The Quagmires of Conducting Clinical Research: One Team's Quest for Creative Solutions

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This narrative describes one research team's experience with conducting clinical research through collaboration with a local social service agency.

Introduction

Conducting research in collaboration with a social service agency can pose numerous challenges. Not only must research methods follow rigorous standards for recruitment, measurement, and sampling, but clinical considerations are also paramount (Resnicow et al., 2001). Intervention studies contain a variety of elements and these multiple components must have the capacity for determining effectiveness. Planning ahead for challenges in the implementation and the process of intervention delivery is highly recommended (Whittaker, Kinney, Booth, & Tracy, 1990); however, there are often many unforeseen difficulties that must be addressed throughout the course of the evaluation.

The following narrative describes one research team's experience conducting clinical research through collaboration with a local social service agency. It is our hope that some of what we have learned and experienced may help others attempting to conduct similar research. Our discussion will describe experiences through the perspectives of the major roles required to implement this study: principal investigator, research assistants, and clinicians.

The Study

The formative study described here was funded by the National Institute on Drug Abuse (5K01-DA015671) to evaluate the retention and engagement of youth and their families in an in-home, family-based intervention model. The family-based intervention was designed to address drug use and other high-risk behaviors of adolescents who had previously run away and returned to their homes. The major objective of the study was to establish feasibility for engagement and retention of youth and their families in the intervention. We partnered with a local multi-service agency that receives federal and state grant funding to provide services to high-risk youth who were experiencing family conflict difficulties. The agency agreed to allow us to provide services to a random sample of clients seeking services for family conflict and youth delinquency, truancy, or runaway behaviors.

The agency's counseling services acted as the comparison group for the study's experimental condition. The counselors were trained and utilize solution-focused brief therapy (SFBT) and offer families up to 12 sessions of family therapy free of charge. This therapeutic approach encourages clients and counselors to focus less on describing the

problem and more on what life would be like when the problem area is solved (Berg & Miller, 1992). Solution building begins with asking clients to describe how they would like their lives to be different as a result of coming to treatment. Future success is the target, rather than where the problems began. Clinicians encourage clients to describe their desired outcomes and note the process of solution development throughout the course of the therapy. Focusing clients on a future in which the problem is solved is central to a solution-focused approach (Pichot & Dolan, 2003).

The experimental intervention was similar to the agency's 'standard care' in that we offered twelve sessions of solution-focused family therapy; however, the experimental intervention was delivered to youth and their families in the home. In addition, "engagement activities" were developed to strengthen the family's motivation to engage in the therapeutic process and were employed during each session. The engagement activities were designed to improve interaction and communication between the youth and their parent(s). Eighteen separate engagement activities were developed, utilized, and evaluated among the experimental families.

Agency Collaboration and Subject Recruitment

Following identification of the agency with whom to develop a partnership and the acceptance of collaboration, the first step was to develop procedures to identify and recruit eligible youth and families. This required understanding the agency's intake procedures and determining how best to incorporate our procedures into those of the agency. This took several meetings with agency staff at various levels of administration. The research team also held brainstorming sessions to ascertain the best approach for successful recruitment. While these sessions were helpful in getting the recruitment process started, the initial process was modified many times and multiple attempts were needed to discover recruitment methods that actually worked.

Initially, the research team and the agency staff agreed that informing clients about the opportunity to participate in the study should take place over the phone at the time clients were being scheduled with a counselor (at intake). It seemed a fairly simple process: when a parent contacted the agency seeking family counseling services, the intake worker would make them aware of the study and ask if they were interested in hearing more about it. If the family agreed, the worker would fill out a bright pink sheet (to ensure staff would not forget to mention the study) with the parent's name, phone number, and address. These were left in a specified mailbox for the research assistant (RA). The RA would then randomly determine the group (experimental or control) into which the family would be placed, contact the family, verify eligibility, and set up a date to conduct the pre-test.

One of the main challenges in this recruitment procedure was the fact that all agency counselors were responsible for conducting intake phone interviews. Ensuring that all counselors remembered to mention the study during intake and follow the protocol consistently became the largest barrier to recruiting families. Although various members of the research team took part in several clinical meetings to remind counselors about the study and answer questions that arose during implementation, this procedure resulted in enrollment of only eight families during the initial five months of the project.

