination by obstetrician
OB-32	Labor room record
OB-33	Delivery room events
OB-34	Obstetrician's summary of labor and delivery
OB-35	Anesthesia record
OB-40	Optional prenatal record
OB-42	Past medical history
OB-43	Initial prenatal examination
OB-44	Prenatal observations
OB-45	Laboratory record
OB-46	Physician's clinic record
OB-47	Summary of antepartum hospitalization (also used in reporting death for both pre- and post-partum)
OB-50	Admission history
OB-51	Admission examination, Part I, General examination
OB-52	Admission examinations, Part II, Abdomino-pelvic examination
OB-55	Delivery report
OB-56	Obstetric summary
OB-57	Anesthetic agents
OB-58	Summary of puerperium
OB-60	Obstetric diagnostic summary

PEDIATRICS

PED-1 Delivery room observation of the neonate

PED-2 Neonatal examination

PED-3 Nursery history

PED-4 Report of fetal or infant death (also used for child death)

PED-5 Results of tests and procedures done on the neonate

PED-6 Neonatal neurological examination

PED-7 Summary of hospital course of neonate

PED-8 Newborn diagnostic summary

PED-9 Four month pediatric examination

PED-[illegible] One year neurological examination

PED-12 Summary of the first year of life after the duration summarized on PED-8

PED-14 Physical growth measurements

PED-20 Interval medical history

PED-29 Summary of medical records of illness or hospitalization (if indicated)

PED-74 Ophthalmology consultant's report, vision screening study (if indicated)

PED-75 Visual screening at 7 years

PED-76 Pediatric-neurologic examination at 7 years

ADM-86 Interdisciplinary diagnostic code one year - seven years (IDC-77)

SEROLOGICAL AND PATHOLOGICAL STUDIES

VIR-[illegible] Blood samples for viral serological study

VIR-5 Special rubella study (used limited time in Project)

PATH-1 Placental examination - gross

PATH-2 Placental examination - microscopic

PATH-3 Autopsy protocol - complete autopsy report

PSYCHOLOGICAL EXAMINATION AT 8 MONTHS

PS-1 CCLR Research form of Bayley Scale of Mental Development

PS-2 CCLR Research form of Bayley Scale of Motor Development

PS-3 Infant behavior profile

PS-4 Additional observations

PS-5 Maternal behavior in testing situation

SPEECH, LANGUAGE AND HEARING EXAMINATION AT 3 YEARS

PS-10 Language reception

PS-11 Language expression

PS-12 Auditory memory for digits and nonsense syllables

PS-13 Hearing test

PS-14 Speech mechanism

PS-15 Speech production

PS-16 Additional observations

PS-17 Final summary of test performance

PSYCHOLOGICAL EXAMINATION AT 4 YEARS

PS-20 Stanford-Binet Intelligence Scale Form L-M

PS-21 Graham-Ernhart Block Sort Test

PS-22 Motor test

PS-23 Behavior profile

PS-24 Additional observations

PS-25 Four year psychological test summary

PS-26 SRA nonverbal form AH (mother)

PSYCHOLOGICAL EXAMINATION AT 7 YEARS

PS-30	Bender Gestalt Test (with Koppitz scoring)
PS-31	Wechsler Intelligence Scale for Children
PS-32	Auditory-Vocal Association Test (Illinois Test of Psycholinguistic Abilities)
PS-33	Goodenough-Harris Draw-A-Person Test
PS-34	Tactile Finger Recognition Test
PS-35	Wide Range Achievement Test
PS-36	Behavior profile
PS-37	Additional observations
PS-38	Test summary

FINAL SPEECH, LANGUAGE AND HEARING EXAMINATION

PS-40	Hearing examination
PS-41	Language comprehension
PS-42	Language expression
PS-43	Speech mechanism
PS-44	Speech production
PS-45	Additional observations

SOCIOECONOMIC AND FAMILY HISTORIES

SE-1	Socioeconomic interview at registration
GEN-5	Family history interview - outcomes from gravida's prior pregnancies and medical conditions in outcomes (at registration)
GEN-6	Family history interview - family composition (at registration)
GEN-7	Family history interview - health of gravida and her family (at registration)
GEN-8	Family history interview - health of baby's father and his family (at registration)
FHH-1	Family health history, Part I (gravida and father of baby)
FHH-2	Family health history, Part II (family of gravida and father of baby)
FHH-3	Family health history, Part III (household income)
FHH-4	Family health history - detailed health information (family of gravida and father of baby)
FHH-9	Family health history review (mother at seven years)

TABLE 2.2. Final Forms Used In The NCPP By Time of Administration

PRENATAL

Registration and First Prenatal Visit

Obstetric administrative record (AR-1)

Reproductive and gynecological history and history since last menstrual period (OB-2,3,4)

Recent and past medical history including infectious disease and system review (OB-5,6,7,42)

Physical examination (OB-43)

Socioeconomic interview (SE-1)

Family history interview including outcomes of prior pregnancies, family composition and health history of parents and their relatives (GEN-5,6,7,8)

Subsequent Prenatal Visits

Repeat prenatal history (OB-8)

Prenatal observations (OB-44)

Laboratory record (OB-45)

Physician's clinic record (OB-46)

Blood samples for serological studies (VIR-1,3)

Summary of Antepartum Hospitalization (OB-47)

LABOR AND DELIVERY

Repeat prenatal history and admission history (OB-8)

Admission examination (OB-51,52)

Laboratory record (OB-45)

Labor room record (OB-32)

Delivery room events (OB-33)

Delivery report (OB-55)

Obstetric summary (OB-56)

Anesthetic agents (OB-57)

Summary of puerperium (OB-58)

Placental Examinations (Gross and Microscopic) (Path-1,2)
Obstetric Diagnostic Summary (OB-60)

NEWBORN

Delivery room observation (PED-1)

Neonatal examination (PED-2)

Nursery history (PED-3)

Results of tests and procedures (PED-5)

Neonatal neurological examination (PED-6)

Newborn Diagnostic Summary (PED-8)

FOUR MONTHS

Pediatric examination (PED-10)

Interval medical history (PED-20,29)

EIGHT MONTHS

Bayley Scales of Mental and Motor Development (PS-1,2)

Infant behavior profile, additional observations, and maternal behavior ratings (PS-3,4,5)

Physical measurements (PED-14)

Interval medical history (PED-20,29)

TABLE 2.2. Final Forms Used In The NCPP By Time of Administration (Cont.)

12 MONTHS

Neurological examination (PED-11)

Interval medical history (PED-20,29)

Diagnostic summary of the first year (PED-12)

18 AND 24 MONTHS

Interval medical history (PED-20,29)

THREE YEARS

Speech, language and hearing examination with tests of language reception and expression, auditory memory and discrimination, speech mechanism and production, additional observations and test summary (PS-10,11,12,13,14,15,16,17)

Physical measurements (PED-14)

Interval medical history (PED-20,29)

FOUR YEARS

Stanford-Binet Intelligence Scale (PS-20)

Graham-Ernhart Block Sort Test (PS-21)

Gross and fine motor tasks (PS-22)

Behavior profile, additional observations and test summary (PS-23,24,25)

Science Research Associates (SRA) non-verbal intelligence test administered to mother (PS-26)

Physical measurements (PED-14)

Interval medical history (PED-20,29)

FIVE AND SIX YEARS

Interval medical history (PED-20,29)

SEVEN YEARS

Wechsler Intelligence Scale for Children (PS-31)

Goodenough Harris Draw-A-Person Test (PS-33)

Bender Gestalt Test (PS-30)

Auditory-Vocal Association Test (PS-32) (Illinois Test of Psycholinguistic Abilities)

Tactile Finger Recognition Test (PS-34) (Halstead-Reitan Battery)

Wide Range Achievement Test (PS-35)

Behavior profile, additional observations and test summary (PS-36,37,38)

Family health history and socioeconomic interview with mother (FHH-9)

Pediatric neurological examination (PED-76)

Visual screening and ophthalmology report (PED-74,75)

Interval medical history (PED-20,29)

Diagnostic summary for years one through seven (ADM-86/IDC-77)

TABLE 2.2. Final Forms Used In The NCPP By Time of Administration (Cont.)

EIGHT YEARS

Speech, language and hearing examination with tests of language comprehension and expression, auditory discrimination, speech mechanism and production, and additional observations (PS-40,41,42,43,44,45)

Physical measurements (PED-14)

Interval medical history (PED-20,29)

GENERAL FORMS

Administrative reports for record inventory, patient follow-up and sample maintenance (AR-2,3,4,5,8; CP-5,9)

Report of fetal, infant, or child death (PED-4)

Autopsy report (PATH-3)

TABLE 2.3. Summary of Form Replacement

Form Number* (At End of Study)	Title of Form	Old Forms Replaced	Date of Replacement
OB-40	Prenatal Record	Page 1 of OB-40 was used to replace page 1 of OB-9 (optional, for hospital use only)	April, 1962
OB-42	Past Medical History	Replaced page 2 of OB-9	April, 1962
OB-43	Initial Prenatal Exam	Replaced pages 3 and 4 of OB-9	April, 1962
OB-44	Prenatal Observations	Replaced clinical findings from OB-10	April, 1962
OB-45	Laboratory Record	Replaced laboratory findings from OB-10	April, 1962
OB-47	Summary of Antepartum Hospitalization	Replaced OB-12	April, 1962
OB-50	Admission History	Replaced OB-30	April, 1962
OB-51	Admission Exam, Pt. 1	Replaced general findings on OB-31	April, 1962
OB-52	Admission Exam, Pt. 2	Replaced portion of OB-31 where results obstetric exams were reported.	April, 1962
OB-55	Delivery Report	Replaced pages 2,3 & 4 of OB-34	April, 1962
OB-56	Obstetric Summary	Replaced page 1 of OB-34	April, 1962
OB-57	Anesthetic Agents	Replaced OB-35	April, 1962
SE-1	Socioeconomic Interview	Card records in master file include data from FHH-1 and FHH-3. Replaced FHH-1,3.	April, 1963
GEN-5,6,7,8	Family Histories	Cards in master file include data from FHH-2 and FHH-4. Replaced FHH-2,4.	May, 1961
PED-8	Newborn Diagnostic Summary	Replaced PED-7	January, 1963

*Copies of actual forms appear in Volume II of the Guide, except OB-40 which was retained by the institutions if used

PHASES IN DATA COLLECTION AND ASSOCIATED FORMS

Prenatal Phase

When a woman was selected in accordance with the approved sampling technique by a collaborating institution, an administrative record (AR-1) with identification information was completed and submitted to the Perinatal Research Branch. At the same time, she was interviewed to complete: her past obstetrical history (OB-2); her menstrual and gynecological history (OB-4); her past medical history, including a history of X-ray exposure, drug intake, and hospitalizations (OB-5, OB-6, OB-7); and history since her last menstrual period (OB-3). This history included information regarding minor and major illnesses, X-ray exposure, visits to physicians or episodes of hospitalization that occurred during the interval between the last menstrual period and registration in the NCPP.

