Patient Feedback: A Performance Improvement Study in Outpatient Settings

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LIST OF ABBREVIATIONS

AE = Adverse Event
ASI = Addiction Severity Index
CALPAS = California Psychotherapy Alliance Scale
CARF = Commission on Accreditation of Rehabilitation Facilities
CEO = Chief Executive Officer
CRF = Case Report Form
CTP = Community Treatment Provider
CTN = National Drug Abuse Treatment Clinical Trials Network
DSMB = Data Safety Monitoring Board
EUCS = End User Computing Satisfaction
IRB = Institutional Review Board
JCAHO = Joint Commission on Accreditation of Healthcare Organizations
LI = Lead Investigator
LMX = Leader Member Exchange
MSQ = Minnesota Satisfaction Questionnaire
NIDA = National Institute on Drug Abuse
PA = Project Assistant
Feedback = Patient Feedback
PI = Performance Improvement
QA = Quality Assurance
RRTC = Regional Research and Training Center
UDS = Urine drug screens

SYNOPSIS

Overview

This study assesses the feasibility of outpatient clinicians and supervisors using a performance improvement[1] (PI) system ("Patient Feedback") to monitor patient ratings of group counseling, improve patient attendance and their ratings of treatment satisfaction. Every other week as patients leave group counseling sessions, they will be invited to complete a 12-item, self-administered survey (Appendix A) in which they rate therapeutic alliance and their group counseling experience, plus provide descriptive information about themselves and their past week substance use. These surveys are faxed to the University of Pennsylvania, Treatment Research Center Data Management Unit where they are converted into feedback reports that are accessible through a password protected website. Clinic supervisors will access an aggregated feedback report that summarizes data from the combined clinic caseload. Individual clinicians will access feedback reports on their own caseloads as well as the aggregated data for the clinic. Each feedback report will consist of seven time-series graphs that display interactions between the performance indicators (therapeutic alliance and group experience rating) and three patient characteristics (gender, length of stay and ethnicity); a seventh graph presents attendance data. On a monthly basis clinicians and supervisors will meet as a team to review the feedback reports, identify performance indicators they'd like to improve, and describe the action steps they propose to implement. These monthly team meetings are guided by a Feedback Manual (Appendix L), and documented on a Team Meeting form (Appendix D). A monthly electronic newsletter (Appendix E) recognizing clinic achievements will be distributed. The feedback system will generate stratified benchmark data on outpatient attendance, self-reported abstinence, therapeutic alliance and group counseling satisfaction that is analyzable by clinician and clinic characteristics. The rapid processing of surveys will enable near real time feedback to clinicians and clinic supervisors. Organizations may share these data with funding sources, regulatory agencies, policy makers, and other stakeholders. This centralized, semi-automated feedback system eases fulfillment of accreditation requirements and may serve as a durable bridge for future patient/practice/research collaborations. This feasibility study is intended to provide a test of whether the patient feedback system can be successfully implemented and sustained in community-based treatment programs.

Objectives

The primary objective of this study is to test the feasibility of implementing a specific performance improvement system - patient feedback – in community based outpatient clinics. To assess feasibility,this study will determine whether:

a) 100% of eligible clinicians will be consented to participate in the study as evidenced by percent of signed informed consents in the study binders.

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[1] The term "performance improvement" is used throughout this protocol to refer to organizational management methods that were widely applied by W. Edwards Deming (1986) in Japan after World War II. Originally called "statistical process control," these methods have evolved over the past 60 years into related methodologies including: "quality improvement," "human performance technology," "performance measurement," "performance monitoring," "quality assurance," "continuous quality improvement," and "total quality management." All of these are methods of improving organizational performance by a) measuring key indicators, b) feeding back objective data, and c) implementing plans intended to continuously improve performance. The term *performance improvement* is used throughout this protocol in deference to the terminology used by the Joint Commission of Healthcare Organizations (JCAHO).

b) 100% of eligible clinicians will complete the Feedback training as evidenced by the training attendance record faxed to the lead node data management unit (DMU).

c) 100% of scheduled Attendance Logs will be faxed by the participating clinics to the DMU as evidenced by data records at the DMU.

d) At least 80% of patients who attend group will complete the feedback survey, as evidenced by dividing the number of surveys collected each month by the number of patients who attended treatment.

e) 100% of the Feedback Reports will be uploaded to the Patient Feedback website within 48-hours of the surveys and attendance Logs being faxed to the DMU, as evidenced by data records at the DMU.

f) 100% of supervisors will download the Clinic Feedback Reports at least monthly as evidenced by website usage records at the Patient Feedback internet site.

g) 100% of supervisors will conduct patient feedback team meetings each month as evidenced by the Team Meeting Forms faxed to the DMU each month.

h) 80% of eligible clinicians will participate in the monthly patient feedback team meetings, as evidenced by the number of eligible clinicians who sign the Team Meeting Form each month.

Study Schema

Six drug-free outpatient clinics with approximately 50 clinicians and 6 supervisors will be enrolled in the protocol.   Figure 1 and Table 1 present the protocol schema and timeline:

Figure 1 - Study Schema

Participants

o 6 Outpatient Clinics

o 30 Clinicians

o 6 Supervisors

Month 1: Pre-intervention Procedures
o Organizational Orientation and Assent
o Staff Informed Consents
o Implementation Calls (2)
o Clinic Characterization Survey
o Leader/Member Exchange
o Minnesota Satisfaction Questionnaire
o Patient Orientation
o Pt. Attendance (alternate weeks)

Month 2: Baseline
o Pt. Attendance (alternate weeks)
o Surveys collected (alternate weeks)
o New Patient Oriented

Months 3-5: Intervention
o Pt. Attendance (alternate weeks)
o PF Training
o Surveys collected (alternate weeks)
o PF Reports Provided (alternate weeks)
o Monthly Team Meetings
o Monthly Newsletter

Month 6: Assessment
o Pt. Attendance (alternate weeks)
o PF Surveys (2xs/mo)
o Leader/Member Exchange
o Minnesota Satisfaction Questionnaire
o End User Computing Satisfaction

Months 7-18: Sustainability
o Open access to PF System
o Staff Interviews
o System Usage Monitoring

Table 1. Timeline and Event Table

Table 1 presents the timeline and events of the patient feedback protocol. This protocol is divided into five phases identified along the top row of the table: Pre-intervention, Baseline, Intervention, Assessment and Sustainability.

Event	Freq.	Pre-Intervention Mo.1	Baseline Mo.2	Intervention Mo.3	Mo.4	Mo. 5	Assessment Mo. 6	Sustainability Mo. 7-18
Organizational Orientation & Assent	1	X						
Staff Informed Consent	1x	X						
Implementation Net Conf. Calls	1x	X						
Follow-up Implementation Call	1x	X						
Leader/Member Exchange	1x	X					X	
Minnesota Satisfaction Questionnaire	1x	X					X	
Clinic Characterization Survey	1x	X						
Patient Attendance	Alt. Weeks	X	X	X	X	X	X	
Patient Orientation	1x	X	X	X	X	X	X	
Feedback Surveys Collected	Alt. Weeks		X	X	X	X	X	
Feedback Reports Training	1x			X				
Feedback Reports Provided	Alt. Weeks			X	X	X	X	
Feedback Team Meetings	Monthly			X	X	X	X	
Feedback Newsletter	Monthly			X	X	X	X	X
Open Access to Feedback System	Ongoing							X
End User Computing Satisfaction	1x						X	
Interviews	1x							X
System Usage Monitoring	1x/mo							X

X = All clinics participate

Month 1: Pre-intervention Procedures
- Organizational Orientation and Assent
- Staff Informed Consent
- Implementation Net Conference Calls
- Follow-up Implementation Net Conference Calls
- Leader/Member Exchange
- Minnesota Satisfaction Questionnaire
- Clinic Characterization Survey
- Clinician Characterization Survey
- Attendance Data Extraction
- Patient Orientation

One-hour net conference calls[2] will be scheduled with the leadership and staff of all clinics wishing to participate in the study to orient them to the study procedures and determine whether their clinic wishes to participate. Following these organizational informed assents, six clinics will be selected and their staff invited to sign an informed consent by a member of the local node RRTC. Initial and follow-up implementation net conference calls with clinic staff will be

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[2] A net conference call combines telephone and Internet to create a virtual meeting, eliminating the cost and inconvenience associated with travel. Net conferencing will be used for all training activities in this protocol.

conducted to review procedures and resolve logistics. A Procedures Manual will be distributed to all clinics and reviewed on these calls. Clinic supervisors will complete a *Clinic Characterization Form* describing the clinic, its staff, and patient populations and clinicians will complete a Clinician Characterization Form; these forms will include a subset of items from the *CTN Baseline Survey* (Greenlick & McCarty, 2001). Supervisors and staff will also complete the *Leader/Member Exchange* (Graen and Uhl-Bien, 1995) and the *Minnesota Satisfaction Questionnaire* (Weiss, Dawis, England, Lofquist, 1967). Every other week project assistants (PAs) will enter attendance data from the clinic's administrative record onto a teleform Attendance Form provided by the lead node (see Appendix C); these forms will be faxed to the lead node's data center every other week.

Month 2: Baseline
- Patient Attendance
- Patient Orientation
- Feedback Surveys Collected

All patients of participating clinicians will be oriented on: a) how to complete the Feedback Survey, b) the study procedures and c) the voluntary nature of their participation. Surveys will be collected during Weeks 2 and 4 from patients attending group sessions. PAs will continue collecting and faxing patient Attendance Logs to the lead node every other week.

Months 3-5: Intervention
- Patient Attendance
- Patient Orientation
- Surveys Collected
- Reports Training
- Reports Provided
- Team Meetings
- Newsletter

Outpatient clinics will continue to collect and fax Attendance Forms, plus the Feedback Surveys, to the lead node twice monthly. In addition, clinicians and supervisors will participate in a *Feedback Reports* net conference call during which they will be provided with their first Feedback Report (see section 6.4) and will be oriented to the team process and Feedback Manual. The Feedback Manual is based on the performance improvement processes required by JCAHO (1998) and others accrediting organizations (Wilkerson et al., 1998); the manual describes how to interpret the Feedback Reports, the monthly team meeting process, and strategies for improving patient ratings. In the monthly team meetings staff examine their Clinic Feedback Reports, prioritize indicators they want to improve, identify action steps for improvement, and document the meeting using the Team Meeting form. Twice a month data for individual clinician caseloads will be posted to a password protected website; clinicians will be notified when their *Caseload* Report is posted. Finally, clinic CEOs, supervisors, and staff will receive a monthly *newsletter* (see section 6.4.3) recognizing clinic achievements and highlighting improvement strategies.

Month 6: Assessment
- Leader/Member Exchange
- Minnesota Satisfaction Questionnaire
- Patient Attendance

- Patient Orientation
- Feedback Surveys Collected
- End User Computing Satisfaction
- Staff Interviews

During the 6th month of the study, feedback surveys will be administered on weeks 2 and 4 to the patients who attend group sessions. All clinics will continue faxing patient attendance data to the lead node. In addition, all clinicians and supervisors will complete a follow-up *Minnesota Satisfaction Questionnaire* and the *Leader/Member Exchange*. The *End-User's Satisfaction Questionnaire* will be administered to all staff and qualitative interviews evaluating the feedback system will be conducted with randomly selected Protocol PI, clinicians and supervisors.

Months 7-18: Sustainability
- Feedback Newsletter
- Open Access
- System Usage Monitoring

Following completion of the feasibility study, all clinics will be given open access to the Feedback System for an additional 12 months; they will be invited to use the patient feedback system any frequency and in any way they wish. The lead node will track usage of the patient feedback system during this 12-month period. The Feedback newsletter will continue to be published for all participating clinics.

Study Population

A "clinic" is an outpatient facility[3] staffed by clinicians and one or more supervisors. Study participants are substance abuse clinicians and supervisors who work in adult outpatient clinics. Patients who attend group sessions will participate by completing the Feedback Surveys.

Eligibility Criteria

Participation in this study is open to all adult outpatient clinics that offer group counseling.

Inclusion Criteria

a) Outpatient drug-free substance abuse treatment clinics that conduct group counseling sessions at least weekly.

Exclusionary Criteria:

a) Methadone maintenance clinics;
b) Outpatient clinics with three or fewer clinicians who conduct group counseling;
c) Clinics in which outpatient staff are unable to meet on a monthly basis;
d) Outpatient clinicians who conduct group sessions less than once a week.

Study Duration & Enrollment

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[3] Outpatient includes outpatient, intensive outpatient and partial hospitalization clinics.

Six outpatient clinics will participate in the study, each with at least 4 clinicians and at least 1 supervisor. The feasibility study will be completed in six months, followed by a sustainability study that continues an additional 12 months.

Human Subjects & Safety

Feedback will be reported privately to individual clinicians in Caseload Reports, and to supervisors and clinic teams in aggregated Clinic Reports; comparisons between clinicians or of clinics will not be provided. Clinicians will receive reports for their caseload only; supervisors will receive reports of aggregated clinician data only. Caseload and Clinic Reports will be posted to a password protected website. All clinicians and supervisors participating in the study will be invited to sign an informed consent and consenting participants will be required to pass an informed consent quiz. Patients will be oriented to the Feedback Survey. All patient data collected throughout the study will be aggregated and anonymous. Clinics and clinic staff will only be identified by name in the *Feedback* newsletter after receipt of written permission from the clinic supervisor.

Primary Outcome Assessments

The primary outcome assessments are:

a) The percent of eligible clinicians who consent to participate in the study as evidenced by the number of signed informed consents in the study binders divided by the number of clinicians on staff.

b) The percent of eligible clinicians who complete the Feedback training as evidenced by dividing the number of clinicians who complete the required by the total number of clinicians on staff; training attendance record faxed to the lead node data management unit (DMU) will be the source data.

c) The percent of scheduled Attendance Logs faxed by the participating clinics to the DMU as evidenced by data records at the DMU; Attendance Logs are to be faxed every other week beginning Month 2 through Month 6.

d) The percent of attending patients who complete the feedback survey, as evidenced by dividing the number of surveys collected each month, by the number of patients who attended treatment.

e) The percent of the Feedback Reports that are uploaded to the Patient Feedback website within 48-hours of the surveys and attendance Logs being faxed to the DMU, as evidenced by data records at the DMU; each clinician and supervisor will receive their own Feedback Report every other week.

f) The percent of supervisors who download the Clinic Feedback Reports at least monthly as evidenced by website usage records at the Patient Feedback internet site.

g) The percent of supervisors who conduct patient feedback team meetings each month as evidenced by the Team Meeting Forms faxed to the DMU each month.

h) The percent of eligible clinicians who participate in the monthly patient feedback team meetings, as evidenced by the number of eligible clinicians who sign the Team Meeting Form

each month.

Secondary Outcome Assessments

Secondary outcome assessments obtained in this study will be used to provide pilot data for future effectiveness studies but will not be used to test the feasibility hypotheses. Attendance and self-reported abstinence measures will be collected every other week, from the baseline phase, through the intervention phase, and for one month after the intervention has ended; attendance data will be extracted from the clinic administrative record, and self-reported abstinence from items #11 and #12 on the feedback survey. Assessments of the intervention's effect on therapeutic alliance and group counseling experience will be obtained in Month 2 and Month 6 using Feedback Survey data. Assessments of the intervention's effect on staff job satisfaction, and clinician/supervisory relations will be made by comparing data from two self-administered instruments that will be administered to staff in Months 1 and 6. Assessment of the intervention's sustainability will begin on Month 7 when the participating clinics are given open access to the intervention for an additional 12 months. Measures of sustainability include ratings on an end user satisfaction measure, qualitative interviews, and feedback system usage data.

Significance

This study is intended to contribute to our understanding of outpatient addiction treatment, and current practice, in six ways: 1) It tests whether a manualized performance improvement process using a custom informatics system is feasible in community-based clinics. 2) Accrediting organizations, funding sources, and other regulatory and governmental agencies require that all healthcare organizations, including CTPs, conduct performance improvement studies. 3) Outpatient clinics rely on group counseling as a primary treatment modality yet few have an information system that enables them to monitor the care being delivered in groups. 4) It tests a semi-automated informatics system that generates objective feedback of patient attendance, therapeutic alliance and group counseling satisfaction. 6) It provides pilot data on outpatient attendance, and ratings of therapeutic alliance and group counseling satisfaction.