The low enrollment rate indicated that we were simply not being able to access eligible families; therefore, these procedures were modified. Instead of the counselor's being required to remember to offer the opportunity to participate in the study during intake interviews, bright pink recruitment sheets were added to the initial packet of materials families were required to complete before meeting

with their counselor. These recruitment sheets contained a description about the study and its purpose, what would be required of participating families, and consent to contact them. Interested families provided names and phone numbers so that the research assistant could call them to further explain the study and then enroll them in it. Again, this new procedure was ineffective and resulted in only two referrals during the course of two months. In addition, several families refused any further contact from the research team to hear about the study.

So, here we were - seven months into a two-year project, and we had only recruited ten families (we had proposed reaching a total of 195 between the experimental and control groups within 2 ½ years). The research team continued to explore the obstacles encountered in accessing and recruiting families. Agency administrators and counselors were as baffled by our difficulties in recruitment as we were. The number of eligible families served by the agency during the seven months was much larger then the number of referrals the study had received; therefore, it was obvious that many families were not being identified through our current procedures. Furthermore, families seemed reluctant to give their contact information based on the study description contained in the pink sheets.

Our next strategy was again developed by collaborative efforts between the research team and the agency staff. It was agreed that the best approach would be to train one of the agency's counselors to retrieve family names from the computer intake system and call *all* eligible families to offer the opportunity to participate in the study and set up the pretest date, even before the family's first appointment with the counselor. Luckily, one of the study's research assistants was also a part-time counselor at the agency and she volunteered to take on this role. These new recruitment procedures resulted in enrolling twenty new families in the study (with very few refusals) over the course of about three months.

This experience is an excellent example of the importance of maintaining a good relationship between the research study team and the agency's staff. Without a working collaboration between both parties, the recruitment procedures would have continued to fail. Utilizing an individual with a dual relationship (counselor at the agency and research assistant for the study) allowed us to bridge the barriers we had confronted. We have learned that it is critical for the person responsible for participant recruitment to be knowledgeable about the research project and agency policies, and above all, have a good relationship with key agency staff that can help open the doors to clients they serve.

Contacting and Interviewing Challenges

Once eligible family's names and contact information were retrieved from the computer's intake system, the RA/counselor would call all families before they were scheduled to attend their first session with a counselor. The purpose of this contact was to explain the study, recruit the youth and their parent(s), and set up a time to complete the pre-test before counseling sessions began. The first challenge was to contact the families. Due to confidentiality issues, a message could not be left on answering machines. Also, if someone other than the youth's parent answered the phone, the RA/counselor could not indicate she was calling from a counseling agency. Rarely was the parent available during the first attempt. More often, the RA/counselor made multiple attempts to contact the family - five attempts appears to be our average for successfully scheduling pre-tests. Conversations with the family member varied from a few minutes to more than thirty minutes. We found that to successfully recruit family, the RA had to establish rapport, explain the

purpose of the study, describe what participation entailed, and work carefully to ensure that all of the individual's questions were answered to their satisfaction.

One research team member explained his first experiences calling families to recruit them and set up appointments for the pre-test:

> *"As I prepared for my first calls, I thought, "Who enjoys unexpected calls from charities, credit card companies, or other sales personnel?" What language would help put the family member at ease, communicate their options clearly, and create curiosity about participation in the study? I was familiar and comfortable with some level of marketing a product, but this felt eerily like a form of telephone sales. I have never thought sales to be a strength, or even something I would enjoy. It didn't take long to find answers to these questions and concerns. Relax. Breathe deep. Stay centered in the genuine interest in the family's well-being and desires. Take your time. When in doubt, slow down. And no matter what the outcome, express thankfulness for the family member's taking time out of their day or evening to visit by phone."*

During the initial phone contact, the RA/counselor described the study to the parent, offered either the experimental or control group depending upon randomization, and set the pre-test date. Some families reported interest but asked for time to discuss the matter with a partner or their child. The longer it took to re-contact them, the less likely these families would agree to participate. For the majority of families that were enrolled during the initial contact with the RA/counselor, the pre-test appointment was set during the first or second phone contact. Families who did not agree to participate tended to have strong reasons that impeded them from participating. For example, one family had a difficult divorce with shared guardianship of the youth, another family decided to seek counseling elsewhere due to benefits they could accrue at work, and in another family, the single parent had a health problem that made it nearly impossible to complete the pre-test instruments.

Another immense challenge was the requirement to conduct post-test interviews in both the experimental and control groups following the family's completion of counseling services. Contacting families who had been in the control group was especially difficult as the research team had had limited contact with them. For experimental families, continuing contact was less difficult as the counselor would remind the family that a member of the study team would be calling to complete the post-test. However, even among some families in the experimental group, we were unable to collect post-test information. One family moved before their twelve sessions in the experimental condition were complete and the youth ran away. The post-test was eventually completed with the parent, but we could not re-contact the youth. Another youth participant was sent to juvenile youth detention and could not be re-contacted. As in conducting pre-tests, these families tended to agree to complete post-test interviews within the first two or three phone contacts. Those that were more difficult to locate often were unwilling to complete these measurement tools.

