Issues in Subject Recruitment and Retention With Pregnant and Parenting Substance-Abusing Women

Judy Howard and Leila Beckwith

INTRODUCTION

A substance abuse treatment program probably has its greatest effect on individuals who participate in all treatment sessions and who continue with the course of therapy until it is completed. Thus, efforts to promote compliance and retention are crucial to an effective study of the effect of substance abuse treatment (Mrazek and Haggerty 1994). Such efforts require knowledge about the characteristics of the target population's lifestyle and needs. To help researchers and clinicians develop strategies for decreasing noncompliance and attrition, this chapter provides examples of how the lifestyle and needs of addicted women with children affect recruitment and retention in treatment research. Pregnant women and women of childbearing age present an array of real-life circumstances that challenge traditional models of substance abuse treatment as well as traditional means of recruiting and retaining subjects in research programs.

This chapter reviews a range of subject recruitment and retention issues specific to pregnant women and women of childbearing age who use illicit substances. Recruiting and retaining study participants overall, in the drug treatment field (Gilchrist and Gillmore 1992, pp. 1-17; Hansen et al. 1990; Stark 1992) and in many other areas of health research, pose difficult issues. For example, in a recent review of treatment research to reduce mental disorders, methodological problems recurred in a variety of studies (Mrazek and Haggerty 1994). The most frequently identified problems related to the difficulty of adhering to a strict randomized trial design and to high attrition among study participants. When subjects are substance-abusing women with children, these same problems commonly arise, but they often are made more complex because they occur in combination with a variety of other unique issues that relate specifically to this population.

SPECIAL ISSUES AFFECTING RESEARCH ON PREGNANT AND PARENTING SUBSTANCE-ABUSING WOMEN

Treating addiction is the core purpose of the Perinatal-20 Treatment Research Demonstration Program. Addiction arises out of multiple adverse circumstances and in turn sets the stage for further difficulties. Within the

populations studied by the majority of the Perinatal-20 projects, a variety of clinical issues were identified as complicating factors in research with this population, many of which stemmed from subjects' family histories and life circumstances. The majority of the addicted women recruited and enrolled in these projects had experienced harsh, abusive childhoods and had been reared by parents who were alcoholics or substance abusers and were unable to provide consistent care for their children. Moreover, the addicted women had experienced problems related to school achievement and employment. They also reported difficulty in establishing stable, supportive relationships with friends and significant others. During the time they participated in the research projects, most subjects were single parents living in poverty with several children, and they were frequently involved with the legal system. Their limited economic and psychological resources produced a broad spectrum of needs in addition to those associated with addiction.

Within this subject population, investigators delineated seven clinical factors that directly contributed to the extraordinary staff efforts needed to recruit and retain subjects in treatment research: (1) addiction severity level, (2) involvement with the legal system, (3) housing problems, (4) difficulties with interpersonal relationships, (5) parenting responsibilities, (6) employment-related issues, and (7) the need for many comprehensive services. Although these variables often cannot be controlled, they have a profound effect on subject retention and attrition and thus on the success of research evaluations. Accordingly, it is important to identify and code these factors to enable researchers to determine those that differentiate subjects who remain in treatment from those who do not (Reed and Grant 1990, pp. 10-56). Such comprehensive information also can help inform future research efforts in defining specific study samples and effective treatment components.

Addiction Severity Level

Addiction is a chronic, relapsing disease that in its most blatant form suppresses other personal goals and becomes the driving force that determines all activities in an addicted individual's life. Within this context, remaining in treatment and becoming abstinent occurs for only a minority of enrolled subjects during a defined time. Because of the way various research investigators view addiction, they approach subject retention in different ways. Some define it by both attendance in the program and abstinence, whereas others define it on the basis of attendance alone. Furthermore, some researchers consider abstinence as not using illegal drugs, whereas others feel that the use of alcohol constitutes a relapse. In still other cases, retention is defined as a subject's continuing willingness to participate in at least some components of the treatment program.

Strict retention guidelines that require both regular participation in the treatment program and abstinence or sobriety may result in the loss, dropout, or attrition of a majority of enrolled subjects. However, such strict guidelines also may better demonstrate the effectiveness of the treatment program by showing significant differences in outcome measures among study group subjects who are retained, subjects in the control group, and study group subjects who drop out.