1.0   INTRODUCTION

This section summarizes the background on performance improvement followed by an introduction to the measures that will be used in this study.

1.1.   Background on Performance Improvement

Performance improvement methods were first introduced by Walter A. Shewhart of Bell Laboratories in the 1930s and then were popularized by his student, W. Edwards Deming. After successfully introducing his "statistical quality control" process to post World War II Japan, Deming began applying his methods with manufacturing companies in the United States. Over the subsequent 60 years Deming's approaches for improving manufacturing output evolved and now are a cornerstone of business and healthcare management throughout the United States. Advances in PI practice are supported by professional associations (e.g. International Society for Performance Improvement, American Health Quality Association, Association for Quality and Participation, National Association for Healthcare Quality), professional journals, manuals and textbooks. Although PI methods have advanced considerably since they were first introduced, the core features have remained the same: a) an organization identifies goals that are important to them, b) objective, measurable indicators reflecting achievement of these goals are specified,

c) performance measurement methods are developed, d) measurement and feedback processes are implemented, e) team processes are employed to review measurement data, f) action plans are implemented to improve performance, g) steps "a-f" are repeated on an ongoing basis. Inherent in the PI process is a participatory management approach that relies upon the interaction of staff and management throughout each step of the PI process. PI team members collaborate in interpreting PI study results, proposing solutions, and then identifying new performance indicators the team considers important.

Both major healthcare accrediting organizations – the JCAHO and CARF - have made performance improvement a central component of their accreditation processes. Although accreditation is voluntary, CTPs seek and maintain their accreditation because it is required by major managed care organizations, other funding sources, and is recognized as an indicator of quality by the public and purchasers of care. A recent national survey of 450 randomly selected private CTPs found that 87% of them were accredited by the JCAHO (Roman and Blum, 1997). PI data collection, analysis, and intra-organization dissemination processes are time-consuming and costly for treatment providers. PI-related expenses are non-reimbursable and therefore must be funded by the CTPs out of their profit, or surplus revenue. As noted in a recent IOM report (Donaldson and Mohr, 2000, p.48-49), healthcare providers are frequently unable to invest in PI informatics or otherwise support PI initiatives at the levels that will provide them with an optimal PI system.

1.1.1 Performance Improvement and Feedback – A central feature of all PI studies is the reporting – or feeding back – of performance results to the study participants. Because feedback plays such a critical role in all performance improvement initiatives, a brief review of the feedback intervention literature is provided.

Feedback is an essential feature of all intelligent organisms and other systems, including organizations (Bertalanffy, 1968; Wiener, 1965; Miller, Galanter and Pribram, 1972). Animals, humans, machines and organizations use feedback to assess the desirability of a condition by comparing current status against a criterion and determining whether optimal conditions are present. To do this, a criterion is established, measurements are made of the current condition are taken, a comparison is made, and then corrective action is taken, if indicated, to bring the current condition closer to the optimal criterion. A simple mechanical feedback system is a thermostat: it monitors temperature and turns on or off an air conditioning system based on its comparison of the current temperature with the desired temperature, or setting. The same feedback process employed in a thermostat can also be applied to systems as complex as human organizations.

1.1.2 Meta-analyses of performance feedback interventions – In a meta-analysis of over 2,500 papers and 500 technical reports on feedback interventions (FI) with humans, Kluger and DeNisi (1996) retained 131 usable studies with 12,652 participants, 23,663 observations, and an average sample size of 39. An average effect size of d. = .41 was obtained across all studies, however there was great variability across studies, with 38% of the studies having negative effects. The authors proposed a preliminary feedback intervention theory to account for these differences in the effect sizes. Based on their analysis, the authors report that the most effective feedback interventions: a) lead the recipients of feedback to compare current performance with recent past performance, b) focus the feedback recipient's attention on the task/s to be learned, rather than on themselves, c) enable the feedback recipient to identify when a solution is correct, and d) provides feedback frequently. In addition, the authors noted that a) verbal praise, b)

verbal FIs and c) FIs that threaten self-esteem tended to attenuate FI's effect size possibly because they lead the participant to focus on themselves rather than mastery of the task.

Strajkovic and Luthans (1997) conducted a meta-analysis of 125 FI studies conducting in the workplace and found 19 that fulfilled their inclusion criteria. The meta-analysis included 115 effect sizes based on a total sample size of 2,818 subjects with an average sample size of 25. The Strajkovic and Luthans meta-analysis revealed that the strength of the effect size varied considerably across studies, ranging from d. = 1.82 to .17. The authors proposed that this variance was moderated by several factors, most notably: a) service organizations (as opposed to manufacturing organizations) that combine social recognition with performance feedback had the largest effects; b) FI effect sizes in studies conducted within manufacturing settings were larger than those conducted in service settings; c) studies employing more objective performance indicators as the basis for feedback had the largest effect sizes. The author's hypothesized that the larger effect sizes found in manufacturing might be due to their tendency to use the most objective measures of performance.

1.1.3   Performance Improvement in Healthcare – The Institute of Medicine has published more than a dozen reports describing and promoting the use of PI to improve healthcare services. A sampling of the most recent reports include: *Improving the Quality of Long-Term Care (*Wunderlich, and Kohler, 2001), *Crossing the Quality Chasm* (IOM, 2001), *Envisioning the National Health Care Quality Report* (Hurtado, Swift, and Corrigan, 2001), *Exploring Innovation and Quality Improvement in Health Care Micro-Systems* (Donaldson and Mohr, 2000), *Enhancing Data Systems to Improve the Quality of Cancer Care* (Hewitt and Simone, 2000), *Health Performance Measurement in the Public Sector* (Perrin, Durch, and Skillman,1999)**,** *Ensuring Quality Cancer Care* (Hewitt and Simone, 1999)*, Managing Managed Care: Quality Improvement In Behavioral Health* (Edmunds, Frank, McCarty and Weisner, 1997)*, Using Performance Monitoring to Improve Community Health* (Durch, Bailey and Stoto, 1997). In addition to these nine IOM Reports, in association with the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services (www.ahcpr.gov), the IOM supports an extensive range of PI research, education and dissemination activities.

As noted elsewhere, the JCAHO (www.jcaho.org) has made performance improvement a central element of its accreditation process. All 19,000 JCAHO accredited healthcare organizations, including all accredited substance dependence treatment programs, are required to fulfill the performance improvement standards that the JCAHO has established. To support and encourage excellence in the conduct of performance improvement activities, the JCAHO published several manuals on performance improvement including *Using Performance Measurement to Improve Outcomes in Behavioral Health Care* (1998). In addition, the JCAHO publishes a monthly peer reviewed journal, the *Joint Commission Journal on Quality Improvement,* a monthly newsletter, *Benchmark*, and sponsors *The Codman Award* to recognize excellence in healthcare performance improvement.

Performance improvement studies have become an important strategy for testing efficacious medical interventions in a wide range of community-based medical settings. A sampling of areas in which healthcare PI studies have been conducted in the past few years include: practitioner hygienic compliance (Harbarth et al., 2002), emergency room physician's use of fluoroscopy (Levine, Yarnold, and Michelson, 2002), appropriateness of radiological referrals (Eccles et al., 2001), chronic disease management (Bonomi, 2002*)*, patient retention in a weight management program (Dent et al., 2002), infection and supplemental oxygen use in neonatal

intensive care clinics (Horbar et al., 2001), inappropriate induced labor (Harris et al., 2000), management of acute myocardial infarction (Mehta et al., 2000), surgical infections (Mintjes-de Groot, et al., 2000), prescribing practices of primary care physicians (Lagerlov et al., 2000), laboratory quantitation rates of Hepatitis C (Schirm et al., 2002), compliance with optometry guidelines (Hilber et al., 2000), and serious chemotherapy medication-errors (Goldspiel et al., 2000).

1.1.4 Performance Improvement in Mental Health Treatment - In mental health settings, Howard et al. (1986; 1992; 1993a; 1993b; 1996) and more recently (Lueger et al. (2000; 2001) developed and refined an outpatient behavioral health feedback system called COMPASS that provides therapists with reports on individual patient progress compared with an expected improvement curve. Using this individually based system, therapists and employee assistance case supervisors can make adjustments in patient care based on feedback of several performance indicators including a measure of therapeutic alliance. Lambert et al. (2001a, 2001b) found that therapists who receive feedback about treatment progress using a red-yellow-green color-coded feedback system achieved significantly better outcomes than therapists who did not receive this feedback. Kordy et al. (2001), employed a computer-assisted feedback system that reports of patient questionnaire data to therapists along a number of clinical dimensions including a measure of therapeutic alliance. Luchins et al. (2000) provided psychiatrists with laboratory data and other feedback on medication usage with the goal of reducing inpatient stays. In a randomized clinical trial Wells et al. (2000) demonstrated that feedback initiatives significantly improved the management of depression by primary care physicians; in a follow-up study, Sherbourne et al. (2001) showed that the effects of this feedback intervention were sustained for several years.

1.1.5 Performance Improvement & Feedback Studies in Substance Abuse Treatment - McCaul and Svikis (1991) demonstrated that feedback to clinicians of patient attendance in individual and group counseling yielded improvements in attendance. Using a pre/post design, monthly written feedback was given to clinicians on patient attendance. Compared to pre-intervention attendance rates, post-intervention attendance was significantly improved. Adnrzejewski, et al. (2001) found that the provision of graphic feedback to clinicians concerning adherence to a research protocol in a methadone maintenance clinic yielded a 71% increase in protocol adherence. Phillips et al. (1995), and then, Ducharme and Luckey (2000) reported on the *NIDA Methadone Treatment Quality Assurance System* (MTQAS) in which feedback reports on quality indicators were provided on a quarterly basis to supervisors in 70 clinics. Ducharme and Luckey noted that the MTQAS project "was successful in achieving all five of its intended goals" (p. 88) demonstrating the feasibility of this kind of initiative. Finney et al., (2000) have developed an ongoing PI system for the Veterans Administration called the Quality Enhancement Research Initiative (QUERI). This PI system includes performance monitoring, feedback, and dissemination of best practice guidelines to administrators and clinicians. The Washington Circle Group (McCorry et al., 2000a; McCorry et al., 2000b) has developed performance measures for substance abuse treatment systems and managed care plans. Similarly, professional organizations such as the Association for Ambulatory Behavioral Healthcare have published performance measurement standards and procedures manual (AABH, 1996) for mental health and substance abuse treatment providers.

2.0   RATIONALE

The following is a rationale for conducting this study.

2.1   Feasibility of Performance Improvement - The feasibility of PI interventions has been demonstrated in a wide variety of healthcare settings and workplaces. Although PI studies are required of CTPs by accrediting organizations, funding sources, and other regulatory and governmental agencies we are unaware of any publications of performance improvement feasibility studies in drug-free outpatient substance abuse treatment clinics. This study provides a test of whether it is feasible to conduct a semi-automated PI intervention in outpatient community based treatment settings.

2.2   Group and Clinic-level Intervention – Since many clinicians working in drug-free outpatient settings rely largely on group treatment approaches, this study provides clinicians with a data-based intervention that is congruent with, and meaningful to, their usual practice. The provision of aggregated group data to clinicians and program supervisors enables them to monitor the treatment progress of their caseload or clinic, and evaluate the effectiveness of improvement efforts they implement.

2.3   Sustainability – This study evaluates whether and how treatment providers will continue to use the experimental intervention after having access to it for five months. Similarly, this study will assess which aspects of the Feedback system staff will use when given open access to it.

2.4   Benchmark Data – The Feedback System will generate stratified benchmark data on outpatient attendance, self-reported abstinence, therapeutic alliance and group treatment satisfaction that can be analyzed by clinician and clinic characteristics. These data will be updated rapidly, enabling near real time monitoring of performance within the participating clinics.

2.5   Efficiency – This study directly helps CTPs fulfill an important and costly regulatory requirement by providing them with a semi-automated PI process maintained by a custom informatics network. PI interventions such as this may serve as a durable bridge for future patient/practice/research initiatives.

3.0 OBJECTIVES

3.1 Primary Objectives

The primary objective of this study is to test the feasibility of implementing the Feedback system in community based outpatient clinics. This study will determine whether:

a) 100% of eligible clinicians will be consented to participate in the study as evidenced by percent of signed informed consents in the study binders.

b) 100% of eligible clinicians will be complete the Feedback training as evidenced by the training attendance record faxed to the lead node data management unit (DMU).

c) 100% of scheduled Attendance Logs will be faxed by the participating clinics to the DMU as evidenced by data records at the DMU.

d) At least 80% of patients who attend group will complete the feedback survey, as evidenced by dividing the number of surveys collected each month, by the number of patients who attended treatment.

e) 100% of the Feedback Reports will be uploaded to the Patient Feedback website within 48-hours of the surveys and attendance Logs being faxed to the DMU, as evidenced by data records at the DMU.

f) 100% of supervisors will download the Clinic Feedback Reports at leastmonthly as evidenced by website usage records at the Patient Feedback internet site.

g) 100% of supervisors will conduct patient feedback team meetings each month as evidenced by the Team Meeting Forms faxed to the DMU each month.

h) 80% of eligible clinicians will participate in the monthly patient feedback team meetings, as evidenced by the number of eligible clinicians who sign the Team Meeting Form each month.

4.0   STUDY DESIGN

Six outpatient clinics will participate in a six-month study to determine the feasibility of the patient feedback system. The fulfillment of the feasibility study's eight objectives will be determined by examining the percents achieved for each of the feasibility measures described above in section 3.1. As a feasibility study, there is no blinding or randomization.

4.1   SAMPLE ESTIMATES

4.1.1   Number of Clinicians – It is estimated that each outpatient clinic will have an average of 6.5 clinicians and 1 supervisor. This estimate is based on an informal polling of the outpatient CTPs that have expressed interest in the protocol.

4.1.2   Number of Outpatient Clinics – It is proposed that six outpatient clinics participate in this study.

5.0   STUDY POPULATION

5.1   The Outpatient Clinic

The IOM Report, *Exploring Innovation and Quality Improvement in Health Care Micro Systems* (Donaldson and Mohr, 2000), recommends the use of a "micro-system" as the unit of analysis for healthcare performance improvement studies. A micro-system has the following characteristics: "a small, organized patient care unit with a specific clinical purpose, set of patients, technologies and practitioners who work directly with these patients" (p. 4). Applying these criteria, this protocol uses the outpatient substance dependence clinic as its unit of analysis.

5.2   Number of Sites and Subjects

Six drug-free outpatient clinics with approximately 50 clinicians will be enrolled in the study.

5.3   Duration of Study

The study timeframe is:

Feasibility Study	
Pre-intervention Procedures	4 weeks

Baseline	4 weeks
Intervention	12 weeks
Assessment	4 weeks
Total	**24 weeks**
Sustainability Study	52 weeks additional weeks

5.4   Informed Consent

5.4.1   Organizational Orientation and Assent – A preliminary orientation was conducted with the leadership from each site that had expressed interest in participating in the feasibility study; representatives from the site management and research center participated on these orientations that were conducted using net conferencing. Protocol PI from these sites completed a Site Summary Form which collected basic information (e.g. location, staff size, census) about the sites interested in the feasibility study, and documented that the node leadership and clinic staff had been oriented to it and agreed to participate if their site was selected. Site Summary Form is provided in Appendix I.

5.4.1   Clinic Staff – During the pre-intervention phase of the study clinic supervisors and clinicians will be presented with the informed consent, asked to review it, and invited to ask any questions they might have about the consent or the protocol procedures. The staff informed consent will describe the:

- Voluntary nature of their participation
- Purpose of the study
- Study procedures
- Compensation
- Potential risks and benefits
- Confidentiality
- Contact information

The lead node will supply all participating sites a sample consent form that will be adapted locally to meet local requirements, and a 10-item Informed Consent Quiz. Staff will be required to pass an Informed Consent quiz by scoring 80% or higher. Clinicians and supervisors who do not pass the quiz after the first administration will be provided with information on the items they missed and then invited to take the quiz again; staff will have up to three tries to pass the quiz (unless the local IRB requires that the quiz be passed on two tries) . Upon passing the quiz, staff will be invited to sign the informed consent.