During one of the early visits to the prenatal clinic, socioeconomic and genetic histories of the woman and her family were obtained. Socioeconomic information (SE-1) covered such items as race, religion, place of birth, education, occupation, family income, housing density, marital status, geographic mobility, etc. Genetic and family health information included information on outcome of prior pregnancies (GEN-5), full and half siblings, twinning, consanguinity (GEN-6) and any history of blood group incompatibility, congenital malformations, motor and sensory disorders or mental retardation in the gravida, her previous offspring, her immediate family (GEN-7) or in the father of the baby and his family (GEN-8).

The obstetrician completed a detailed physical examination (OB-9 or OB-43) of the gravida. As routine laboratory tests, he ordered and recorded (OB-10 or OB-45) a hemoglobin and/or a microhematocrit, a complete urinalysis, serologic tests for syphilis, and blood typing for ABO and Rh type. A Coombs' test was performed on all Rh negative gravidas.

The patient returned to the prenatal clinic for reexamination at intervals of four weeks during the first seven months of pregnancy. This schedule changed to visits every two weeks during the eighth month, and to weekly visits following the eighth month of pregnancy. At each visit, interviews were conducted to elicit information on illnesses occurring after her most recent visit to the prenatal clinic (OB-8). In addition, the obstetrician obtained information about the presence or absence of certain intercurrent events such as bleeding, edema or trauma, observed the presence or absence of fetal heart activity, and noted presentations (OB-10). A blood pressure reading was obtained and repeat urine tests performed to identify albuminuria and glycosuria.

If the patient reported she had been examined by non-study physicians during the prenatal period, or in a special clinic, or was hospitalized for an intercurrent illness, either in the study hospital facility or an outside hospital, verification of this information was sought. The physician responsible for her care in each instance was contacted. A report (OB-12) of each episode of hospitalization was completed.

Blood samples of 20 milliliters were collected in Vacutainers at the first visit to the prenatal clinic (VIR-1; VIR forms are not on the master file and are not included in Volume II. See Volume IV, Work Files.). Repeat samples of blood were drawn according to a specific schedule; at bi-monthly intervals through pregnancy, at delivery, and finally at six weeks post partum. After proper separation, the serum from these blood samples was frozen and shipped to the Section on Infectious Diseases of the Perinatal Research Branch.

Labor and Delivery

When the gravida was admitted to the hospital for delivery or observation, her admission history (OB-30 or OB-50) was established, and a reevaluation of her physical status obtained (OB-31 or OB-51-52). During labor and delivery, she was under surveillance by a trained observer who obtained, at specified intervals, data on blood pressure, fetal heart rate, the frequency and spacing of her contractions, and any other intercurrent events, such as bleeding or meconium staining of amniotic fluid (OB-32). The observer also recorded information on the progress of labor as narrated by the obstetrician in charge. Any other remarkable events occurring during labor and delivery were documented by the observer (OB-33). Observers were usually nurses who had been trained specifically for this role. Records were completed identifying anesthetic agents administered during labor or delivery (OB-35 or OB-57).

The obstetrician, after termination of the delivery, completed the summary form of labor and delivery (OB-34 or OB-55). The placenta was placed in a plastic bag (sealed to avoid dessication) and sent to the study pathologists for examination (Path-1-2).

Newborn Phase

When the child was born, the 1-, 2-, and 5-minute Apgar scores were obtained by a person specially trained for this purpose (usually the delivery room observer). In addition, the onset of respiration relative to time of birth was recorded, as well as information on types of resuscitation (PED-1). The information collected was designed primarily to record the time and sequence of events taking place at the time of delivery and to record the functional integrity of the infant and any potentially stressful influences present immediately after birth.

The newborn child was examined (PED-2) by a pediatrician within 24 hours after delivery. Repeat pediatric (PED-2) examinations were performed at 24-hour intervals and children who remained in the hospital longer than one week were examined at weekly intervals. A newborn neurological examination (PED-6) was performed at two days of age. Observations of the child in the nursery, such as body temperature, respirations, feedings, and other intercurrent events, were made and recorded by nurses (PED-3). Determination of bilirubin was done on every child at 36 hours of age and repeated at 24-hour intervals as long as the most recent value was above 10 milligrams percent. Bilirubin determinations on premature infants were done at daily intervals until five days of age and discontinued unless the most recent value was above 10 milligrams percent. Hemoglobin and/or microhematocrit

determinations were obtained on every child at 48 hours of age (PED-5). ABO and Rh blood typing was performed at the same time, followed by a Coombs' test if the Rh factor was negative. Other laboratory determinations were done as indicated. Following discharge from the newborn nursery, a diagnostic evaluation of the data collected during the newborn period was made by a physician, who completed an extensive, structured, diagnostic summary (PED-8).

Four Months Phase

Each child was scheduled for a physical examination (PED-10) at four months of age. Concurrently, an interval history (PED-20) was obtained to establish information concerning possible visits to physicians or hospitals following discharge from the newborn nursery. If this information revealed that the child was hospitalized or was seen by a physician for anything other than routine care, a copy of the physician's and/or hospital record (PED-29) was obtained.

Eight Months Phase

A psychological examination, utilizing an early research version of the Bayley Scales of Infant Development, was administered at age 8 months to assess the child's mental development (PS-1) and fine and gross motor development (PS-2). The Bayley Scales were supplemented by observations of the child, ratings of behavior characteristics (PS-3), additional information on physical and behavioral abnormalities and hearing acuity (PS-4) and interactions of the mother with the infant (PS-5). At this time, an interview took place covering intercurrent events and medical history during the interval since the last examination (PED-20). Physical growth measurements were also taken (PED-14).

Twelve Months Phase

At one year of age, a neurological examination (PED-11) was given and an interval history (PED-20) obtained. After completion of the one-year examination, a diagnostic summary (PED-12) was completed to summarize events, illnesses and conditions that occurred or were recognized during the interval beginning with the terminal date of the PED-8 summary and ending with the PED-11 examination.

Three Year Phase

At three years of age, the child was brought back for examination of speech, language and hearing status (PS-10 through PS-17). At that time, an interval history (PED-20) was obtained and physical growth measurements were taken (PED-14). Language reception (PS-10) and expression (PS-11) were evaluated, as was auditory memory for digits and nonsense syllables (PS-12). A hearing test (PS-13) was administered during the visit. In terms of speech evaluation, both speech mechanism (PS-14) and speech production (PS-15) were examined. Additional observations, such as observable physical anomalies or unusual behaviors during the test period, were recorded (PS-16). Following the testing, a final summary of the speech, language and hearing examinations was prepared (PS-17).

Four Year Phase

At four years of age, the child was seen by a psychologist and a detailed examination conducted. This was accomplished by administration of the Stanford-Binet Intelligence Scale (PS-20), in addition to assessment of fine and gross motor development (PS-22), and a test of the child's concept formation skills (PS-21). A behavioral profile (PS-23) consisting of examiner ratings of the child's behavior during the examination was included. Additional observations of the child's appearance and behavior were recorded (PS-24). A test summary (PS-25) prepared on the child included the examiner's clinical impressions. At the time of the four-year exam, an intellectual assessment of the mother or mother-surrogate was performed (PS-26). An interval history (PED-20) and physical growth measurements (PED-14) were also obtained for the child at this time. Thereafter, interval histories (PED-20) were obtained at five and six years of age, usually by home visits.

Seven Year Phase

At age seven, the child returned for a neurological examination (PED-76), visual screening (PED-75), and an interval history (PED-20). An ophthalmologic consultation (PED-74) was also carried out when required. During the same visit, or shortly thereafter, a detailed psychological examination was also performed. The tests evaluated the child's intelligence by means of the Wechsler Intelligence Scales for Children (WISC) (PS-31) and examined the child's perceptual-visual-motor skills by means of the Bender Gestalt Test (PS-30). Other psychological tests administered at age seven included the Auditory-Vocal Association Test (Illinois Test of Psycholinguistic Abilities) (PS-32), Goodenough Harris Draw-A-Person Test (PS-33), Tactile Finger Recognition Test (PS-34), Wide Range Achievement Test (PS-35), and a behavioral profile (PS-36). Additional observations were also made of the child's appearance, movements and behavior (PS-37). Researchers recorded any attendance in a special class or school and prepared a summary of the psychological examinations and clinical impressions (PS-38).

During the seventh year of the child's life, the genetic and socioeconomic information collected prenatally was brought up-to-date (FHH-9). This form was designed in such a way as to permit comparison of information at two points in time.

Subsequent to these examinations, a diagnostic summary (PED-77, ADM-86, IDC-77) was again completed for each child by NINDB staff, covering all conditions and events that were recognized or had occurred since the completion of the diagnostic summary at age one year.

Eight Year Phase

At eight years of age, the child returned to the study facility for a detailed evaluation of speech, language, and hearing status (PS-40 through PS-45). A thorough hearing examination was conducted (PS-40). Language comprehension (PS-41) and expression (PS-42) were evaluated. In terms of speech, both speech mechanism (PS-43) and speech production (PS-44) were examined. Additional observations recorded at the time of the speech, language and hearing examinations (PS-45) included observable anomalies and

aberrant behavior. An interval history (PED-20) covering intercurrent medical events and final physical growth measurements were recorded at this time (PED-14).

Supplementary Information

Data obtained during scheduled examinations in the follow-up of study children were supplemented by: (1) interval medical histories (PED-20) obtained at 18 months, 24 months, five years and six years of age, usually by home visits, and (2) summaries of medical illness or hospitalization (PED-29) for illness, injury, condition or hospitalization completed from the hospital records of the study facility, and other hospitals, clinic, private physicians, etc., where study children were seen for diagnostic purposes.

PROCEDURE AND INSTRUCTION MANUALS

All of the study forms for the Collaborative Perinatal Project were accompanied by manuals that detailed how the forms were to be completed. For each form, information was provided on the purpose of the form, general instructions, specific instructions for the completion of each item on the form, procedure for examinations and observations, and working definitions of variables. A general manual containing a history of the development of the Collaborative Perinatal Project and information on the methodology, case selection, data analysis and the administrative and organizational framework of the project was also available.