On the other hand, the application of less rigorous retention guidelines also benefits research by adding new knowledge to the field, thus contributing to the development of appropriate services to treat the majority of women who form the attrition group and allowing investigators to trace patterns of relapse and recovery that can inform new treatment paradigms using different outcome measures. For example, there is a growing recognition in the field that addicted clients may need pretreatment services to help them work through denial and facilitate their commitment to abstinence. Development of pretreatment services and evaluation of their effectiveness may result from less restrictive retention guidelines.

Involvement With the Legal System

Because the use of illegal drugs involves illegal activities, many subjects are involved with the legal system, within either the criminal or civil courts. For example, among subjects who are involved with the criminal justice system, extended periods of incarceration often interfere with retention in a research study. In the authors' experience, a subject who was highly motivated to stop using cocaine attended treatment sessions regularly and remained abstinent during the last 4 months of her pregnancy; however, she relapsed just prior to delivery, with subsequent positive urine toxicology screens for herself and her infant at delivery. In spite of the positive toxicology screens, she was awarded custody of her infant because of her involvement in the treatment program. However, when the subject was discharged from the hospital, the maternal grandmother refused to allow her daughter and grandchild to live with her. Following this event, despite staff members' efforts to obtain housing, the subject resisted treatment services, eventually returning to the streets and addiction. She was arrested on drug-related charges, lost custody of her infant, and was incarcerated for 4 months. Thus, although intensive efforts on the part of clinical staff members had resulted in 4 months of abstinence for this subject, she ultimately was dropped from the study.

On the other hand, brief periods of incarceration do not necessarily end a subject's participation in a research program. However, such legal involvement can place extraordinary demands on clinical staff members who are attempting to decrease subject attrition. In another example from

the authors' project, an enrolled subject who experienced several brief periods of incarceration repeatedly called staff members from jail to express her desire to continue with substance abuse treatment and receive additional assistance from program personnel. The clinical staff members responded to her telephone calls from jail by making preparations for housing and treatment on her release. Invariably, when released from jail, the subject not only resumed program attendance but also returned to her familiar neighborhood and continued with her illegal activities, which resulted in repeated incarcerations. Thus, despite her stated willingness and attempts at attendance, after several months it became clear that this subject could not participate in treatment over the long term, and she was dropped from the study.

Another issue related to subject involvement with the legal system is child custody and mandated treatment. Not infrequently, addicted pregnant women or women who have lost custody of their children enroll in drug treatment programs to demonstrate to the court that they are trying to become abstinent. Furthermore, the court may mandate such participation for these women to maintain or obtain custody of their children. Sometimes, once the court makes its ruling regarding child custody, the subject drops out of the study because of lack of motivation, thus increasing attrition. For example, loss of child custody may precipitate a mother's decision to give up and not return to treatment. On the other hand, a court decision to award custody also may remove the motivation for undergoing treatment.

Housing Problems

It is critical for a subject to have a stable residence so that staff members can locate and contact her. Yet the housing problems commonly experienced by low-income substance-abusing mothers can place considerable demands on clinical staff members who are trying to maintain subjects in a research program. For example, in one study conducted by the authors, a subject was unable to continue making rent payments and was evicted from her apartment. She felt intimidated and was unable to secure a place by herself; she asked staff members to help her locate housing, make telephone calls to get information about rentals, and transport her and her infant to view prospective residences. In addition, she needed help in filling out rental application forms, acquiring furniture, and setting up the household. Similarly, clinical staff members assisted another subject in obtaining housing by reviewing advertisements with her and taking her to various neighborhoods to help her decide where she could live. In both these instances, staff members' efforts were rewarded, and the subjects were retained.

Difficulties With Interpersonal Relationships

Subjects' relationships with their significant others are an important part of their lives and therefore also affect their participation in research studies. Within the population reported here, these relationships often are marked by instability, discord, and in some cases, violence. For example, one subject was involved in a violent episode with her significant other during which, under the influence of cocaine, he broke down her front door and demanded money. Fearing for her own and her children's lives as he battered her, she stabbed him. The police were summoned, and the man was incarcerated. Following this incident, the subject required extensive support and one-on-one counseling from clinical staff members to recover from the emotional trauma, develop strategies to prevent its recurrence, and continue her participation in the study.

In another situation, staff members invested months of effort attempting to address the relationship problems between a subject and the father of her children. To retain her in the study, clinical staff members worked extensively with the couple, making numerous home visits and conducting couples counseling at the program site. Although the mother was the identified subject, her significant other used the program hotline extensively during all hours of the day and night because the subject frequently left him with the children when she was bingeing. Despite these efforts, maintaining the subject in this relationship failed, and staff members secured a placement in a homeless shelter for her and her children. Her attendance in the program increased after this placement, but because of the lack of social and family supports, she eventually decided to move to another area to be with her mother and was subsequently lost to the study.

