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How Practice and Science Are Balanced and Blended in the NIDA Clinical Trials Network: The Bidirectional Process in the Development of the STAGE-12 Protocol as an Example

Dennis M. Donovan, Ph.D.^{1,2}, Dennis C. Daley, Ph.D.^{3,4}, Gregory S. Brigham, Ph.D.⁵, Candace C. Hodgkins, Ph.D.⁶, Harold I. Perl, Ph.D.⁷, and Anthony S. Floyd, Ph.D.⁸

¹Alcohol & Drug Abuse Institute, University of Washington, Seattle, WA, USA

²Department of Psychiatry & Behavioral Sciences, University of Washington School of Medicine, Seattle, WA, USA

³Department of Psychiatry, University of Pittsburgh, Pittsburgh, PA, USA

⁴Western Psychiatric Institute and Clinic, Pittsburgh, PA, USA

⁵Maryhaven, Inc. Research Institute, Columbus, OH, USA

⁶Gateway Community Services Inc., Jacksonville, FL, USA

⁷National Institute on Drug Abuse, Bethesda, MD, USA

⁸University of Washington, Seattle, WA, USA

Abstract

Background—Bidirectional, collaborative partnerships between academic researchers and practitioners have been a fundamental vehicle to achieve the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) goal of improving outcomes of community-based drug treatment. These partnerships blend clinical perspectives of practitioners and methodological expertise of researchers working together to address clinically meaningful issues through randomized clinical trials conducted in community treatment settings.

Objectives—Bidirectionality is a guiding principle of the CTN, but its operationization at the practical level in protocol development and implementation has not been articulated. This descriptive article presents the development of one protocol as an example and model of this bidirectional, collaborative, iterative partnership between researchers and practitioners.

Methods—This article illuminates several specific issues encountered while developing STAGE-12, a behavioral intervention to facilitate 12-step mutual support group involvement, as well as the rationale for decisions taken to resolve each.

Results—The STAGE-12 protocol was successfully developed through a series of decisions taking into account both design factors and clinical practice needs and realities, thus maintaining a balance between methodological rigor and generalizability.

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Address correspondence to Dennis M. Donovan, Ph.D., Alcohol & Drug Abuse Institute, University of Washington, Seattle, 1107 NE, 45th Street, Suite 120, Seattle, WA 98105-4631, USA. Tel: 206-543-0937. Fax: 206-543-5473. ddonovan@u.washington.edu.

Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

Conclusion—The review demonstrates the process by which research and practice have been blended in protocol development, exemplifying the underlying principle of bidirectionality, a key element in the success of the NIDA CTN.

Scientific Significance—Bidirectional partnerships as derived in the CTN, employing a hybrid model of efficacy-effectiveness research, are capable of designing and implementing protocols that are both methodologically rigorous and clinically meaningful, thus increasing likelihood of adoption and eventual improvement in public health.

Keywords

bidirectionality; research; clinical practice; internal validity; external validity; clinical trials network; protocol development

INTRODUCTION

In the early 1980s, Miller and Hester (1) documented the lack of overlap between those interventions for alcohol dependence having demonstrated efficacy and those routinely being used in alcohol treatment programs. They noted that treatment “follows a standard formula that appears to be impervious to emerging research evidence” (p. 162). A similar but more recent pattern was found in drug dependence treatment: limited use of a number of empirically supported behavioral treatments in drug dependence treatment programs, while many programs were widely using treatments that had not undergone evaluation of their efficacy (2). This “gap” in the substance abuse field reflected a disconnect between clinical researchers, who work primarily in academic centers, and the providers, who deliver the majority of addiction treatment, namely clinicians working in community-based drug abuse treatment programs (3,4). As a result, many new and promising treatment approaches that have emerged from academic settings have failed to address the specific clinical, programmatic, and/or fiscal needs and realities of community-based treatment programs (CTPs), thus decreasing their adoption into standard clinical care (5–7).

