1 Introduction

1.1 Purpose of the Pregnancy Risk Assessment Monitoring System (PRAMS)

PRAMS was initiated in 1987 as part of the Centers for Disease Control and Prevention (CDC) initiative to reduce infant mortality and low birthweight. In recent years, the program has been expanded in support of CDC's Safe Motherhood Initiative to promote healthy pregnancies and the delivery of healthy infants. PRAMS is an ongoing, population-based surveillance system designed to identify and monitor selected maternal experiences and behaviors that occur before and during pregnancy and during the child's early infancy among a stratified sample of women delivering a live birth.

Epidemiologic surveillance is the ongoing and systematic collection, analysis, and interpretation of health data used for describing and monitoring a health event or behaviors associated with a health event. This information is used for planning, implementing, and monitoring health programs and for informing policy.

The decision to develop the PRAMS surveillance system was based on research that showed:

- The US infant mortality rate was no longer declining as rapidly as it had in past years.
- The prevalence of low birthweight was showing little change.
- Maternal behaviors such as alcohol and tobacco use and limited use of prenatal care and pediatric care were contributing to the slow rate of decline.

PRAMS was initiated to help state health departments establish and maintain an epidemiologic surveillance system of selected maternal behaviors and experiences. PRAMS was designed to supplement data from vital records and to generate data for planning and assessing perinatal health programs in each participating state. Findings from PRAMS are meant to be used to enhance understanding of maternal behaviors and their relationship with adverse pregnancy outcomes. PRAMS data can also be used to aid in the development and assessment of programs designed to identify high-risk pregnancy and reduce adverse pregnancy outcomes and to inform policy in each participating state.

1.2 History of PRAMS

Funding for PRAMS became available to the Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention in 1987. Funding was made available through cooperative agreements and all state and territorial health departments and the District of Columbia were eligible to apply. In the late summer of 1987, funds were awarded to the District of Columbia, Indiana, Maine, Michigan, Oklahoma, and West Virginia to establish PRAMS surveillance.

The original PRAMS questionnaire was developed in 1987 with the participation of numerous individuals within and outside of CDC. To create the questionnaire, potential topics and questions were identified and researched by staff in the Division of Reproductive Health at CDC. Data collection was initiated in the fall of 1988. Because surveillance methods were not well established for the target population of PRAMS, states were encouraged to experiment with different methodologies. For this reason, the first period of data collection from fall 1988 to summer 1990 was treated as a pilot phase and was referred to as Phase 1.

After one year of data collection, the questionnaire was evaluated and, with input from all participating states, was revised and placed in the field in fall 1990. This questionnaire was known as the Phase 2 questionnaire.

Also at this time, the methodology became more streamlined. The primary conclusion at the time was that mail/telephone surveillance yielded reasonable response rates in most populations. However, the population of minority women who lived in urban areas yielded the lowest response rates. To reach this population of minority women, Michigan successfully piloted a hospital-based data collection activity during Phase 1 in the cities of Detroit and Flint as a supplement to the mail/telephone surveillance. The methodology was modified slightly and became the basis for a standardized hospital supplementation methodology. Due to their unique geographic situation, hospital surveillance without mail/telephone surveillance was initiated in the District of Columbia in fall 1991. The PRAMS tracking software was updated so that one standard version of the software was used by all states. In summer 1990, the new software was installed.

Since the initial phase of PRAMS, the project has undergone substantial growth. In 1990, Alaska approached CDC about establishing a PRAMS project with their state funds. In fall 1990, Alaska became the seventh state to actively collect PRAMS data.

In 1991, additional funds became available through the Infant Health Initiative to expand PRAMS. This second funding cycle for PRAMS was established for five years. A total of 13 states were awarded PRAMS funds at that time: the six original states, six new states (Alabama, Florida, Georgia, New York, South Carolina, and Washington), and Alaska, which had been operating without federal funding. Meanwhile, at the beginning of 1991, California approached CDC about establishing PRAMS surveillance in certain regions of the state using their own funding. Between January and September 1993, the six new states and California began PRAMS data collection. The new states of Alabama (1991 only), California, Georgia, and New York chose to supplement the mail/telephone surveillance with hospital-based data collection.