Copies of all instruction manuals are included along with the individual forms in Volume II. The manuals were revised when the forms were revised; the manuals included are those that accompanied the final version of the forms.

PROCEDURES INSTITUTED TO ENSURE
CONSISTENCY AND ACCURACY OF PRIMARY DATA

As mentioned above, efforts to ensure the consistency and accuracy of the data collected throughout the study were made continuously. Staff members from the collaborating institutions met in workshops. Films were produced describing the neonatal and one-year neurological examinations and were used in training neurologists and pediatricians. An interchange of visits among personnel from the Perinatal Research Branch and the collaborating institutions occurred, with the purpose of exchanging views and standardizing examination techniques and the recording of data.

Because the NCPP encompassed multiple medical centers and involved numerous personnel with various levels of training completing many types of forms, it was obvious from the beginning that strong efforts were needed to establish and maintain uniformity of data collection. Some of the approaches used to ensure the necessary consistency have been noted. The data on pregnancy, birth and on the infant's first year were collected and processed using those approaches. With the subsequent examinations, active quality control programs were instituted. The quality control programs developed for the psychology, speech, language and hearing and seven year pediatric-neurological examinations are described in Appendix C.

CHAPTER 3. DATA PROCESSING PROCEDURES

DATA PROCESSING AT THE COLLABORATING INSTITUTIONS

All records of examinations, observations, interviews, etc., were reviewed by non-medical personnel in the collaborating institutions and compared with hospital records to check legibility, consistency, completeness, and adherence to study requirements and definitions. Discrepancies were brought to the attention of the person responsible for the completion of the form for consideration and resolution. Corrections on study forms were made in such a manner that the original information could be identified on the record. Before the forms were submitted to the Perinatal Research Branch, they were edited in detail for consistency and accuracy by medical personnel. After review and editing, copies of the completed forms were sent to the Perinatal Research Branch for key punching and data entry.

DATA PROCESSING AT THE PERINATAL RESEARCH BRANCH

Data processing procedures at the Perinatal Research Branch were designed to minimize errors and identify mistakes that might have occurred at the collaborating institutions. The data processing system included comprehensive reviews and edits at every stage. Niswander and Gordon (1972) describe the organization of the system as follows:

> 1. When an examination was completed and reviewed at the Center, a copy of the form was sent for data processing to the Perinatal Research Branch.
>
> 2. The form was then edited by specially trained nurses for completeness and accuracy, and was then coded.
>
> 3. Cards were punched, verified, and sent to the computer facility.
>
> 4. The next stage of processing included a screening of every column in every card for invalid codes.
>
> 5. The data on the cards were checked to determine whether they fell outside a range of levels established by the medical group responsible for that particular form. For example, the record for a child with a first breath recorded in excess of ten minutes after birth, and who was reported to be liveborn, would be questioned. Similar reviews were made for many other measurements.
>
> 6. The cards earmarked for review in this procedure were returned to the appropriate evaluations unit, which then examined the original form. If a mistake was found, the card was corrected and returned for processing. If the item was correctly recorded, it was then forwarded to the physician in charge who attempted to ascertain the reason for the unusual reading. He had two options. The first was to accept the recording as legitimate and send the data back to the processing group. The second option was to

request a review by the hospital for confirmation or rejection of the observation and a substitution of the correct observation, if known. If the observation was incorrect and no substitution was possible, the item was classed as unknown.

7. After data were processed into the computer file, frequency distributions were tabulated periodically for specific items in the file so that unusual values could be rechecked. The original forms were examined to provide a review of these unusual observations."

The same general procedure was employed for pediatric and behavioral data.

ACCURACY OF THE DATA PROCESSING

The quality of the data processing effort is reflected in the results of a study of the data processing operation described by Niswander and Gordon (1972). The case numbers of 20 NCPP registrants were selected at random; photocopies of all of the study forms filled out for these mothers and their children were requested, and computer printouts were made of the data processed from these records. Cases were selected from women registered in each of the several years of the study.

A total of 40,000 separate pieces of information in this sample was examined. In all, 34 unique errors were identified, yielding an error rate of less than one-tenth of one percent, which is very low for the large volume of records processed. A similar review of 100 cases carried out at the Johns Hopkins Center compared study information and hospital records and found a similarly small error rate.

In another study, the validity of obstetric information in the NCPP records was assessed at two hospitals. This was accomplished by comparing study records with the hospital records. At these two hospitals a sample of eight percent of the records was reviewed; the records were stratified to insure a sufficient number of normal pregnancies in the NCPP sample.

A sample of cases was drawn and the centers were requested to provide the actual hospital records for the sample. Arrangements were made for the hospital records to be reviewed by a physician. Information on demographic, prenatal, delivery, postpartum and infant characteristics was obtained from 14 different NCPP forms and records. The hospital and the NCPP forms for each selected patient were reviewed and abstracted "blind" and independently by the same physician. Forty of the most important characteristics were selected for detailed analysis. The items can be characterized as five demographic, ten prenatal, thirteen delivery, four postpartum, and eight infant.

The review showed that more information was missing from the hospital records than from NCPP forms. In addition, the NCPP forms contained more detailed information than did the hospital records.

An insignificantly small number of patients had important facts missing from both study and hospital records. The only frequent omissions in both records were the results of a failure to check "not present" or "not done"

boxes for the rare conditions and procedures. In one hospital, five important items were totally absent for a small proportion of the patients. These items were: maternal pre-conception weight and height for 1 percent of the patients; birthweight for 0.5 percent of the babies; blood pressure measurements for 1.5 percent of the patients; and postpartum temperatures for 1 percent of the patients. Only one item, the staff position of the person who delivered the baby, was completely missing for a significantly large number of patients: 19 percent in one hospital and 3.5 percent in the other.

The NCPP forms were also compared with the hospital records by computing the percent of records in which the item was present in both hospital and study records, and also the percent of the hospital records with items missing that were present in the study records. When the hospital record contained an item of information, it was generally present in the study record; when the item was absent in the hospital record, it again frequently appeared in the study record. More of the important items of information were recorded in the NCPP forms than in the hospital records.

The study concluded that the NCPP forms contained extensive and detailed information not available in the other hospital records and that the study records had a high standard of completeness in the two centers where they could be evaluated.

POOLING OF DATA FROM THE COLLABORATING INSTITUTIONS

During NINDB Perinatal Statistical Ad Hoc Committee review, one of the major questions that the committee attempted to resolve was the appropriateness of pooling information from the collaborating institutions.

The committee recognized generally that the data for white and black gravidas should not be combined. While many similarities existed between white and black women with respect to the medical and obstetrical conditions and complications they experienced, their demographic characteristics were very different. In addition, there was interest in examining differences between racial groups in pregnancy outcome, and neurological and behavioral attributes of the children. The two groups differed in mortality rates, in low birthweight rates, and in the morbidity experienced by the child from birth onward to the end of the study period.

In studying the problem of pooling data for each race across collaborating institutions, the committee found that the application of standard statistical measures of variability was not a useful way to identify biologically meaningful variation. In many instances, demonstration of statistical significance, because of the relatively large sample sizes, need not correspond to substantive significance. Medical investigators could not be assumed to consider such variation unusual or suspect.

The committee found that, as would be expected, demographic characteristics of the gravidas varied considerably among collaborating institutions. This is a basic strength of the NCPP. that a group of collaborating institutions, heterogeneous with regard to the demographic characteristics of their gravidas, show, in general, the same basic relationships of prenatal characteristics to fetal outcome.

The committee also found that antepartum characteristics, with the exception of "infections during pregnancy," were quite uniform. They found that the labor and delivery characteristics were, for the most part, fairly uniform. As might be expected, the committee found that the relative frequencies of "definite" findings were much more consistent than were "suspect" findings.

DATA FILES CONSTRUCTED

The data from the first prenatal visit through pregnancy, birth and the eight years of follow-up on the children, collected using approximately 100 study forms for each mother-child pair, were transferred from the completed study forms to computer data files. This transfer occurred throughout the 16 year span of the NCPP data collection phase and continued into subsequent substantive analysis phases. The data files documented by this user's guide include all primary data that were computerized. Not all data items were computerized. For example, clinical comments and notes recorded on study forms were usually not coded or computerized as such.

There are three major groups of data files: the master file, the variable file and the work files. The names of the files reflect historical name conventions and partially reflect their characteristics. At the time the study was conducted, punched cards were the standard data entry method. Throughout this document we refer to cards as a convenience; the actual cards were discarded after their images were archived on magnetic tape.

Master File

The master file consists of computer cards that were punched directly from completed study forms (see Volume II for specific details). These computer cards are tied to specific study forms and contain data items as defined by the definition of codes accompanying each study form. The master file consists of approximately six million unblocked, 80 column card images.

Not all study forms have corresponding computer cards in the master file. In some cases, information from a study form was never computerized; in other cases, the study forms were computerized, but appear only as work files and were not entered on the master file.

The master file has the advantage of containing most of the primary data, but it is unwieldy and complicated. Data for each case are grouped together; all cases appear in the same file. As a result, the user must search extensively for specific data items involving a number of patients, since cards of the same type are not grouped together. Each case does not have the same number or even the same types of computer cards. The file is structured so that the cards appear (if present) in the same order for each case. This structure facilitates accessing all data from a particular case at the same time and allows combining of data across study forms.

The master file requires 16 computer reels at 1600 bpi or four reels at 6250 bpi. The computer tapes are encoded in EBCDIC. The data are sequenced by case number and within a case, the cards are arranged to reflect the gathering of data through forms and subsequent revisions to the forms

(Figure 3.1). Knowledge of the relationship between card numbers and study form identification numbers is helpful in understanding where information is located.

In most instances, a researcher will access the master file only once for each research project. This is due mainly to the size of the master file and its associated cost. Accessing the master file should result in the creation of a work file that can be used in a specific research project. A researcher who must access the master file should clearly define his research project's data requirements and thoroughly understand what information must be extracted from the master file. A computer program tailored to the specific data request must be written or an extensive data base management system be designed.

Master File Card Number and NINDB Case Number Rationale

Computer cards for each NCPP study form are numbered to reflect their origin and possible revisions. Card numbers are assigned to identify the type of data (subject), the presence of multiple cards in a series, NCPP study form and form revisions. The first five digits of each card on the master file are the card number. The study forms and card numbers are given in Figure 3.1.

The first fourteen columns of each master file computer card contain the master file card number and the NINDB case number. Table 3.1 identifies the function of each of these columns.

TABLE 3.1. Derivation of Master File Card Number and NINDB Case Number.