In response to this state of affairs, a special Institute of Medicine (IOM) panel was convened to recommend methods by which evidence-based interventions developed in academic settings could be transferred more effectively to and implemented in CTPs. One of the recommendations from the resultant IOM report, “Bridging the Gap between Practice and Research: Forging Partnerships with Community-Based Drug and Alcohol Treatment” (8), was to provide a mechanism to facilitate the communication, interaction, and shared involvement of researchers and community-based practitioners in the development and testing of interventions. This led the National Institute on Drug Abuse to develop the National Drug Abuse Treatment Clinical Trials Network (CTN) (3,9), whose mission is to improve the outcomes of community-based drug treatment programs, using science as the vehicle. Consisting of drug abuse treatment researchers in 17 regional centers and the directors and clinical staff of affiliated CTPs, the goal of the CTN is to develop and implement provider-informed clinical trials to be conducted in community-based drug treatment settings as a means of generating and validating interventions that fulfill the practical needs of such programs (3). Researchers and practitioners from each regional center have equal representation within the CTN, with a principal investigator (PI) and a representative from an affiliated CTP from each regional center having a vote on the Steering Committee (see (3) for more details about CTN structure and governance).

The CTN provides a framework and an infrastructure for substance abuse researchers and treatment providers to work together collaboratively to develop, implement, and test interventions that blend the best of addiction research balanced by the everyday realities of

community-based treatment delivery (9). The transition from conducting research in academic settings to designing and conducting clinically relevant community-based trials having an increased likelihood of intervention adoption is an important goal but a difficult process (6). It involves a shift in both thinking and methodology from efficacy toward effectiveness research. It requires an informed appreciation of a number of factors in addition to research methodology, such as feasibility, generalizability, acceptability, relevance, and the potential sustainability of the intervention (6).

Meeting this mission necessitated developing bidirectional, collaborative partnerships between academic researchers and community-based practitioners. This process is meant to bring together clinical perspectives and methodological expertise to identify clinically meaningful issues, evaluate evidence-based interventions in multisite randomized clinical trials conducted in CTPs to address these, and disseminate their findings. However, developing protocols to be implemented in CTPs requires a balance and some compromises between scientific rigor and practical, clinical, and programmatic realities and between study designs that increase the generalizability of data derived from such trials (external validity) versus tightly constrained designs that impose conditions that enhance methodological rigor at the expense of generalizability (internal validity) (6). The need to achieve such an equilibrium within CTN trials has led to the development of a hybrid model that blends elements of both efficacy and effectiveness studies (2).

Although bidirectionality has become the guiding principle of the CTN (3), there has not been a description of how this process has been operationalized and has played out in protocol development. This article describes the bidirectional collaborative process that occurred between researchers and community treatment providers in all aspects of the development of a CTN protocol in which two evidence-based interventions were adapted for use in intensive outpatient programs (IOPs) to facilitate stimulant-addicted patients' attendance at and engagement in 12-step self-help meetings. It further describes a number of decisions that reflect the balance between research and practice considerations. The bidirectional protocol development process described here is an exemplar.

BIDIRECTIONALITY IN CTN PROTOCOL DEVELOPMENT

Initial ideas about potential CTN protocols are first submitted for review by a Concept Review Group, composed of both researchers and CTP practitioners, that considers both methodological and feasibility issues. If provided with positive feedback, the concept is then referred to the CTN and NIDA leadership for further consideration. If approved for further development from concept to elaborated protocol, a protocol development team is formed. This team typically is composed of investigators with research methodology and content expertise; representatives from CTPs, who provide input about the "real-world" issues that need to be taken into account; quality assurance, regulatory affairs, data management, and statistical experts associated with the CTN Clinical and Data Management/Statistical Coordinating Centers; a liaison from the Center for Clinical Trials Network (CCTN); and a national project director who coordinates the activities of this group. In this protocol, there was also an executive committee, which had the decision-making responsibilities. The executive committee was composed of the Lead and Co-lead Investigators (the first two authors of this article); two representatives from CTN-affiliated treatment programs having interest in the protocol topic (the third and fourth authors); and the NIDA CCTN liaison (the fifth author). This was the decision-making group; thus, the CTPs played an important and equal role in the details of the protocol as it evolved. Deliberations were informed by input from the literature, clinical practice, and the expertise of other development team members. Decisions were most often reached by consensus, but in the case where consensus was not achieved, the Lead-Investigator had the final decision. The process was facilitated by