Clinical services for this population often must be directed not only toward the subject and her significant other but also toward the subject's family of origin. Not infrequently, grandmothers provide housing and money to enrolled subjects and their children, and such enmeshment in this extended relationship can make unusual demands on the clinical staff. For example, after one subject was enrolled in the study, staff members became aware that she was violent and abusive toward her own mother and siblings. After staff members had worked closely with her and her family to obtain a psychiatric assessment as well as placement in an inpatient mental health facility, the subject disappeared. Although she was dropped from the study, her mother continued to seek assistance and counsel from the clinical staff in caring for her grandchild.

Parenting Responsibilities

Parenting responsibilities also present obstacles to attendance and compliance with drug treatment. In one instance, a subject was making good progress in recovery after participating for 6 months in a drug treatment program with her infant when, despite her wishes, the legal system returned her four older children to her custody. She had never had custody of all her children before. In this case, family reunification resulted in the subject's dropping out of the center-based day-treatment program and increasing demands on the clinical staff members, who helped this mother locate a larger apartment, apply for Aid to Families With Dependent Children, identify local schools for her children, and organize afterschool activities. Staff members also had to help her develop daily routines to shop, cook, and do laundry for her newly enlarged family, as well as provide inhome counseling to help her deal with the older children's behavioral issues. Because of these increased parenting responsibilities, the mother was no longer able to participate in the center-based program and had to be dropped from the study.

Thus, family reunification, which for many clients is a marker of success in a treatment program, also can result in subject attrition. Many subjects in the authors' attrition group were unable to coordinate their attendance at the day-treatment program with their responsibilities in caring for their children after kindergarten and elementary school. Although the program provided transportation and child care for one pre-school-age sibling beyond the focus (target in the research program) child, there were not enough resources to provide comprehensive child care (afterschool care) for the enrolled subjects' offspring. (These mothers had an average of three children of varying ages.)

However, for other subjects, clinical staff members' support of parenting responsibilities, when family reunification occurred, resulted in the mothers' recognition of the help that the program could provide, not only in maintaining abstinence but also in providing for the day-to-day needs of their children. For example, one subject disappeared from the authors' treatment program when she became overwhelmed with the responsibilities of caring for her new infant and 9-year-old son, who was reunited with her after having been in out-of-home placement for several years. Following family reunification, the 9-year-old exhibited a variety of behavioral problems at home, was absent from school for weeks on end, and acted out when he was in class. On the basis of recommendations made by program staff members after they lost contact with this subject, child protective services took custody of both children until the mother resumed her participation in the treatment program and demonstrated efforts at maintaining abstinence. Once this occurred, clinical staff members helped

this subject reach out to her own mother for support; the grandmother in turn assisted the mother as she planned for the safety and care of her children. This added support resulted in the subject's being retained in the study.

In summary, knowledge to date does not enable investigators in this field to determine which subjects will be able to work on recovery and parenting responsibilities simultaneously. Yet this is a critical issue in retaining parenting women in substance abuse treatment.

Employment-Related Issues

During the course of their participation in a research program, some parenting women who are receiving substance abuse treatment become legally employed. Generally, this is viewed as a measure of the subject's recovery, and treatment programs can count the subject's employment as a measure of success. However, within a research design that involves set times and days for treatment, employment schedules often conflict with the treatment protocol and thus push subjects into the attrition group. Nonetheless, some women are able to combine both treatment and employment. For example, one subject in the authors' project became employed as a home health care aide; her sufficiently flexible work schedule allowed her to perform her job duties (bathing and caring for elderly people in their homes) as well as continue her attendance in the research program.

Need for Many Comprehensive Services

Research demonstration projects that investigate treatment approaches for substance-abusing mothers require an extraordinary range of service components to promote subject enrollment and retention. When treatment efforts are directed toward pregnant women or women of childbearing age, basic parenting-related needs (e.g., child care; physical space for infants' and young children's sleep, eating, and play activities; transportation to day treatment centers) must be met if substance-abusing mothers are to be able to address their addiction through participation in appropriate treatment. Furthermore, in addition to having drug treatment counselors on staff, programs need to employ staff members who can provide child care while mothers are participating in substance abuse treatment sessions. Although it is physically possible for mothers to care for their own children during drug treatment sessions, it has been the authors' experience that this added responsibility increases mothers' stress and interferes with their ability to focus on critical issues of addiction and recovery. In addition, a child care component should encompass food, formula, child car seats, diaper bags,

clothing, toys, kitchen equipment, and appropriate furniture (including floormats, cribs, child-size tables and chairs, and potty chairs). Moreover, if parenting and health education are incorporated into the treatment design, additional space must be provided and staff members must be hired to provide these service components as well. Finally, the various activities of these interdisciplinary staff members need to be coordinated in an organized, integrated, and meaningful way to help subjects benefit more fully from program participation.