A final challenge associated with contacting families was their frequent failure to keep appointments to complete the pre- and post-tests. Often a family member would call to reschedule, but other times they would simply not be at home when the research assistant arrived. The research team was very

persistent, calling them daily or every other day until they completed the testing or the family asked to be dropped from the study. Diligence proved to be the key ingredient in successful completion of pre- and post-testing; however, the research team had to be careful not to invade the family's privacy by calling too often. This tended to be a subjective decision based upon the reactions of the parent on the phone. In sum, multiple calls, at random times, and persistence seem to be the order of the day.

Conducting research in community settings creates many challenges, not the least of which regards the interviewer's perceived and genuine safety. Entering communities that may be uncomfortable at best, and dangerous at worst, is an obstacle difficult to overcome when attempting to collect data from participants in their homes. Another important distinction should be made between situations that are perceived to be dangerous due to internalized stereotypes and those that are realistically unsafe. This distinction is difficult to make in the moment, and the advice of self defense specialists is often to "trust your gut." If it feels truly dangerous, then dedication to a research project should never override personal safety.

This process is exemplified in the following account of one research assistant's experience going into a new area to conduct a pre-test.

> *"I drive up to the big, orange, metal gate that encases the apartment complex in which the family lives that have agreed to participate in our study. The gate will not open for me; I am prohibited from parking within the apartment complex. So I find a parking spot on the street and walk the two blocks back to the apartment complex where I intend to collect my data. As I walk I cannot help noticing the economically depressed condition of the neighborhood. The streets look socially isolated from the outside world and the buildings appear to barely meet the definition of shelter. I know I am in a "rough" area of town, but that has never stopped or fazed me before. As a researcher and social work practitioner, I have willingly been in many situations that might be perceived as dangerous or risky.*
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> *However, as I enter this apartment complex, I have an instinctual feeling of insecurity and fear- a powerfully strong feeling that I had never experienced before. I slowly start the long walk from one end of the complex to the other, trying to find "building 12". As I walk further into the gated and confined area where there is no outlet, I feel more and more trapped. I am confined in an environment that is not my own and in which I obviously do not belong. I realize that as a white, middle-class, female, wearing a backpack, and looking lost, I obviously do not fit in with these surroundings. The stares and curiosity from the residents escalate as one group of men standing by a corner of one building start whistling and calling out to me. Not knowing how to react, I look straight ahead and try to appear as if I know what I am doing.*
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> *Upon finally finding the respondent's apartment, heart beating rapidly and palms sweaty, I knock on the door. No answer."*

As a research team we have worked to determine how best to handle these situations. Questioning personal stereotypes at debriefing sessions has been invaluable for the entire team. Continuous sharing of experiences by members of the research team contributed to identifying a variety of strategies to improve safety. First, communication between the research team members about where and when interviews were being conducted was identified as extremely important. We decided that an appropriate initial strategy was to call another research team member when arriving at a home that seemed uncomfortable to "check in" and let them know the start and approximate end time of the interview. In these cases, the other team member would expect another call within an hour or so, the time it typically takes for data collection to be completed. As a result, other team members would be aware of the interviewer's whereabouts and expect a call to know that things had gone as planned.

Second, enlisting the help of the study participants was identified as a way to increase feelings of security. Asking the study participant to meet at the interviewer's car and help the interviewer find the way to their apartment increased the likelihood the participant was home when the interviewer arrived, and also addressed the concern of walking into an unsafe situation alone. We found, however, that this request must be discussed sensitively, without offending the participant. The interviewer never suggested the neighborhood is "unsafe," "in a bad area," or "socially disadvantaged," just simply that they needed additional assistance in finding the participant's home.

Third, we determined that meeting respondents in a neutral, safe location, such as the fast-food restaurant near their home, was an appropriate method for collecting pre- and post-test information that was in written form and required little private conversation. We have found that some participants, especially those in the control group who had little interaction with members of the research team, preferred this as well. Recognizing the role of the researcher and the challenges this role can create is important in implementing a research project in the community. Working as a supportive research team is critical in increasing comfort and safety for the interviewer while respecting participant's needs.