weekly conference calls during the early phases of development, with calls every other week in later stages. The development team also had face-to-face meetings at quarterly National CTN Steering Committee meetings. Prior to the final sign-off by NIDA, the fully elaborated protocol had to be reviewed and approved by an independent Data and Safety Monitoring Board (DSMB), which evaluated both design and safety aspects of the trial and monitored its progress across time.

FOCUS ON 12-STEP APPROACHES IN THE CTN

Practitioners within the CTN expressed interest in developing a protocol that would address questions about the 12-step mutual support programs such as Alcoholics Anonymous, Cocaine Anonymous, and Narcotics Anonymous. Such groups represent an ubiquitous, readily available, no-cost recovery resource that has benefited millions of substance abusers, as evidenced by an increasingly large body of data demonstrating the benefits of early, consistent, and more frequent meeting attendance and involvement in increasing abstinence, psychosocial functioning, and self-efficacy, and in reducing health-care utilization and costs (10–18). The 12-step philosophy, which plays a prominent role in substance abuse treatment (19), is consistent with treatment practices and philosophies of many CTPs, is applicable to a broad range of clients in different settings, and can augment a wide range of standard treatments. Combining the 12-step meeting attendance and the engagement in 12-step recovery activities with formal treatment leads to better outcomes than found for either alone (20,21).

Despite these potential benefits, a relatively small percentage of substance abusers attend 12-step groups and many drop out (15,20–26). Approaches to encourage patients' attendance at 12-step meetings typically involve unsystematic referrals that have been minimally effective (11,18,27,28). Consequently, there have been recommendations to develop, implement, and evaluate strategies for treatment programs to more effectively facilitate engagement in 12-step groups and activities (12,15,29–31). These recommendations contributed to the decision to conduct a multisite study of such an approach within the CTN. This decision was strongly supported by representatives of CTN-affiliated CTPs; 82.1% of 317 counselors affiliated with 10 organizations in the Delaware Valley CTN, with a total of 50 addiction treatment programs in a wide range of treatment settings (primarily outpatient programs or IOPs) in Pennsylvania, New Jersey, and Delaware, indicated that 12-step programs should be used more in addiction treatment (32). Also, a facilitated research prioritization process of CTN researchers and practitioners held as part of a quarterly CTN Steering Committee meeting in 2005 resulted in conducting research on some form of 12-step intervention being rated as the highest priority. CTPs saw such an approach as consistent with current practice within most of their programs, potentially easy to train, augmenting a wide range of treatments, usable by counselors of varying skill levels and recovery status, and quite sustainable over time.

STIMULANT ABUSER GROUPS TO ENGAGE IN 12-STEP

NIDA was particularly interested in addressing the escalating problem of methamphetamine abuse and suggested that the protocol target individuals with methamphetamine problems. Based on discussions with CTPs, the scope of the study was expanded to include cocaine abuse which broadened the appeal of the approach, given that many of the CTPs serve a much higher proportion of clients with cocaine use disorders than those with methamphetamine use disorders. This decision also expanded the geographical range of potential participating CTPs since methamphetamine was most prevalent in Western and Midwestern states with little presence in Eastern states (33,34); it increased the overall generalizability of the intervention to stimulant abuse. The potential utility of 12-step

approaches for stimulant abusers (30) was demonstrated in NIDA's Collaborative Cocaine Treatment Study (CCTS) (35,36). A protocol development team composed of researchers and clinicians collaborated to design a 12-step facilitative intervention for stimulant abusers consisting of empirically supported components that were acceptable to CTPs and could be adequately evaluated.