These types of service components are expensive and thus necessitate a small number of subjects within a study sample. However, the costs of providing such treatment for pregnant women may be offset by the reduced costs to society related to decreased perinatal complications for newborns during and after delivery and fewer inhospital days. For example, Lee and Svikis (1995, p. 482) compared health costs for the delivery of infants born to cocaine-abusing women who received drug treatment with those of cocaine-abusing women who did not receive drug treatment during pregnancy. Neonatal intensive care unit (NICU) use rates decreased by nearly 50 percent for infants whose mothers had been enrolled in drug treatment. The average length of stay in the NICU also decreased—6.5 days ($9,750) for infants of mothers in the treatment group vs. 41 days ($61,500) for infants of mothers who did not receive treatment. The average cost for drug treatment during pregnancy was $6,700 per mother.

Despite this evident cost-effectiveness, one strategy for reducing the number of research dollars required for research demonstration projects is to fund discrete studies collocated within ongoing treatment programs. This approach can involve hazards if the continuing treatment program and the research team have not established mutual goals, mutual trust, and a similar philosophy of treatment. On the other hand, if there is close collaboration between the research and clinical teams, this solution for decreasing costs per study may be effective, thus enabling more research to be conducted.

SPECIFIC ISSUES AFFECTING RECRUITMENT

Samples of Convenience

As in any field of study, it is useful in addiction research for investigators to examine recruited samples that span the full range of the disorder (Mrazek and Haggerty 1994). If, for various reasons, samples are biased—as they were among the majority of the Perinatal-20 projects, which

included only low-income, chronic, heavy users in their midtwenties to late twenties—then study results cannot be generalized across the broader population of addicted women of childbearing age (Gorelick 1992).

Because almost all Perinatal-20 study samples were recruited on the basis of referrals from public health or social services agencies, they are biased but convenient samples. This method of recruitment allowed investigators to recruit quickly from populations that have a visibly high rate of addiction. Problems related to addiction were already fairly certain among referred subjects because public health and social services agencies have been making efforts to identify addiction among pregnant women or women with children throughout the past decade.

Despite these convenient samples, after referral the research teams had to follow their own protocols for inclusion criteria, which incorporated a toxicology screen (e.g., urinalysis, analysis of meconium, hair analysis, self-report). Although the decision to use one or more of these specific criteria was simple, implementation of screening procedures was more or less difficult, depending on the referred sample. Recruiting from large county hospitals or child protective services agencies—rather than from many small, private sector providers, for example—yielded a higher rate of return for staff time invested and resulted in a lower subject recruitment cost. Conversely, recruiting from the private sector forced investigators to solicit across a larger number of agencies and to educate staff members, monitor testing, and in some cases, institute toxicology screens and interviews within the offices of a larger number of referral sources—all with a potentially low rate of return.

Although diversity of samples within a field of study is valuable, within an individual research demonstration project, homogeneity of client characteristics is a necessary requirement to control for intrinsic variability, which would swamp the observed effects of treatment. For instance, current research contains a paucity of information about the effectiveness of treatment for mothers who are just beginning to use drugs. Furthermore, little is known about the extent and severity of addiction among adolescents and young women or about effective treatment for these groups. Moreover, treatment studies of women who have greater economic and psychological resources are lacking as well. To remedy limitations related to recruitment of convenient samples and in recognition of the importance of studying a broader range of substance abusers while still constituting homogeneous study groups, future requests for proposals should encourage and support researchers in identifying and recruiting subjects from more diverse segments of the population. Unless this effort is made, future investigators are likely to continue to study only the limited, convenient sample that has been most widely researched to date.

Maintaining a Strict Randomized Design

A strict randomized trial design that includes a formal retention protocol and a designated duration of treatment also is necessary to ensure study validity. It is also necessary to describe how many participants were recruited, how many were screened, how many passed and how many failed the screening, how many consented to participate in the study, and why refusals occurred. After enrollment, it is important to assess how many subjects entered their assigned randomized groups and why others did not. After group assignment, it is critical to determine how many subjects completed the program and why others did not. Finally, researchers also should examine the baseline factors that were linked to dropout and determine whether they were the same for the experimental and comparison groups (Mrazek and Haggerty 1994).

