Two Therapeutic Communities for Substance-Abusing Women and Their Children

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INTRODUCTION

How does one design and implement a randomized clinical trial in a therapeutic community (TC)? This was the question confronting two Perinatal-20 Treatment Research Demonstration Program grantees, Amity, Inc., in Tucson, Arizona, and Operation PAR, Inc., in St. Petersburg, Florida. This chapter describes the issues encountered by these two agencies in developing clinical laboratories for research demonstration programs in two TCs for substance abusers. Some of the problems were readily worked through, but several remain.

Both research demonstration programs proposed randomized clinical trials to determine the efficacy of permitting substance-abusing women to bring one or more of their children to live with them in a TC. The idea had its origins in the 1960s when Synanon allowed some staff members and residents to bring their families to its California TC to live, realizing that some women would not enter the program if they could not bring their children. Even with the addition of children, Synanon was still primarily a male-oriented model and did not focus on the family unit. Although an etiological study of the children raised in the community was conducted (Missakian 1976, 1977),[1] no formal research was conducted on the effect of resident family members on treatment outcome for the women (Yablonski 1989).

Odyssey House in New York City appears to be the first TC to evaluate the effect of admitting children in a National Institute on Drug Abuse (NIDA)-funded demonstration program in the late 1970s. Cuskey and associates (1979) evaluated the program and found that substance-abusing women admitted to this TC—primarily women with children, pregnant

[1]Dr. Elizabeth Missakian received a National Institute of Mental Health grant to conduct an etiological study of children raised in a TC. Synanon designed an extensive kibbutz-like school at its Tamalas Bay, California, facility, which at one point had 160 children ranging in age from newborns to 17-year-olds. Outcomes showed that the children raised in the Synanon school scored as high as, and in many cases higher than, children raised in high socioeconomic status households in Marin County, California, on measures of emotional, psychological, and academic functioning.

women, or pregnant women with additional children—had better-than-expected postdischarge outcomes. Improved outcomes included decreased substance use and criminal behavior, increased employment, and improved self-concept, mother-child relationships, and parenting skills. In addition, these outcomes improved with longer stays in the residential program.

In 1982 Amity permitted women to bring their children into its TC residence and found that the women dramatically increased their length of stay (Stevens et al. 1989). Given the promising results of these initial programs, the authors felt further investigation was indicated.

The shared hypothesis of the two studies stated that admitting substance-abusing women into a TC with their children would increase the women's retention in treatment and would improve the long-term outcomes for them and their children. The authors felt a randomized clinical trial design would be optimal, but the literature contained few precedents for clinical trials within TCs. Bale and colleagues (1980) randomly assigned substance-abusing male veterans to varying modalities, including a TC. More recently, De Leon (1991, pp. 218-244) compared approaches to initial socialization into a TC by offering different approaches to admission cohorts during alternate months. However, no studies in the literature reported randomly assigning participants to different treatment conditions within a TC.

This chapter describes how Amity and Operation PAR developed laboratories in their TCs for randomized clinical trials to test the hypothesis explained above. Problems encountered and their solutions also are described. The chapter also discusses the implications of the authors' joint experiences for future treatment research in TCs.

IMPLEMENTATION OF THE DEMONSTRATION RESEARCH PROGRAMS

Study Design

A randomized, open treatment trial was the design selected by both Amity and Operation PAR. The studies hypothesized that women who were permitted to live in a TC with one or more of their children would stay in treatment longer and have better posttreatment outcomes than women who received the standard TC treatment (no children).[2] Improved

[2]In the standard TC, women must enter without their children. This means that a woman must place her child(ren) either with family members, often the very individuals who abused the woman as a child

outcomes mean less substance use and illegal activity and better attitudes toward parenting and child-rearing, employment, and other social activities. Women who agreed to participate and met eligibility criteria were randomly assigned to (1) the demonstration program with infant and child care available (experimental group) or (2) the standard TC without child care (control group). Eighteen months of residential care was projected for both treatment groups.

Eligibility criteria differed in the two research demonstration programs. Both programs required that women have custody of their children or legal permission to admit them to the TC and have no legal constraints that required incarceration following treatment. Operation PAR required that women be 18 years or older and meet Diagnostic and Statistical Manual of Mental Disorders (Third Edition-Revised) (American Psychiatric Association 1987) criteria for cocaine abuse or dependence. Amity admitted women who were 18 years or older with a history of abusing any type of substance (including alcohol), although several adolescents (ages 15 to 17) also were included.