5.4.2   Patient Orientation - Beginning in the Pre-intervention phase of the study all patients will be oriented to the Feedback intervention. In accordance with section 45CFR46.116(d) of the *Code of Federal Regulations, Title 21 – Food and Drugs Good Clinical Practice*, a waiver for the informed consent of patients participating in the study will be sought from the associated IRBs. Since this protocol: a) introduces no additional risks or burdens to the patient beyond what may normally be expected in clinic practice, and b) is intended to directly benefit those patients that participate in the study, patients will not need to be consented (Casarett, Karlawish, and Sugarman, 2000). Also, since no identifiable patient information will be collected, a HIPAA waiver will be sought. The patient orientation process will be conducted by a member of the clinic staff and will address the following points:

- Purpose of the Feedback Survey
- Procedures for completing the Feedback survey
- Confidentiality of their responses
- Manner in which survey results will be fed back to staff
- The voluntary nature of their participation
- Benefits and risks

The lead node will provide the participating sites with a copy of a Patient Orientation Form (Appendix M) summarizing these points.

5.4.3 Patient Compensation

Due to the minimal departure from usual practice, no compensation is proposed to patients for their participation.

5.4.4 Staff Compensation

Participating clinics will receive approximately $5,000 in information technology equipment (two computers w/printers and one commercial grade fax machine). In addition, salary support as outlined in the budget section of this protocol (see Appendix K) will be provided to offset costs of participating in the research study.

5.5 Inclusion Criteria

5.5.1 Inclusion criteria - The inclusion criteria for this protocol are:

a) Outpatient drug-free substance abuse treatment clinics that conduct group counseling sessions at least weekly.

5.6 Exclusion criteria - The exclusion criteria for this protocol are:

a) Methadone maintenance clinics;
b) Outpatient clinics with three or fewer clinicians who conduct group counseling;
c) Clinics in which outpatient staff are unable to meet on a monthly basis;
d) Outpatient clinicians who conduct group sessions less than once a week.

5.7 Outpatient Clinic Discontinuation Criteria

Outpatient clinics may discontinue their participation in the study for any reason; outpatient clinicians may elect to discontinue their participation in the study for any reason.

5.7.1 Required Termination

5.7.1.1 Required Termination of Outpatient Clinics - Outpatient clinics will be required to discontinue participation in the study if in the opinion of the LI, the NIDA Safety Officer, or the IRB: 1) continuation of the study would present a serious medical or psychological risk to the clinic staff or its patients. Similarly, a clinic may be subject to termination from the study if:

a) The outpatient clinic no longer meets the inclusion criteria

b) The outpatient clinic violates exclusionary criteria for more than three weeks as determined by the LI and/or NIDA Safety Officer.

5.7.1.2   Required Termination of Outpatient Clinicians - Outpatient clinicians will be required to discontinue participation in the study if in the opinion of the LI, the NIDA Safety Officer, or the IRB: 1) continuation of the study would present a serious medical or psychological risk to the clinician or his/her patients; or 2) The clinician no longer conducts outpatient group sessions at least once a week.

5.7.2   Consideration of Early Termination

This study may be considered for early termination if NIDA and/or the lead investigator determine that the intervention is substantially disruptive to the participating clinics.

5.7.3   Procedures for Discontinuation

The LI in conjunction with the NIDA Safety Officer and the node's collaborating investigator/s and CTP supervisors will establish procedures for discontinuation. These procedures will be addressed in the project SOP.

5.8   Replacement of Study Participants

An annualized clinician attrition rate of 25% is anticipated; during the 6-month feasibility study it is expected that 1-2 clinicians will terminate employment from each of the participating study sites. As new staff are brought onto the clinic, they will be oriented to the study, complete the consenting process, trained in the study procedures, and given full access to the Feedback System. Because new staff will not participate in the study for the full six months, however, data from their pre/post measures (e.g. the Minnesota Satisfaction Questionnaire) will not be examined separately and will not be incorporated into the main analyses.

6.0   THE PATIENT FEEDBACK SYSTEM

6.1   Feedback Survey Items – Items included in the Feedback Survey were developed in accordance with the participative procedures employed in performance improvement initiatives (JCAHO, 1998; CARF, 1998; Meyers, 1994). Beginning with an initial pool of over 40 possible survey items including ones that had previously been used in earlier PI studies (Forman, in review), the California Psychotherapy Alliance Scale (Gaston et al., 1991), the Experience of Healthcare Outcomes Survey (ECHO, Eisen, et al., 1999; Shaul, 2001) and the CARF performance standards (Wilkerson, et al., 1998), members of the protocol team selected 12 items for inclusion in the Feedback Survey. To facilitate the item selection process, the lead investigator conducted seven net conference calls on 5/3/02; 5/15/02; 5/16/02; 5/17/02; 5/22/02; 5/24/02; 5/31/02; 4/11/03 with a total of 45 members of the CTN including 21 CTP supervisors, 18 Protocol PI and 5 NIDA CCTN staff. At the outset of these calls the LI placed an upward limit of no more than 10-12 items to so that respondents would be able to complete in 1-3 minutes.

The 12-items included on the Feedback Survey fall into four categories: a) therapeutic alliance; b) group treatment satisfaction; c) demographic; d) self-reported substance use. A copy of the Feedback Survey is provided in Appendix A.

6.1.1   Therapeutic Alliance Items (Survey Items 1-4)

Item 1. Did you feel <u>accepted and respected</u> by your clinician[4]?
Item 2. Did you feel that you and your clinician were <u>working together</u> to overcome your problems?
Item 3. Did you feel that your <u>clinician understood</u> what you hoped to get out of your treatment?
Item 4. Do you feel confident that through your own efforts and those of your clinician you will <u>gain relief</u> from your problems?

6.1.1.1   Rationale for Therapeutic Alliance Items - Two meta-analyses have found a positive relationship between therapeutic alliance and treatment outcomes irrespective of the type of therapy, length of treatment (Horvath & Symonds, 1991) or the type of outcome rater, time of alliance assessment, type of treatment provided, or publication status of the study (Martin, Garske, & Davis 2000). Since that time additional studies have reported a positive association between therapeutic alliance and treatment outcome (Connors et al., 2000; Barber et al., 2001; DeWeert-Van-Oene et al., 2001; Andrusyna et al., 2001; Ackerman and Hilsenroth, 2003). Following the initial work of Bordin, (1979) and Luborsky et al (1983; 1985), Gaston (1991) proposed that therapeutic alliance is a multidimensional construct consisting of 4 components: a) the patient's capacity to work, b) the patient's affective bond with the therapist, c) the therapist's empathic understanding, and d) the agreement between patient and therapist on the goals and tasks of psychotherapy. Several self-report questionnaires have been developed to measure therapeutic alliance, including the 24-item California Psychotherapy Alliance Scale (CALPAS; Gaston et al., 1991). Using multiple patient samples, Crits-Christoph (unpublished data) conducted item analyses of a pool of the CALPAS to arrive at an optimal four-item alliance scale that has acceptable internal consistency reliability (alpha =0.78). This 4-item brief scale correlates 0.77 with the CALPAS total score (deleting the four items from the total) with each item assessing one of the four dimensions identified by Gaston.

6.1.2   Treatment Satisfaction Items (Survey Items 5-6)

Item 5. Did you feel comfortable raising issues or concerns?
Item 6. Were <u>things explained</u> to you in a way you could understand?
Item 7. Was the session <u>helpful</u>?

Items 5 -7 are intended to provide respondents with the opportunity to evaluate their satisfaction with three aspects of their treatment: a) did they feel comfortable raising issues or concerns, b) were things explained in a way that could be understood, and c) Was the session helpful?

6.1.2.1 Rationale for Treatment Satisfaction Items – Items #5, #6 and #7 in the Feedback Survey provide respondents with the opportunity to evaluate aspects of the group treatment experience that were considered to be of greatest importance by the site supervisors and investigators participating in this study. These three items were adapted from a larger pool of items that had been used previously in the Experience of Healthcare Outcomes Survey (ECHO, Eisen, et al., 1999; Shaul, 2001) study. The 88-items in the ECHO survey were derived by the Behavioral Health Measurement Advisory Panel (BHMAP) and the National Committee for Quality Assurance (NCQA) from two instruments, the Mental Health Statistics Improvement Program consumer survey (MSHIP) and the Consumer Assessment of Behavioral Health

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[4] The original CALPAS term "counselor" was replaced with the term "clinician" because of recognition that individuals other than counselors will be conducting groups.

Services instrument (CABHS), that were most suitable for collecting consumer ratings of behavioral healthcare services.

The three ECHO items that were selected by the Patient Feedback protocol team for adaptation and inclusion had a high correlation with overall patient satisfaction (Item #5 = .49; item #6 = .52; Item #7 = .56) and were considered by the participating clinic supervisors and investigators to be most the most relevant measures for capturing patient satisfaction with their group counseling experience. Additionally, in selecting items from the ECHO, efforts were made to avoid items that addressed a content domain that was similar to other items that had already been selected (e.g. "accepted and respected" or other therapeutic alliance-type items). The original wording of ECHO items was modified to accommodate to the needs of this study. For example, the ECHO item: *"In the last 12 months, how often did the people you went to for counseling or treatment explain things in a way you could understand?"* was shortened to make it consistent with the timeframe of this survey (item # 6). The chair of the ECHO development team (Shaul) has given permission to the LI to use items from their survey (personal communication, 2/11/03).

Finally, in selecting these three items, an organizational performance research standard was employed, specifically: a) the item needs to monitor something that workers are in a position to improve and, b) improvement in the item's ratings are considered likely by staff to be associated with increases in outcomes that are important to the organization (Meyers, 1994).

6.1.2.1   Scale – The first seven items employ the same five point Likert-like scale that was originally employed on the CALPAS:

   Not at all - A little Bit – Moderately - Quite a bit - Very much so

6.1.3   Patient Demographic Items (Survey Items 8-10)

In order to enable examination of Feedback Reports by patient characteristics, the protocol team selected four demographic items for inclusion on the Feedback survey based on the demographics items used in the CTN Demographics form:

Item 8. Do you consider yourself (select all of the answers that are true for you): White; African American/Black; American Indian or Alaska Native; Hispanic or Latino; Asian; Native Hawaiian or Pacific Islander;

Item 9. Are You: Male; Female

Item 10. Concerning this admission, about how long have you been in treatment?   Less than 1 week; Between 1 week and 1 month; Between 1 and 3 months; More than 3 months

6.1.3.1 Rationale for Demographic Items – These three demographics items were selected in order to enable reporting and analysis of patient feedback based on the respondents gender, ethnicity, and length of stay (LOS) in treatment. Inclusion of each of these three items is important for two reasons: first, it enables the analysis of data by patient gender, ethnicity and LOS so that clinicians and supervisors can know whether there were differences in ratings by specific patient subgroups. This knowledge may enable clinicians and supervisors to target improvement activities (i.e. training, staffing), and track the effectiveness of their interventions. Second, the inclusion of these demographic items will be useful in subsequent data analyses.

6.1.4 Self-report Substance Use (Survey Items 11-12)

Alcohol – How many days in the PAST WEEK did you drink any alcohol (beer, wine, liquor)?

Drugs – How many days in the PAST WEEK did you use any drugs (marijuana, cocaine, heroin, or other "street" drugs)?

Patient responses to these two items will <u>not</u> be fed back to supervisors or clinicians in the Feedback Report; these items will be used to assess abstinence and patients will be informed that the self-reported substance use will not be reported to their clinician, even in aggregated form.

6.1.4.1 Rationale for Self-reported Substance Use Items – These two substance use items were adapted from the Drug and Alcohol sections of the Addiction Severity Index (McLellan et al., 1980), capturing the "number of days in the past week" that the patient drank or used. The "number of days" metric was used instead of "dollars spent" because the cost of substances varies considerably across the country, and patients do not always pay for their drugs (e.g. trading sex for drugs; using surplus from drug sales). The "past week" time frame was selected because patients would be most likely to have the best recall for this time frame. In a review of the literature on self-reported substance use data (Harrison, 1997, p.32) the author concludes, "most validity research, in fact, shows quite high congruence rates between self-report and assay results." Two factors that increase the validity of self-reported substance use are: a) obtaining self-reports from patients that are in treatment and b) using self-administered surveys instead of verbal self-report. Both of these practices will be employed in this protocol.

There are several reasons for utilizing self-reported substance use rather than a UDS in this study. First, the use of UDSs varies considerably among outpatient CTPs with few clinics testing more than once a week, many clinics testing monthly, and some not administering UDS at all. The introduction of a standardized UDS schedule in clinics would be an intervention in itself potentially confounding study results. Second, the cost and impact of implementing UDS tests with all patients in all sites – and the informed consent processes that would be required – would be disruptive of clinic operations and introduce costs that are difficult justify given the relative ease with which self-report can be obtained.

Note: Patient responses to the two substance use self-report items will not be included in the Feedback Report – even in aggregated form – in order to minimize patient concerns about possible sanctions for accurately reporting use. These self-reported substance use data will only be used for hypothesis testing in the effectiveness study.

6.2   Attendance Calculations – Every other week the PA will use the Attendance form (see Appendix C) to record attendance for each participating clinician's caseload. The PA will extract data used to calculate attendance from the clinic's administrative record. Custom software developed by the lead node data management center will calculate the attendance rates using the following formula:

Caseload Attendance = Total # of pt. sessions attended by the clinician caseload
                                    Total # of sessions scheduled

Definitions:
- "Total # of pt. sessions attended by clinician caseload" is the sum of all patients that

attended group sessions during the designated four-week period.

- "Total # of sessions scheduled" is the sum of all patients scheduled to attend group sessions during the four-week period.

6.2.1 Rationale for Feedback of Attendance Data – Treatment attendance is a critical issue for outpatient and intensive outpatient CTPs because their funding depends upon it. Attendance (measured as treatment retention) has been demonstrated to be associated with improved treatment outcomes (McKay et al., 1994; Gottheil et al., 1992, 1998; Hubbard et al., 1997; Simpson 1991, 1997; Simpson and Brown 1998). The importance of attendance has been incorporated into NIDA's *Principles of Drug Addiction Treatment* (1999) and was endorsed as a priority by a national panel of outpatient treatment providers (CSAT IOT TIP Consensus Panel, April 13, 2001). The calculations and procedures used to assess attendance are presented in section 6.0 of the protocol. Outpatient CTPs views attendance rates as the single most important performance indicator because their funding is determined by fee-for-service. Clinics with low attendance rates will have reimbursement rates that are equally low.

6.3 Sample Feedback Report

Feedback Reports compare a clinic's or individual clinician's current data with data from the prior data collection timeframes. The following is a sample *Clinic Report*. Note: the *Caseload Report* is formatted identically to the Clinic Report except that the Caseload Report feeds back ratings for an individual clinician's caseload instead of the entire clinic.