Contents	Columns
Master File Card Number	
card identifier	1
general subject matter	2
form number	3-4
revision code	5
NINDB Case Number	
collaborating institution	6-7
type of patient selection	8
gravida identification number	9-12
order of the pregnancy	13
identifies child or gravida	14

Column 1 identifies multiple cards in a series. It contains a zero for cards unique to a particular form (that is, no other cards are present), for example OB-3, or for cards where repetitive data are contained. Cards for

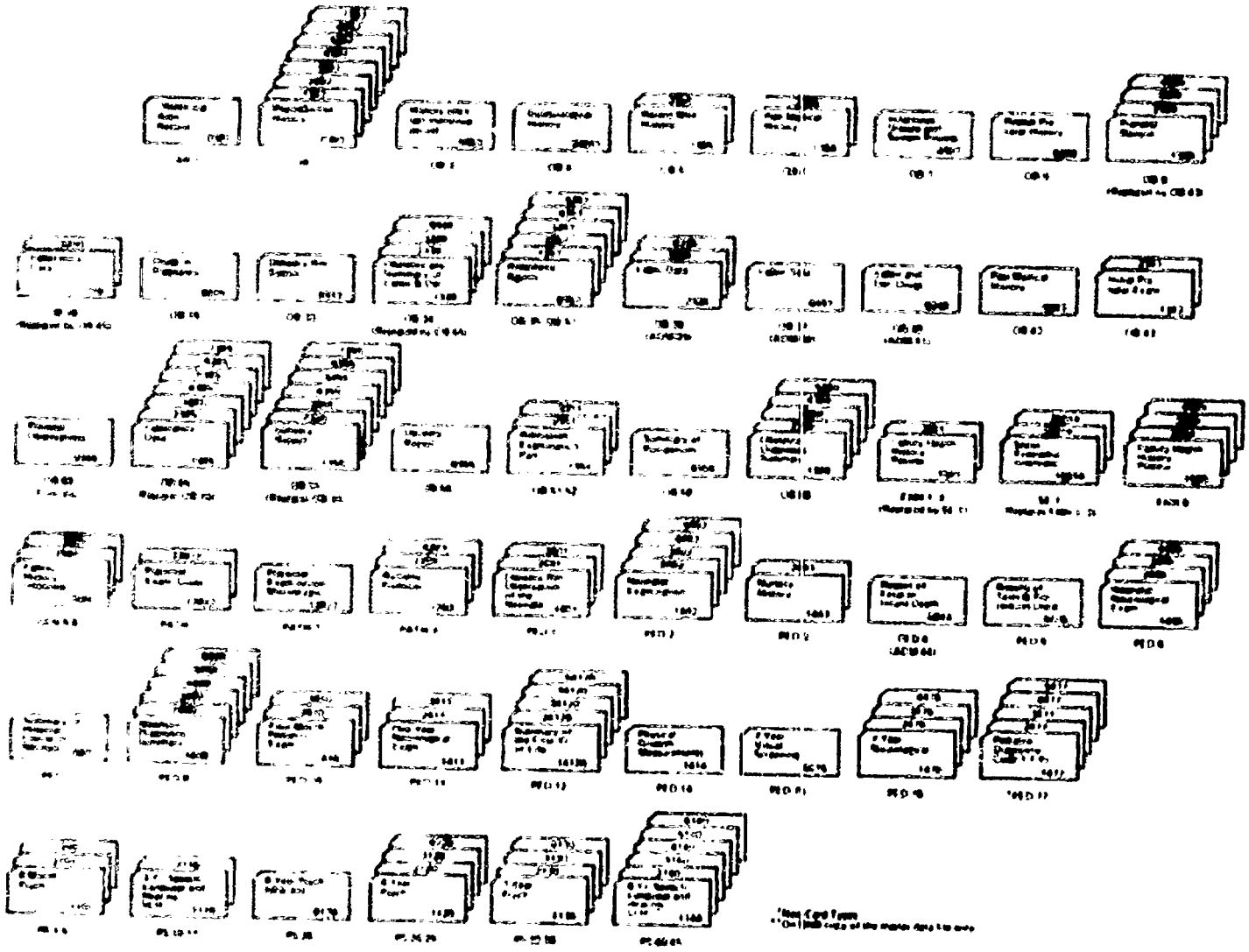


FIGURE 3.1. Cards on the Master Data File

OB-2 are an example of this second type; no new categories of information are included on successive cards, but previous births in excess of four must be recorded on an add-on card. For card series where data entered are unique to a card and more than one card is required to complete the series, a "1" is used to designate the first card, for example OB-5. OB-57, PATH-2 and PED-14 are exceptions to these rules.

The second digit on the card reveals the general subject matter covered by data on the card. All cards containing information pertaining to obstetrics, for example, are designated by a "3" in column 2; family histories are designated by a "5"; pathology with a "2"; pediatrics, with a "4"; and psychological testing with a "1".

Columns three and four reveal the form number. In the case of forms where old and new forms having different numbers are included together, the number of the latest form appears on the master file. This rule does not apply to data abstracted from several forms by NINCDS staff (ADM forms).

Column 5 of the card contains a revision code indicating which form or combination of forms was used in arriving at data on a particular card. A typical card will have one to three revision codes, with a zero indicating the first version of a form and "1", "2", and "3" indicating later revisions. As a rule, revision codes used on cards differ from card to card; investigators should check the definition of codes provided in Volume II to determine the meaning of revision codes used.

Each woman and child studied in the project received a unique case number (NINDB case number) composed of nine digits, recorded in columns 6 through 14 of all master file cards. The case number identified the institution, the mother and the child. The first two digits represented the collaborating institution (see Table 3.2 below). The third digit indicated the type of patient selection. A "1" was used for patients selected for the central core study; a "6" indicated that a patient had been transferred from one institution to another, and a "7" indicated that the patient was part of a special study undertaken by the collaborating institution. The fourth through seventh digits were used to identify the gravida, while the eighth digit identified the order of the pregnancy of a given gravida in the project. The ninth digit was used to identify the gravida or child of the pregnancy; "9" indicated the gravida, "0" indicated the child of a single birth, "1" indicated the first child of a multiple birth, "2" indicated the second child of a multiple birth, etc.

Variable File

The variable file was created by NINCDS to facilitate research studies based on the NCPP data. It contains 1222 explicitly defined items of primary interest to NCPP and was created mainly from the master file with a few items abstracted from internal work files.

The variable file is unique in that:

1. It is the only source where each case is associated with the specific study cohorts shown in Table 1.2 and defined in Appendix B.

2. Each computer record refers to a single case. Hence, in contrast to the master file, the variable file is easy to access and use for research analysis.

3. Individual diseases and conditions from the Obstetric Diagnostic Summary (OB-60), the Newborn Diagnostic Summary (PED-8), and the Summary of the First Year of Life After the Duration Summarized on the PED-8 (PED-12) appear on the variable file as individual data items. This information appears on the master file in coded form but not as individual data items.

4. It contains some items (such as Parity, Weight Gain During Pregnancy, etc.) which were computed from specific data items on the master file.

The variable file data items and their derivation are documented in Volume III.

TABLE 3.2. Collaborating Institutions and Their Code Number (Columns six and seven of all master file cards.)

05 - Boston, Massachusetts
Harvard Medical School
Boston Lying-In Hospital
Children's Hospital Medical Center

10 - Buffalo, New York
University of Buffalo
Children's Hospital

15 - New Orleans, Louisiana
Charity Hospital
Tulane University School of Medicine Medical Center
Louisiana State University

31 - New York, New York
Columbia University College of Physicians & Surgeons
Columbia-Presbyterian Medical Center

37 - Baltimore, Maryland
The Johns Hopkins University School of Medicine
The Johns Hopkins Hospital

45 - Richmond, Virginia
Virginia Commonwealth University
Medical College of Virginia

50 - Minneapolis, Minnesota
University of Minnesota Hospital
Health Sciences Center

55 - New York, New York
New York Medical College
Metropolitan Hospital

60 - Portland, Oregon
University of Oregon
Medical School

66 - Philadelphia, Pennsylvania
University of Pennsylvania
Pennsylvania Hospital
The Children's Hospital of Philadelphia

71 - Providence, Rhode Island
Brown University
Child Study Center

82 - Memphis, Tennessee
University of Tennessee
College of Medicine
Gailor Hospital

Work Files

During initial analyses of NCPP data, significant efforts were undertaken to create a number of specific work files. In most cases, the data items on the work files are not direct transfers of information from either the master file or variable file. The data items are derived quantities or the result of combined search of the master file and hand review of original completed study forms. Data items found on the work files are preferred over similar data items on the master file.

The work files are structured similar to the variable file; they are easy to access and use. Four types of work files are available: files that contain data that are basic to NCPP, meant to augment the master file; special subject or study files; serology files, and administrative files. Eighteen separate work files are documented in Volume IV, Selected NCPP Work Files. The names of the files are given in Table 3.3.

TABLE 3.3. NCPP Work Files Documented

File	Work File Name
W1	Socioeconomic index at registration
W2	Socioeconomic index at seven years
W3	Drugs taken during pregnancy, trade names
W4	Drugs taken during pregnancy, active compounds
W5	Congenital malformations, one and seven years
W6	Cerebral palsy diagnosis
W7	Abnormalities at seven years
W8	Speech, language and hearing at eight years
W9	Toxemia classification
W10	Rupture of membranes
W11	Survey of viral, bacterial, parasitic and fungal infections during pregnancy
W12	Serological testing - complement fixation tests
W13	Serological testing for toxoplasmosis and rubella
W14	Serological testing, cord blood
W15	Serological testing, abnormalities and controls
W16	Serum specimen inventory
W17	Family linkage
W18	Visit summary

NON-COMPUTERIZED DATA

Collaborative clinical research projects by their very nature collect information that is not amenable to computerization. The NINCDS Collaborative Perinatal Project is not an exception. Computing capabilities during the active stages of the project were far less sophisticated than at present. Data in the written comments sections of study forms could not be easily

handled for computerization. Consequently, all such amplifying information is available on the microfilm only. In some cases, complete study forms are available only on microfilm. The NINCDS microfilmed all original study forms completed during the project; these records are available for research use.

Study forms available only on microfilm include:

OB-11/46	Record of Current Pregnancy/Physician's Clinical Record
OB-12/47	Summary of Antepartum Hospitalization
OB-30/50	Admitting Record/Admission History
OB-31	Admitting Examination by Obstetrician (See OB-51/52)
OB-32	Labor Room Record (See ADM-49/50/51)
PED-20	Interval Medical History
PED-29	Summary of Medical Records of Illness or Hospitalization
PED-74	Ophthalmology Consultants Report Vision Screening Study

A researcher considering use of the microfilm records should consult Chapter 5 to determine the applicable requirements and procedures.