The resultant intervention, Stimulant Abuser Groups to Engage in 12-Step (STAGE-12), consists of five group and three individual sessions delivered over 5–8 weeks in an intensive outpatient treatment setting. These replaced treatment-as-usual (TAU) sessions so as not to create additional burden for programs, clinicians, or patients. STAGE-12 combines elements of two empirically supported interventions: the Project MATCH 12-Step Facilitation Therapy (TSF) adapted for both group therapy delivery (37) and use with drug-dependent clients (28,38–41); and an Intensive Referral (IR) procedure (18,42). The goal of the former component is to introduce participants to 12-step concepts and principles while the latter component actively attempts to get participants involved in 12-step meetings by having 12-step members serve as “buddies” or temporary sponsors and take participants to meetings in the community.

ISSUES AND DECISIONS IN THE STAGE-12 PROTOCOL DEVELOPMENT

Table 1 lists a number of issues the protocol team had to address to maintain the balance between internal and external validity during intervention development while also maintaining and capitalizing on crucial buy-in from CTPs and practitioners by developing an intervention and clinical trial that they saw as having direct clinical applicability and that incorporated their input.

RATIONALE FOR COMBINING IR WITH 12-STEP FACILITATION COMPONENTS

An initial question dealt with combining components from two approaches, each with independently demonstrated efficacy. Both interventions had compelling and complementary features likely to enhance participants' engagement in 12-step groups and activities. Rather than choosing between the two, the decision was made to integrate elements of each into a combined intervention. This decision was consistent with prior findings suggesting that interventions like the IR that are effective in increasing 12-step attendance may be insufficient to ensure active and continued involvement (43). Individuals' inability to embrace or utilize other aspects of the 12-step program may contribute to early attrition. Individuals who are attending 12-step groups but are having difficulty embracing key aspects of the program may benefit from professional assistance that focuses more on 12-step practices and tenets and less on meeting attendance. Thus, in STAGE-12, the active engagement component, IR, is complemented by TSF, which focuses more on providing a basic understanding of 12-step philosophy.

Another important aspect of the combined intervention is its blending of professional counseling and peer support. STAGE-12 is delivered by counselors in CTPs but connects participants with community-based 12-step group members. The volunteer provides an orientation to 12-step programs, accompanies the person to a meeting, introduces him/her to other members, and serves as a temporary source of support. Such a “buddy system” has often been used informally and unsystematically in treatment programs. Consistent with and modeled after the Alcoholics Anonymous (AA) “Bridging the Gap” program, this approach, available through local AA groups, allows CTPs to develop and sustain this active engagement component with relatively limited costs. Such an approach also allows 12-step

members to partake in service and “give back,” which is also beneficial to the volunteer (44).

GROUP VERSUS INDIVIDUAL THERAPY

The next issue in the development process was how to deliver the STAGE-12 intervention. Prior research on TSF used an individual counseling format (28,36,45), primarily because it is simpler to maintain experimental control and examine therapist effects in studies of individual therapy. Yet, group formats represent the modal form for delivering substance abuse treatment services (46–49), chosen because of its cost-efficiency, ability to provide services to larger numbers of clients, and perceived effectiveness at engaging patients. Further, groups may involve a number of “curative factors” that facilitate behavior change and the acquisition and maintenance of abstinence (47,48). Groups are also more consistent with the delivery of 12-step interventions, since an individual format neither offers the potential curative benefits of group approaches nor prepares clients for the group context and process that they will encounter in 12-step groups in the community (50).

Addiction researchers have focused considerably less on evaluating group treatment than it has been studied in other areas of behavioral health (51). This constitutes a major gap between substance abuse research and practice (8) that has been difficult to address across the field in general and within the CTN. This point was noted in feedback from the CTN Concept Review Group of an earlier concept for this protocol that proposed studying individual therapy: “The decision to use individual rather than group treatment appears justified. But the sustainability of individual treatment at CTPs and the dearth of group treatment manuals are a CTN dilemma.”