Three therapeutic alliance graphs for an imaginary clinic are presented below:

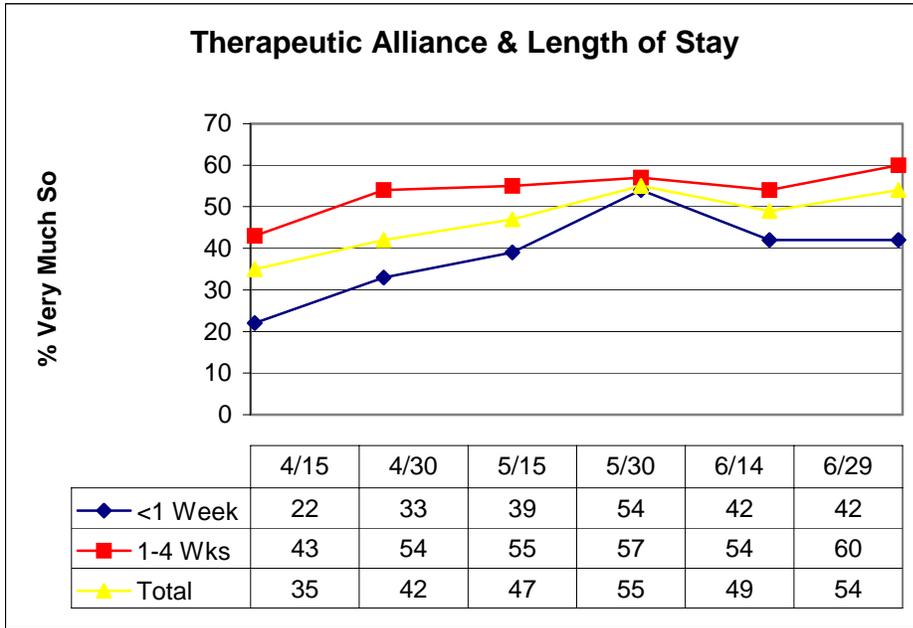**Figure 2 - Sample Therapeutic Alliance & Length of Stay Graph**

Therapeutic Alliance & Length of Stay

	4/15	4/30	5/15	5/30	6/14	6/29
<1 Week	22	33	39	54	42	42
1-4 Wks	43	54	55	57	54	60
Total	35	42	47	55	49	54

Figure 3 - Sample Therapeutic Alliance & Ethnicity Graph

Therapeutic Alliance & Ethnicity

	4/15	4/30	5/15	5/30	6/14	6/29
White	31	38	22	34	42	41
African American	37	44	70	79	80	87
Hispanic & Latino	34	40	67	61	74	80
Total	35	42	47	55	52	54
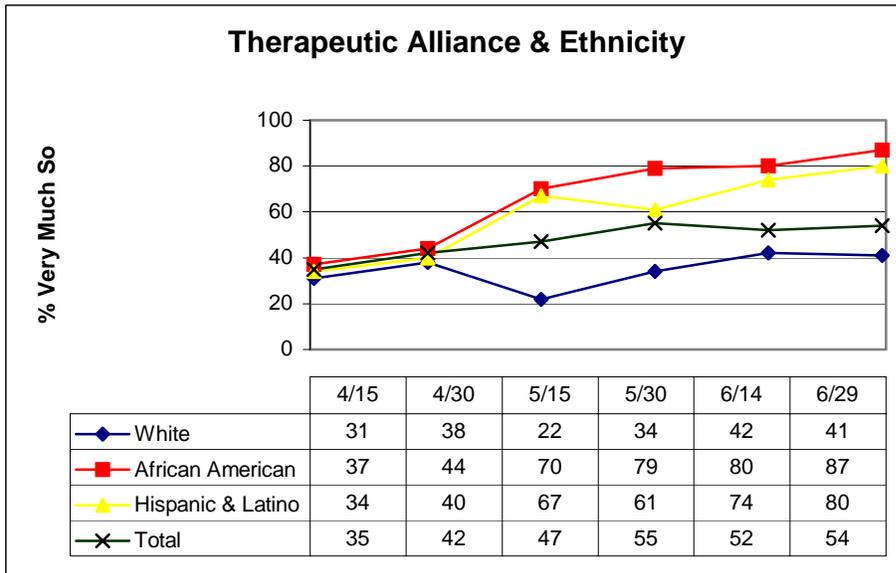
Figure 4 - Sample Therapeutic Alliance & Gender Graph

Therapeutic Alliance & Gender

	4/15	4/30	5/15	5/30	6/14	6/29
Female	39	44	40	44	42	44
Male	50	62	54	61	74	87
Total	64	62	54	74	87	76
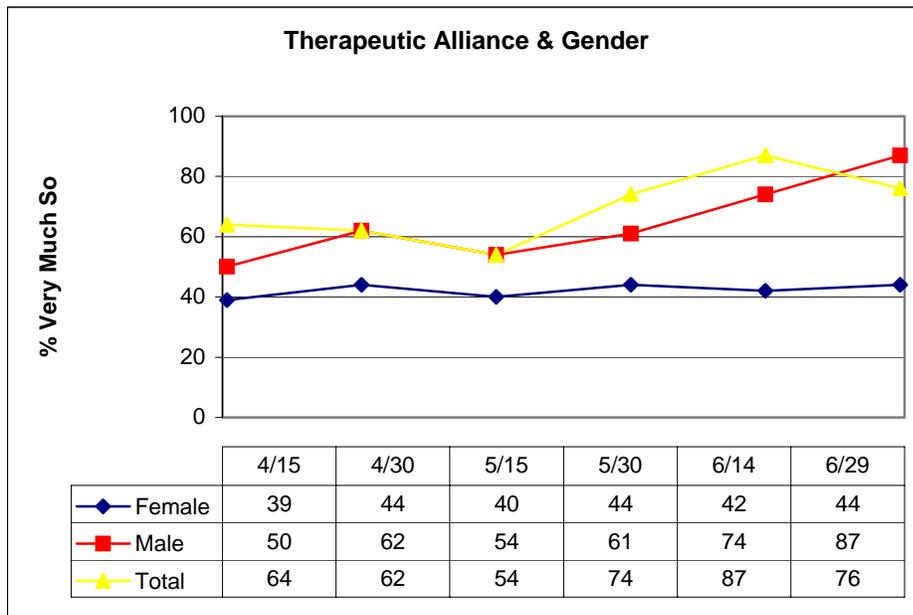
Each Clinic and Caseload Feedback Report will present a total of seven time series graphs:

1. Therapeutic Alliance and Length of Stay
2. Therapeutic Alliance and Ethnicity
3. Therapeutic Alliance and Gender
4. Treatment Satisfaction and Length of Stay
5. Treatment Satisfaction and Ethnicity
6. Treatment Satisfaction and Gender
7. Attendance
•

Feedback Reports will be posted to the password protected website as Excel worksheets (described in section 6.6);all computers used in this study will be supplied with the Microsoft Excel software application.

6.3.1   Report Format – A time-series format will be used to feedback ratings and attendance rates with each time-series graph being accompanied by the data associated with the data points. The six reports based on patient ratings will use the percent of respondents who rated the therapeutic alliance (or treatment satisfaction) as "very much so." Pilot data obtained at a test site (Presbyterian Medical Center of the University of Pennsylvania Health System) indicates that 25-50% of respondents will provide a rating of "very much so" when the surveys are first administered. A numerical value of 3.5 will be used for "very much so;" (the rating scale begins with "not at all" = 0, "a little bit" = 1, "moderately" = 2, "quite a bit" = 3 and "very much so" = 4). Custom software residing on the DMU server will calculate the therapeutic alliance and treatment satisfaction ratings by averaging the ratings for the four therapeutic alliance items and the three satisfaction items.

Protection Against Inadvertent Disclosure of Patient Responses – Feedback Reports will only present data for patient categories in which there are **at least five respondents** to ensure that individual responses from clinic minorities or caseload minorities, are not inadvertently disclosed. For example, if a clinic has only two individuals who identify themselves as "Asian" a line graph for Asians will not appear on the clinic or caseload reports. Their data will be

included in the Total data, only. As a consequence, Caseload Reports will have less categorical detail than the Clinic Reports.

6.3.1.1 Data Details – In addition to these seven graphs, Feedback Reports, clinics will also be provided with detailed reports on each of the first nine items of the caseload and clinic surveys.

6.3.1.2 Rationale for Design of the Feedback Report – The use of time-series graphs is consistent with the approach recommended for performance improvement studies (Deming, 1986; Walton, 1986, JCAHO, 1998) because of efficiency and clarity in communicating large amount of information (Adair & Vohra, 2003). Clinicians and supervisors will be trained in the interpretation of these graphs and the Feedback Manual provides additional guidance in graph interpretation.

6.3.2 Feedback Surveys Collection Estimates – It is estimated that approximately 200 Feedback Surveys will be collected on a monthly basis at each outpatient clinic. This estimate is based on the following assumptions:

a) Estimated number of clinicians per outpatient clinic = 6.5
b) Estimated number of unique patients per clinician that will complete a survey in a week = 15
c) Number of Survey administrations per month = 2

Number of Feedback Surveys per clinic (1 month) = 6.5 clinicians x 15 patients x 2 = **195**

**Number of Feedback Surveys per month from 6 feasibility sites =** 195 x 6 =**1,170**

6.4 Team Training – In month 3, supervisors and clinicians will participate in a 3-hour net conference call during which they will review their first Clinic Report using data collected during Month 2. The Team Report Training will cover the following topics: a) Background on performance improvement and patient feedback, b) Interpreting Feedback Reports, c) Conducting Team Meetings, d) The Feedback Manual, e) The Feedback Newsletter and f) Data Integrity. Each of these topics is also addressed in the Feedback Manual. The training plan is provided in Appendix J.

6.5 The Feedback Manual

The Feedback Manual addresses: a) Background on Performance Improvement and Patient Feedback, b) Interpreting Feedback Reports, c) The Team Meeting Process, d) Improvement Strategies, and d) Data Integrity.   The Feedback Manual is based on the principles and procedures described in the JCAHO manual ***Using Performance Measurement to Improvement Outcomes in Behavioral Health Care*** (1998) and will be distributed in electronic and color print formats to all supervisors and clinicians the week prior to their participation in the Team Training.

6.6 Feedback Newsletter

On a monthly basis, an electronic (.pdf) newsletter will be published by the lead node and distributed to the clinic leadership, staff, and other interested parties.   This monthly newsletter will recognize the successes achieved by participating clinics and highlight strategies that were implemented those clinics. The purpose of this newsletter is to
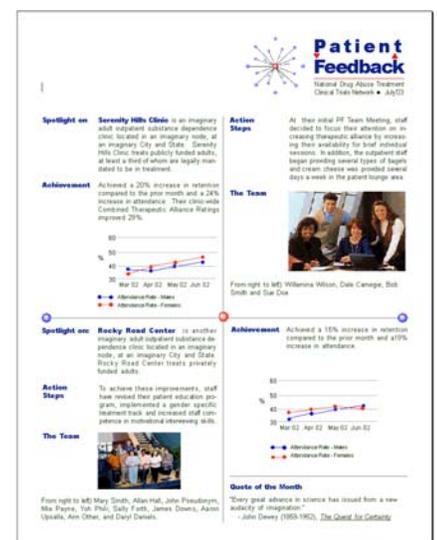
provide recognition for the achievements of clinic staff and highlight their performance improvement initiatives. In each issue the staff of clinics will be recognized with photographs, brief interviews, or listing by name.   Staff are welcome to distribute the Patient Feedback News to whomever they wish. A sample page of the Patient Feedback newsletter is provided in Appendix E.

6.7   Uses of Feedback Reports & Newsletter

Supervisors and clinicians will be encouraged to use the Feedback Reports in several ways:

a) Monthly Team Meetings – On a monthly basis the clinic supervisor and clinicians will participate in a team meeting during which they will review the Clinic Feedback Report and establish priorities and plans for achieving improvement. These meetings will be structured according to guidelines in the JCAHO PI manual (JCAHO, 1998). A Team Meeting form (see Appendix D) will be used to structure the team meetings and facilitate documentation of the meeting.

b) Caseload Report Reviews – On a monthly basis all clinicians will receive a confidential Feedback Report on their own caseload. Clinicians will be free to discuss their Feedback Reports with other clinicians and their supervisor.

c) Resource Allocation Decisions – Supervisors may use Clinic Feedback Report data to assist in making decisions about training, supervision, staffing, and resource allocation. Suggestions for possible actions to be taken to improve ratings on specific items will be provided in the Feedback Manual.

d) Fulfill Accreditation & Related Requirements – Supervisors can incorporate these reports into their clinic PI activities, incorporate in their Clinic Feedback Reports and Patient Feedback Newsletter into their accreditation reports, and/or reports to other regulatory agencies.

e) Stakeholder, Board & Funding Source Reports – Clinic management may include these Reports and Newsletter in presentations to their stakeholders, Board of Directors and funding agencies.

6.8   Procedures

6.8.1   Study Personnel

Individuals with specific responsibilities in conducting this protocol are:

6.8.1.1. Lead Investigator

The lead investigator (LI) has overall responsibility for the design, coordination and implementation of the study. He will maintain regular contact with the project managers, NIDA Center for Clinical Trials Network staff, Protocol PI and CTP supervisors. He will develop the Feedback manuals and project materials; in addition he will work with the lead node data center in designing all CRFs, reports and study software. In addition the LI (along with members of the lead node protocol team) will conduct the net conference calls, andpublish monthly Patient Feedback newsletterProtocol PI.

6.8.1.2. CTP Director

CTP Director will review the protocol's Synopsis, participate in a one-hour Director net conference call, and review, approve the study budget and agree to support their clinic's participation in the study by allocating CTP management, clinician and PA time according to the budget (Appendix K).

6.8.1.3. Project Managers

One project manager will assist the LI in the management of this protocol. This individual will have extensive experience in the conduct of clinical trials and will be responsible for the day-to-day implementation of the study; duties will include maintaining regular contact with CTP supervisors, Protocol PI, quality monitors, PAs, lead node data center and LI. In addition, the project manager, the lead node will also have a fulltime research assistant, a part time data manager, and a part time QA monitor assigned to this protocol.

6.8.1.2. CTP Supervisor(s)

Each participating outpatient clinic will have at least one CTP supervisor who will participate in the study. This individual will: a) participate on the initial site recruitment call, b) participate on the Procedures Net Conference calls c) participate on the Team Meeting net conference call, d) read and be familiar with the Feedback Procedures and Feedback Reports manuals, e) facilitate the Feedback team meetings, f) document the Feedback team meetings by completing the Feedback Team CRF. The selection criteria for CTP supervisors are: a) completion of the informed consent to participate in the study and b) holding the position of supervisor in the participating site. CTP supervisors will need to have e-mail and Internet access. Note: In clinics where there is a Director of Performance Improvement, or a similar position, it is anticipated that these individuals will play a supportive role in this protocol, assisting and collaborating with the implementation of the study – these individuals may work directly with the CTP supervisor in implementing the protocol. However, the primary responsibility for leading the team meeting will be with the outpatient clinic supervisor; this responsibility should not be delegated to the Director of Performance Improvement.

6.8.1.3. CTP Project Assistant (PA)

Each participating study site will select two CTP project assistants (PAs) to perform Feedback study procedures. The selection criteria for these individuals is: a) they have up to 4-hours every other week available to extract the attendance data from the administrative record and accurately record these data onto the Attendance Logs; b) agree to treat the surveys and data in a confidential manner consistent with GRP standards; c) have access to and can use, e-mail and fax equipment. Non-clinical members of the CTP administrative support staff will typically be selected to fill these roles. Because the PA will be functioning in a role that is equivalent to that of a research technician, these individuals need to have adequate time available to perform their study responsibilities. Consequently, PA's workload should be evaluated to determine whether they have adequate time to complete the additional responsibilities associated with this protocol – or whether additional staff time needs to be allocated. Two PAs are required to ensure coverage during vacations, illnesses or other potential coverage gaps. PAs will be provided with the *Patient Feedback SOP Manual* describing the tasks they are to perform and will participate

on the two implementation calls. The CTP Supervisor, QA monitor and Protocol PI will review these tasks with the PAs before the initiation of the study.

6.8.1.4. CTP Clinicians

Clinicians will: a) complete an informed consent, b) participate on a Team Meeting net conference call, c) read and become familiar with the *Patient Feedback Manual,* d) orient patients on the Feedback Survey, e) participate in the monthly Feedback team meetings, and f) review their own Caseload Feedback Reports at least once a month. The selection criterion for clinicians is that they conduct an addiction therapy group at least once a week and complete the informed consent procedures. Clinicians will need to have confidential access to the Internet (although they are not required to have their own computers).

6.8.1.5. Protocol PI

Each participating node will identify one or more individuals to serve as Protocol PI. The Protocol Principal Investigator will: a) have the overall scientific responsibility for implementation of the study at his or her node's site/s, b) participate in the initial site recruitment call, c) participate on the Director conference call, Feedback Implementation net call, and Feedback Reports net conference call, d) read and become familiar with the *Feedback Procedures* and *Feedback Reports Manuals*, e) be available to consult with CTP supervisors regarding study procedures and study management, and f) be responsible for submitting the protocol to their local IRB, and report AEs and SAEs to the LI and their local IRB (if AE/SAE reporting is required by their local IRB). The Protocol Principal Investigator and/or his/her designee will conduct the informed consent process with the CTP staff.

6.8.1.6. QA Monitor

The Protocol Principal Investigator of each participating node will identify a QA Monitor who will be responsible for monitoring adherence to the protocol according to the QA Plan, and submit QA reports. This individual will have experience in research QA monitoring and be a member of the RRTC staff or faculty. This individual will: a) monitor the accuracy of the data entered by the PA onto the Attendance Logs, b) monitor 100% of the informed consent documents; c) participate in the initial site recruitment call, d) participate in the Feedback Procedures and Team Meeting net conference calls, d) read and become familiar with the Feedback Procedures and Feedback Reports Manuals, e) participate on the monthly QA Monitoring Calls, and f) conduct other monitoring activities as described in the QA Monitoring Plan for this protocol.