Such stringent requirements may challenge the morale and cooperation of researchers and clinicians who are working together in treatment research (Howard et al. 1990, pp. 66-79). Thus, to ensure a successful project, both groups must be informed about the research plan and objectives and be enthusiastic about and committed to study goals. They also must recognize the necessity of adhering to the research design and the consequences of deviating from it (Mrazek and Haggerty 1994). However, even when such initial agreement is present, there commonly exists a basic tension between research requirements and clinical services and needs (Sacks 1983). Although it is difficult to lessen these types of tensions, it is imperative that investigators consider these problems and make efforts to prevent or contain them to maintain a study design that will enable an evaluation of treatment effectiveness. Even when research investigators are not able to control external forces, these factors at least should be recorded to inform future studies. There are at least three levels on which such tensions may occur.

Clinical Staff. Substance abuse treatment research is no different from research in other clinical fields, insofar as conflicts often emerge between the clinical staff and the research design. These conflicts may arise even before data collection is initiated, when an investigator is trying to select an appropriate individual to conduct recruitment—a task that is crucial to the success of any study. On the one hand, a researcher-recruiter understands the need to fill both the treatment and control groups equally but may not possess sufficient clinical acumen to interest subjects in participating. On the other hand, a clinician-recruiter may be able to increase the participation rate but may resist enrolling subjects in the control group. In the authors' Perinatal-20 project, for example, the decision was made to employ a drug treatment clinician-recruiter.

However, because of ambivalence about the research design, this individual impeded recruitment for both treatment and control subjects. Her growing frustration about her lack of control over random client assignment to the experimental or community comparison group and her emerging belief that experimental subjects received more effective and appropriate services eventually resulted in her hesitancy about recruiting subjects for fear that they might be assigned to the control group.

Another conflict between the research design and clinical staff may arise when clinical staff members' perceptions about good clinical care run counter to the research treatment protocol. For example, one pregnant, cocaine-addicted woman who continually expressed interest in participating in a study involving day treatment attended sporadically and did not keep her prenatal obstetric appointments. When she delivered her infant, who tested positive for cocaine metabolites at birth, clinical staff members felt that this subject could no longer benefit from the program's services and referred her and her newborn to a residential drug treatment program in the community. After this woman had remained abstinent for 6 months, one of her three older children also joined her and her infant in this residential treatment setting. However, despite this positive outcome, which occurred as a result of the efforts of the study's clinical staff members, for research purposes this subject had to be counted as a member of the attrition group. In another case, also based on the perceptions about appropriate clinical care of this same clinical team, another client, who had a similar pattern of noncompliance in the day treatment program, was referred to another community-based residential program. After 6 weeks, this subject left the residence without permission and was terminated from the residential service. She recontacted the day treatment staff, admitted to living in a crack house and using crack cocaine daily, and stated that she was not interested in a second referral for residential treatment. She told the clinical staff, "I do not need a drug program. What I need is a place to live with my kids, and then I'll be able to stop using drugs on my own." Although the therapeutic outcome for this subject was not successful, once again research rules required that she be included as a member of the study attrition group. In most cases substance abuse treatment professionals are not yet able to determine precisely which subjects will benefit from specific treatment modalities (e.g., day treatment, residential treatment, transitional housing, therapeutic community, etc.). Thus, clinical staff members must be aware of what is known and what is not yet known in the substance abuse treatment field so that the research design is not unnecessarily compromised (Price and D'Aunno 1992, pp. 37-60).

Statistical considerations within the research protocol also may cause dissension between the research design and clinical staff members.

For example, in the authors' project that had a designated treatment period of 18 months, some subjects delivered two children within that interval. Although, for purposes of research, only the first child was considered the target child, clinical staff members felt an ethical responsibility to focus as much effort on the new babies as on the designated target children. Clinical staff members and mothers alike pressured research staff members to conduct research assessments of these younger siblings, which restricted the research staff members because of the extra time and money required to perform these additional evaluations. Furthermore, the data related to these second children could not be included in statistical analyses because of the need to exclude correlated data.

Referring Community Professionals. When the research design includes a control or comparison group, tensions may develop between the program and community professionals who refer subjects to the study. Because community professionals want to secure the best possible treatment for people in need, they may resist referring clients to a research program where there is random assignment to a control or comparison group. In addition, referring parties may try to pressure clinical staff members or negotiate services for those subjects who are assigned to the control or comparison group. These circumstances can undermine clinical staff members' confidence in the research program and can place stress on staff morale if it calls into doubt the community's regard for the value of the program with which staff members are associated.

