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Why We Wrote This Monograph

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Background

Our motivation for developing this monograph on research compliance grew out of our involvement in a multisite treatment-matching study called Project MATCH (*M*atching *A*lcoholism *T*reatments to *C*lient *H*eterogeneity). In 1989, the National Institute of Alcohol Abuse and Alcoholism initiated a large-scale clinical trial to validate and extend prior matching hypotheses. It involved nine clinical research units throughout the United States. Individuals recruited into the study represented a heterogenous population as seen in typical inpatient and outpatient treatment facilities around the country.

These participants were randomized to one of three types of treatment: Cognitive-Behavioral Therapy, Motivational Enhancement Therapy, or Twelve-Step Facilitation. Clients were seen in two types of settings: outpatient and aftercare. In the latter settings, participants (N=1726) were assigned to one of the three MATCH treatments following a regimen of inpatient or intensive day treatment. They were followed for 15 months after the initiation of treatment (Project MATCH Research Group 1993, 1997, in press). In the continuation study of Project MATCH (1994–97), only participants in the outpatient settings (N=954) were followed up at 3 years after the initiation of treatment (Project MATCH Research Group, submitted).

In Project MATCH, as in any clinical trial, maintaining participants in followup was particularly critical to the success of the study, since losing a substantial proportion of subjects could result in having particular subgroups disproportionately represented. This would cause serious difficulties not only in testing the matching hypotheses but in interpreting treatment outcomes as well. The investigators would not be able to assert with any assurance that a specific treatment could account for differences found among clients (Flick 1988). Thus, any conclusions drawn about the study would be weakened by having a substantial number of participants dropping out.

Challenges to Compliance

Matching studies are specifically designed to answer questions about what kinds of treatments are suitable or not suitable for certain kinds of participants or situations (Carroll et al. 1994). Thus, it is necessary to include a large, heterogenous sample population that varies in problem severity, demographics, and individual social and coping resources while employing treatments that vary in philosophy, theoretical orientation, treatment goals, and treatment intensity (Donovan et al. 1994). The high degree of variability in the client population and the contrasts across treatments usually result in various subsets of clients deriving important benefits from particular treatments (i.e., matching) while others do not (i.e., mismatching). More specifically, this means that sizable proportions of clients will likely be assigned to treatments that are unrelated to their particular needs, capabilities, and resources.

Clients' aversive reactions to treatment often carry over to followup, since participants do not routinely distinguish between them. Research has shown that such negative reactions on the part of participants often lead to future compliance problems (Stout et al. 1996). Thus, as in all outcome studies, but perhaps more so in matching studies, investigators are continually confronted with the daunting task of obtaining valid outcome data from a sizable number of clients who have aversive reactions to their treatment assignments.

Moreover, contrary to conventional wisdom, it cannot be assumed that all compliance problems in alcoholism treatment research stem from the negative experiences of participants in the treatment setting. Increased work and family responsibilities resulting from an improvement in the drinking behavior can account for some individuals having difficulties remaining committed to the research. These persons may become less motivated as they become increasingly involved in day-to-day activities. Not surprisingly, they may want to forget that time in their lives when they engaged in excessive alcohol use. Evidence suggests that individuals refusing further contact (in contrast to those lost at followup) do as well as those who remain in the study (Silverman and Beech 1979).

At the same time, there is an ongoing concern that the high task demands placed upon clients could contribute to low attrition rates, especially among individuals residing in socially unstable settings. This was a concern in Project MATCH, since clients had to undergo extensive testing on a regular basis, and much of the information was not used for treatment purposes.

In addition, the length of the followup period in Project MATCH (15 months for aftercare clients and 39 months for outpatient

clients) was seen as creating potential compliance problems. A rule of thumb in outcome research is that the longer the posttreatment period, the greater the number of difficulties in maintaining participation. Studies have shown that the number of hardships stemming from drinking (e.g., family problems) is a significant predictor of noncompliance (Zweben et al. 1988). Given the day-to-day pressures experienced by clients, the length of time between intake and the final followup appointment could conceivably have a negative impact on the research.