Both programs allowed each woman to bring up to two infants or children into residence. Amity set the child's upper age limit at 8 years; Operation PAR allowed children up to 10 years of age to live with their mothers. Pregnant women were not included in the Amity study.[3] Participants with serious or life-threatening medical problems—other than those who were asymptomatic HIV positive—were not eligible for either program. An exception was if a child or mother became ill while in the program. One participant at Amity gave birth to a severely medically compromised infant. The mother and child remained in the program, receiving all needed care and support.

Treatment Conditions

Amity operates two TCs in Tucson with a joint capacity of 220 beds (120 in the men's facility and 100 in the women's facility). The programs are located on two former guest ranches, separated only by a road. This proximity allows for joint programming and special community events. In addition, both the men's and women's programs have a similar

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and/or who led her into substance abuse, or in foster care. Many women who have already lost their children to child protective services have no voice regarding what happens to their children when the women enter treatment.

[3]Pregnant women were not allowed into the Amity study because Amity staff members felt it would not be ethical to randomly assign a pregnant woman to the control group (no children) and thus have to remove the child from the mother after birth. To compensate for this, Amity wrote a proposal for and received a demonstration grant from the Center for Substance Abuse Treatment to provide residential treatment to pregnant and postpartum women and their children.

curriculum and programmatic structure, although sex-specific activities have been added for the women. Special buildings in the women's facility (with a capacity for housing 40 women and 80 children) were designated for use by study participants. Amity's developmental learning center at the women's facility provides specialized services throughout the day, after school, and on weekends for children in residence and for those who visit. Standardized developmental assessments are completed on each resident child on a quarterly basis. Staff members work to meet the needs of mother and child individually and as a family unit. Staff members for both the women's and children's components include academically trained professionals with degrees in social work, education, and nursing as well as experienced staff members who are certified substance abuse counselors and are credentialed by Therapeutic Communities of America, Inc. (TCA).

PAR Village is the Perinatal-20 treatment demonstration component of Operation PAR's 149 adult-bed TC in Largo, Florida. The Village permits women to live with their children while they participate in residential treatment. PAR Village is separated from the main TC grounds by a small pond and a 1-minute walk. It is composed of 14 houses with a capacity of 14 women and 28 children younger than 10 years. Operation PAR's child development center (CDC) occupies one building in the Village. It was licensed by the local government as a day care facility and had a capacity of 35 infants and preschool children. CDC activities were supervised by an experienced clinical social worker, and the staff included eight early childhood specialists and a master's-level clinical supervisor. Using standardized instruments, developmental specialists conducted individual assessments of each child. The child's developmental intervention plan was formulated with the participation of the mother. A developmental pediatrician visited once or twice a month to perform developmental evaluations and prescribe special interventions. A developmental psychologist visited weekly for additional testing and to focus on mother-child interactions and bonding.

Both Amity and Operation PAR had experience in developing special programming for substance-abusing women before implementing this study. Amity had made this a special emphasis beginning in 1981 and by 1982 had doubled the number of women participants. From 1982 to 1987 Amity permitted a few women to bring their children to live with them in the TC (Stevens et al. 1989); therefore, experienced staff members were available to begin the project in 1990. Operation PAR established its first program to meet the special needs of substance-abusing women and their children in 1987 so that experienced staff members were available to implement the demonstration program in 1989.

The general design of the program for women and children was similar in both the Amity and Operation PAR programs. Women in the experimental and control groups participated in the same habilitation activities and attended the same therapy groups and parent training classes. The major parameters of the 18-month TC programs adhered closely to the model described by De Leon and Rosenthal (1989, pp. 1379-1396).

The only differences for women in the experimental and control groups were the living quarters and the availability of onsite child care for the experimental group. Amity offered several housing configurations for women with children. In some, two women shared a bedroom, and their children shared adjoining bedrooms. In others, a woman and her children shared a bedroom as did other mother-child families in a house, with all families sharing the kitchen and family room. At Operation PAR, most experimental group women had one bedroom for themselves and an adjoining bedroom for their children, sharing a common kitchen and family room with another woman and her children. The pattern also varied, with some women sharing a room with their children; some houses were large enough for three or four women with their children.