6.8.1.7 Feedback Data Manager – The lead node will employ a data manager who will be dedicated to managing the data processing functions associated with this protocol. This individual will work with CTP Supervisors, and PAs to coordinate the transmission of Feedback Surveys and the Attendance Logs. In addition, this individual will work with representatives from DMAS, IMC and NIDA, in coordinating the data management procedures.

6.9   Administration of Intervention

6.9.1   Randomization

As a feasibility trial, there will be no randomization. All eligible clinicians can participate in the study.

6.9.2   Blinding

This is a non-blinded study.

6.9.3   Quality Control

Each participating node will assign a QA monitor to conduct monitoring visits onsite and participate on QA Monitoring calls conducted by the lead node. While the ultimate responsibility for the protocol's QA activities rest with the LI, the lead node's QA activities will be directly managed at the participating sites by the local QA Monitors, with support from the lead node. The Feedback informatics system is designed to identify emerging trends and flag potential and actual quality control problems. In addition, the web-based data management system is being used for all CRFs and as such, only allow for responses that are in range and complete. A detailed QA Monitoring Plan, approved by the CTN QA Subcommittee, has been developed and distributed to the participating sites.

6.9.3.1 Staff Informed Consent Monitoring - Auditing of this trial will be done in accordance with the written procedures established by the Quality Assurance (QA) and Data Management subcommittees of the CTN. These procedures provide guidance on what to audit, how to audit, and the frequency of audits. QA Monitors will perform 100% monitoring of staff informed consent to ensure compliance with human subjects protections. QA and Data Plans have been submitted and approved by these CTN Subcommittees.

6.9.3.2 Feedback Survey Collection Monitoring - The survey collection rates will be monitored to ensure that collection rates remain above 80% of the census. Collection rate data will be generated automatically by the data management system and will be monitored by the lead node project manager and reported to QA Monitor and the LI. There will be monthly contact between the lead node staff and the Protocol PI, local Project Manager, and/or QA monitor for each participating site. The site CTP supervisor will also participate on the monthly conference calls to identify and address any survey collection problems as they are identified.

6.9.3.3 Monitoring of Measures - The Protocol PI from each node will work with the CTP supervisors and CTP PAs to ensure the proper collection and storage of the study documents. Details of the monitoring procedures are in the QA Monitoring Plan for this study.

All measures are described in the Measures section of this protocol (section 8.0). The University of Pennsylvania data management center has developed a web-based data management system for all of the staff measures (e.g. LMX-7, Minnesota Satisfaction Questionnaire, and the End User Computing Satisfaction); these staff measures will be completed by staff online using the web-based data system. In addition, the Feedback Surveys, Coversheets, Team Meeting, Attendance CRFs and all other measures used in the study will be processed centrally through the lead nodes' data management center.

6.9.4   Feedback Survey Collection Procedures

6.9.4.1 Patient Orientation – At intake, or shortly after intake, all patients will be oriented on how to complete the Feedback Survey by a member of the outpatient clinic staff. These orientation meetings will be conducted individually or in small groups of not more than 8 people, and will cover the following points:

a. Purpose of the Feedback Survey Process
b. How to complete the Feedback Survey
c. Voluntary nature of their participation
d. Confidentiality of their Responses
e. How information is Fed Back to Staff

Patients will be provided with an Orientation Form that addresses the feedback systems' purpose and procedures. A member of the staff will review the Orientation Form with the patients and answer any questions they have. This orientation will be incorporated into the clinic's regular patient orientation process. If there is no clinic patient orientation currently in place, this will be done in small groups by a supervisor, project assistant, or clinician. The procedures for each site's orientation procedures will be reviewed during the Procedures Net Conference call.A log will be maintained at each study site documenting the number of participants who have been oriented each week. A copy of the Orientation Form is provided in Appendix M. The Orientation Form may be modified by sites if required by their circumstances or their local IRB.

6.9.4.2 Feedback Survey Collection Schedule – Feedback Surveys will be administered every other week in the outpatient clinics during Months 2 *through* 6. On the weeks that have been designated for survey collection, all patients of participating clinicians will be asked to complete a Feedback Survey after Monday's group session. Then, on each subsequent day, through to Saturday, at the end of group patients that had not yet completed a survey that week will be invited to complete one. Patients will be reminded not to complete more than one survey in any given week.

6.9.4.3 Feedback Survey Collection Procedures – For each participating clinician, 100 sheet Feedback Survey tablets will be printed with he clinician's name clearly printed on the top. Prior to the start of group on the designated survey collection weeks, the PA will deliver the Feedback Survey tablets to the clinician's group room. At the end of each group, the clinician will invite group members to complete the Feedback Survey and distribute the tablets to those patients who have not yet completed a survey during that collection periodPatients will complete the survey away from the presence of their clinician (in the group counseling room after the clinician leaves, in a waiting room, or in a specially designated area). Either the PA, or a senior member of the group will read the Survey Completion Instructions and Patient Feedback Survey items out loud. Patients will be advised to drop their completed survey into a locked metal survey collection box that will be either in the group room, an adjacent hallway, or other easily accessible common area nearby. The survey collection box will be locked with an opening at the top large enough to easily accept completed Feedback Surveys. The survey collection box will be clearly identified with a label "Place Surveys Here" and "Please Do Not Fold Surveys." Only the PA, Protocol PI and lead node research coordinator will have the combination to the survey collection box lock combination. The individual logistics of where the survey collection box will be placed will be reviewed during the Implementation Net conference calls.

6.9.4.4 Feedback Survey Fax Transmission Procedures – All sites will have a calendar indicating the day and timeframe they are to fax the Feedback Surveys and Attendance Logs to the lead node. One day before the scheduled fax transmission day, a reminder notice will be e-

mailed and faxed to the PA, CTP Supervisor, and Protocol PI with a request that they confirm by email or phone that they will be transmitting according on schedule. Fax transmissions will occur every other weeke. Prior to each fax transmission of Feedback Surveys, the PA will count the number of surveys twice and enter that number of surveys to be transmitted on to the Feedback Survey Coversheet (supplied by the lead node; see Appendix B). The lead node's fax server computer system will be programmed to check whether the number of Feedback Surveys received matches the total Feedback Surveys sent by the PA. If there is a discrepancy between the number of surveys received and the number of surveys reported to have been sent by the PA, the Feedback data management system will automatically generate a notice to the lead node data supervisor, project manager and local PA. Upon receipt of this notification, the PA will re-count the Feedback Surveys, correct the Coversheet, if indicated, and re-fax all documents. The lead node Feedback data system will purge the previous transmission. This process will be repeated (if necessary) until the discrepancy is resolved.

6.9.4.5 Feedback Website – The lead node data management center will maintain a secure website to which the Clinic and Caseload Feedback Reports will be posted every other week. Supervisors and clinicians will be given a unique user ID and password for themselves that will enable them to access the specific Feedback Reports for which they have been authorized. Clinic supervisors will be able to access the Clinic Report; clinicians will be able to access the Clinic Feedback Report and their own Caseload Report. In addition to all of the Feedback Reports, the website will also include the present and past issues of the Feedback Newsletter, the Patient Feedback Manual, the Operations Manual, the Feedback Team Meeting form and other protocol-related resources.

6.9.4.6 Equipment Specifications

Outpatient Clinician Equipment - All participating clinics will be provided with one dedicated commercial grade, high capacity and high speed fax machine. Additionally, each outpatient clinic will be supplied with two desktop computer systems with a color ink jet printer, and an Internet connection (broadband unless it is unavailable). At least one of the two desktop computer systems will be located in an area that clinicians are able to access privately. This room may be available for other uses, but the room needs to be available to clinicians who wish to download and print their Feedback Reports privately. The second computer is for use by the PA and CTP supervisor and should be located in the administrative office.

Lead Node Equipment - The lead node will utilize RightFAX Business Server running V8.X Teleform Elite Software located at the Data Management Unit (DMU), Center for Studies of Addiction, University of Pennsylvania. Additionally, a 4-channel BrookTrout TR144-P4L Intelligent Fax Board, equipped with four incoming lines, 2 Two Channel Loop Start Fax Boards, and a BrookTrout PCI bus, will rout incoming and outgoing fax transmissions between the lead node and the participating clinics. This high speed/high capacity 4-line fax processing system will be capable of processing 1 page in just under 6 seconds, or more than 600 pages an hour. Each Feedback Survey and CRF will be electronically converted into a .tif file by the Cardiff teleforms software. Data from these files will be translated into an SPSS file for analysis.

6.9.4.8 Fax Management Plan – Given the small number of sites participating in the feasibility study, it is unlikely that there will be congestion at the DMU fax server. Nonetheless, in order to test the feasibility of the fax management plan that will be implemented during a larger effectiveness trial, a fax transmission schedule will be developed for each site. To reduce the potential for delays in faxing, the fax machines will be equipped with 120 page memories so that

if they do encounter a busy signal from the fax server they will be able to re-dial and attempt to transmit automatically until they find an open line.

6.10   Survey Storage

After the forms have been successfully transmitted to the Lead Node (as documented by a confirmation from the Lead Node) the Patient Feedback Surveys, Attendance Forms and Trailer Page are then placed in a sealed envelope. The Coversheet form is then stapled to the sealed envelope. The sealed envelope will then be transported to the academic research center associated with the participating clinic. The research center staff will maintain the sealed envelopes in a locked filing cabinet only available to authorized research staff. As required under the National Institute on Drug Abuse's (NIDA), the Protocol Principal Investigators and Lead Investigator will cooperate fully with NIDA's disclosure of data plan.

6.10.1   Study Site Storage

Each participating research center, after receipt of the Feedback surveys, Survey Count, Attendance Forms,will store these documents in a dated and sealed envelope; these envelopes will be stored in a locked cabinet, in chronological order. Only the research staff will have access to this locked cabinet.

6.10.2   Data Management Clinic Storage

The faxed surveys from each clinic will be converted to .tif files. Each .tif file received at the data management clinic will be archived on CD-ROMs for permanent storage. These CD-ROMs will be labeled and stored in a locked, fireproof safe at the lead node's RRTC data management center.

6.10.3   Document Accountability

The QA Monitor for each participating study site will monitor the collection and storage of Feedback Surveys, Attendance, Coversheet CRFs, and staff measures according to procedures established in the protocol QA Plan.

7.0   CONCOMITANT THERAPY

7.1   General Considerations

Clinic supervisors and clinicians will continue to provide treatment as usual without any additional restriction on their practice.

7.2   Medications Prohibited During the Trial

No efforts will be made to prohibit the delivery of usual care at study sites, including their administration and monitoring of medications.

8.0   MEASUREMENTS, EVALUATIONS, AND ANALYTICAL METHODS

8.1   Clinic & Clinician Characterization Surveys

The *Clinic Characterization Survey* and the Clinician Characterization Survey are composed of a *subset* of items from the Baseline Surveys (B & C) from CTN protocol #0008 (LIs: Greenlick & McCarty). These surveys will be used to collect data that characterizes the participating outpatient clinics, participating clinic staff, and patients. Items will be selected from the supervisor (Survey B) and clinician (Survey C) versions of the Baseline Survey. The Clinic Characterization Survey will be completed only once, during the outset of the study (Month 1).

8.2 Leader/Member Exchange (LMX-7)

The LMX (Graen & Scandura, 1985) is a widely-used self-administered instrument designed to measure the quality of the working relationship among supervisors and employees. Respondents rate their working relationship using a Likert-like scale. Several versions of the LMX exist; this protocol will employ the seven-item version since it has emerged as the "gold standard" (Graen and Uhl-Bien,1995). Sample items from the LMX-7 include: "How well does your supervisor understand your job problems and needs?" "How well does your supervisor recognize your potential?" The full LMX-7 is provided in Appendix H. All participating staff will complete the LMX at months 1 and 6.

8.3 Minnesota Satisfaction Questionnaire (MSQ)

The Minnesota Satisfaction Questionnaire (MSQ) (Weiss, Dawis, English, and Lofquist, 1967) is a widely used measure of job satisfaction. The short form contains twenty self-administered items measuring intrinsic and extrinsic satisfaction. Sample items include ratings of how satisfied respondents are with their opportunities to: "… tell people what to do" and … "to do something that makes use of my abilities." The MSQ is provided in Appendix G. All participating staff will complete the MSQ at months 1 and 6.

8.4 Feedback Survey

The lead node has developed the Feedback Survey (Appendix A) with input from the protocol team; additional information about the Feedback Survey is provided elsewhere in the protocol (see section 6.1). The lead node will print and ship to the participating outpatient clinics 100-sheet Feedback Survey tablets for each clinician. The clinician's name will be clearly marked on the Feedback Surveys and there will be unique optical mark recognition coding identifying Feedback Surveys by clinician and outpatient clinic to the fax server and data management center. The Feedback Survey tablets will be created using Teleform software and will be printed by a vendor with extensive experience with printing teleforms documents. These 100-sheet tablets will have a cardboard backing designed to provide sufficient support to the respondent so that clipboards will not be required. The twelve items on the Feedback Survey include four items from the CALPAS (Gaston, 1991) assessing therapeutic alliance, three items assessing satisfaction with their group counseling experience, two self-report substance use indicators, adapted from the Addiction Severity Index Drug Use section (McLellan, et al., 1980) and three demographic items. The Feedback Survey will be distributed and collected from the patients during Months 2 *through* 6. Data from the Feedback Survey will be fed back to clinicians and supervisors during Months 3 through 6.

8.5 Attendance Log

The lead node will create and distribute to each participating clinic a 100-sheet packet of Attendance Logs for *each participating clinician* with unique identifying optical mark

recognition coding (see Appendix C). Every other week the clinic PA will enter onto the Attendance Log the Beginning and Ending timeframe information, the study week, the number of patients scheduled to attend, and the number of patients that actually attended group during each of the two weeks in the Log timeframe window. The Attendance Log will be developed for use by the lead node's data management center's teleforms system. The Attendance Log and will be faxed to the lead node's data management center where data entered by the site PA's will be converted to attendance rate data.

8.6   Feedback Team Meeting Form

The lead node will print and distribute to each participating clinic a 50-sheet packet of Team Meeting Forms (see Appendix D). On a monthly basis the CTP Supervisor will use the Feedback Team Meeting Form to structure and document the Feedback Team meeting. The Feedback Team Meeting Form was developed based on JCAHO and similar performance improvement guidelines. The supervisor, or his/her designee, will enter the names of clinicians that participated in the meeting, the meeting date, performance indicators selected for improvement, and action plans proposed (including: action steps, individual responsible for implementation, and status of action plan). On a monthly basis, a completed Team Meeting Form will be faxed to the lead node.

8.7   End User Computing Satisfaction Instrument (EUCS)

The EUCS (Doll and Torkzadeh, 1988) is a 12-item self-administered measure designed to assess satisfaction with computer-based information systems. Developed for the information technology industry, the EUCS is comprised of five component measures (content, accuracy, format, ease of use, timeliness) and will be used as an assessment of the acceptability of the Feedback system by outpatient clinic staff. All clinicians and supervisors participating in the study will complete the EUCS at the beginning of Month 7. The EUCS employs a Likert-like scale; sample items from the EUCS are: "Do you get the information you need in time?" and "Do you think the output is presented in a useful format?" The EUCS data will be used by the Feedback protocol team to inform the development of future versions of the Feedback system, should study results warrant. A copy of the EUCS is provided in Appendix F.

8.8   Feedback System Server Log

Throughout this study (feasibility and sustainability phases) data from the data system server will be used to monitor usage of the website, and fax activity.

8.9   Qualitative Assessment of End User Satisfaction

Twenty-five percent of the clinicians and supervisors, selected through random assignment, will be invited to participate in a structured interview to obtain their evaluation of the Feedback system. These interviews will be based the 12-item EUCS, but will be open-ended allowing for more subjective appraisals and specific recommendations for retaining, enhancing or eliminating aspects of the Feedback system. The lead node project team will conduct, record and transcribe these interviews during the first month of the sustainability phase (month 7) of the study. These qualitative reports will be used to inform the development of future version of the Feedback system, should study results warrant.