Thus, it became apparent in Project MATCH that much thought and preparation would be needed to deal with compliance problems. Without an adequate plan, there was a strong possibility of substantial numbers of participants dropping out from both treatment and followup. Therefore, it was deemed necessary to devise a trialwide strategy for addressing compliance issues. The investigators and staff drew upon their knowledge of the compliance literature and experience in conducting outcome studies to develop a coherent framework for dealing with compliance problems across different clinical research settings. The next section describes the conceptual framework that guided trial investigators in their attempts to define, measure, and maximize compliance with the protocol.

Research Compliance Model

In Project MATCH, as in many alcohol treatment outcome studies, compliance problems were viewed from a multidimensional perspective. That is, how well participants fulfill the research task demands is related to a combination of individual, interactional, and contextual issues.

- *Individual.*—Participants may be so frustrated or dissatisfied with their prior treatment experiences that they may be unable to engage in the research protocol. Or, because of problems associated with drinking, their lives may be too disorganized or stressful to meet the demands of the study.

- *Interactional.*—A lack of consensus between worker and participant about the latter's roles and responsibilities could lead to future compliance problems. For instance, a participant's uncertainty or ambivalence about undertaking the necessary research task demands may not have been adequately addressed in the pretreatment interview. It is not uncommon for participants to initially give lip service to carrying out the study requirements in order to gain access to innovative and free study treatments or reimbursement for the initial assessment interview. Others may participate to look good for an upcoming court appearance.

- *Contextual.*—Participants may encounter barriers in the setting that interfere with their commitment to the research, such as poor transportation, inconvenient office hours, and other obstacles (e.g., no Spanish-speaking workers, no childcare arrangements).

Recognizing that a number of issues affect participant involvement, the general approach undertaken in Project MATCH was to use information generally known about individuals afflicted with alcohol problems and the unique cultural, social, and personal circumstances of the individual client to develop a plan for maintaining the participant's involvement with the research protocol. The aims of these compliance strategies are to address concerns that arise during the course of the study *before* they result in serious noncompliance behaviors. This gives researchers a head start in reducing potential barriers (e.g., client resistance) that could eventually interfere with obtaining accurate data, thereby improving the efficiency of the research enterprise.

Practical Strategies

Alcoholism is a chronic disorder with unexpected relapses, family disorders, and social upheavals. Consequently, individuals afflicted with alcohol problems may require help at unexpected times. This dynamic interplay of personal, social, and situational factors requires a continuum of strategies to maintain participant involvement in and commitment to the research protocol. These strategies may involve reducing task demands on participants, such as administering a questionnaire via telephone rather than in person, or increasing support for participant involvement through a variety of outreach activities, such as conducting interviews in a participant's home instead of at the trial site.

Many of these strategies are geared to creating what has been termed a user-friendly environment. This usually entails choosing a site that is readily accessible, having flexible appointment times, and providing important amenities such as transportation vouchers, childcare, and emergency referrals. Such an approach helps participants balance concerns of everyday living with the demands of the research. This is especially important for those with limited resources.

Other strategies may involve the use of prompts, reinforcers, and incentives to facilitate client participation. This means that participants routinely receive brochures or pamphlets explaining followup procedures, letters or phone calls reminding them about appointment times, and trinkets such as mugs, tee shirts, and pens with the study logo on them. Also, clients are offered remuneration for providing blood and urine samples and for participating

in followup interviews. Together, these strategies help to reinforce commitment to the research.