Women in both programs were expected to take their children to the CDC in the morning, pick them up by 4 p.m., and care for them during evenings and weekends. At PAR Village, women were responsible for arranging pediatrician visits and babysitting, if they wished to attend a meeting during the evening or on the weekend. Babysitting was provided by community volunteers and TC participants who had received babysitting training.

The Amity control group women lived at the same facility as the experimental group women; however, they generally were housed in separate buildings. Women in the control group at Operation PAR slept in a 20-bed building on the adjoining TC campus, with an average of 6 to 8 women to a room. Consistent with the usual TC practice, control group women in both the Amity and Operation PAR programs did not live with their children. Their children resided with family or friends or in foster homes and were brought to the TC to spend time with their mothers during visiting hours. At Operation PAR these children were allowed to participate in outpatient groups held several times weekly for all children whose mothers lived at the TC. Transportation was provided for these groups.

IMPLEMENTING THE DEMONSTRATION PROGRAMS: PROBLEMS AND SOLUTIONS

Facilities

Although some remodeling was required at the Amity facility to accommodate children, the first cohort of women was admitted into the program and moved to the facility within 3 months of the grant award. These women assisted in readying the property for their children. All necessary licenses for occupancy and provision of services were already in place and covered the new program. Therefore, there were no facility-related delays in program implementation for Amity.

PAR Village also was able to implement its program quickly. Although full construction and renovation of the houses at the Village were required, work progressed quickly enough to begin admitting women and children 7 months after formal notice of the grant award. As a nonprofit community agency, Operation PAR was able to avoid the red tape that would have been inevitable if the facilities had been acquired by the local government or a university. Operation PAR was able to negotiate with a nearby city government to acquire 14 houses scheduled for demolition, obtain funds to move them to the TC campus, and then renovate them to meet programmatic, zoning, and licensing requirements.

Personnel

Both Amity and Operation PAR had the staff depth needed to expand the TC program to meet the special needs of women. For Amity, no new staff members were required to work with the women; experienced staff workers in other special programs for women were moved to this program. At PAR Village, women were served by existing TC counselors; about half were male.

Experience and expertise for infant and child care were limited at both programs. Amity had only one special education teacher, who became the program manager for the children's program. Operation PAR had only one child therapist. In addition, the new programs were to be broader in scope and more intensive than these staff members had previously experienced. Both Amity and Operation PAR had to recruit an entire team for their children's programs. The teams had to be trained not only in specific job responsibilities but also in the TC model and women's substance abuse issues.

Program for Infants and Children

Although Amity had previously provided the opportunity for some children to live with their mothers, a proposed therapeutic learning center for this program had not been established. This necessitated the development of a children's program in its entirety (i.e., facility, staff, curriculum).

Operation PAR already had established a child day care center for outpatient substance-abusing women in 1987 and had experience in acquiring age-specific furniture, educational materials, and toys. However, this program also included infants with perinatal cocaine exposure and provided an 8-hour-per-day learning environment. PAR Village staff members screened each child to identify developmental problems and establish individual treatment plans. The infants program was staff intensive: Local regulations required 1 trained staff member for every 3 infants younger than 12 months, for every 5 children between ages 13 and 24 months, for every 10 children ages 25 to 36 months, and for every 15 children older than 3 years. Because of the special needs of some children, it was often necessary to have a higher staff member-to-child ratio than regulations required.

Both programs provided for the physical safety of the children. Because the mothers and other participants were serious substance abusers who had been victims of sexual violence and other abuse and had neglected their families, safeguards were required to protect children from abuse. Procedures were introduced at Amity and Operation PAR to screen all residents for history of child abuse and potential for future abuse. Differences in the physical facilities at Amity and PAR Village led to different solutions. At Amity, the main TC campus was physically separate from the perinatal program, so it was possible to provide security by not permitting participants identified as potential child abusers to visit the perinatal program facility. At PAR Village the perinatal facilities and main TC campus were adjacent to one another, and the two programs were fully integrated. Therefore, it was necessary to transfer several PAR Village residents to other programs and to screen future admissions for child abuse potential. All participants (male and female) were educated regarding appropriate behaviors and language to use when in proximity to young children.