Study Subjects. Some study subjects also experience tensions associated with a research design that involves random assignment. For example, experimental group subjects who value the intervention services they are receiving commonly want to refer friends to the program but only if they can be assigned to the intervention group. If random assignment places a friend in the control or comparison group, the referring subject may pressure clinical staff members to provide additional services. For example, in the authors' experience, where groups comprise women randomly assigned to residential treatment programs with and without their children, mothers assigned to the group that did not include children expressed guilt and concern about how the study may have interfered with their maternal responsibilities. Likewise, within a program where residential treatment was compared with outpatient or day treatment, tensions developed when women did not like their assignments and requested to transfer to the other treatment option.

Resentment or ambivalence about prescribed treatment in a population that over the past decade has become more knowledgeable about treatment options can contribute to attrition. Attrition represents an additional potential bias because subjects who remain in a study may

differ generically from those who do not. In one Perinatal-20 project, the majority of subjects who stayed in treatment had reported more psychological distress and less independence at the onset of their participation in the study than the women who rejected treatment (D. Haller and S. Schnoll, personal communication, June 16, 1994), whereas other studies have found different factors to be associated with retention (Gainey et al. 1993; Kleinman et al. 1992; Stark and Campbell 1988; Williams and Roberts 1991). These findings emphasize the importance of including sufficient and appropriate baseline measures—such as measures of intelligence, personality, and social supports—to enable researchers to determine potential biases in samples related to retention and attrition (Mrazek and Haggerty 1994).

ETHICAL ISSUES

Ethical concerns, which are inherent in conducting treatment research with substance-abusing populations, arise out of many of the issues described above. First, research to date has not clarified specific types of treatment approaches that are effective in meeting specific client needs. Investigators can be caught between this lack of empirical knowledge and clinical staff members' perceptions about subjects' treatment needs, particularly when staff members feel that a subject requires interventions that lie beyond the research parameters. For instance, clinical staff members who provide day treatment may perceive that a subject's addiction is so out of control that, in their clinical judgment, she requires residential treatment to separate her from a high-risk environment. Such anxiety on the part of clinical staff members then poses an ethical issue for the principal investigator, who must weigh the need to retain subjects and ensure the integrity of the project vs. the risk of providing insufficient or inappropriate treatment, when current knowledge provides no clear guidelines regarding this treatment option.

A second ethical question relates to the termination of pregnant women from treatment studies because of relapse. Even during periods of noncompliance, a woman's enrollment in substance abuse treatment may have a mitigating effect on her level of drug use. Because of concerns about a possible association between higher levels of drug use and premature labor and delivery, staff members may have strong concerns about the consequences of a subject's potential escalated drug use once she is terminated from a study and finds herself in an unsupervised situation and without the medical and supportive services that the program provides. From this point of view, although the study design may consider only the woman to be the subject of the treatment research, in reality she and her fetus cannot be differentiated as a treatment unit. The resulting ethical

dilemma relates to maintaining the integrity of the research retention protocol (i.e., adhering to termination guidelines) vs. potential damage to the fetus, who is at high risk for preterm delivery.

A third ethical issue relates to the role of the investigator when a subject is involved with the legal system because of child abuse and neglect. For many such subjects, the civil court and child protective services agencies determine whether the mothers retain custody of their children. Frequently, the court may mandate participation in a drug treatment program as a condition for either obtaining or maintaining custody. However, obeying the court order to obtain custody may conflict with a mother's participation in a research demonstration treatment study. Two situations highlight this point. First, if the court stipulates drug treatment as one of the conditions for child custody, random assignment to a control group that does not receive treatment in cases where drug abuse treatment is part of the study design would violate this mandate. Second, if a research project offers residential treatment with random assignment to groups that do and do not include children, and the judge awards child custody to a mother on the condition that she enroll in drug treatment, the subject faces a dilemma if she is randomly assigned to the treatment group that does not include children. How does she comply with the court order to enter treatment and maintain custody when random assignment may place her in a situation where she can receive treatment but is not allowed to live with her children while obtaining treatment?