CHAPTER 4. NCPP DATA: HIERARCHICAL CLASSIFICATION AND PERSON, TIME AND SUBJECT CATEGORIZATION

A researcher can acquire a general overview of the type of information or data items collected throughout the NCPP from reading the description of the study forms given in Chapter 2. Some researchers will find that description sufficient to determine if the NCPP data applies to their research question. Other researchers require more specific information. The purpose of this chapter is to provide that information. It is not feasible to list here all data items that are available; over 7,000 of them exist on the three types of computer files. To help a researcher obtain an idea of the contents of the NCPP data base, a hierarchical classification and a person, time, and subject categorization were constructed. The person, time, subject categorization is used extensively in Volumes II-VII and is considered an integral part of each data item name (see Chapter 6).

HIERARCHICAL CLASSIFICATION

The data from the NCPP can be placed into 20 primary data classes within the following seven subject areas: obstetrics; placenta; pediatrics; psychology; speech, language and hearing; socioeconomics; and family history (Table 4.1). Data were collected on over 4000 data items in these areas. In addition, other data items were derived from items recorded on the data collection forms. These included such simple calculations as gestational age, which was based on the date of the last menstrual period and the date of delivery, to complex scores of socioeconomic status that were based on several variables. Because of the diversity and complexity of the data, a researcher may have difficulty discovering specific information that is available.

A hierarchical classification has been developed to aid visualization of the overall scope of the collected data. Within each primary data class, the types of study information are classified into lower levels. The hierarchy is designed to allow the researcher to determine what types of information related to a specific research area are included in the data base.

The hierarchy is not intended to direct a researcher to a specific data item. The approach taken in developing the hierarchy is to organize information simultaneously according to major subject area, stage of pregnancy (for obstetric variables) or age of the child (for other variables), type of examination, and topical areas under which data were collected. This allows a researcher to determine relatively easily what general information is available concerning a particular topic.

In developing the general data classification as represented in this hierarchy, it was thought that a system that combined a time-frame dimension along with a biological or behavioral classification was potentially more useful than one that attempted to classify only on the basis of subject. For example, the inclusion of all prenatal laboratory tests under one rubric was preferable to making laboratory tests the major heading and then including prenatal, postnatal and pediatric tests under individual headings. The framework adopted also follows the design of the data collection forms and the organization of the data items in the master file.

Using a two level classification of data collected in the NCPP, a researcher can determine, at a general level, if data on certain subjects are available (Table 4.2). For example, the tests included in the four-year psychological examination are identified.

A more detailed examination of the organization of the study data items is given in Table 4.3. Here, a tertiary level of organization has been added and the data classes are referenced to the study forms on which the data were collected. With this information, a researcher can use Volume II of this guide to identify the specific questions that were asked, the way the data were recorded, the coding procedures used for the study data items, availability of data records, and the location of the variables on data tapes.

The tertiary data classes should enable a potential user of the NCPP data base to determine if the type of information required for a proposed research project is available. At a minimum it will aid a researcher in deciding if further investigation for specific data items is worthwhile. The reference given to NCPP study forms is one mechanism to help a researcher continue his search. It is not the only, or in certain circumstances, even the best way to proceed (see Chapter 6). The study form identification does not exclude the possibility that either the variable file or one of the work files may contain the relevant data items as well. A researcher is advised to consult the documentation for these files (Volumes III and IV) in addition to the study forms found in Volume II.

TABLE 4.1. Hierarchical Classification: Primary Data Classes for the NCPP

Subject Area	Class Number	Primary Data Class
Obstetrics	1	Registration and personal information
	2	History
	3	Prenatal examinations and miscellaneous prenatal records
	4	Admission for delivery
	5	Labor
	6	Delivery and postpartum
	7	Diagnostic summary
Placenta	8	Placental examination
Pediatrics	9	Newborn
	10	Infant
	11	One to seven years
Psychology	12	Psychological examination at eight months of age
	13	Psychological examination at four years of age
	14	Psychological examination at seven years of age
Speech, Language and Hearing	15	Speech, language and hearing examination at three years of age
	16	Speech, language and hearing examination at eight years of age
Socioeconomics	17	Socioeconomics
Family History	18	Family history at time of study pregnancy
	19	Family history reviewed at the time the study child is seven years of age
Family Linkage	20	Linkage of related individuals included in the study

TABLE 4.2. Hierarchical Classification: Secondary Data Classes for the NCPP

1. Obstetrics - registration and personal information
   - A. Identifying information
   - B. Study registration
   - C. Personal information

2. Obstetrics - history
   - A. Gynecological history
   - B. History of prior pregnancies
   - C. History since last menstrual period
   - D. Recent medical history
   - E. Past medical history
   - F. Repeat prenatal history

3. Obstetrics - prenatal examinations and miscellaneous prenatal records
   - A. Initial prenatal examination
   - B. Return prenatal examinations
   - C. Laboratory examinations
   - D. Physician's clinic record
   - E. Drugs in pregnancy
   - F. Special rubella study
   - G. Summary of antepartum hospitalizations
   - H. Visit summary

4. Obstetrics - admission for delivery
   - A. Admission history
   - B. Admission examination

5. Obstetrics - labor
   - A. Labor room record
   - B. Summary of labor

6. Obstetrics - delivery and postpartum
   - A. Delivery room events
   - B. Delivery report
   - C. Anesthetic agents
   - D. Summary of the puerperium

7. Obstetrics - diagnostic summary
   - A. Diseases/conditions - before pregnancy; during pregnancy; post partum
   - B. History of hypertension
   - C. Toxemia screen
   - D. Toxemia classification
   - E. Infections during pregnancy

8. Placental examination
   - A. Gross
   - B. Microscopic

9. Pediatrics - newborn
   - A. Delivery room observations
   - B. Neonatal examination
   - C. Nursery history (newborn period summary)
   - E. Report of fetal or infant death
   - F. Neonatal neurological examination
   - G. Newborn diagnostic summary
   - H. Summary of the hospital course of the neonate

10. Pediatrics - infant
    - A. Four-month pediatric examination
    - B. Blood samples for viral serological study
    - C. One-year neurological examination
    - D. Summary of the first year of life after the newborn period
    - E. Physical growth measurements

11. Pediatrics - one to seven years
    A. Seven-year pediatric and neurologic exam
    B. Seven-year visual screening and examination
    C. Seven-year diagnostic summary

12. Psychological examination at eight months of age
    A. Bayley Scales of Mental Development
    B. Bayley Scales Motor Development
    C. Infant behavior profile
    D. Additional observations on physical and behavioral abnormalities
    E. Maternal behavior in testing situation

13. Psychological examination at four years of age
    A. Stanford-Binet Intelligence Scale
    B. Graham-Ernhart Block Sort Test
    C. Motor test
    D. Behavior profile
    E. Additional observations on physical and behavioral abnormalities
    F. Psychological test summary: clinical impressions
    G. Intellectual assessment of study mother or mother surrogate

14. Psychological examination at seven years of age
    A. Bender Gestalt Test with Koppitz scoring
    B. Wechsler Intelligence Scale for Children (WISC)
    C. Auditory-Vocal Association Test
    D. Goodenough-Harris Draw-a-Person Test
    E. Tactile Finger Recognition Test
    F. Wide Range Achievement Test
    G. Behavioral profile
    H. Additional observations on physical and behavioral abnormalities
    I. Psychological test summary: clinical impressions

15. Speech, language and hearing examination at three years of age
    A. Language reception
    B. Language expression
    C. Hearing test
    D. Speech mechanism
    E. Speech production
    F. Auditory memory - digits and nonsense syllables
    G. Additional observations
    H. Final summary of speech, language and hearing test performance

16. Speech, language and hearing examination at eight years of age
    A. Hearing
    B. Language comprehension
    C. Language expression
    D. Speech mechanism
    E. Speech production
    F. Additional observations

17. Socioeconomics
    A. Socioeconomic data at the time of the study pregnancy
    B. Socioeconomic data reviewed at the time the child was seven years of age

18. Family history at time of study pregnancy
    A. Outcomes from gravida's prior pregnancies
    B. Family composition
    C. Health of gravida and her family
    D. Health of father of baby and his family

19. Family history reviewed at the time the study child was seven years of age
    A. Outcome of prior pregnancies
    B. Pregnancies since study pregnancy
    C. Outcome of all pregnancies
    D. Conditions in study child, parents, or siblings since birth of study child

20. Linkage of related individuals included in the study
    A. Family linkage - mother's relationships
    B. Family linkage - children's relationships
    C. Family linkage - relationship groups

TABLE 4.3. Hierarchical Classification: Tertiary Data Classes for the NCPP.

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
1. Obstetrics - Registration and personal information	A. Identifying information (Form AR-1)	1. Study number and hospital number 2. Name, address, and telephone number
	B. Study registration (Form AR-1)	1. Date registered 2. Date form initiated 3. Sampling frame patient
	C. Personal information (Form AR-1)	1. First day of LMP 2. Date of birth 3. Marital status 4. Race 5. Patient status
2. Obstetrics - History (See also 7. Obstetrics - Diagnostic summary: 17. Socioeconomics; and 18. Family history at time of study pregnancy)	A. Gynecological history (Forms OB-4,9)	1. Menstrual history 2. Fertility and contraceptive history
	B. History of prior pregnancies (Forms OB-2,9)	1. Record of pregnancies in chronological order 2. Characteristics of prior pregnancies and their outcome
	C. History since last menstrual period (Form OB-3)	1. History of symptoms, conditions, and exposures 2. Intercourse frequency 3. Smoking history
	D. Recent medical history (Forms OB-5,15)	1. Illness or disability requiring confinement - prior 12 months 2. Non-confining illness or disability - prior 12 months 3. Medications or injections - prior 12 months
	E. Past medical history (Forms OB-6,7,9,42)	1. Hospitalizations 2. Radiologic exams or treatments - prior 12 months 3. Other radiologic exam or treatments 4. Examinations and treatments of extremities 5. All other examinations and treatments 6. Blood and transfusions 7. Blood tests taken 8. Series of injections 9. System review 10. Surgery 11. Childhood diseases 12. Other infectious diseases 13. Parasitic diseases
	F. Repeat prenatal history (since last visit) (Form OB-8)	1. Symptoms, conditions and exposures 2. Intercourse frequency 3. Smoking - cigarettes per day 4. Medications