Program for Women

One of the major problems encountered by both programs was the issue of special privileges for women with children. Although TCs believe that all individuals are entitled to enter the TC if they are interviewed and found suitable by other participants and the staff, once individuals are in

the program, all their privileges must be earned. Everyone starts at the bottom and works up. Certainly one of the greatest privileges is for mothers to have their children live with them. The random assignment of women to the experimental or control group removed the community "clinical judgment" regarding the readiness of the women to receive this privilege. This goes against one of the most central tenets of the TC—that privileges must be earned and must be acknowledged by the community. An additional tenet of the TC dynamic is that residents be treated fairly and equally. That some women should receive superior or inferior treatment is an affront to these principles. Experimental group women required time for care of their children, so they had to be freed from some responsibilities assigned to control group women without children. They were given privileges such as additional snacks and rest periods. The living accommodations for women with children permitted greater privacy. Experimental group women were seen as receiving these rewards without working for them. Some women who did not have their children with them raised the issues of fairness and special treatment.

Clinical staff members were concerned about the negative consequences for children when their mothers had to be terminated from treatment for noncompliance or a major rule violation. For this reason, some Amity staff members were initially overprotective of the children by not permitting mothers to make mistakes and overlooking violations, which caused some experimental group women to believe and act as if they did not have to follow TC rules. At first, some of these women felt they should receive special treatment for participating with their children and providing research data.

To address the variety of issues raised by the demonstration programs, the following steps were taken at Amity (A) and/or PAR Village (P):

- Schedules were rearranged for *all* women in the program (experimental and control groups) so that women with children were neither missing out on essential curriculum components nor being dismissed from duties that all TC participants were expected to do (A, P).

- Parenting classes were provided for all participants, including those who were not in the demonstration program (P). All women (experimental and control groups) received parenting classes (A).

- Emphasis on staff training and TC resident curricula focused on helping the women take responsibility for their own decisions and behaviors as well as helping each other be accountable (A).

- Babysitting training classes were offered to all appropriate TC residents, and a roster of evening sitters was developed (P).

- Weekly family meetings consisting of the woman's primary counselor, a developmental specialist, the woman, and her child(ren) were held to assist with emerging problems. Meetings also were held with the control group women during or following visits with their children (A). Such meetings were held only when a mother or staff member felt it was indicated (P).

- A mother's group was organized for both experimental and control group women to teach basic skills such as housecleaning and organization, infant/child hygiene and feeding, meal preparation and nutrition, and time and money management (A, P).

The need for emergency and routine medical care for resident children and pregnant women at PAR Village was greater than expected. Much staff time was required to accompany ill children and mothers to the health care provider, which increased the workload of staff members who remained at the facility. Another significant expense at PAR Village was a threefold increase in the cost of prescription medications.

RESEARCH PROBLEMS AND SOLUTIONS

Randomization

When the programs were originally designed, administrative and clinical staff members in both programs expressed concerns about the randomization of participants to the two treatment conditions. They felt it was insensitive and arbitrary—principles that were not acceptable in a TC. However, it was recognized that randomization was the most scientifically sound procedure by which to study substance abuse in women and that any other procedure was less likely to be funded in a research demonstration proposal. In addition, programs for women were scarce, and the control side of the random assignment (treatment without children) was considered to be an acceptable alternative. Faced with the likely choice of *no* program for women and children or one with randomization, the clinical staff acquiesced to use of randomization.

The method for making the random assignment was considered to be extremely important. Amity staff members felt that the woman should be totally removed from the process, thus removing any sense of guilt for not choosing "correctly." It also was considered important to remove the clinical program staff from any connection with the decision so that staff

bias for or against a woman would not be an issue. The final decision was to use computer assignment, which would be given to each woman by the research assistant.

The Operation PAR team had similar concerns about randomization but developed a different procedure. The research team felt that the women might be suspicious if a computer assigned them to the less desirable treatment group. The procedure for assignment would have to be seen as fair and credible. The procedure chosen was to have the participant pick one of two cards that looked identical on one side but on the other side were printed with the words "Mom + baby in program" or "Mother only in program." The cards were periodically examined and replaced to avoid the possibility that participants could identify and choose the preferred card.

Clinical staff members and most women in both programs felt that the experimental treatment was superior and were highly sympathetic toward women who were randomized to the "wrong program." When randomization did not permit a woman to have her child(ren) with her, she would invariably be upset; some women became extremely distraught. To help resolve this problem, it was requested that a clinical staff member be present at the randomization to serve as witness to a proper and fair choice and provide support if the woman became upset.