From the perspective of the principal investigator and the ultimate manager of this process, it seems that effective research assistants are those who are enthusiastic about the project, are knowledgeable about and comfortable explaining the study clearly, and are respectful, non-judgmental, and personable with prospective participants. Most important, though, is the ability to persevere and remain motivated to continue working through the challenges that seem to appear at every turn. This project's success is due in large part to the tenaciousness of the research assistants involved in this study.

Conducting Interventions in the Home

Conducting clinical research with youth and families in their own homes leaves one open to all kinds of possibilities, outcomes, dilemmas, and experiences far beyond the variables considered for study. It is this opportunity for unanticipated variation that makes research in the community difficult but also leads to rich and interesting clinical experiences. Providing counseling services in an office is fairly contrived and consistent as the environment is controlled by the clinician and circumstances are generally the same from session to session. However, conducting therapeutic sessions with families in their homes is seldom consistently the same, often amusing and opportunistic, and always challenging. Frequently, in-home sessions create a process far beyond that intended in typical counseling sessions.

Clinician Challenges

From the perspective of clinicians in this study, a variety of challenges had to be overcome. One example is the space in a client's home in which to conduct the session. Unlike office settings, this was often variable. When many people live in one home, there was often a shortage of private, quiet spaces. For example, one family had nine people living in a three-bedroom home with only a kitchen and living room as shared space. During sessions with this family, there were often several small children running around, and almost always someone in the living room watching television. If the family members who were part of the therapeutic session chose to sit in the living room and turn the TV off, the other family members often sat and listened in on the session. This close observation made it extraordinarily difficult to conduct confidential conversations with the participant family members.

Given the flexibility needed to conduct in-home interventions, the clinicians for this study developed their own unique strategies for dealing with challenges. At times they have conducted sessions in the car, creating a portable private office. They have talked to many parents and youth on the front porch or in the back yard. In other households that have a variety of spaces to meet, the youth and parent typically choose the specific space in their home. This often provided the clinician with insights into how the family member participants were feeling. For example, in one family, the parent and youth would always choose to sit at the kitchen table when they were angry with each other, but when they felt more calm and had better communication, the sessions were conducted in the den.

One of this study's clinicians described it this way:

> *"It is a dance of using every moment and opportunity to make the most efficient and effective use of the availability of space and time. Unfortunately, I sometimes trip in that dance, and there is plenty of opportunity for awkwardness or having to make a quick change in plans. In an office, a therapist generally has full control over space and pace. In someone's home, a lot of that control goes out the window."*

Other challenges come in the form of distractions – situations that would likely never happen in an office setting. Distractions come from all directions when conducting sessions in a client's home. Some can be managed and changed; others must simply be tolerated. The distractions in people's homes can be just that, distracting; however, they can lead to discussions of more important matters, are entertaining, provide a release when discussions become tense, and form a bond between the clinician and the family. The dog that sleeps on one clinician's feet seems to have adopted her as the Tuesday night guest – a highly unlikely happenstance in an office setting.

Some distractions can be managed and dealt with, such as the family who lived in an efficiency apartment that did not have electricity when the clinician first met them. The initial session was conducted in the dark. After that, the clinician always brought large candles and matches to subsequent sessions. Even in this situation, however, the clinician remarked at the family's dignity and their motivation to continue their therapeutic sessions despite difficult circumstances.

Television is often a distracting part of family life. Some families kept their TVs on, while others responded to requests to turn it off. For others, muting it but leaving it on is their choice. One family said they left it on

because it kept the dogs calm, and "Trust me, you want us to keep the dogs calm." The TV stayed on.

Younger siblings and relatives are almost always a distraction, or at least their trail of things is a distraction – the spilled milk on the table, the Popsicle sticks on the floor, all of the toys in various stages of play. How younger children are managed reveals a lot about family dynamics. One family's three-year old child always greeted one clinician at her car, gave her a hug, escorted her into the home, and introduced her to everyone (again). Another family's three-year old insisted on doing all of the "engagement activities." The clinician noted that the youth client was more patient and caring in response to that child than in any other aspect of her life. Viewing the interactions of the family with each other, within their own environment, can lead to many more insights than is often possible in office-based sessions.

And then there are the animals - the hamster in the living room that drank water incessantly and made odd noises - the three kittens that climbed all over the clinician and snuggled together on his lap - the dog who slept on top of the clinician's feet under the kitchen table each time he met with the family. Animals are usually considered part of a family, and observing how families and their pets interact can not only be entertaining, but revealing as well. Having animals around can be distracting, but they can also add humor to tense moments and provide great conversation, often crucial to building rapport.