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
3. Obstetrics - Prenatal examinations and miscellaneous prenatal records (See also 7. Obstetrics - Diagnostic summary)	A. Initial prenatal examination (Form OB—9,43)	1. Weight, height, vital signs 2. General examination 3. Obstetric examination 4. X-ray pelvimetry 5. Clinical pelvic mensuration 6. Diagnostic impressions
	B. Return prenatal examinations (Form OB-10,44)	1. Gestational age 2. Weight, blood pressure, urinalysis 3. History of symptoms, complications and fetal activity 4. Obstetric examination
	C. Laboratory examinations (Forms OB-10,45; VIR-1)	1. Virology 2. Blood type and Rh 3. Antibody tests 4. Serology 5. Blood chemistry and hematology 6. Urinalysis 7. X-ray pelvimetry and diagnostic X-ray 8. Cultures 9. Glucose tolerance tests 10. Pap smear 11. Other laboratory studies
	D. Physicians clinic record (Form OB-46)	1. Medications 2. Diagnoses and impressions 3. Signs and symptoms 4. Treatments and procedures
	E. Drugs in pregnancy (Form OB-15)	1. Date of LMP 2. Drugs taken by lunar month of pregnancy
	F. Special rubella study (Form VIR-3)	1. Exposure to rubella during study pregnancy 2. Administration of gamma globulin during study pregnancy
	G. Summary of antepartum hospitalizations (Form OB-47)	1. Place hospitalized 2. Admission impression 3. Condition of fetus at discharge 4. Condition of mother at discharge 5. Surgical procedures 6. Discharge diagnoses 7. Anesthesia given 8. Radiation exposure 9. Drug therapy 10. Laboratory work
	H. Visit summary	

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
4. Obstetrics - Admission for delivery	A. Admission history (Form OB-50)	1. Prior pregnancies 2. Pelvic surgery 3. History of labor 4. History of rupture of membranes 5. History of vaginal bleeding 6. Reason for hospital admission
	B. Admission examination (Forms OB-51,52)	1. Weight and vital signs 2. General examination 3. Abdomino-pelvic examination 4. Diagnostic impressions
5. Obstetrics - Labor	A. Labor room record (Forms OB-32; ADM-49,50,51)	1. Maternal vital signs 2. Fetal heart rate 3. Membranes 4. Bleeding 5. Meconium 6. Pelvic examination 7. Medications
	B. Summary of labor (Forms OB-34, OB-35)	1. Onset and duration 2. Position and station 3. Rupture of membranes 4. Induction and use of uterine stimulants 5. Arrested progress of labor 6. Complications and other procedures
6. Obstetrics - Delivery and post partum	A. Delivery room events (Form OB-33)	1. Timing of delivery events 2. Vital signs 3. Bleeding 4. Meconium
	B. Delivery report (Forms OB-34,55)	1. Type of delivery 2. Vertex delivery procedure 3. Vertex delivery with forceps or vacuum extractor 4. Breech delivery procedure 5. Breech delivery with forceps or internal version 6. Indications for forceps, vacuum extraction or version 7. Cesarean section and other surgical procedures 8. Indications for cesarean section 9. Duration of pregnancy and birthweight 10. Umbilical cord 11. Placenta 12. Complications and other procedures 13. Fetal condition
	C. Anesthetic agents (Forms OB-35,57)	1. Who administered agent and who provided information 2. Gaseous agents used 3. Intravenous agents used 4. Deepest anesthesia prior to clamping cord 5. Conduction agents used 6. Response of patient 7. Other medication
	D. Summary of the puerperium (Form OB-58)	1. Post partum blood pressure - highest and lowest diastolic 2. Temperature - highest 3. Postpartum transfusions 4. Summary postpartum data and diagnoses

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
7. Obstetrics - Diagnostic summary (See also 2. Obstetrics - History; and 3. Obstetrics - Prenatal examinations and miscellaneous prenatal records	A. Diseases/conditions - before pregnancy; during pregnancy; peri partum (Form OB-68)	1. Cardiovascular 2. Pulmonary 3. Hematologic 4. Metabolic/endocrine 5. Venereal 6. Urinary tract 7. Gynecological 8. Neurologic/psychiatric 9. Gastrointestinal 10. Integument/appendages 11. Complications of pregnancy 12. Complications of puerperium 13. Other diseases or conditions 14. Special studies
	B. History of hypertension (Form OB-68)	
	C. Toxemia screen (Form OB-68)	1. Blood pressure 2. Proteinuria 3. Edema 4. Other conditions related to toxemia
	D. Infectious diseases during pregnancy (Form OB—68)	1. Viral 2. Bacterial 3. Parasitic 4. Fungal 5. Etiology unknown 6. Vaccination - live attenuated
8. Placental examination	A. Gross (Form PATH-1)	1. Size and shape 2. Umbilical cord 3. Membranes and fetal surface 4. Maternal surface 5. Cut surface 6. Multiple births 7. Abnormalities
	B. Microscopic (Form PATH-2)	1. Cord 2. Membranes 3. Decidua 4. Terminal villi 5. Intervillous space 6. Multiple births 7. Other abnormalities

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
	A. Delivery room observations (form PED-1)	1. Date and time of birth 2. Race and sex 3. Birth weight 4. Timing of cord clamping, first breath and first cry 5. Suction and resuscitation procedures 6. Apgar scores 7. Physical examination (delivery room)
	B. Neonatal examination (form PED-2)	1. Age at time of exam 2. Measurements 3. Respiration 4. Physical examination - system review with comments 5. Alert response 6. Motor activity 7. Tone 8. Weight 9. Dysmorphism 10. Clinical impression
	C. Nursery History (newborn period summary) (form PED-3)	1. Special conditions 2. Weight 3. Temperature 4. Feeding method 5. Activity 6. Cry 7. Abnormalities and clinical signs 8. Medications and procedures
9. Pediatrics - Neonatal		
	D. Report of fetal or infant death (forms PED-4, PATH-3)	1. Sex 2. Date of delivery or date and time of death 3. Place of delivery or place of death 4. Weight and crown-rump length (fetal death) 5. Birth injuries (infant death) 6. Cause of death 7. Malformations present 8. Autopsy findings
	E. Neonatal tests and procedures (form PED-5)	1. Cord blood studies 2. Serum bilirubin 3. Hemoglobin 4. Hematocrit
	F. Neonatal neurological examination (form PED-6)	1. Time of examination and last feeding 2. Age of child 3. Eyes 4. Movement and motor activity 5. Cry 6. Grasp 7. Jerk and ankle clonus 8. Suck 9. Response to stimulus or position 10. Reflexes 11. Tone 12. Transilumination 13. Tonic neck reflex 14. Impression
	G. Newborn diagnostic summary (form PED-8)	1. Summary data on abnormalities, malformations conditions, infections and procedures by organ system 2. Specific diagnoses - suspect and definite 3. Procedures
	H. Summary of the hospital course of the neonate (form PED-7)	1. Date of birth and discharge 2. Clinical data and description of events 3. Clinical impression

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
	A. Four-month pediatric examination (Form PED-10)	1. Age 2. Weight, length, and head and chest circumference 3. Vital signs 4. Physical examination - system review with comments 5. Neurological evaluation - examination with comments 6. Cry and vocalizations 7. Maternal - child relationship evaluation 8. Impression/diagnosis
	B. Blood samples for viral serological study (Form VIR-1)	1. Records, specimens obtained from abnormal infants and controls at four months of age
	C. One-year neurological examination (Form PED-11)	1. Age 2. Weight, length and head circumference 3. Physical examination - system review with comments 4. Responsiveness 5. Phonation 6. Locomotor and postural development 7. Neurological evaluation - examination with comments 8. Impression
M Pediatrics - Infant		
	D. Summary of the first year of life after the newborn period (Form PED-12)	1. Neurologic abnormality - suspect and definite 2. Related central nervous system and skeletal conditions - other - suspect and definite 3. Abnormalities, malformations, conditions, and infections by organ system - suspect and definite 4. Procedures 5. Social and environmental conditions 6. Summary data on abnormalities, conditions and procedures
	E. Physical growth measurements (Form PED-14)	1. Weight 2. Length 3. Head circumference
	F. Interval medical history (Form PED-20,29)	1. Age at history and date 2. Informant 3. Health care 4. Medical problems not treated by a physician 5. Hospitalization information 6. Summary of informant's account of medical care 7. Summary of medical records

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
	A. Seven-year pediatric and neurological examination (Form PED-76)	1. Age 2. Physical measurements 3. Blood pressure 4. Physical examination - system review 5. Neurological examination 6. Mental status 7. Intellectual status 8. Other signs, reflexes, tests, etc. 9. Neurological abnormalities 10. Abnormality on visual screening 11. Non-neurological abnormalities
11. Pediatrics - One to seven years	B. Seven-year visual screening and examination (Forms PED-74,75)	1. Age 2. Wears glasses? (If yes - test repeated with glasses) 3. Visual acuity - each eye 4. Muscle balance 5. Color tests 6. External examination 7. Refractive error 8. Ophthalmoscopic examination 9. Diagnosis
	C. Seven-year diagnostic summary (Forms ADM-86, IDC-77)	1. Forms reviewed 2. Specific conditions, diagnoses and sources
	A. Bayley Scales of Mental development (Form PS-1)	1. Age, sex and race 2. Scoring and diagnosis 3. Age placement on Bayley Scales (0 to 15 months)
	B. Bayley Scales of Motor development (Form PS—2)	1. Scoring and diagnosis 2. Age placement on Bayley Scales (0 to 12 months)
12. Psychological examination at eight months of age	C. Infant behavior profile (Form PS-3)	1. Orientation to objects 2. Orientation to persons 3. Activity level 4. Physical development - clinical impression 5. Mental development - clinical impression 6. Fine motor development - clinical impression 7. Gross motor development - clinical impression 8. Social/emotional development - clinical impression 9. Adequacy of examination
	D. Additional observations on physical and behavioral abnormalities (Form PS-4)	1. Face, mouth, hearing, eyes 2. Comparative function of arms, hands and grip 3. Unusual muscular movements or postural adjustments 4. Deviant or stereotyped behavior 5. Specified obvious defects or anomalies
	E. Maternal behavior in testing situation (Form PS-5)	