The timing of when randomization occurred in the course of each woman's treatment differed in the two programs and within each program over time. The Amity program originally set the point of randomization at 3 months into treatment. This timeframe was chosen so that women would be fairly well integrated into the TC and less likely to drop out if they did not like the random assignment they received. After approximately 6 months of using this timeframe, staff members decided to shorten the randomization point to 1 month, which was done to increase the number of women in the program. (Too many women dropped out before the 3-month randomization point.)

An unanticipated complication of performing the randomization earlier in the woman's treatment was greater difficulty in clarifying the availability of the children for the program. At intake into Amity, several women said they would be able to admit their children to the program should they receive the random assignment. Unfortunately, the shortened period of 1 month prior to randomization did not allow enough time to negotiate custody details with child protection agencies that were frequently involved with children being considered for the study. This resulted in some women who were assigned to the experimental group being unable to admit their children to the Amity TC. Because of the nature of the research question, it was desirable for the child to enter the program within the first 6 months

of the mother's treatment. If this did not happen, the mother was removed from the study and placed in a comparison group consisting of all women at Amity's TC who were not part of the demonstration program.

In the pilot phase of the Operation PAR program, randomization was done prior to admitting the woman to the TC. This resulted in some control group women subsequently not reporting for admission. The protocol had to be changed to require TC residence of the mother at least several days before randomization. The majority of children of Operation PAR women were also in protective custody, which caused delays in their admission. There were several other potential Operation PAR participants who did not receive child protection agency permission to admit their children.

Randomization remained a chronic, unresolved issue. In both programs, researchers continued to prefer randomization for scientific reasons whereas clinicians and participants continued to be greatly distressed by it; this remains a significant, unresolved issue. It would be difficult to obtain TC clinical staff agreement to a similar randomized clinical trial in the future. The randomization in this study involved one of the most emotional issues that a woman could confront: whether to be with or without her child(ren) for an extended period. Most likely, randomization around other, less sensitive issues would be better accepted within the TC.

Early in the study clinical staff members of both programs and participants raised the question of whether a woman randomized to the control group could drop out of the study and reapply, thereby having a second, and possibly a third, chance to have her child(ren) with her in the TC. This question was raised because the women believed the experimental group condition was more desirable. To avoid questions of this nature, the clinical staff members and researchers of both programs developed a similar rule. For Operation PAR, this was called the "Two Worlds Rule": Women in one "world" could enter a TC and reside there with one or two children. There also was another world where women could enter a TC only without their children. Once assigned to either world, a woman would remain there until her 12-month posttreatment followup was or could have been completed. This rule was useful in explaining and helping to deal with questions about changing group assignment.

Maintaining Integrity of the Two Treatment Conditions

The study design called for the two groups of women to have as similar a treatment experience as possible. One difference was that experimental group women had overnight responsibility for their children, beginning at approximately 4 p.m. and ending at 8 a.m. the next day.

The issue was dealt with differently by the two programs. Given the tradition of equality and fairness for TC residents and the value placed on the mother-child relationship, clinical staff members wished to permit the control group women to have more frequent visits with their children and other family members. This increased visitation was written into the Amity grant so that the only significant difference between the two groups was the opportunity and responsibility of having children live with their mothers. All other opportunities to form mother-child attachments and to have hands-on parenting experiences with staff guidance and feedback were provided for both groups (although experimental group women had more time for these experiences). This design was considered sound by the research team because the issue of child residence was the main research question under study by the program. Should differences be found between the groups, these differences could be clearly attributed to the one factor that varied (mothers living with or without their children).

At PAR Village, the issue of equality between groups and the importance of the mother-child relationship also was raised. Treatment staff members and residents became increasingly enthusiastic about the value of mother-infant bonding and raised the issue of bringing the infants of control group women in for a weekend to facilitate bonding. In contrast, research staff members cautioned that the more the control and experimental programs resembled one another, the more likely no treatment group differences in outcome would be found at followup. Research staff members continued to "resist" efforts to make the control group experience more like that of the experimental group with respect to the major independent variable in the study. An exception was made for one control group mother who was pregnant when she entered the program and delivered in her second month of residence. She was permitted to have her infant with her in the TC for 3 weeks following delivery. The children of control group women attended weekly outpatient groups, participated in monthly outings, and occasionally slept over on weekend visits.

Ideally, the treatment in a clinical trial should remain the same from beginning to end, but the TC is a complex living, dynamic, and everchanging group process, with no possibility of freezing this process at any given time. However, it was possible to keep the two treatment conditions distinctive in their essential difference: child living with vs. not living with the mother in the TC.