A related but separate situation may arise when a mother does not have custody of her children on entrance into a research demonstration study, but later, when she begins to recover from her addiction, the court is pleased with her progress and returns the children to her custody. In such cases, a subject not only may feel overwhelmed by her struggle to maintain abstinence (although she is successful to date) but also may be reluctant to tell the court that she is not yet ready to assume the added responsibility of day-to-day parenting for fear of permanently losing custody of her children. What priority is placed on the mother's efforts to become well? At what point during a subject's recovery is she ready to successfully take on the responsibilities of parenthood? Furthermore, should research investigators attempt to negotiate with the courts to foster subject retention and support staff members' efforts to provide effective substance abuse treatment?

These are some ethical concerns faced by investigators involved with this population. Future studies may be able to circumvent some of these difficulties by carefully considering them in advance, deciding on practical solutions, and addressing these issues in the consent form signed by each research subject at the time of enrollment. For example, such statements might include the following:

- Termination from the project may occur if the treatment staff members perceive that another form of treatment will be more helpful to you. If this occurs, staff members will recommend programs that offer the preferred method of treatment.

- Relapse may be a condition for termination from the study. If you are pregnant at the time of relapse, staff members will refer you to a health care facility that has agreed in advance to provide necessary medical services to promote the health of you and your baby. Staff members also will refer you to other available drug treatment programs.

- Your participation in this substance abuse treatment program is separate from any involvement that you may have with the legal system regarding your addiction. Program staff members will not communicate with the court about your drug use or your recovery from addiction. If the court requires reports about your drug use, we will refer you to other drug treatment programs. However, if you agree to participate in our program, we *will* communicate with the legal system about any incidence of suspected child abuse or neglect, as required by State law.

  Or

- Besides reporting any incidences of suspected child abuse or neglect, program staff members will comply with court requests for information about your substance abuse and your efforts at recovery. As required, staff members also may report such information at custody hearings. However, the court will base its decisions on all the information it has regarding your case, and not on our reports alone.

SUMMARY AND CONCLUSIONS

To advance knowledge about the treatment of addiction among pregnant women and other women of childbearing age, investigators must adhere to the requirements of a strict experimental research design while concurrently providing clinical services. This means that researchers must address a variety of difficult questions, including the following:

- Was the sample large enough?

- Were the criteria for subject inclusion and exclusion well defined?

- Did the process of recruitment result in a sample that could be generalized to a larger population, or was the sample biased in some way?

- Was assignment to groups clearly random?
- What was the attrition rate?
- Was attrition the same in both experimental and comparison groups?
- Did baseline measures collect enough information to permit a description of the factors that were associated with attrition in each group?
- Was the attrition rate so high that the retained sample had special characteristics? If so, what were these features?

This chapter highlights several problems related to these questions, describes the difficulties that investigators have faced in meeting clinical and research challenges to date, and suggests strategies for overcoming some obstacles.

In establishing the Perinatal-20 project, the National Institute on Drug Abuse took an informed first step in organizing a substantial research effort to investigate treatment modalities that incorporate services specific to the needs of substance-abusing women who have children. This initial effort has resulted in a beginning knowledge base that can be used to refine and expand future treatment efforts. Even the issue of the "study unit" for this population is evolving. Today's researchers are attempting to determine whether the mother alone or the mother along with her dependent children constitutes the study unit. This question also has led professionals in the field to examine a range of specific outcome priorities, and investigators just now are beginning to determine exactly what needs to be evaluated in gauging the effectiveness of treatment. Is success measured on the basis of the woman's progress with abstinence alone, or does it also include her role with her children? Is it determined on the basis of her relationship with her children or the children's growth and development? Compared with providing services for and studying single adult subjects, developing treatment for women and their children presents researchers with a more complex task and requires expanded clinical services (Gallagher 1990, pp. 540-559).

As in most fields of study, initial research data in substance abuse treatment for pregnant and parenting women are derived from samples of convenience, as described above. To put this information in perspective, future research will require a wider and more representative spectrum of the population. Furthermore, tensions between clinical needs and research requirements must be considered in advance, and methods for relaxing these tensions will be critical to the success of future efforts. For example,

members of both the research and clinical staff teams must be absolutely clear about the study design and the requirements of reliable research. Where possible, potential ambiguities about group assignment, project services, subjects' responsibilities, and so forth must be incorporated into subject consent forms so that the subjects also are apprised of potential problems and their solutions. A final caution to future investigators is to be aware of the economic, physical, and personnel limitations of the range of treatment services that can be provided in a research demonstration study involving this population. Because of these limitations and the extensive range of services the subjects of the studies require, treatment components must be discrete and carefully defined to prevent programs from becoming impractically diverse and unclear. Research goals must be attainable and measurable. Finally, researchers must not underestimate the contribution that a small but well-designed and well-described study can make to this developing field.