Dealing with Difficult Clients

For most participants, the above strategies are sufficient to address anticipated or potential compliance problems in alcoholism treatment research. However, despite careful planning, some participants do not remain committed to the research protocol; their idiosyncratic circumstances have a negative impact on their involvement in the study. This requires adapting the protocol to address these particular circumstances or events and developing new strategies to deal with the unique concerns of these participants. For example, some clients may want to withdraw from the study after a period of heavy drinking. They may experience a great deal of guilt about their drinking and feel embarrassed about sharing this information with a followup worker. Some clients may be isolated from their family and friends and consequently lack the requisite support to continue in the study. Conventional strategies such as offering financial incentives for completing assessment interviews usually prove to be futile or counterproductive with such participants. Thus, innovative and creative methods are needed to maintain high followup rates.

A review of procedures employed in Project MATCH indicated a commonality in efforts made across the settings in responding to special needs or circumstances of participants. It is important to point out here that tailor-made or customized strategies were typically used when the commonly employed strategies were not successful in maintaining participants in the study. In this monograph, we have tried to integrate these experiences to show how the various strategies can be used differentially to deal with various kinds of compliance issues.

Finally, time and financial constraints of a study dictate an efficient use of strategies by tailoring the approach to reflect the capacities, needs, and resources of hard-to-reach participants. Using customized strategies does not necessarily mean you are working *harder* but rather working *smarter.*

Maintaining Boundaries Between Data Collection and Therapy

Obtaining subjects' compliance with the research protocol without compromising the integrity of the study has been a troublesome issue in outcome research. Research staff are expected to work at rapport building and help confirm a clients' commitment to the research protocol. Such involvement is expected to facilitate obtaining accurate and complete data from the client population. However, participants often fail to distinguish between research and clinical activities during the course of the study even though efforts are made to separate the different functions. Clients often

consider frequent followup interviews as equivalent to aftercare treatment (Sobell and Sobell 1982), and such blurring of clinical and data-collection roles may contaminate the results. If clients believe that the interviewers are more committed to helping them change their drinking behavior than to obtaining accurate and complete information, they may enhance their self-reports in order to give the interviewers what they think they want to hear.

Therefore, how to maintain the boundaries between research and therapeutic components is given serious attention in this monograph. The question is not whether social interaction between participants and research staff could become therapeutic but, rather, how to minimize this therapeutic component in followup. The concern is that research staff might cross over the boundary of data collection and serve in an active helping capacity with participants. To address this issue, Project MATCH established a coordinating center that was responsible for (1) the training, monitoring, and supervising of staff that collected the data generated in the trial and (2) the conduct and monitoring of the study treatments. These two functions were carried out in separate settings employing different staff members. Separating these functions helped to prevent the blurring of roles related to data gathering and therapy.

High Compliance Rates in Project MATCH

In Project MATCH, research compliance was simply defined as the extent to which a participant met the requirements of the followup protocol (Mattson and Delboca, submitted). This was measured by a variety of indicators such as attendance at followup sessions, timeliness of attendance, accuracy and completeness of data, provision of urine and blood specimens, and the identification of a collateral informant.

At the 15-month followup, 92.5 percent of Project MATCH participants were interviewed. Complete followup data were obtained on 95 percent of the participants at 15 months, and 85 percent at 39 months. The latter group included outpatient clients only. Further, the mean number of followups attended for the 15-month period was 4.45 (out of a total of 5 appointments); 83 percent of blood and urine samples were obtained at 15 months; and collateral information was collected on 75 percent of the sample. At the same time, the self-report data were found to be highly accurate, as evidenced by the reliability and validity studies conducted during the course of the study (Project MATCH Research Group 1997).

Project MATCH compliance rates for the research protocol are excellent when compared with those reported in other studies. For example, Miller et al. (1994) in reviewing alcoholism treatment

outcome literature discovered that only 57 percent of studies could account for 85 percent of the cases at one or more followups. Moreover, in a large-scale study conducted by the National Institute on Drug Abuse, the average followup completion rate among the various research sites was 49 percent (Desmond et al. 1995).

Thus, our positive experiences in Project MATCH provided the impetus for developing this monograph on research compliance to share what was learned with other researchers.