Introduction to the Perinatal-20 Treatment Research Demonstration Program

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During the 1980s sufficient evidence accumulated to suggest that the use of cocaine and other illegal drugs by pregnant women presented a major public health problem (Frank et al. 1988; Neerhof et al. 1989). Prenatal alcohol and other drug abuse was occurring in all racial and ethnic groups and across all social strata. For example, the results of a study conducted in 1989 in Pinellas County, Florida, found that positive toxicology for illegal drugs varied little between women admitted to public health clinics for prenatal care and women seen in several private obstetric practices (Chasnoff et al. 1990).

In response, the National Institute on Drug Abuse (NIDA) undertook the support of research demonstration grant projects that focused on the treatment of drug-abusing pregnant and postpartum women and their drug-exposed offspring. The intent of this program was twofold: conduct treatment research and, at the same time, create many new treatment slots for the women and their children. Toward these aims, NIDA funded 10 projects in September 1989 and another 10 in September 1990, the sum of which became known as the "Perinatal-20 Treatment Research Demonstration Program" or "Perinatal-20" for short (see appendix for key Perinatal-20 personnel).

Each project was designed to scientifically evaluate either a comprehensive treatment program composed of an integrated system of services or a specific targeted therapeutic intervention embedded in a comprehensive continuum of care. Each study targeted either the drug-abusing woman of childbearing age (predominantly pregnant or postpartum) in treatment *with* her children or the woman in treatment *without* her children.

As slightly different research questions were addressed by one or more of the Perinatal-20 studies, each could be described as experimental, quasi-experimental, or correlative by design and be represented by one of the following:

Research Question 1:	What is the differential effectiveness of two types of treatment?

Example: Determine the differential effectiveness of a hospital-based *residential* treatment program (type 1) and a hospital-based *outpatient* treatment program (type 2).

Design Feature: Random assignment to each condition.

Research Question 2: What is the differential effectiveness of treatment-as-usual and treatment-as-usual plus enhancement?

Example: Determine the differential effectiveness of treatment for mothers in a therapeutic community with residence provided for the women but not for their children (*treatment-as-usual*) and treatment for mothers in a therapeutic community with residence provided for the women *and* their children (*treatment-as-usual plus enhancement*).

Design Feature: Random assignment to each condition.

Research Question 3: To what extent is type 1 treatment effective and to what extent is type 2 treatment effective when determining treatment outcome by use of a common set of intake and outcome measures?

Example A: Determine the effectiveness of an outpatient treatment program specializing in *women's services* (type 1) and the effectiveness of an outpatient treatment program based on a traditional model of *services for both men and women* (type 2).

Design Features: Nonrandomized, case-controlled, group comparisons.

Example B: Determine the effectiveness of an *outpatient* treatment program for mothers (type 1) and the effectiveness of a *residential* treatment program for mothers (type 2).

Design Features: Nonrandomized, case-controlled, treatment process study, with assignment of each woman to the outpatient program or the residential program based on the results of the intake assessment and clinical judgment.

Given that treatment research in this area was somewhat uncharted and certainly underdeveloped at the time the Perinatal-20 studies were first designed, many investigators said they might benefit from sharing

problems and solutions associated with their efforts to establish or expand a clinical site, integrate a research project within that site's daily operations, and conduct a study on a smooth and continuous long-term basis. Pooling knowledge and experience had the potential for a greater and more rapid yield than might otherwise occur if the 20 projects did not communicate until all study results were published.

Precedence was set for a cooperative examination of a variety of challenging issues asserted to be inherent in this area of research. In July 1990 a technical review was held on methodological issues in epidemiological, prevention, and treatment research on drug-exposed women and their children that resulted in the publication of a NIDA research monograph (Kilbey and Asghar 1992). Several Perinatal-20 researchers contributed to this earlier volume because they had already encountered some of the difficulties associated with conducting research in this area.

This volume presents a sample of what has been learned since then about the challenging areas of (1) services research implementation; (2) subject selection, recruitment, and retention; (3) clinical assessment and program evaluation; and (4) data management and statistical analyses. It anticipates that shared experiences, products, and procedures used in one or more of the Perinatal-20 studies might be of benefit to researchers, practitioners, and program administrators. Furthermore, it is hoped that the methodologies presented in this monograph can be of special value to those who wish to establish new services in combination with study protocols in clinical sites that heretofore have never participated in research.

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KEY: PI=current principal investigator; Co-PI=coprincipal investigator;
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