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
13. Psychological examination at four years of age	A. Stanford-Binet Intelligence Scale (Form PS-20)	1. Chronological age 2. Mental age 3. Intelligence Quotient (IQ) 4. Test performance on specific items 5. Adequacy of examination
	B. Graham-Ernhart Block Sort Test (Form PS-21)	1. Scores by level and trial 2. Summary scores
	C. Motor test (Form PS-22)	1. Gross motor 2. Fine motor 3. Dominance 4. Overall summary
	D. Behavior profile (Form PS-23)	1. Orientation to testing situation 2. Orientation to examiner 3. Orientation to test materials 4. Activity 5. Communication 6. Examiner comments
	E. Additional observations on physical and behavioral abnormalities (Form PS-24)	1. Face, mouth, eyes and ears 2. Unusual muscular movements or postural adjustments 3. Deviant or stereotyped behavior 4. Specified obvious defects or anomalies 5. Enrollment in nursery school 6. Examiner comments
	F. Psychological test summary: Clinical impressions (Form PS-25)	1. Intelligence 2. Fine motor development 3. Gross motor development 4. Concept formation 5. Behavioral 6. Adequacy of examination 7. Overall impression 8. Examiner comments
	G. Intellectual assessment of study mother or mother surrogate - SRA non-verbal form (Form PS-26)	

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
	A. Bender Gestalt Test with Koppitz scoring (Form PS-30)	1. Performance on specific figures 2. Total score and time 3. Adequacy of examination
	B. Wechsler Intelligence Scale for children (WISC) (Form PS-31)	1. Verbal tests and scale scores 2. Performance tests and scale scores 3. Full scale IQ 4. Adequacy of examination
	C. Auditory-Vocal Association Test (Form PS-32)	1. Scoring 2. Adequacy of examination
	D. Goodenough-Harris Draw-A-Person Test (Form PS-33)	1. Scoring 2. Percentile rank 3. Adequacy of examination
	E. Tactile Finger Recognition Test (Form PS-34)	1. Right hand 2. Left hand 3. Adequacy of examination
	F. Wide Range Achievement Test (Form PS-35)	1. Personal data 2. Spelling test 3. Reading test 4. Arithmetic test
14. Psychological examination at seven years of age		
	G. Behavior Profile (Form PS-36)	1. Separation from mother 2. Fearfulness 3. Rapport with examiner 4. Self-confidence 5. Emotional reactivity 6. Degree of cooperation 7. Level of frustration tolerance 8. Degree of dependency 9. Duration of attention span 10. Goal orientation 11. Level of activity 12. Nature of activity 13. Nature of communication 14. Assertiveness 15. Hostility
	H. Additional observations on physical and behavioral abnormalities (Form PS-37)	1. Face, mouth, eyes and ears 2. Unusual muscular movements or postural adjustments 3. Deviant or stereotyped behavior 4. Specified obvious defects or anomalies 5. Additional observations 6. Enrollment in special class or school
	I. Psychological test summary: Clinical impressions (Form PS-38)	1. Intelligence 2. Bender Visual Motor Production 3. Educational Achievement (WRAT) 4. Goodenough-Harris Drawing Test 5. Abstract Language Thinking (ITPA Aud Voc) 6. Tactile Finger Recognition Test 7. Behavioral 8. Overall impression

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
	A. Language reception (Form PS-10)	1. Verbal expression 2. Alternate expression
	B. Language expression (Form PS-11)	1. Verbal comprehension 2. Alternate comprehension (single word and pantomime)
	C. Hearing test (Form PS-13)	1. Spondaic Word Test (verbal) 2. Spondaic Word Test (non-verbal) 3. Pure Tone Screening Test
	D. Speech mechanism (Form PS-14)	1. Examination of the lips 2. Examination of the tongue 3. Examination of the soft palate 4. Diadochokinesis
15. Speech, language and hearing examination at three years of age	E. Speech production (Form PS-15)	1. Voice 2. Articulation 3. Intelligibility of connected speech 4. Fluency of speech production
	F. Auditory memory - digits and nonsense syllables (Form PS-12)	1. Recall of digits 2. Recall of nonsense syllables
	G. Additional observations (Form PS-16)	1. State of child's health on day of examination 2. Observable physical anomalies 3. Unusual behavior observed during test period
	H. Final summary of speech, language and hearing test performance (Form PS-17)	1. Language reception 2. Language expression 3. Hearing 4. Speech mechanism 5. Speech production 6. Global scoring 7. Auditory memory 8. Adequacy of examination 9. Referral

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
16. Speech, language and hearing examination at eight years of age	A. Hearing (Form PS-40)	1. Pure tone audiometry - air conduction 2. Abnormal auditory adaptation 3. Pure tone audiometry - bone conduction 4. Discrimination test 5. Auditory memory 6. Scoring 7. Adequacy of examination
	B. Language comprehension (Form PS-41)	1. Auditory verbal comprehension 2. Reading 3. Morphology - knowledge of linguistic form 4. Scoring 5. Adequacy of examination
	C. Language expression (Form PS-42)	1. Connected discourse 2. Writing from dictation 3. Summary evaluation 4. Scoring 5. Adequacy of examination
	D. Speech mechanism (Form PS-43)	1. Examination of the lips 2. Examination of the tongue 3. Concomitant movements present while performing 4. Examination of the soft palate
	E. Speech production (Form PS-44)	1. Rate and fluency of connected speech 2. Voice 3. Intelligibility of connected speech 4. Articulation 5. Scoring
	F. Additional observations (Form PS-45)	1. State of child's health on day of examination 2. Observable physical anomalies 3. General behavior aberrations observed during test period - specified
17. Socioeconomics	A. Socioeconomic data at the time of study pregnancy (Forms SE-1; FHH-1,3)	1. Birthplace and education of gravida 2. Language, religion and race of gravida 3. Marital history of gravida 4. Work history of gravida 5. Household arrangement 6. Age, birthplace, education, religion and race of father of baby 7. Work history of father of baby or husband 8. Family income and number of persons supported 9. Socioeconomic index
	B. Socioeconomic data reviewed at the time the study child was seven years of age (Form FHH-9)	1. Birthdate, sex and race of child 2. Residence of child 3. Socioeconomic data on foster parent, adoptive parent or guardian 4. Marital history of mother 5. Household arrangement 6. Education and employment of mother 7. Employment history of husband 8. Family income and number of persons supported 9. Socioeconomic index

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
	A. Outcomes from gravidas, prior pregnancies (Form GEN-5)	1. Number and outcome of prior pregnancies 2. Prior liveborn children 3. Medical care and hospitalization of siblings 4. Summary of medical conditions in outcome pregnancies 5. Rh or other blood incompatibility 6. Congenital malformations or physical defect 7. Seizures, convulsions, epilepsy 8. Motor defects 9. Sensory defects 10. Developmental retardation 11. Inability to attend regular school 12. Description of conditions
18. Family History at time of study pregnancy (See also 2. Obstetrics - History; and 7. Obstetrics - Diagnosis summary	B. Family composition (Form GEN-6)	1. Family of gravida 2. Family of father of baby
	C. Health of gravida and her family (Form GEN-7)	1. Physical defects/congenital malformations 2. Sensory defects 3. Diabetes 4. Seizures, convulsions, epilepsy 5. Motor defects 6. Mental retardation, special schools 7. Mental illness, nervous problems or psychiatric treatment 8. Additional diseases 9. Multiple pregnancies
	D. Health of father of baby and his family (Form GEN-8)	1. Physical defects/congenital malformations 2. Sensory defects 3. Diabetes 4. Seizures, convulsions, epilepsy 5. Motor defects 6. Mental retardation, special schools 7. Mental illness, nervous problems or psychiatric treatment 8. Radiation

Primary Data Classes	Secondary Data Classes	Tertiary Data Classes
19. Family history reviewed at the time study child was seven years of age	A. Outcome of prior pregnancies (Form FHH-9)	1. Fetal death 2. Live born 3. Summary of conditions
	B. Pregnancies since study pregnancy (Form FHH-9)	1. Total number 2. Miscarriages/abortions 3. Multiple pregnancies
	C. Outcome of all pregnancies (Form FHH-9)	1. Fetal death 2. Live born 3. Summary of conditions
	D. Conditions in study child, parents or siblings since birth of study child (Form FHH-9)	1. Rh/blood incompatibility 2. Congenital malformations/physical defects 3. Developmental retardation 4. Child unable to attend regular school 5. Seizures, convulsions, epilepsy 6. Motor defects 7. Sensory defects 8. Diabetes 9. Mental illness, nervous problems or psychiatric treatment 10. Deaths of children 11. School and achievements of study child
20. Linkage of related individuals included in the study	A. Family linkage - Mother's relationships	
	B. Family linkage - Children's relationships	
	C. Family linkage - Relationship groups	

PERSON, TIME AND SUBJECT CATEGORIZATION

The NCPP collected information from approximately 58,000 pregnancies and included over 7,000 individual data items. In the previous section, a hierarchical classification was used to describe the general types of data items collected. This section describes an alternative categorization that was devised in conjunction with the naming of individual data items. Each data item was named and given a unique data item identification (see Chapter 6). In completing this process, it became apparent that an implicit categorization was involved: data items could be described based on the person, time, or general subject area they represented (Table 4.4).

A researcher can categorize his research project variables according to which person(s), what time(s) and what subject(s) apply. Working definitions used for each of the categories are given in Table 4.5. It is emphasized that this is only one group's attempt to define usable categories. Other groups would choose slightly different ones. A researcher should view the categories as an aid to locating specific data items and not as an end in themselves. As such, more than one combination of categories should be checked before deciding that a specific type of information is not available.

Volume VII, Categorization of Data Items by Person, Time of Collection or Measurement and General Subject Area, enables a researcher to use the categorization to locate individual data items of potential interest. Chapter 6 gives an example of how this is accomplished.

Volume VII is divided into three parts:

Part A: Categorization of Data Items Organized by Person

Part B. Categorization of Data Items Organized by Time of Measurement or Observation

Part C: Categorization of Data Items Organized by General Subject Area.

The information contained in each part is the same, differing only in the organization of the categories. In Part A, data items are ordered by person, time, subject, while data items in Part B are ordered by time, person, subject. Data items in Part C are ordered by subject, person, time.

In part A all the computerized data items are organized by the person categories shown in Table 4.4. This allows a researcher to identify readily all the data items included in the computer files that relate to mothers, children, fathers, etc.

In Part B of Volume VII, the researcher can identify all computerized data items grouped on the basis of time of occurrence, observation, or measurement. For example, all the data items that relate to the neonate are listed under the category Neonatal. Such a categorization enables the user of the guide to determine all the information on a particular topic within a chronological category.

Finally, all the computerized variables are organized into general subject area categories in Part C of Volume VII (Table 4.4), providing an alternative classification to that developed earlier in this chapter. Unlike the example of prenatal laboratory tests given in the hierarchical classification, the classification scheme employed in Volume VII Part C includes all the clinical laboratory tests under a single heading.