Another possibility was some combination of group and individual therapy. Results from the CCTS suggested that group-based 12-step approaches may be enhanced further by the addition of individual sessions that reinforce and augment the groups’ 12-step emphasis. A combination of intensive manual-guided individual drug counseling plus group drug counseling was more effective for treatment of cocaine dependence than either independently or compared to professional psychotherapy (36). A combination of individual plus group counseling is also a common method of delivering care in intensive outpatient treatment (52). Thus, such a format would be compatible with current clinical service delivery practices; there also may be a potential fiscal advantage for some clinics providing a combined group plus individual approach when compared to either group or individual sessions alone, depending on how and by whom they are reimbursed for services.

A step that has been used during the development of many CTN protocols has been to survey CTPs about their potential interest in participating in the protocol, their ability to recruit the target patient population, and about the issues of study and intervention feasibility. This step both informs protocol development and facilitates implementation planning (3). Consistent with this approach and in order to help guide this decision, the protocol team chose to seek input from constituent programs within the CTN. Surveys were sent to the coordinator at each of the CTN regional centers to be distributed to their affiliated nonopioid substitution outpatient programs and IOPs. Sixty-seven CTPs responded, with 1 to 7 responses from each of the 17 regional centers in the CTN at the time. Given the nature of the survey distribution process and the fact that this was an informational not a scientific survey, the number of CTPs to which the survey was sent, and thus the percentage of respondents, is not known. Of the 67 responding CTPs, 12 were hospital affiliated (4 of which were Department of Veterans Affairs) and the remaining were community based. Most were nonprofit or not-for-profit organizations. The organizational characteristics of this sample are similar to those found for the CTN more broadly. Compared to pooled

representative samples of public-sector and private-sector programs, CTN-affiliated programs are more likely to be nonprofit, accredited, and outpatient-only (53).

CTPs were asked for the type of delivery they would be most likely to use to adopt a 12-step facilitative intervention for their programs. They rank-ordered three alternatives: individual therapy alone, group therapy alone, or group plus individual therapy. Combined group plus individual treatment was ranked first (i.e., most likely to be preferred) by 59.4% of the 67 responding CTPs; group alone was ranked first by 39.1%; and individual treatment was ranked first by only 1.6%. These expressed preferences led to the decision to develop STAGE-12 as a combined group and individual intervention.

COHORT VERSUS ROLLING ADMISSION GROUPS

The next question was what method to use to enroll individuals into the group. Two alternatives included cohort/closed admission, in which a set number of participants enter and remain in group together without replacement through a sequential curriculum, and open/rolling admission, in which individuals can enter the group at any session (54). Advantages of the cohort approach are that it may contribute to greater group cohesiveness, leading to increased support, bonding, and willingness to interact over time, all of which may serve as “curative” factors. Disadvantages are primarily logistical, namely, that it typically takes a long time to constitute a cohort and many potential group members may not wait around; also, once a group begins, attrition without replacement leads to small group size. Rolling admission has the advantage of shorter waiting periods prior to group initiation and a regular flow of new members into the group, thus “filling the seats” (which is important from business as well as clinical standpoints). As disadvantages, rolling admission may result in lower group cohesion, since new members are entering regularly and have to introduce themselves to the group; it also requires a flexible curriculum that accommodates participants entering the sequence of group sessions at any point without need for prerequisites.

Morgan-Lopez and Fals-Stewart (54) noted that of these two approaches to group entry, rolling admission/open-enrollment groups are far more common in CTPs than are cohort groups; 84% of the directors of 57 randomly selected outpatient community-based substance abuse treatment programs in the Northeastern United States surveyed reported using open enrollment group admission. These program directors cited economic reasons (e.g., able to keep group filled with patients receiving billable service) and clinical reasons (e.g., reduced wait times for group) for their preference. Consistent with this, the STAGE-12 protocol development group asked CTPs “If you were to deliver some or all of a 12-step intervention in a group format, which type of group would you most likely use?”; 95.4% of the 67 respondents endorsed open/rolling admission groups. Based on this, the protocol development team devised a curriculum to accommodate the incorporation of the combined group plus individual intervention into the context of a rolling admission format.