9.0 ASSESSMENT AND REPORTING OF ADVERSE EVENTS

Reporting of Adverse Events and Serious Adverse events will be conducted in accordance with the requirements of the local IRBs.

9.7 Human Subject Safety

9.7.1 Patient Orientation – At intake, or shortly after intake, all patients will be oriented on how to complete the Feedback Survey by a member of the outpatient clinic staff. These orientation meetings will be conducted individually or in small groups of not more than 8 people, and will cover the following points:

a. Purpose of the Feedback Survey Process
b. How to complete the Feedback Survey
c. Voluntary nature of their participation
d. Confidentiality of their Responses
e. How information is Fed Back to Staff

Patients will be provided with an Orientation Form that addresses the feedback systems' purpose and procedures. A member of the staff will review each of the five points with the patients and answer any questions they have. A log at each participating site will be maintained to document that participants have been oriented. A copy of the Survey Orientation is provided in Appendix M.

Patient Informed Consent - A waiver for obtaining informed consents from patients will be sought because:

a) completion of feedback surveys involves no more than minimal risk to the patients
b) completion of feedback surveys involves no more than minimal burden to the patients
c) the feedback process is intended to directly benefit the patients
d) the completion of satisfaction questionnaires is a routine practice in healthcare settings
e) obtaining informed consents from patients would make the study impractical to conduct
f) an orientation to the voluntary nature of the surveys will be provided to all patients
g) obtaining informed consent will result in a reduction in patient confidentiality because "consented patients" will need to be singled out to complete the Feedback Surveys.

Confidentiality of Survey Data - All patient data collected throughout the study will be voluntary, aggregated and anonymous. Feedback Reports will only present data for patient categories in which there are **at least five respondents** to ensure that individual responses from clinic minorities or caseload minorities, are not inadvertently disclosed. For example, if a clinic has only two individuals who identify themselves as "Asian" a line graph for Asians will not appear on the clinic or caseload reports. Their data will be included in the Total data, only. As a consequence, Caseload Reports will have less categorical detail than the Clinic Reports.

9.7.2 Staff Informed Consent – The lead node will supply all participating sites a sample consent form that will be adapted by the Protocol Principal Investigator to meet local requirements, and a 10-item Informed Consent Quiz.
Staff will be required to pass an Informed Consent quiz by scoring 80% or higher. Clinicians and supervisors who do not pass the quiz after the first administration will be provided with

information on the items they missed and then invited to take the quiz again; staff will have up to three tries to pass the quiz unless fewer tries are required by a site's local IRB. During the informed consent process, CTP supervisors and clinicians will be advised of the potential risks associated with the intentional (e.g. a clinician may elect to discuss her Clinician Report with a supervisor or fellow clinician), or inadvertent disclosure of Feedback Reports (e.g. a Report is left on a clinician's desk and read by a co-worker). Upon passing the quiz, staff will be invited to sign the informed consent unless a local IRB requires that staff obtain a passing score prior to signing the Informed Consent.

9.7.3   Staff Privacy - There is a risk that a clinician's Caseload Report may be unintentionally disclosed to another clinician, supervisor or patient and it is possible that this unintended disclosure could produce embarrassment. To reduce this risk, Caseload Reports will not have the clinician's name on it, but instead will have a caseload code number which will be known only to that clinician and members of the lead node protocol team. Nonetheless, if a clinician prints and then leaves his Caseload Report on his desk, others might guess that the Report belongs to him. Staff concerned about the privacy of their Caseload Reports can reduce the risk of unintended disclosure by: a) storing their Caseload Reports in a locked file, b) shredding their Caseload Reports after they view them, c) not discussing their Caseload Reports with others, and d) not printing their Caseload Report.

9.8   Data Safety Monitoring Board

The Data Safety Monitoring Board monitoring is not required for this study.

9.9   Data System

9.9.1   Web-based Data Collection – Staff measures will be collected on a secure web based system developed by the Delaware Valley Node. The Lead Node research staff will be responsible for maintaining accurate, complete and up-to-date records, and for maintaining any source documentation related to the study in accordance with the standards for Good Clinical Practice and the Food and Drug Administration.

9.9.2   Data Accrual, Editing and Control - Data will be collected and entered directly into the web- based system. This system will provide an audit trail of data entry and on-line QA functions. Once the data have been entered a data query document will be produced and forwarded to the participating node if inconsistencies or questions arise. The collaborating nodes will be responsible for distributing these queries to appropriate personnel for timely resolution. Sites will resolve data inconsistencies and errors with the Delaware Valley Data Management Center.

9.9.3 Data Backup - All data entered into the data entry system is stored in SQL Database Server tables. The data on the SQL database server is replicated to a backup server in real-time. In addition the data are also backed up daily on tape. Two sets of tapes are maintained with one set being stored off-site.

9.9.4   Data Entry, Processing and Analyses - Data from the web-based system will be submitted to the NIDA central data repository according to specified procedures.

9.9.5   Study documentation and Records Retention - Study documentation will include all case report forms, data correction forms, electronic data files, workbooks, source documents,

monitoring logs, logs, sponsor-investigator correspondence, and regulatory documents (e.g., signed protocol and amendments, Ethics or Institutional Review Committee correspondence and approved consent form and signed subject consent forms, Statement of Investigator form, and clinical supplies receipt and distribution records).

Source documents include <u>all</u> recordings of observations or notations of all reports and records necessary for the evaluation and reconstruction of the study. Accordingly, source documents include, but are not limited to manager notes and any other reports or records of any procedure performed in accordance with the protocol. Whenever possible, the original recording of an observation should be retained as the source document; however, a photocopy is acceptable provided that it is a clear, legible, and exact duplication of the original document.

Government regulations require that the participating investigators retain all study documentation pertaining to the conduct of a clinical trial for a minimum of two years after the approval of an NIDA.

Survey Processing and Posting of Feedback Reports – As noted previously, Feedback Surveys, Attendance Forms, Trailer Sheets and Coversheets will be faxed to the University of Pennsylvania Data Management Unit (DMU) every other week and then stored in a locked filing cabinet at the research centers associated with the participating clinical sites. The DMU Feedback data system will convert the surveys into Feedback Reports which will be posted to password-protected website. The Feedback Surveys will have unique optical recognition marks that link the surveys to the specific clinician; these forms will also have the clinician's name printed on it. Feedback Reports are accessible to clinic staff through the password protected website within minutes after the surveys have been successfully faxed to the DMU.

10.0 DEPARTURES FROM PROTOCOL

Definitions for protocol departures will be described in the protocol SOP; in addition required action steps including documentation, reporting requirements, and specific reporting forms and timeframes will be included in the SOP.

11.0 STATISTICAL ANALYSIS

11.1 Primary Outcomes and Hypotheses

The hypotheses for this feasibility study are:

a) 100% of eligible clinicians will be consented to participate in the study as evidenced by percent of signed informed consents in the study binders.

b) 100% of eligible clinicians will complete the Feedback training as evidenced by the training attendance record faxed to the lead node data management unit (DMU).

c) 100% of scheduled Attendance Logs will be faxed by the participating clinics to the DMU as evidenced by data records at the DMU.

d) At least 80% of patients who attend group will complete the feedback survey, as evidenced by calculating the proportion of surveys faxed to the DMU during each scheduled collection period, from patients who attended treatment.

e) 100% of the Feedback Reports will be uploaded to the Patient Feedback website within 72-hours of the surveys and attendance Logs being faxed to the DMU, as evidenced by data records at the DMU.

f) 100% of supervisors will download the Clinic Feedback Reports each month as evidenced by website usage records at the Patient Feedback internet site.

g) 100% of supervisors will conduct patient feedback team meetings each month as evidenced by the Team Meeting Forms faxed to the DMU each month.

h) 80% of eligible clinicians will participate in the monthly patient feedback team meetings, as evidenced by the number of eligible clinicians who sign the Team Meeting Form each month.

11.2 Secondary Outcomes

The secondary outcomes will include: Attendance and self-reported abstinence measures, collected every two weeks from the baseline phase through the intervention phase, and for one month after the intervention has ended (attendance data will be extracted from the clinic administrative record and entered onto the Attendance Log, and self-reported abstinence will be obtained from items #11 and #12 on the feedback survey); Assessments of the intervention's effect on therapeutic alliance and treatment satisfaction (obtained in Month 2 and Month 6 using PF Survey data); Assessments of the intervention's effect on staff job satisfaction, and clinician/supervisory relations (obtained from two self-administered instruments that will be administered to staff in Months 1 and 6); Assessment of the intervention's sustainability (ratings on an end user satisfaction measure, interviews, and feedback system usage) will begin in Month 7 when outpatient clinics are given open access to the intervention for 12 months.

11.3 Study Population

The analysis of the primary and secondary outcomes will be based on all Supervisors, Site managers, and clinicians who consent to participate in the study.

11.4 Demographic Profile

Demographic information will be collected on all clinicians and, in more aggregated format, on all patients. Demographic data about clinician will be a subset of items used on the CTN Baseline protocol #0008 (LIs: Greenlick & McCarty).

11.5 Analysis of Primary Feasibility Outcomes

The data to be used to test the feasibility of the patient feedback intervention are obtained by audit of the collection of the primary source records described below. An independent monitor selected by the CTN will perform these audits. The key parameters in the different feasibility hypotheses are proportions completing various tasks related to the intervention. After gathering and analyzing the data, we will report the overall proportions for each hypothesis obtained for the aggregated sites. Where there is sufficient within-site variation, we will also report the within-site proportions, and for some hypotheses we will also examine trends over time. Because of the small number of clinics and clinicians involved in this feasibility study, and because we expect that the proportions will be very close to 1.0, we will rely on simple summary statistics for these analyses. The principal difference across the hypotheses will be in the denominators used to calculate the various proportions. We therefore include estimates of those denominators.

a) 100% of eligible clinicians will be consented to participate in the study as evidenced by percent of signed informed consents in the study binders.

b) 100% of eligible clinicians will complete the Feedback training as evidenced by the training attendance record faxed to the lead node data management unit (DMU).

It is estimated that on average each clinic will have 6.5 eligible clinicians and 1 supervisor yielding an estimate of 20 eligible clinicians and 3 supervisors in the feasibility study. Note: the actual number of eligible clinicians will be established at the beginning of the study; this number is likely to differ from the estimate provided for these calculations. Thus, the proportions for Hypotheses (a) and (b) will be based on approximately 20 clinicians.

c) 100% of scheduled Attendance Logs will be faxed by the participating clinics to the DMU as evidenced by data records at the DMU.

Attendance Logs will be completed and faxed by each site every other week for six months, or twelve times. One Attendance Log will be completed and faxed for each eligible clinician. Using our estimate of 6.5 eligible clinicians per site, a total of 6.5 clinicians x 3 sites x 12 collections = 234 Attendance Logs. Our primary goal is to establish an overall high rate of completion and fax-transmission, which will be measured by overall proportions. However, we are also interested in checking for possible declines in these rates over time, so we will also examine trends in weekly rates.

d) At least 80% of patients who attend group will complete the feedback survey, as evidenced by calculating the proportion of surveys faxed to the DMU during each scheduled collection period, from patients who attended treatment.

We have estimated that each clinician will have 15 unique patients in his or her caseload. Based on our estimate of about 20 clinicians, this will yield approximately 300 surveys distributed during each collection period. As for Hypothesis (d), we are interested in the overall rate, and expect to obtain a rate in excess of 80%. We will also examine trends across the periods, and will also examine each site separately.

e) 100% of the Feedback Reports will be uploaded to the Patient Feedback website within 72-hours of the surveys and attendance Logs being faxed to the DMU, as evidenced by data records at the DMU.

There will be one Feedback Report for each clinician plus one Clinic Report for each Clinic. These reports will be generated every other week, or 8 times during the phase of the study in which Feedback Reports are being provided. Thus, there will be about 156 Feedback reports, and about 24 Clinic Reports, to be transmitted over the course of the study.

f) 100% of supervisors will download the Clinic Feedback Reports each month as evidenced by website usage records at the Patient Feedback internet site.

g) 100% of supervisors will conduct patient feedback team meetings each month as evidenced by the Team Meeting Forms faxed to the DMU each month.

For Hypotheses (f) and (g), each of the three clinics will send one Feedback Report, and one Team Meeting Form, per month, so the proportions for each of these hypotheses will be based on

12 forms.

h) 80% of eligible clinicians will participate in the monthly patient feedback team meetings, as evidenced by the number of eligible clinicians who sign the Team Meeting Form each month.

Based on our estimate of 20 clinicians, there will be about 80 Team Meeting Forms to be signed. Again, we will examine the overall proportion of the 80 for which signatures are obtained, and will also consider within clinic proportions, and trends over the four periods.

11.6 Analysis of Secondary Outcomes

Secondary outcome assessments in this feasibility study are all those measures that will serve as the primary outcome measures in a future effectiveness trial of the patient feedback intervention. Our principal aim in collecting these assessments in the feasibility study is to assess the acceptability and feasibility of their collection in community based treatment settings. We will also perform exploratory analyses of change on these measure between the pre- and post intervention stages of the study. These analyses will provide pilot data that will inform future effectiveness studies, but our small sample size, and lack of a control group, will not allow us to adequately address the question of effectiveness in this study.

11.7 Sample Size and Statistical Power

The analyses described above are exploratory, and our primary interest lies in estimating certain proportions. In this setting, precision (the accuracy with which the parameters are estimated) is more relevant than power (the probability of correctly rejecting a null hypothesis). The usual standard error associated with the estimate is given by the square root of p.hat*(1-p.hat)/ss, where p.hat is the estimate of the proportion, and ss is the sample size (numerator) on which the estimate is based. In all cases, we expect that we will find very high proportions, usually over 90%. Based on the various numerators described above, we find standard errors of between 0.07 and 0.10 for the proportions in Hypotheses (a), (b), (e - Clinic reports), (f), and (g); and standard errors of between 0.02 and 0.04 for the proportions in Hypotheses (c), (d), (e – Feedback reports), and (h). These standard errors will provide enough precision to adequately address the different hypotheses.

11.8 Analysis of Safety Measures

As described in Section 9.1, all adverse events will be recorded on the Adverse Events Form. These data will be summarized, using elementary statistical methods, and communicated to the Collaborating Investigators, the DSMB, and other groups, as described in Section 9.2

11.9 Interim Analyses

All studies meeting one or more of the following criteria must have an interim analysis plan included in the protocol that will allow presentation of efficacy data by treatment group to the DSMB on an ongoing basis:
- Enrolling >1000 subjects (all treatment groups combined) or
- Enrolling any number of subjects for > 6months of active treatment or
- Measuring deaths, serious adverse events, or significant morbidity as an efficacy outcome or
- Testing a pharmacological treatment (including alternative dosage forms) not currently approved by the FDA for the treatment of the addiction under study

Since our study does not meet any of the criteria listed above, nor are there any known predictable ethical or safety concerns with the two study treatments, we plan no interim analysis. However, such analyses may be requested at the discretion of the DSMB.

12.0   STUDY TIMETABLE

Estimated study start date	12/1/03
Estimated date when study will be 50% completed	3/1/04
Estimated study end date for feasibility study	6/1/04
Estimated study end date for sustainability phase of study	5/31/05

12.1   Enrollment of Outpatient clinics

Six outpatient clinics will be enrolled in the study.

13.0   DISCONTINUATION OF STUDY

The study may be discontinued either because of it having a significant adverse impact on the functioning of the participating treatment programs as determined by the NIDA Officer and lead investigator.

The LI has successfully implemented PI studies similar to this for six years at four sites without any adverse events. However, the expanded scope of this protocol, with the participation of 6 outpatient clinics represents a new level of implementation. Despite efforts to carefully monitor and maintain adequate collection and participation rates, there is a risk that significant problems could arise that compromise the quality of the data collected. Interim monitoring processes and rules for discontinuing a site that no longer meets the eligibility criteria have been specified elsewhere in the protocol.

14.0   DISCLOSURE OF DATA

The information and data included in this protocol may be disclosed to and used by the investigator's staff and associates as may be necessary to conduct this clinical study. The lead investigator will make the data available to NIDA and will cooperate fully with NIDA's disclosure of data plan.