REFERENCES

Gainey, R.R.; Wells, E.A.; Hawkins, J.D.; and Catalano, R.F. Predicting treatment retention among cocaine users. *Int J Addict* 28(6):487-505, 1993.

Gallagher, J.J. The family as a focus for intervention. In: Meisels, S.J., and Shonkoff, J.P., eds. *Handbook of Early Childhood Intervention*. New York: Cambridge University Press, 1990. 760 pp.

Gilchrist, L.D., and Gillmore, M.R. Methodological issues in prevention research on drug use and pregnancy. In: Kilbey, M.M., and Asghar, K., eds. *Methodological Issues in Epidemiological, Prevention, and Treatment Research on Drug-Exposed Women and Their Children*. National Institute on Drug Abuse Research Monograph 117. DHHS Pub. No. (ADM)92-1881. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1992.

Gorelick, D.A. Sociodemographic factors in drug abuse treatment. *J Health Care Poor Underserved* 3(1):49-58, 1992.

Hansen, W.B.; Tobler, N.S.; and Graham, J.W. Attrition in substance abuse prevention research: A meta-analysis of 85 longitudinally followed cohorts. *Eval Rev* 14(6):677-685, 1990.

Howard, K.I.; Cox, W.M.; and Saunders, S.M. Attrition in substance abuse comparative treatment research: The illusion of randomization. In: Onken, L.S., and Blaine, J.D., eds. *Psychotherapy and Counseling in the Treatment of Drug Abuse.* National Institute on Drug Abuse Research Monograph 104. DHHS Pub. No. (ADM)91-1722. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1990.

Kleinman, P.H.; Kang, S.Y.; Lipton, D.S.; Woody, G.E.; Kemp, J.; and Millman, R.B. Retention of cocaine abusers in outpatient psychotherapy. *Am J Drug Alcohol Abuse* 18(1):29-43, 1992.

Lee, J.H., and Svikis, D. Cost-effectiveness of comprehensive care for drug-abusing pregnant women. In: Harris, L.S., ed. *Problems of Drug Dependence 1994: Proceedings of the 56th Annual Scientific Meeting, The College on Problems of Drug Dependence, Inc., Volume II.* National Insitute on Drug Abuse Research Monograph 153. NIH Pub. No. 95-3883. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1995.

Mrazek, P.J., and Haggerty, R.J., eds. *Reducing Risks for Mental Disorders: Frontiers for Preventive Intervention Research*. Institute of Medicine. Washington, DC: National Academy Press, 1994. 605 pp.

Price, R.H., and D'Aunno, T.A. The organization and impact of outpatient drug abuse treatment services. In: Watson, R.R., ed. *Drug Abuse Treatment. Vol. 4. Drug and Alcohol Abuse Reviews.* Totowa, NJ: Humana Press, 1992.

Reed, R.J., and Grant, I. The long-term neurobehavioral consequences of substance abuse: Conceptual and methodological challenges for future research. In: Spencer, J.W., and Boren, J.J., eds. *Residual Effects of Abused Drugs on Behavior*. National Institute on Drug Abuse Research Monograph 101. DHHS Pub. No. (ADM)91-1719. Washington, DC: Supt. of Docs., U.S. Govt. Print. Off., 1990.

Sacks, M.H. The interaction between clinical research and treatment. *Hillside J Clin Psychiatry* 5(2):169-176, 1983.

Stark, M.J. Dropping out of substance abuse treatment: A clinically oriented review. *Clin Psychol Rev* 12(1):93-116, 1992.

Stark, M.J., and Campbell, B.K. Personality, drug use, and early attrition from substance abuse treatment. *Am J Drug Alcohol Abuse* 14(4):475-485, 1988.

Williams, M.T., and Roberts, C.S. Predicting length of stay in long-term treatment for chemically dependent females. *Int J Addict* 26(5):605-613, 1991.

AUTHORS

Judy Howard, M.D.
Professor of Pediatrics
(310) 794-1456 (Tel)
(310) 206-4215 (Fax)

Leila Beckwith, Ph.D.
Professor Emeritus
(310) 794-1456 (Tel)
(310) 206-4215 (Fax)
lbeckwith@ucla.edu (Internet)

Child Development Studies
Department of Pediatrics
University of California, Los Angeles School of Medicine
300 UCLA Medical Plaza, Suite 3300
Los Angeles, CA 90095-7033

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