Providing therapy in individual's homes is a little harder to conduct than is typically the case in scheduled hour-long sessions in an office. In the home environment, where the clinician has little control, there are many opportunities for unintended developments. This fact makes it more difficult to pace sessions. Some families answer the phone during sessions, and if there is an important call, they stop the session to take the call. This can change who participates in the session and the topics of discussion. In addition, even if the clinician attempts to prioritize and achieve agreement between the participants concerning the focus of the session, the clinician is "on their turf" and has an obligation to respect their priorities, regardless of what the clinician may request – a very different dynamic than found in an office setting.

Clinician Insights

The clinicians conducting in-home sessions for this study have noted that families seem to feel a different obligation to the therapeutic process and the counselor than those families who come into an office setting. Families appear to have a different sense of control; the clinician is in their territory, not the other more typical arrangement in office settings. Clinicians in this study often had to defer to family's schedules and activities more than the family seemed willing to conform to the clinician's schedule. This can appear, and in some circumstances may reflect, a lack of value attributed to the therapeutic experience by some family members. Although most families seemed to appreciate the time and efforts made to meet them in their own environment, many families seemed to expect more flexibility on the part of the counselor than they might expect in office settings.

Scheduling can be a challenge when a counselor goes to clients' homes. It typically had to be in the evening or on weekends, especially when youth participants were in school. Even when schedules appeared to meet the demands and needs of the family, sometimes they would forget appointments completely or were late arriving home. This often left the counselor sitting in a car or on the door steps - waiting. If families did not have phones, it was difficult to remind them about appointments. But no matter what the clinicians in this study expected, they went to the family's home, hoping someone would be

there. If nobody showed, at least they got to know another part of the city and to observe a part of the family system (the neighborhood, apartment complex, neighbors) that they typically miss. Always attempting to view experiences from a 'strength-based perspective,' the clinicians in this study took advantage of whatever opportunities presented themselves. That was also part of the positive experience of visiting clients in their homes - the ability to observe them in-context. Although it was not rare that a family forgot or was not home when the appointment for an in-home session was scheduled, sometimes even that irritating experience provided a unique opportunity. One experience exemplified a clinician's taking an opportunity when it presented itself:

> *"One session I showed up at the client's home and the client and mother had forgotten, but the mother's boyfriend was there. He apologized for them and located them, but they were in opposite ends of the city and did not have a way to get to their home in a timely manner. I was ready to leave, but the boyfriend started to tell me all about the family and how things like this happen all the time. He proceeded to tell me about the relationship between the client's mom and her mom and how that affected the relationship of the client with his grandmother. This is information I most likely would have never received, at least not from an outsider, and almost never would I have reason to invite an outsider to a session or request consent to talk to mom's boyfriend to get additional information. But there it was, thanks to a no show. Again, I had to be careful about how I processed that information, and I categorized it as outsider information from a boyfriend who was mad at his girlfriend, but it was interesting data that added a new light to some observed dynamics."*

Other experiences have occurred when the parent was present, but the youth was not. In these instances, it seemed the parent was relieved to have the counselor's full attention so she could receive additional support and have time to talk candidly. Because creating and finding private time and space for individual work with family members was often difficult, these unplanned moments of privacy were sometimes crucial to moving the therapeutic process forward.

From the principal investigator's perspective, it is critical to find clinicians who are creative, invested in the therapeutic and research process, intrinsically motivated to help youth and parent(s) who are struggling, and have a high degree of flexibility. As was identified as the most important characteristic for research assistants and interviewers, clinicians also must be highly motivated to work through the numerous challenges of doing this type of therapeutic work and possess a high level of innate perseverance. Driving an hour to visit a family who is a "no-show" requires not only immense patience, but a constant focus on the strengths of the families they serve.

Lessons Learned

Conducting this clinical-intervention study in collaboration with a community agency and delivering our intervention in client's homes has been extraordinarily difficult, frustrating, informative, and rewarding. This type of research is not for the faint of heart, the unmotivated, or the inflexible as so much can happen within the unstructured boundaries within which this work is conducted. However, it is not simply challenging; the challenges have often led to treasured

experiences, relationships, and plenty of entertaining stories.

As we continue our work on this study, we understand that many more challenges lay ahead. However, the opportunity to assist families who are struggling with a variety of challenges makes the effort worthwhile. Social work as a profession has long been concerned with strategies for effectively helping multi-problem families (Whittaker et al., 1990). A critical task for assisting families facing a myriad of challenges is to discover interventional approaches and examine their application and effectiveness. Thus, even with the challenges associated with conducting this clinical research, the desire to increase families' functioning and improve parent/child relationships motivates us to continue.

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