LENGTH OF INTERVENTION: HOW MANY SESSIONS OVER WHAT TIME PERIOD

A practical disadvantage of previous 12-step-oriented interventions, delivered either in group (55,56) or combined group plus individual format (36,57), is their length and its impact on client attrition. Relatively high attrition rates suggested that many participants were not receiving the prescribed dose of treatment in these lengthy interventions. Many CTPs also indicated that it would be difficult to accommodate or sustain such lengthy interventions in the current climate of briefer treatment episodes. Concurrently, a number of clinical researchers were suggesting the need to develop and evaluate briefer 12-step

facilitative interventions (11,12,15). Whatever the nature of the 12-step facilitative intervention, it needed to fit within the framework of standard, currently available treatment offerings. Thus, a briefer 12-step facilitative intervention would fit the realistic clinical and fiscal constraints of CTPs.

The protocol development team designed the STAGE-12 to consist of an initial individual session to orient participants to STAGE-12 and the 12-step approach and to incorporate the IR procedures, five 1.5-hour group sessions that could be joined at any point in the sequence, with an individual check-in session midway through and a final individual termination session at the end of the group component. This format was intended to increase the likelihood of fitting STAGE-12 into the typical structure of most IOPs while still being able to deliver the “core” components of the intervention and allow sufficient time to let people attend meetings and work on assigned recovery tasks between sessions. To accommodate these needs, it was decided that the STAGE-12 intervention would be delivered over a 5–8-week time frame. For clinical implementation outside the research context, this time frame could be compressed; also, while designed for implementation in an IOP setting, STAGE-12 could also be delivered in residential or outpatient settings.

STAGE-12 AS AN ADD-ON TO TAU VERSUS INTEGRATED INTO TAU

A related issue was how to incorporate STAGE-12 into the participating CTP programs. Two options were available: as an add-on to TAU or integrated into TAU; each has practical as well as methodological tradeoffs. Adding STAGE-12 to TAU produces differential amounts of treatment, making TAU plus STAGE-12 longer than standard TAU. This would make it difficult to determine whether any observed benefits accruing to STAGE-12 were attributable to the content of the intervention or to receipt of more treatment. Also, adding five group and three individual sessions to TAU might create attrition problems. However, integrating STAGE-12 into TAU while maintaining comparable overall length of treatment would require displacing other components of standard treatment, resulting in a “modified TAU.”

Both possible approaches focus on increasing the study’s generalizability and external validity and have impacts on other methodological considerations (58,59). While both approaches address questions relevant to providers, program directors, and policy makers, each addresses slightly different questions (59). The primary question addressed by the additive approach is, “What is the impact of *adding* a new treatment intervention to an existing treatment program or TAU?” This design is most suitable for testing an intervention that is inherently an add-on to an existing treatment program, not a replacement for part of TAU. The integrative approach addresses the question “What is the impact of substituting a new treatment intervention for an existing component of TAU?” It is most suitable for testing interventions that are inherently substitutes for a component or service currently provided as part of TAU. CTP representatives indicated that the basic question that they were most interested in answering was “Does integrating STAGE-12 into treatment as it is typically delivered lead to better outcomes than the TAU that we currently provide?” This led us to decide to integrate STAGE-12 into TAU, which is also consistent with how most CTPs are likely to integrate a 12-step facilitative intervention into their programs.

DEFINING “TAU” AND ITS BOUNDARIES

Another possible option was to compare STAGE-12 against a control condition added to or integrated into TAU (58,59). Such a design, which is more often employed in efficacy trials, favors internal validity by more fully standardizing the comparison condition and reducing variability. This option was considered but discarded in favor of the integrative approach given CTPs’ interest in determining the benefit of incorporating STAGE-12 into their

current clinical offerings. However, concerns remained about the lack of standardization and the differing nature of TAU across participating CTPs, particularly because standard treatment is often based on a 12-step orientation, often includes 12-step meetings in their clinics, and often provides referrals to 12-step meetings. The potential overlap with STAGE-12 might reduce the effect size between conditions.