In fall 1994, the states and CDC convened jointly to determine topic priorities for the questionnaire revision (the Phase 3 questionnaire). For the next year, question modules, known as standard questions, were developed and tested. States were able to choose questions from the standard set when selecting questions for the state-specific sections of the survey. States could also use state-developed questions, those they developed and tested on their own. Thus, the state-specific section of the questionnaire included two types of questions: standard or state-developed. PRAMS states implemented the Phase 3 questionnaire between November 1995 and July 1996.

In fall 1996, funds were awarded for another five-year PRAMS funding cycle. One of the goals at that time was to expand the program into new states. As additional funds were not available to expand while maintaining previous funding levels, CDC decided to reduce the awards to existing PRAMS states and to discontinue support for the costly hospital-based component of data collection. At this time, three existing states discontinued participation in PRAMS. In October 1996, funds were awarded to ten existing states to continue PRAMS activities and to five new states (Arkansas, Colorado, Illinois, New Mexico, and North Carolina) to establish PRAMS surveillance.

After the 1996 awards, the demand for PRAMS continued to be high. In response to numerous requests for unfunded technical assistance (TA) from states that were interested in proceeding with PRAMS without federal funding, CDC brought Louisiana into PRAMS as an unfunded TA state. CDC provided all technical assistance needed to implement the project and Louisiana provided the funding. In 1999, Ohio and Utah started PRAMS under this unfunded TA mechanism.

In 1999, additional funds became available for the expansion of PRAMS into new states. Awards were made for a two-year funding cycle to four new states and one city: Hawaii, Maryland, Nebraska, New York City, and Vermont. In 2000, funding became available to fund two additional states from the 1999 announcement. Delaware and Mississippi were awarded funds at that time. CDC

also began providing federal funding for the three states that had been receiving unfunded TA to conduct PRAMS.

In fall 2000, CDC announced expansion of funding for PRAMS under the Safe Motherhood legislation. The value of PRAMS data was well documented and the demand for PRAMS continued to grow. With this funding cycle, CDC had three aims. First, CDC wanted to expand into new states. Funds were awarded to six new states (Michigan, Minnesota, New Jersey, Oregon, Rhode Island, and Texas) as well as the 25 states and cities that were already conducting PRAMS. Second, CDC wanted to allow states an opportunity to develop and implement enhanced surveillance activities. Colorado was awarded funds to develop a component to enhance their standard surveillance activities. Third, CDC wanted to provide an opportunity for states not suited for ongoing surveillance to collect PRAMS data. A point-in-time survey methodology was developed, and Montana and North Dakota were funded to conduct point-in-time surveys.

During this funding cycle, one state ceased operations, Colorado completed its enhanced activities in 2003, and Montana and North Dakota completed their point-in-time projects.

With the same process utilized in previous questionnaire evaluations and revisions, the Phase 4 questionnaire was developed and placed in the field in spring 2000. The Phase 4 questionnaire was arranged in two-column format, with instructions to help respondents move through the questionnaire appropriately. Also, the core and standard questions were integrated. Where appropriate, standard questions that relate to core topics appeared with the core questions. Standard questions on topics not covered in the core, as well as all state-developed questions, remained in a separate section at the end of the survey. Following the major revision, the states were provided an opportunity to revise their state-specific questions for 2002 births. About one-half of the states participated in this optional, mini-revision, and their revised Phase 4 questionnaires went into the field in spring 2002.

The Phase 4 questionnaire was evaluated and revised in 2003 with the Phase 5 questionnaire implemented in the states with 2004 births. The core questionnaire was revised slightly, and several new standard questions were developed for states to choose according to their needs. The layout of the questionnaire remained the same, and states still had the option of inserting specific standards questions within the core section. The Phase 5 questionnaire was evaluated in 2007. The Phase 6 questionnaire was revised in 2008 and scheduled for implementation with 2009 births.