15.0   ETHICAL, REGULATORY AND ADMINISTRATIVE CONSIDERATIONS

The ethical and regulatory requirements will be observed and comply with appropriate CFR's, ICH Guidelines and the Principles of Good Clinical Practice for the conduct and monitoring of clinical investigations. By signing this protocol, the investigator agrees to adhere to these requirements. All Institutional Review Boards with oversight of the participating sites must review and approve the study. Specific issues relating to informed consent procedures and other protections of human safety are described in this protocol.

15.1   Reporting to Sponsor

To be determined.

15.2   Publications and Other Rights

To be determined.

16.0   DISPOSITION OF DATA

Completed and signed Case Report Forms for all subjects entered into the study will be submitted to the sponsor or its designee. These data will be retained for a period of two years from completion of the study.

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18.0   AMENDMENTS

None at this time.

Appendix A. Feedback Survey

Draft	0016 | 01 | 01 | 007 Protocol Node Site Clinician	**Feedback Survey** Mary Smith	

**National Drug Abuse Treatment
Clinical Trials Network**

Thinking about the session you just attended, please answer each question by filling in the circles like this ●. Please fill in only one circle for each question. Do not write your name on this form. **Your individual answers will not be reported to anyone**. Skip any items you prefer not to answer. Thanks for helping to improve our program!

Thinking about the session you just attended:

	Not at All	A little bit	Moderately	Quite a bit	Very much so
1. Did you feel <u>accepted and respected</u> by your clinician?	○	○	○	○	○
2. Did you feel that you and your clinician were <u>working together</u> to overcome your problems?	○	○	○	○	○
3. Did you feel that your <u>clinician understood</u> what you hoped to get out of your treatment?	○	○	○	○	○
4. Did you feel confident that through your own efforts and those of your clinician that you will <u>gain relief</u> from your problems?	○	○	○	○	○
5. Did you <u>feel comfortable raising issues or concerns</u>?	○	○	○	○	○
6. Were <u>things explained</u> to you in a way you could understand?	○	○	○	○	○
7. Was the session <u>helpful</u>?	○	○	○	○	○

Tell us about you:

8. Do you consider yourself (please select only one):

○ White   ○ Asian   ○ American Indian or Alaska Native

○ Hispanic or Latino   ○ African American/Black   ○ Native Hawaiian or Pacific Islander

9. Are You: ○ Male   ○ Female

10. Concerning this admission, about how long have you been in treatment?

○ Less than 1 week   ○ 1 - 4 weeks   ○ 1 - 3 months   ○ More than 3 months

Alcohol or Other Drugs in the past week?

	Number of Days							
	0	1	2	3	4	5	6	7
11. How many days in the PAST WEEK did you drink <u>any alcohol</u> (beer, wine, or liquor)?	○	○	○	○	○	○	○	○
12. How many days in the PAST WEEK did you use <u>any drugs</u> (marijuana, cocaine, heroin, speed, other)?	○	○	○	○	○	○	○	○

Draft

version: 6/20/03

Appendix B. Coversheet

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0016	01	0701
Protocol	Node	Site

National Drug Abuse Clinical Trials Network

Coversheet

The name of this clinic is:

_____

Forms for the time period BEGINNING:

Month	Day	Year
Jan		2003
Feb		
Mar	0 0	2004
Apr	1 1	
May	2 2	2005
Jun	3 3	
Jul	4	
Aug	5	
Sep	6	
Oct	7	
Nov	8	
Dec	9	

Forms for the time period ENDING:

Month	Day	Year
Jan		2003
Feb		
Mar	0 0	2004
Apr	1 1	
May	2 2	2005
Jun	3 3	
Jul	4	
Aug	5	
Sep	6	
Oct	7	
Nov	8	
Dec	9	

Visit Week

0	0	
1	1	1
2	2	
3	3	3
4	4	
5	5	5
6	6	
7	7	7
8	8	
9	9	9

Today's Date

Month	Day	Year
Jan		2003
Feb		
Mar	0 0	2004
Apr	1 1	
May	2 2	2005
Jun	3 3	
Jul	4	
Aug	5	
Sep	6	
Oct	7	
Nov	8	
Dec	9	

Attendance Forms

0	0
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9

PF Survey Forms

0	0	0
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8
9	9	9

28686

version: 9/15/03

Appendix C. Attendance Form

0016	01	0701	0001
Protocol	Node	Site	Clinician

Attendance

16114

National Drug Abuse Clinical Trials Network

Attendance data for the time period **BEGINNING**:

Month	Day	Year
Jan		2003
Feb		
Mar		2004
Apr		
May		2005
Jun		
Jul		
Aug		
Sep		
Oct		
Nov		
Dec		

Attendance data for the time period **ENDING**:

Month	Day	Year
Jan		2003
Feb		
Mar		2004
Apr		
May		2005
Jun		
Jul		
Aug		
Sep		
Oct		
Nov		
Dec		

1st WEEK: # of pts <u>scheduled</u> for group each day

Mon	Tue	Wed	Thu	Fri	Sat

2nd WEEK: # of pts <u>scheduled</u> for group each day

Mon	Tue	Wed	Thu	Fri	Sat

1st WEEK: # of pts <u>attended</u> for group each day

Mon	Tue	Wed	Thu	Fri	Sat

2nd WEEK: # of pts <u>attended</u> for group each day

Mon	Tue	Wed	Thu	Fri	Sat

16114

version: 9/15/03

Appendix D. Team Meeting Form

7224

National Drug Abuse
Clinical Trials Network

Name of staff participating in the Team Meeting (in boxes below)

Instructions: Please fill in circles for <u>each</u> performance indicator (e.g. Attendance) or clinical subgroup (e.g. Male) your team plans to focus improvement efforts on this month. Select as many - or as few - performance indicators and subgroups as you wish.

Performance Indicator:

◯ Attendance   ◯ Therapeutic Alliance   ◯ Group Treatment Satisfaction

Racial/Ethnic Group:

◯ White   ◯ Asian   ◯ American Indian or Alaska Native

◯ Hispanic or Latino   ◯ African American/Black   ◯ Native Hawaiian or Pacific Islander

Gender: ◯ Male   ◯ Female

Length of Stay:

◯ Less than 1 week   ◯ 1 - 4 weeks   ◯ 1 - 3 months   ◯ More than 3 months

Improvement Plans

In the space below, indicate the specific action steps your PI team plans to initiate over the next month:

Action Step Title	Specific Actions to be Taken	Will specific individuals implement Action Step?	Status of Action
1		___ No - plan will be implemented by the entire team. ___ Yes, the following individuals have the primary responsibility:	*(Write Date)* ___/___ Planned ___/___ Initiated ___/___ Completed
2		___ No - plan will be implemented by the entire team. ___ Yes, the following individuals have the primary responsibility:	___/___ Planned ___/___ Initiated ___/___ Completed
3		___ No - plan will be implemented by the entire team. ___ Yes, the following individuals have the primary responsibility:	___/___ Planned ___/___ Initiated ___/___ Completed

version: 9/18/03

Appendix E. Sample Page of Feedback Newsletter

Patient Feedback News
A Study in the National Drug Abuse Clinical Trials Network

Pilot Study Takes Off at Presbyterian

Team Focusing on Therapeutic Alliance

"People won't open up if the relationship is strained."

Four Dimensions of Therapeutic Alliance

- Patient's capacity to work
- Patient's affective bond with the therapist
- Therapist's empathic understanding
- Agreement between patient and therapist on the goals and tasks of therapy.

Upon beginning the pilot study at Presbyterian Medical Center, nine staff (pictured right) were asked about their thoughts about participating in the Patient Feedback protocol. Overwhelmingly, the staff focused upon the issue of "therapeutic alliance" and the role that Patient Feedback might play in helping them monitor and increase it. Why all the fuss?

Dozens of studies have found a positive relationship between therapeutic alliance and treatment outcomes regardless of the type of therapy or length of treatment (see sidebar for background on "therapeutic alliance"). The staff at Presbyterian agrees that therapeutic alliance can have a powerful impact on their treatment outcomes. Here's what some of the clinicians at "Presby" (as it's known it Philadelphia) had to say about therapeutic alliance and getting started with the

Back Row, Left to Right: Paul Boyd, Andrea Martin-Perry, Pam Bobe, Tenrika Savage, and DeEdryle Khrebb Front Row, Left to Right: Time Dow, Vincent Wright, Larry Brooks, and Vivian Cantrell

Of Outcomes with Megabits

When asked about the use of the internet in Patient Feedback most clinicians find the idea intriguing.   Clinicians access the Patient Feedback website with a personal username. Once "inside" the Patient Feedback website, a whole world of addiction treatment materials becomes freely available. Some of the website features include: dozens of patient education handouts, a message board facilitating communication with other clinicians and supervisors around the country who are participating in the study, links to addiction treatment websites, as well as other resources for addiction professionals.   Larry Brooks loves the internet and currently utilizes it for up-to-date treatment techniques. "This will make it easier to find out what's new in addiction." Paul Boyd comments that most research is

Vincent Wright on technology.

Appendix F. Measure Of End-User Computing Satisfaction

MEASURE OF END-USER COMPUTING SATISFACTION
Doll, William J. and Torzadeh, Gholamreza, "The Measure of End-User Computing Satisfaction," *MIS Quarterly*, **Vol. 12, No. 2, June, 1988, pp. 259-274**

Does the system provide the precise information you need?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Does the information content meet your needs?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Does the system provide reports that seem to be just about exactly what you need?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Does the system provide sufficient information?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

ACCURACY

Is the system accurate?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Are you satisfied with the accuracy of the system?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

FORMAT

Do you think the output is presented in a useful format?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Is the information clear?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

EASE OF USE

Is the system user friendly?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Is the system easy to use?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

TIMELINESS

Do you get the information you need in time?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Does the system provide up-to-date information?	Almost Never	Some of the Time	About Half of the Time	Most of the Time	Almost Always
	1	2	3	4	5

Appendix G. Minnesota Satisfaction Questionnaire (MSQ)

Minnesota Satisfaction Questionnaire (MSQ)*
Short Form

<u>**Ask yourself: How satisfied am I with this aspect of my job?**</u>

5 = Very Satisfied, means I am very satisfied with this aspect of my job.
4 = Satisfied, means I am satisfied with this aspect of my job.
3 = Neutral, means I can't decide whether I am satisfied or not with this aspect of my job.
2 = Dissatisfied, means I am dissatisfied with this aspect of my job.
1 = Very Dissatisfied, means I am very dissatisfied with this aspect of my job.

1.   Being able to keep busy all the time   .

2.   The chance to work alone on the job   .

3.   The chance to do different things from time to time   .

 4.   The chance to be "somebody" in the community   .

 5.   The way my boss handles his/her workers.

 6.   The competence of my supervisor in making decisions .

7.   Being able to do things that don't go against my conscience   .

8.   The way my job provides for steady employment   .

9.   The chance to do things for other people   .

10.   The chance to tell people what to do   .

11.   The chance to do something that makes use of my abilities .

12.   The way company policies are put into practice   .

13.   My pay and the amount of work I do.

14.   The chances for advancement on this job.

15.   The freedom to use my own judgment .

16.   The chance to try my own methods of doing the job   .

17.   The working conditions   .

18.   The way my co-workers get along with each other .

19.   The praise I get for doing a good job   .

20.   The feeling of accomplishment I get from the job.

Appendix H. Leader/Member Exchange (LMX7)

Leader/Member Exchange (LMX7)

1. Do you know where you stand with your leader…do you usually know how satisfied your leader is with what you do? (Does your member usually know?)

     Rarely   Occasionally   Sometimes   Fairly Often   Very Often

2. How well does your leader understand your job problems and needs? (How well do you understand?)

     Not a Bit   A Little   A Fair Amount   Quite a Bit   A Great Deal

3. How well does your leader recognize your potential? (How well do you recognize?)

     Not at All   A Little   Moderately   Mostly   Fully

4. Regardless of how much formal authority he/she has built into his/her position, what are the chances that your leader would use his/her power to solve problems in your work? (What are the changes that you would?)

     None   Small   Moderate   High   Very High

5. Again, regardless of the amount of formal authority your leader has, what are the chances that he/she would "bail you out" at his/her expense? (What are the chances that you would?)

     None   Small   Moderate   High   Very High

6. I have enough confidence in my leader that I would defend and justify his/her decision if he/she were not present to do so. (Your member would?)

     Strongly   Strongly
     Disagre   Disagree   Neutral   Agree   Agree
     e

7. How would you characterize your working relationship with your leader? (Your member?)

     Extremely   Worse Than   Better Than   Extremely
     Ineffective Average   Average   Average   Effective

   Notes: Continuous scale of sum of 5-point items (1 left to 5 right). Leader's form consists of same seven items asked about member of (leader in parentheses). Expected agreement between leader and member reports is positive and strong and used as index of quality of data.

Appendix I. Site Summary Form

National Drug Abuse Clinical Trials Network

Patient Feedback - Protocol #0016
Site Summary Form
February 24, 2003

Introduction – Thank you for your interest in the patient feedback protocol. You are invited to submit one or more applications for clinics within your node that are interested in participating in the Patient Feedback feasibility study. The feasibility study will include three clinics and last six months. Clinics that participate in the feasibility study will be given open access to the patient feedback system for an additional 12-months and usage of the system will be monitored to assess the sustainability of the intervention. Sites not selected for the feasibility study will be given first consideration in the effectiveness study if it is approved. The feasibility study is scheduled to begin in the Summer of 2003. This form is intended to collect information about the clinics interested in participating in the Patient Feedback feasibility study.

Inclusion Criteria – Outpatient, intensive outpatient and partial hospitalization substance abuse treatment programs are eligible to participate.

Exclusionary Criteria – a) Methadone maintenance clinics; b) Outpatient clinics in which less than 100% of the clinicians agree to participate in the study; c) Outpatient clinics with three or fewer clinicians who conduct group counseling sessions d) Outpatient clinicians who conduct group sessions less than once a week, and e) Outpatient clinics unable to meet on a monthly basis for 1 hour to discuss the Feedback Reports.

Instructions: A one-hour net conference call will be scheduled with representatives from your node to review the protocol and answer questions you may have about completing this form. Please complete one form for each clinic that you would like considered. When you have completed the form, please e-mail it to: bforman@tresearch.org by March 15, 2003. If you have any questions about the site selection process, please email or call me (215-388-0980). Receipt of your form will be confirmed. Thank you for your interest in this study.

1. Name of Clinic:_____
2. Name of Node:_____
3. Site Address: _____
4. CTP Primary Contact Name and e-mail address:_____
5. RRTC Primary Contact and e-mail address: _____
6. Number of fulltime <u>and</u> part time clinicians <u>who conduct group at least once a week </u>at this clinic: #FT ___ #PT___
7. Approximate number of patients who attended outpatient groups in the last week (AKA: active census): _____
8. Approximate percent of admissions under criminal justice supervision: _____
9. Approximate percent of admissions with severe and persistent mental illness[5]: _____
10. Number of outpatient clinics managed by the CTP (parent organization): _____
11. Does this clinic anticipate any major disruptions[6] to service in the next 12 months?   ____Yes   _____No
12. Have all eligible clinicians been at least briefly oriented to the study?   ____ Yes   _____ No
13. Have all eligible clinicians tentatively agreed to participate in the study[7]?   ____ Yes   _____ No
Have the following individuals approved this site's participation?
14. CTP Director   ____ Yes   _____ No
15. Node Principal Investigator   ____ Yes   _____ No
16. Name of individual completing this form: _____

Thank you for taking the time to complete this survey. Shortly after March 15th the sites selected for the feasibility study will be identified.

---

[5] "Severe and persistent mental illness" includes patients with the diagnosis of a) psychosis, b) bi-polar disorder and/or b) major depression. This does not include patients with personality disorders, anxiety disorders or other non-psychotic conditions.
[6] A "major disruption" would be a move, a merger or significant downsizing.
[7] *Participation for clinicians includes***:** a) reviewing Caseload Reports monthly; b) participating in monthly Team Meetings; c) distributing Feedback Surveys to patients *every other* week. *Participation for supervisors includes*: a) examining Clinic Reports every other week; b) preparing for and leading monthly Team Meetings; and c) completing the monthly Team Meeting Form.

NIDA's Requirements for Clinical Trials

[Discuss general requirements and specific requirements for protection of study subjects, monitoring, recording of data, drug accountability, study documents and record retention, and legal requirements.]