This concern was countered by a number of factors. Even programs that are based on a 12-step philosophy typically do not use approaches that actively support involvement in 12-step self-help groups, and when counselors do attempt to support 12-step self-help group involvement, they rarely use empirically supported methods (12). Counselors' referrals for clients to attend 12-step meetings are typically unsystematic, often consisting of nothing more than suggesting that he/she attend a meeting and providing the person with a list of meetings (11). This type of referral has been shown to be relatively ineffective at increasing attendance and engagement (18,27,42). It has been recommended that CTPs, even those presenting themselves as 12-step oriented, examine their practices and encourage counselors to use empirically validated techniques to support 12-step group involvement, which will be far more likely to lead to increased meeting attendance and engagement (11,12). It was felt that the systematic, manual-guided STAGE-12 intervention was sufficiently distinct from the typical 12-step-oriented activities found in TAU to allow a meaningful comparison with minimal overlap.

SUMMARY AND CONCLUSION

The mission of the CTN is to foster bidirectional, collaborative working partnerships between practitioners and researchers in order to address clinically meaningful issues and test potentially effective interventions in the context of community-based treatment. The subtitle of the 1998 IOM report (8), "Forging Partnerships with Community-Based Drug and Alcohol Treatment," connotes a degree of effort necessary to shape and mold the partnership in order to develop its bidirectional and collaborative process. Though labor-intensive and challenging, this process was meant to balance and blend scientific innovation and methodology with practical issues of quality of care, the constraints of clinical budgets, federal, state, and local regulations, and the challenges of implementing evidence-based treatment in clinical practice (3,7).

This CTN mission has been presented at a conceptual level, but the methods by which bidirectionality is operationalized at the practical level in protocol development and implementation have not been articulated. The processes employed in developing the STAGE-12 protocol exemplify a truly collaborative, bidirectional, iterative, and interactive partnership between researchers and practitioners. The STAGE-12 concept emerged from strong practitioner interest in having a 12-step protocol included in the CTN. The protocol developed through a series of decisions that incorporated methodological factors with clinical practice needs and realities. The result is a protocol and an intervention that blend clinical and research approaches, balance methodological rigor and generalizability consistent with a hybrid model that evolved from within the CTN (2), and exemplify the process underlying bidirectionality, a key element of the success in the CTN.

The CTN also represents an experiment about the bidirectional, collaborative process among researchers and community-based treatment providers in selecting and implementing trials that integrate practicality and sound science (7). Intended outcomes of this process are an increased awareness on the part of researchers about the influence that results from clinically relevant research may have on clinical practice and an increased appreciation on the part of practitioners that research can address clinically meaningful questions and improve the quality and effectiveness of care (3,7). A review of the first decade of the CTN's operation

suggests that it has been successful at a number of levels. First, utilizing bidirectional protocol development processes similar to the one described, the CTN has developed, implemented, and successfully completed over 20 clinical trials involving over 11,000 individuals from community-based treatment programs (see (3) and the CTN Dissemination Library [<http://ctndisseminationlibrary.org/>] for additional information about CTN protocols). Second, exposure to or involvement in CTN has increased the likelihood of intervention adoption among CTPs (53). Third, there is evidence of increased positive working relationships and mutual trust between the academic researchers and community-based clinicians within the CTN (7). The CTN has invested heavily in the process of bidirectionality and it appears to be paying positive dividends.

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TABLE 1

Methodological and practical clinical issues encountered in the development of STAGE-12 protocol and the bidirectionally determined decisions.

Methodological/clinical issue	Bidirectionally determined decision
Why combine elements of two evidence-based approaches?	• To capitalize on different targets of attendance and engagement
Individual versus group therapy (internal vs. external validity)	• Combined group plus individual (leaning more toward external validity)
Cohort versus rolling admission groups	• Rolling admissions
Length of intervention How many sessions	• Five group plus three individual sessions
Over what time period	• 5–8 weeks
In what setting	• Intensive outpatient
STAGE-12 as add-on versus integrated into TAU	• Integrated into TAU
Comparison condition Standardized versus CTPs' TAU	• TAU

Note: STAGE-12, Stimulant Abuser Groups to Engage in 12-step; TAU, treatment as usual; CTP, community-based treatment program.