SUMMARY

The data classification and categorization provided by Tables 4.1 through 4.4 of this chapter allow the guide's user to develop an understanding of the types of information collected as part of the NCPP. The hierarchical classification directs a researcher directly to study forms (Volume II) to locate specific data items. The person, time and subject categorization (Volume VII) directs a researcher to specific data items under a categorical listing and then to the source of the data item: master, variable or work file. Thus, the researcher can develop an understanding of the data available on the basis of biological-behavioral categories and stage of pregnancy/development and, in turn, identify the specific data items on the study forms and the data items in the computer files that relate to his/her research interests.

TABLE 4.4. Person, Time and Subject Categories for the NCPP Data Items

Person	Time	Subject
Mother	General	Administrative
Father	Preconception	Anesthesia
Placenta	Registration	Clinical Impression
Fetus	Prenatal	Clinical Laboratory
Child	Admission	Current Pregnancy, General Information
Mother Surrogate	Intrapartum	Environmental Exposures
Family	Delivery	Events
Sibship	Post Partum	Hearing
	Neonatal	Hospitalization
	Four Month	Language
	Eight Month	Linkage
	One Year	Malformation
	Three Year	Medical Diagnoses and Conditions
	Four Year	Medical History
	Seven Year	Medications
	Eight Year	Neurological Examination
		Observations
		Pathology
		Physical Examination
		Procedures
		Psychological Examination
		Reproductive History
		Serology
		Socioeconomic
		Speech
		Vision
		Work History
		X-ray
		Summary
		Gynecological History
		Special Studies
		Family/Genetic History
		SLH Examination

TABLE 4.5. Definition of Person, Time and Subject Categories

PERSON	DEFINITION
Mother	Study registrant bearing the "study pregnancy"; biologic mother of the "study child"; gravida.
Father	Biologic father of the study child or study pregnancy; in the case of socioeconomic data, this category may indicate either the "father of baby" (not necessarily husband of the mother) or the "husband" (not necessarily related biologically to the study child).
Placenta	The organ of metabolic and gaseous interchange between the fetus and mother; also included in this category are gross and microscopic pathologic data from examination of the umbilical cord.
Fetus	Conceptus; the product of conception including the embryonic stage, i.e., from conception to the moment of birth.
Child	Product of the study pregnancy from the moment of birth onward; study child.
Mother Surrogate	Person or persons substituting for the mother of a stud, child, e.g., adoptive parents, foster parents or guardian.
Family	Person or persons biologically related to the mother or father of the study child.
Sibship	Child or children having one or both of the same biologic parents as the study child; siblings; half siblings; full siblings.

TABLE 4.5. Definition of Person, Time and Subject Categories (Cont.)

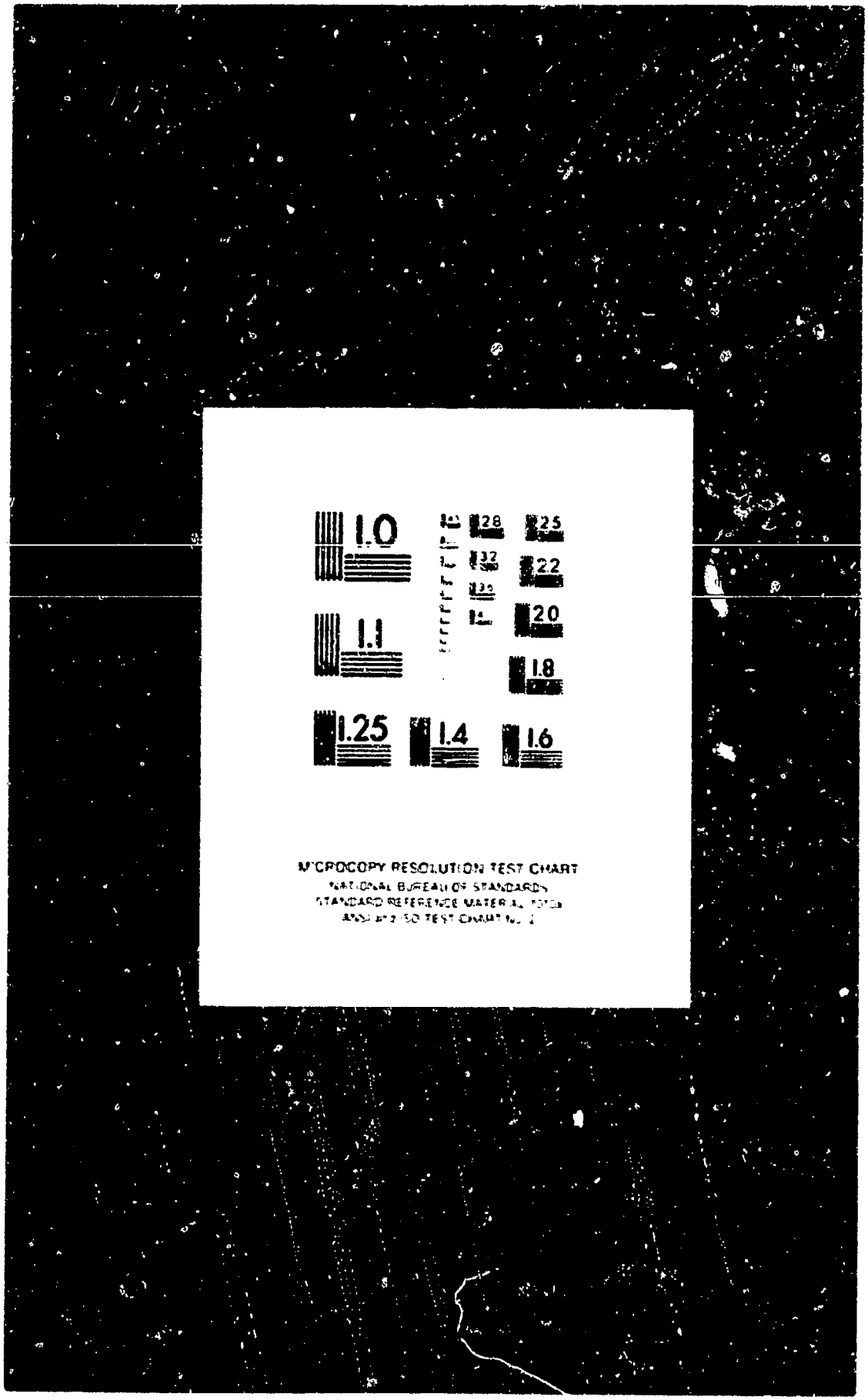
TIME	DEFINITION
General	Data with no pertinent time period or data pertaining to more than one time period.
Preconception	Data pertaining to the period prior to conception of the study pregnancy.
Registration	Data collected at the time of study mother's registration in the study.
Prenatal	Data pertaining to the period from conception of the study pregnancy to delivery of the study child.
Admission	Data collected at the time of study mother's admission to the hospital for delivery of the study child.
Intrapartum	Data pertaining to the period from admission for delivery or onset of labor to delivery of the study child.
Delivery	Data pertaining to the time period during which delivery of the study child occurred.
Post Partum	Data (pertaining to the study mother) collected during the period immediately following birth of the study child.
Neonatal	Data pertaining to the study child during the period from birth to one month of age; the majority of these data were collected prior to or at the time a study child was discharged from the hospital.
Four Month	Data collected at the time of the four month examination of the study child.
Eight Month	Data collected at the time of the eight month examination of the study child.
One Year	Data collected at the time of the one year examination of the study child.
Three Year	Data collected at the time of the three year examination of the study child.
Four Year	Data collected at the time of the four year examination of the study child.
Seven Year	Data collected at the time of the seven year examination of the study child.
Eight Year	Data collected at the time of the eight year examination of the study child.

TABLE 4.5. Definition of Person, Time and Subject Categories (Cont.)

SUBJECT	DEFINITION
Administrative	Data pertaining to the administrative aspects of the study.
Anesthesia	Data on medications and procedures used to obtain anesthesia.
Clinical Impression	Impression of abnormality or dysfunction gained by an examiner following evaluation of clinical signs and symptoms and including a subjective component.
Clinical Laboratory	Data obtained from laboratory examination of clinical specimens.
Current Pregnancy General Information	Personal data and medically relevant information pertaining to the study pregnancy for which the mother is enrolled.
Environmental Exposures	Data on exposure to occupational or other environmental entities or hazards.
Events	Data related to a specific event, occurrence or incidence.
Hearing	Data obtained from examination and testing of hearing function.
Hospitalization	Data on specific hospital admissions or the number of hospitalizations.
Language	Data obtained from examination and testing of language function.
Linkage	Data on the genetic relationships of family members to the study mother, father or child.
Malformation	Data on the conditions in which failure of normal development has resulted in abnormal physical traits existing at the time of birth.
Medical Diagnoses and Conditions	Data on specific diagnoses or conditions obtained from past medical history or examination during the study.
Medical History	Data obtained from the study participant or medical records relevant to past or current medical diagnoses or conditions.
Medications	Data on drugs or medications used.
Neurological Examination	Data obtained from observation and physical examination of the central nervous system.
Observations	Data obtained from observations not categorized elsewhere.
Pathology	Data obtained from clinical and anatomical pathological examination.
Physical Examination	Data obtained from physical examination of the study participant.
Procedures	Data relating to specific procedures performed on the study participant prior to or during the period of enrollment in the study.
Psychological Examination	Data obtained from the psychological examinations and observations.

TABLE 4.5. Definition of Person, Time and Subject Categories. (Cont.)

SUBJECT	DEFINITION
Reproductive History	Data pertaining to the outcome of pregnancies prior to and or during the period of enrollment in the study.
Serology	Data obtained from the laboratory examination of serum by specific immunologic methods.
Socioeconomic	Data related to the social and economic characteristics and environment of the study participant.
Speech	Data obtained from examination and observation of speech function.
Vision	Data obtained from examination of the eyes.
Work History	Data pertaining to occupation and employment prior to and during the period of enrollment in the study.
X-Ray	Data on diagnostic x rays and diagnostic or therapeutic radiological procedures.
Summary	Data presented as a summary of data collected and recorded elsewhere.
Gynecological History	Medical history specifically related to the female genital tract, reproductive physiology and endocrinology.
Special Studies	Data pertaining to participation in other special organized studies conducted during the period of enrollment in the study.
Family/Genetic History	Data on the medical histories of family members genetically related to the study child.
SLH Examination	Data obtained from the speech, language and hearing examinations not specifically or exclusively related to one of these areas.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