Clinicians and Researchers Sharing Information

The research protocols for both Amity and Operation PAR were written to assure participants that they could report information to the researchers without fear of sanctions by the treatment staff or agencies to whom the

treatment staff reported (e.g., courts or child protective services) unless required by law. This policy did not pose problems at Amity, but it became an issue at Operation PAR regarding the sharing of urine drug test results.

In the initial planning meetings of the Operation PAR clinical and research teams, the principle of preserving an independent research database was accepted. It was agreed that the laboratory would send separate urine drug-testing reports to clinicians and to researchers so that the two groups need not share data. This seemed a reasonable arrangement, but problems developed. Research interviewers, seen as "TC outsiders," initially encountered difficulties in obtaining observed urines and having them sent to the laboratory. After a series of frustrating experiences, a sympathetic TC administrator facilitated the urine collection and shipment to the laboratory. Given the frustrations and delays, as well as recruitment of a new research interviewer, the "split urine" agreement was forgotten, and only the research team received reports. In the 18th month of the project, this developed into a major issue when a clinician heard about researchers collecting urine specimens and clinicians not receiving reports.

A series of tense meetings was held in which researchers acknowledged an honest mistake but were not able to turn over laboratory results or to tell clinicians whether there were positive urines in the TC. Clinicians were frustrated, and researchers were bewildered by the strong emotions and temporary breakdown in communications. The issue was extremely important to TC staff members, who felt frustrated with the researchers for not living up to an agreement, and to researchers, who wondered why urine drug-testing reports were suddenly so important when the researchers had such problems getting them done. For clinicians, not having results of the urine tests raised concern as to who among the participants might have been using drugs without staff knowledge. Not revealing information about a participant's drug use strikes at the heart of the TC dynamic.

The immediate crisis was resolved by holding a meeting with the study women residing in the TC and explaining the breakdown in procedure. Clinical staff members requested that the women voluntarily give permission for release of their urine test results, and all complied. One woman was informed she had a positive urine, which she disclosed to the clinical staff. It was handled as a treatment issue in keeping with usual practice at the TC.

Following this crisis, Operation PAR researchers surveyed other treatment research programs and noted a frequent arrangement in which drug screens were done at specific times as defined in these programs'

protocols. The dominant practice was to have both clinicians *and* researchers receive copies of the reports. For clinicians to receive a positive drug screen report was considered a benefit to the participant—not a danger—because treatment staff members then could work more intensively with the participant on the relapse issue. This would be a reasonable and economical arrangement in future studies. For Operation PAR, a change in procedure would require, among other things, the approval of the funding agency, review by the human subjects committee, a change in the consent form, and an approach to the women in the study with new consent forms. The original agreement to split urine screens between the clinicians and researchers was not changed; it was simply implemented.

Committed Clinicians vs. Dispassionate Researchers

During periods when TC clinical staff members were concerned about the restrictions of the study design, the research interviewers occasionally would receive negative comments during visits to the TC. On occasion, research staff members would be the recipients of highly emotional communications from both the clinicians and research participants. Although most of the researchers in both programs absorbed these communications with equanimity, some research staff members responded with frustration, bewilderment, and anger.

A related problem was the different value orientations of clinicians and researchers. The researchers were trained to be dispassionate, rational, and objective. The TC movement was a rebellion against the "professional" approach to treatment. A basic tenet of the TC is the removal of the "we/they" dichotomy. The staff members at Amity and Operation PAR, many of whom had experienced the recovery process, felt that professional distance is harmful and represents the complete antithesis of an effective TC. In comparison, research staff members in both projects saw this professional distance as crucial to appropriately performing their jobs. At times, clinicians would become uncomfortable when researchers spoke matter-of-factly about relapse of subjects, "interesting" relationships in the research data, and potential participants who did not meet study admission criteria even though they were in great distress and required the type of help available through the study.

Both Amity and Operation PAR resolved these differences in much the same way. These incidents and issues were discussed informally and at the monthly formal team meetings. Differences in the communication and emotive styles of clinicians, researchers, and participants were accepted, and substantive issues were resolved. For example, Amity and Operation PAR each held two slots in the mother-with-child condition as "compassionate beds." These slots were filled by the clinical staff on the

basis of need with women who did not fit the study design and were not considered part of the study.