Appendix J. Training Plan

Patient Feedback (Protocol #0016)
Protocol Training Plan Forms

Introduction: The table below ("NIDA CTN Training Checklist") presents the 0016 training requirements using the standard codes and template provided by the Training Subcommittee (TSC). **As training gets completed at your node, we will be asking you to reference this document, and the codes for the modules.** Because 0016 has some unique training requirements, we had to "force" elements of our trainings into the categories provided in the standard template. On page 2 we have included our original Training Plan which describes our trainings. To "cross walk" the TSC's Checklist with our original training plan, we have added the TSC's training codes next to the names of each of our training modules (far left-hand column). **As we conduct the trainings at your site we will review the documentation requirements with you since these are new documentation requirements.**

NIDA CTN Training Checklist (PTP-001)

Protocol#: NIDA-CTN- 0016

Protocol Name: Patient Feedback: A Performance Improvement Study in Outpatient Settings

Training Module	Module Length	Trainees							
		IN	RS	RX	TH	TX	MD	PH	QA
Core Modules									
01=ASI-Lite	N/A								
02=Biological Measures	N/A								
03 =CIDI	N/A								
04 = GRP*	8 hours	x	x	x		x			x
05 = Risk Behaviors Survey	N/A								
Protocol Specific Modules									
50=Study Synopsis	1 hour	x	x	x	x	x	x**		x
51=Recruiting & Enrollment	--								
52=Protocol Specific Assess-RS compl.	1.5 hours	x	x			x			x
53=Protocol Specific Assess-TH compl.	3 hours	x	x	x	x	x			
54=Protocol Specific Assess-MED	--								
55=Follow-up procedures	--								
56=Safety & AE Reporting	--								
57=Medication Dispensing/Handling	--								
58=Therapy/Behavioral Intervention	2 hours	x	***	x					
59=Therapy/Behavioral Interv.	--								

IN= Investigator (LI, PI, etc.)	QA=QA Staff	
RS= Research Staff (PA, RA, study coord.)	RG=Regulatory Staff	Protocol Training Coordinator
RX= Research Superv. Staff	DM=Data Management Staff	Date
TH= Therapist	DX=Data Management Superv. Staff	

TX= Therapy Supervisor	BO=Business Operations Staff	Lead Investigator Date
MD= Medical Staff	RO=Research Staff –Other	
PH= Pharmacy Staff	NR= Non-research Staff	

*if MD is member of outpatient team

**Training must be provided by someone who has successfully completed the TTT training for this module

***Site utilizing Research Assistant to support training in the data system should include RA in this training

Patient Feedback Training Checklist

	Training Module	Module Length	IN	RS	RX	TH	TX	MD	QA
Core Modules		# hours							
04 - GRP*		8	X	X	X		X		X
Protocol Training Modules									
O 50 - *Preliminary Team Orientation*		1	X	X	X	X	X	*	
Patient Feedback System Overview		.2							
Study Procedures		.5							
Eligibility		.1							
Budget		.1							
Protocol Timeline		.1							
52 - *Protocol Procedures*		2	X	X	X		X		X
Protocol Overview		.2							
Regulatory Requirements		.5							
Equipment & Supplies		.2							
Training Requirements		.2							
Patient Feedback Survey Faxing		.5							
Data Management Orientation		.2							
Accessing Support from the Lead Node		.2							
53 - *Team Training*		3	X	X	X	X	X		X
Patient Orientation		.5							
Completing Web-based Assessments		.5							
Distribution & Collection of Surveys		.5							
Conducting Team Meetings		.5							
Interpreting Feedback Reports		1							
D 58 - *Data Management*		2	X	**	X				
Logging onto the Data Entry System		.2							
Completing Web-based Assessments		.6							
Practice online		.6							
The Patient Feedback website		.4							
Obtaining support		.2							

IN= Investigator (LI, PI, etc.)	
RS= Research Staff (RA, PA)	
RX= Research Superv. Staff	
TH= Therapist	
QA = QA Monitor	
TX= Therapy Supervisor	

*if MD is member of outpatient team
**Site utilizing RA to support training in the data system should include RA in this training

Training Plan Abstract (PTP-002)

NIDA CTN Training Plan Abstract (PTP-002)
<u>Instructions</u>: In general, the Training Plan Abstract should provide an overview of the training plan for the Protocol Specific Modules. Examples of things to be addressed include training materials that will be provided to staff (e.g., operations manual, therapy manual, etc.), training models to be used (e.g., centralized, train the trainer), trainer/trainee competency assessments, and plans for training replacement staff.

The protocol specific training for the Patient Feedback Protocol is divided into four components: a) Preliminary Team Orientation, b) Protocol Procedures, c) Team Training and d) Data Management.   All training will be conducted using Net Conferencing in order to minimize cost and disruption to the normal functioning of the clinical programs. The total training requirements, not counting GRP, is seven hours. The only Core Training module required for this protocol is: Good Research Practice. The Patient Feedback training model is <u>centralized</u> but it is expected that the research supervisor or coordinator might assist in training any replacement staff as needed. Training replacement staff will be handled on an as needed basis using a combination of local, on the job training, and net training calls.

The ***Preliminary Team Orientation*** is composed of: a) an overview of Patient Feedback System, b) a summary of the study procedures, emphasizing what work will need to be performed by staff, c) a description of the clinic and clinician eligibility requirements, d) orientation to the Patient Feedback Website e) budget requirements f) an estimated timeline. The purpose of the Orientation is to ensure that the clinic management, the RRTC leadership, and clinical staff understand the study requirements and agree to participate. This session is conducted prior to staff being invited to sign the informed consent; this orientation is completed in one hour. This session is conducted one-site at a time.

The ***Protocol Preparation Training*** is designed to review the protocol timeline and activities that the study staff completes prior to the beginning of data collection (during Month One). This two-hour session is divided into seven sections: a) Protocol Overview, b) Regulatory Requirements, c) Purchasing of Supplies and Equipment required for the protocol, d) Training Requirements, e) Patient Feedback Survey Faxing Procedures, f) an orientation to the Data Management System, and g) how to Access Support from the lead node protocol team. During this net call participants are invited to raise any questions they might have about the study. This 2-hour session is conducted one-site at a time; specific logistical issues related to the placement of the Survey Collection Containers and extraction of attendance data are addressed during this session. A follow-up session will be scheduled with representatives from the participants if open issues need to be resolved.   A ***Standard Operations Procedures (SOP) Manual*** will be provided to participants in this training, the contents of which parallel the topics covered.

The ***Team Training*** is conducted approximately one-month after the implementation of study, just prior to the release of the first set of Feedback Reports. This training includes: a) an orientation to the Patient Feedback system, b) instructions on using the web-based data entry system, c) a review of the PF Survey distribution and collection procedures, d) guidelines for

conducting the Team Meetings, and e) an introduction to Interpreting the Feedback Report. This component of training will last two-three hours (depending on questions) and will parallel information provided in the *Patient Feedback Manual.*

The *Data Management* training is intended to create at each participating CTP several local experts on the use of the two websites used in the Patient Feedback protocol. The main focus of the data management training will be on the Data Entry System, including how to logon, complete CRFs, and get support if there are any problems. The remaining time in this training is to provide an opportunity for trainees to practice using the website, under the supervision of the trainers who will observe and certify them as the local, onsite experts.

3.3 Protocol-Specific Module Description (PTP-003)

Protocol-Specific Module Description (PTP-003)
Protocol#: NIDA-CTN- 0016
Protocol Name: Patient Feedback: A Performance Improvement Study in Outpatient Settings

Module:	***Preliminary Team Orientation***
Description:	The ***Preliminary Team Orientation*** is composed of: a) an overview of Patient Feedback System, b) a summary of the study procedures, emphasizing what work will need to be performed by staff, c) a description of the clinic and clinician eligibility requirements, d) orientation to the Patient Feedback Website e) budget requirements f) an estimated timeline. The purpose of the Orientation is to ensure that the clinic management, the RRTC leadership, and clinical staff understand the study requirements and agree to participate. This session is conducted prior to staff being invited to sign the informed consent; this orientation is completed in one hour. This session is conducted one-site at a time.
Developed by:	Robert F. Forman, Ph.D.
Training Format:	Net conferencing
Training Model:	Centralized
Trainer Requirements:	Expertise in the protocol procedures
Trainee Requirements:	Key personnel including local LI and representatives of clinic management
Module Length:	1 hour
Competency Assess:	none
Continuing Education:	Periodic teleconference calls.

Module:	***Protocol Preparation Training***
Description:	The ***Protocol Preparation Training*** is designed to review the protocol timeline and activities that the study staff complete prior to the beginning of data collection (during Month One). This two-hour session is divided into seven sections: a) Protocol Overview, b) Regulatory Requirements, c) Purchasing of Supplies and Equipment required for the protocol, d) Training Requirements, e) Patient Feedback Survey Faxing Procedures, f) an orientation to the Data Management System, and g) how to Access Support from the lead node protocol team. During this net call participants are invited to raise any questions they might have about the study. This 2-hour session is conducted one-site at a time; specific logistical issues related to the placement of the Survey Collection Containers and extraction of attendance data are addressed

	during this session. A follow-up session will be scheduled with representatives from the participants if open issues need to be resolved. A **Standard Operations Procedures (SOP) Manual** will be provided to participants in this training, the contents of which parallel the topics covered.
Developed by:	Robert F. Forman, Ph.D.
Training Format:	Net conferencing
Training Model:	Centralized
Trainer Requirements:	Member of the protocol team with expertise in these research procedures and instruments
Trainee Requirements:	Local lead investigator, QA monitor, clinic manager(s), project assistant
Module Length:	2-3 hours depending upon questions
Competency Assess:	NA
Continuing Education:	Periodic teleconference calls.

Module:	**Team Training**
Description:	The **Team Training** is conducted approximately one-month after the implementation of study, just prior to the release of the first set of Feedback Reports. This training includes: a) an orientation to the Patient Feedback system, b) instructions on using the web-based data entry system, c) a review of the PF Survey distribution and collection procedures, d) guidelines for conducting the Team Meetings, and e) an introduction to Interpreting the Feedback Report. This component of training will last two-three hours (depending on questions) and will parallel information provided in the **Patient Feedback Manual.**
Developed by:	Robert F. Forman, Ph.D.
Training Format:	Net conferencing
Training Model:	Centralized
Trainer Requirements:	Member of the protocol team with expertise in the data management procedures.
Trainee Requirements:	All
Module Length:	2-3 hours, depending on the number of questions
Competency Assess:	NA
Continuing Education:	Periodic teleconference calls.

Module:	***Data Management System***
Description:	The ***Data Management*** training is intended to create at each participating CTP several local experts on the use of the two websites used in the Patient Feedback protocol. The main focus of the data management training will be on the Data Entry System, including how to logon, complete CRFs, and get support if there are any problems. The remaining time in this training is to provide an opportunity for trainees to practice using the website, under the supervision of the trainers who will observe and certify them as the local, onsite experts.
Developed by:	Chris Petro and Robert F. Forman, Ph.D.
Training Format:	Net conferencing
Training Model:	Centralized
Trainer Requirements:	Member of the protocol team with expertise in the data management procedures.
Trainee Requirements:	Investigator, research/clinic supervisor, onsite tech support
Module Length:	2 hours, depending on the number of questions
Competency Assess:	NA
Continuing Education:	Periodic teleconference calls.

3.4 Core Module Modifications (PTP-004)

Core Module Modifications (PTP-004)
Protocol#: NIDA-CTN-0016
Protocol Name: Patient Feedback

Do you plan to make any modifications to the Core Modules developed by the Training Subcommittee?

  X No   ___ Yes

If Yes, please list each module that you intend to change and describe the intended changes (if no, then leave the rest of the form blank):

Module:	
Description of intended changes:	

Module:	
Description of intended changes:	

Module:	
Description of intended changes:	

Module:	
Description of intended changes:	

Appendix K. Study Cost Projections

Four separate **budget estimates** are presented below for: a) the RRTC, b) site protocol equipment, c) and Site Staff Support. The $/Hr cost estimates are intended to include both salary and benefits. These projections do not include indirect charges. RRTCs and CTPs will negotiate their specific agreements based on local conditions.

Site Equipment & Supply Support Estimate	Cost/Unit	Freq.		# Units	Total
Internet Access	$50	12 mos.		1	$600
Computer w/monitor and color inkjet printer	$1,500	n.a.		2	$3,000
High Capacity Fax	$1,300	n.a.		1	$1,300
Office Supplies	$50	8 mos.		N/A	$400
Total					**$5,300**

RRTC Budget Estimate*	Who	$/Hr	# of Staff	# Hrs	Total
Preliminary discussions with LI	Protocol Principal Investigator	$80	1	1	$80
IRB Approval Process	RRTC Reg.	$40	1	4	$160
Staff Consent	Protocol Principal Investigator	$80	1	2	$160
Implementation Net Call	Protocol Principal Investigator	$80	1	3	$240
	Q.A. Monitor	$40	1	3	$120
Follow-up Implementation Net Call	Protocol Principal Investigator	$80	1	2	$160
	Q.A. Monitor	$40	1	2	$80
Staff Measures	Protocol Principal Investigator	$80	1	3	$240
Protocol Implementation Monitoring	Q.A. Monitor	$40	1	18	$720
Feedback Reports Training Net Call	Protocol Principal Investigator	$80	1	3	$240
Protocol Principal Investigator - Miscellaneous	Protocol Principal Investigator	$80	1	4	$320
Total				46	**$2,520**

*All data management can be provided by lead node.

CTPStaff Budget Estimate*	Who	$/Hr	# of Staff	# Hrs	Total
CEO Net Conference Call & Project Review	CTP Leadership	$90	1	2	$180
Preliminary Discussions with CTP Manager	Supervisor	$60	2	1	$120
Implementation Net Call	PA	$25	2	3	$120
	Supervisor	$60	2	3	$300

Participant Orientation	Clinicians	$35	6.5	6	$1,365
Processing CRFs; faxing PF Surveys (semi-monthly)	PA	$25	1	3hr x 12 wks = **36**	$900
Feedback Reports Training Net Call	Clinicians	$35	6.5	3 hrs	$683
	Supervisor	$60	2	3 hrs	$360
Staff Measures	All eligible staff	$50	8	3 hrs	$1,200
Feedback Team Meetings/Supervision	Supervisor	$60	2	2 hr x 4 mos. = **8**	$960
	Clinicians	$35	6.5	1.5 hr x 4 mos. = **6**	$1,365
Total					**$7,553**

*Does not include indirects.

Appendix L. Patient Feedback Manual (provided as a separate document).

Appendix M.
Feedback Project
Participant Orientation   **[ON CLINIC LETTERHEAD]**

Dear Program Participant:

Every other week you will be invited to complete a "Feedback Survey" in which you rate your treatment experience. Here is some background information about the Survey:

a. **Purpose of the Feedback Surveys**
We are asking you to complete this Survey so that we can continue to improve the care we are providing to you and all other program participants. We are interested in your opinion and hope that you will tell us what you think.

b. **Voluntary**
We want to get the opinions of all program participants, but if for any reason you do not want to complete the survey you do not have to.

c. **Confidential**
Your name will not appear anywhere on the survey and because we collect surveys from almost everyone who attends treatment, your survey answers will be completely anonymous and confidential.

d. **Instructions**
Please answer each question with **only one answer** and fill in the circle completely. If you what to change an answer, please erase the wrong answer completely before filling in the new answer. **Please Do Not Fold Your Survey**. Please answer each item accurately.

e. **Survey Collection**
Surveys will be distributed during the last 5 minutes of your group session. After you have completed your survey, please place it into the locked Survey Filing Cabinet. Only the Project Assistant and research staff have the key to this cabinet.

f. **Trouble Reading?**
If for any reason you would like someone to read the survey to you, please let me know so arrangements can be made for reading the items to you.

g. **What Happens to the Surveys?**
All surveys are faxed to the University of Pennsylvania where they are "read" by a computer, analyzed, and turned into statistical reports and graphs. The staff of the clinic will then study the feedback and use it to guide the program. The information you provide cannot be traced back to you.

h. **Thank You!**
Your answers will help us provide better care for you and other people in our program. Thank you for being willing to help us continuous to improve.