Implementing Research in Community Treatment Programs: Findings from a CTN Trial

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Background

- The Clinical Trials Network (CTN) was established by the National Institute on Drug Abuse (NIDA) in 1999 to facilitate evidence-based addiction treatment into community treatment settings.
- Implementation of CTN trials has resulted in a network of participating community treatment programs (CTPs) with responsibilities for conducting "hybrid and pragmatic" research studies in community settings.
- This presentation illustrates the evolution of two Pacific Region Node CTPs, and describes organizational experiences in their participation in an ongoing trial: *Starting Treatment with Agonist Replacement Therapies* (START; CTN 0027), designed to evaluate hepatic safety in opiate-dependent individuals receiving Suboxone or methadone pharmacotherapy for 24 weeks.
- The Bay Area Addiction Research and Treatment, BAART (Turk St., San Francisco) and the Matrix Institute on Addictions (Los Angeles) CTPs (both characterized as "traditional" methadone treatment programs serving largely lower income and indigent populations) adapted their opioid treatment programs to include suboxone, an evidenced-based medication.

CTP Descriptions

The Matrix Institute and BAART/Turk each have 17 years experience as addiction treatment programs, offering opiod agonist replacement therapy (methadone) for opioid dependence, counseling and other psychological and medical services. Matrix, a moderate sized program with approximately 300 patients maintained on methadone, had prior experience conducting research studies outside of the CTN. BAART/Turk St., with a larger census of approximately 700 patients, had no experience conducting medication trials prior to START.

Before START, neither program had been successful at incorporating Suboxone as an option to methadone under their OTP license and very limited Suboxone treatment was available under the clinic physicians' personal DEA waivers. While such programs were permitted to use Suboxone under OTP licensing, the medication was not on the State formulary and cost was prohibitive. Federal regulations provide challenges in offering Suboxone as a treatment option in traditional methadone programs.

Challenges and Issues

Staffing: Turnover and loss of highly trained and experienced research staff during study implementation is challenging and both sites lost key research staff during the START trial. At BAART, site PI changed three times with two research assistants having to be replaced while Matrix replaced their PI twice, PA three times and R/As four times.

Recruitment: Recruitment for both CTPs primarily targeted individuals for whom treatment would likely have been unaffordable or financially burdensome. Treatment through 32 weeks was offered at no cost to participants. Common to both sites were recruitment strategies which included newspaper advertising, community outreach, fliers and announcements, and patient word-of-mouth. Although at times recruitment was very challenging, both programs successfully contributed significant numbers of patients to the study:

CTP	Total Consents	% Screens to Randomizations	Total Randomizations			% Actual/ Expected
			B	M	Total	
BAART	296	63	109	78	187	105
Matrix	223	57	78	50	128	91

Retention: Retention was critical to assess treatment safety, with a total requirement of 600 patients (300 in each arm) to remain on study medication for 24 consecutive weeks in order to be considered evaluable. Across sites, differential retention rates were observed in the two arms, with 73% of the methadone and 46% of the buprenorphine patients completing 24 weeks of medication assisted therapy. The result of this finding moved NIDA to conduct an "add-on" study to look at specific contributors to this differential retention rate.

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Lessons Learned

Much was learned during the four years it took to complete the START study at Matrix and BAART. Both programs were tasked to integrate a relatively new treatment technology into their existing and very busy clinic schedules, with staff and patient populations largely naïve to treatment with Suboxone. Shared lessons included:

- Substantial and ongoing training and QA support is critical and was provided by the Lead Node staff at UCLA /ISAP
- Integrating research staff and patients into the existing fabric of the CTP is critical to reducing barriers and ensuring successful study completion
- Loss of trained and experienced research staff during the START study presented difficult but manageable stresses. Wherever possible, it is optimal to be able to retain research staff within and particularly across studies
- Overall experience gained from START was rich and invaluable

Conclusions

The overarching goal of the NIDA Clinical Trials Network is to bridge the gap between research and practice, improving "the quality of drug abuse treatment throughout the country using science as the vehicle." The process requires a two-way communication and willingness to adapt and learn, which was well exemplified in the four years of participation by Matrix and BAART in the CTN START trial. The experiences of BAART and Matrix illustrate that conducting pragmatic clinical trials research in community treatment settings is not only possible but necessary to assist adoption of research results among physicians, clinicians, providers and patients.

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