Subject Recruitment

This has been one of the most difficult problems to resolve for both programs. When Amity wrote the grant proposal for this program, there were no other services available in the Tucson area for substance-abusing women and their children. By the time the grant was awarded, three local programs for women had been established. Because the other programs did not require random assignment, eligible women applied there first. This reduced the pool of eligible participants for Amity. In addition, most major referral sources expressed concern over not knowing which treatment condition their participants would be receiving and preferred to refer participants to programs where the women would be with their children. Through intense efforts, this situation improved but continued to be a recruitment problem.

Initially, recruitment into Operation PAR was slow because the original study design required each child to have been exposed to cocaine during pregnancy and to be younger than 6 months of age. To speed up recruitment, the perinatal cocaine exposure criterion for children was dropped, and the age criterion was expanded to 10 years or younger. Recruitment again became a problem in the second year when competing programs for female substance abusers were established in the local community. Although Operation PAR was able to keep the program beds full, competing programs continued to cause recruitment problems.

DISCUSSION

Positive Accomplishments

Researchers often refer to the TC as the “black box”—a complicated and everchanging treatment system that cannot be operationally defined for systematic clinical trials. Recent efforts by TCA have attempted to gain consensus on the essential components of the TC, and a generic TC program has been described (De Leon and Rosenthal 1989, pp. 1379-1396). This chapter describes two examples of TCs that collaborated with university researchers to make the TC black box more friendly to rigorous research.

An important aspect of the programs is that they demonstrated the feasibility of conducting randomized clinical trials in TCs. It was possible to develop clinical laboratories for the research by establishing facilities

and programs for children and their mothers within existing TCs. Additional time will be required to test the study hypotheses.

Shared Problems

People in both Amity and Operation PAR had serious problems with randomization, primarily because of the mismatch between random assignment and the basic tenets of the TC. In addition, an issue raised by Amity concerned the probability that the random assignment in effect changed the program and, therefore, did not measure the TC model as generally implemented. People in both programs have strong reservations about participating in a future randomized trial to compare treatment conditions where staff members and participants believed one condition was clearly superior.

The types of services described herein were not available at the time the study was designed. Moreover, publicity surrounding the programs helped stimulate expansion of treatment services for women and their children. In addition, most of the women in this study did not have legal custody of their children at the time of admission. Randomization to the control group continued the noncustody relationship with their children. Randomization indeed facilitated the ability of experimental group women to live with their children during long-term treatment—a highly unlikely scenario if the study had not been conducted.

Both programs observed tensions between clinicians and researchers, although such tensions and differences in orientation are not unique to these two programs. Some differences may become exaggerated when researchers work with TC clinicians, who expect total respect for the TC treatment environment. In these programs, clinicians did not decide which women would be allowed to bring their children into treatment, but in the traditional TC, this decision would be made by a concerned community of staff members and senior residents—not by random selection or computer assignment.

TCs frequently encourage expression of intense emotions and often have group norms that differ from those of a research staff. Researchers who visit TCs often are trained to be unemotional and dispassionate in their work and frequently are unaware of how these styles diverge from TC norms. In this program, initial training of research staff members attempted to sensitize them to participant issues by asking researchers to review clinical records and attend treatment team meetings. Despite such efforts, tensions and misunderstandings can be anticipated, and clinicial and research teams should meet frequently to resolve issues. It is also

important to maintain strong support for the unique requirements of the research at the highest administrative levels of the TC.

Implications for Therapeutic Community Research

Prior to these two studies, researchers had implemented clinical trials in which participants were randomly assigned to different treatment modalities, including TCs (Bale et al. 1980). The two studies described in this chapter demonstrate the feasibility of clinical trials that randomly assign participants to different treatment conditions within TCs, albeit not without complication. Clinicians, researchers, and participants were blind neither to the psychosocial treatment conditions being compared nor to which participants received which treatment. In both the Amity and Operation PAR studies, one treatment was viewed by clinicians and participants as more desirable, which caused considerable tension and had the potential for biasing results.

Yet the overall experience suggests that the TC modality is likely to benefit from further experience with the clinical trial methodology, especially in examining the efficacy of treatment innovations. The Center for Therapeutic Community Research, headed by George De Leon, Ph.D., is the recipient of a NIDA research center grant to conduct a systematic study of TCs.[4] The center will focus on the issues encountered by the two programs described herein. This argues well for increasingly systematic clinical research in a collaborative network of TCs.

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