In 2006 CDC again received funding to expand PRAMS. Funds were awarded to nine new states as well as the 30 states and cities that were already conducting PRAMS. Eight of the new states (Delaware, Massachusetts, Missouri,

Pennsylvania, Tennessee, Virginia, Wisconsin, and Wyoming) were funded to conduct ongoing PRAMS surveillance. South Dakota was funded for a point-in-time survey focusing only on their American Indian population. States participating in PRAMS now account for 75% of all U.S. births.

PRAMS data collection is primarily conducted by mail with telephone follow-up to nonresponders. Prior to 2006, some states developed their own Computer Assisted Telephone Interviewing (CATI) systems to assist in collecting telephone interviews. Others recorded interviews on paper and later keyed them into data entry software. The dual modes used and the variations in CATI systems developed by the states created data management problems for PRAMS.

In 2004, CDC PRAMS contracted with Research Triangle Institute (RTI) for the development and support of a standard CATI system. This change in data collection methodology standardized the way telephone interview data are collected across PRAMS states. The Web-based CATI system takes advantage of automated technology currently available. It collects and generates data files in a consistent manner to facilitate data cleaning and preparation of analysis datasets. All states implemented the standardized CATI during 2006 and 2007. Full implementation of CATI has allowed CDC to provide data to states in a more timely manner, thereby improving the usefulness and effectiveness of PRAMS. Having a more timely and effective surveillance system ultimately supports CDC's mission of promoting healthier pregnancies and reducing poor birth outcomes.

1.3 Purpose and Use of the PRAMS Surveillance Protocol

A research protocol assures the standardization, consistency, and continuity of a project. It also provides invaluable historical information about project development and design. The protocol is the cookbook that is followed to develop and establish the surveillance system. A standardized protocol is essential for ensuring comparability of data when data are collected in multiple sites and aggregation of data is a goal of the system as it is for PRAMS.

Specifically, the purpose of writing the PRAMS protocol is fourfold:

1. It provides a means of recording the procedures used during the process of collecting survey data.

2. It provides a means of assuring that similar surveillance methods are used in each project area (i.e., state or city).

3. It requires the state team to think through each step of the process of developing PRAMS to assure that the desired information will be obtained from the system.

4. It institutionalizes PRAMS in the state and provides a document that informs and guides users – those who are part of the PRAMS team as well as those who are not.

A successful surveillance system requires a balance of the many components that make up the system. During the development of each state-specific PRAMS surveillance system, each of the system components will need to be addressed. Each of the system components is presented in the body of this protocol. The discussion of components is not presented by order of importance or by order of action for system implementation. Several components will be under development at one time and each will be critical for the overall success of the surveillance system. Necessary tasks to develop these components have been arranged into seven major categories: Personnel, Training, and Steering Committee; Sampling; Data Collection; Data Management; Analysis, Use, and Limitations of Data; Human Subjects Protection; and Evaluation.

The state's protocol is a document that should be the cornerstone of the state PRAMS operation. It is not intended to be developed and left unused. This protocol should be reviewed carefully, and tailored to each project by addressing each state-specific task. In addition, project staff should replace <STATE> throughout the body of the text and "PRAMS Model" in the footer sections with the project's state name. The protocol should be a constant source of information and should be amended or modified promptly as procedures change. As changes are made, the footer section should be updated as appropriate to indicate when the document was revised. The state-specific protocol will be reviewed during site visits by CDC PRAMS staff.

In addition to this protocol, several independent pieces of documentation exist to guide project staff in operations and training activities to assist in the successful implementation of PRAMS. These documents are distributed to each project area:

- ***PRAMS Implementation Manual*** provides specific guidance on the use of software, data collection and data management procedures, and other information needed for the implementation of the PRAMS system.

- ***PRAMS Interviewer Training Manual and Video*** are materials to guide the training of telephone interviewers.

- ***Guidelines for State Analysis of PRAMS Data*** provide a general overview of issues relating to PRAMS data analysis.

- ***CATI System "How to" Documentation and CATI Training Videos*** are materials to provide training for the standard CATI system.

- ***Human Subjects Training Manual*** provides a general overview of human subjects issues related to PRAMS and the measures employed to ensure protection of PRAMS participants.