# A RANDOMIZED TRIAL OF ALTERNATIVE TREATMENTS FOR PROBLEM DRINKING EMPLOYEES: STUDY DESIGN, MAJOR FINDINGS, AND LESSONS FOR WORKSITE RESEARCH

DIANA CHAPMAN WALSH
*Harvard University*
RALPH W. HINGSON
DANIEL M. MERRIGAN
SUZETTE MORELOCK LEVENSON
L. ADRIENNE CUPPLES
TIMOTHY HEEREN
*Boston University*

This paper presents the rationale, design, implementation and results of a 10-year study comparing alternative treatments for problem drinkers identified on the job. It presents greater detail than has been previously reported, both on the logistics of the study and on selected results. The study assigned 227 newly-identified alcohol-abusing EAP clients to three alternative alcoholism rehabilitation regimens: the first began with a three-week period of mandatory inpatient rehabilitation; the second mandated only that the employee attend Alcoholics Anonymous meetings; the third offered subjects a choice among treatments. All three groups improved, and no significant differences were found among the groups in job- related outcome variables. On measures of drinking and drug use, the hospital group fared best and that assigned to AA the least well. The differences among the groups were especially pronounced for workers who had used cocaine within six months before study entry. The paper concludes with cautions and caveats and with recommendations for policy and for future research.

The rapid growth, since the early 1970s, of company-sponsored employee assistance programs (EAPs) (Roman 1988) has outpaced solid research on how best to structure them (Kurtz, Googins, Howard, 1984). As their most essential function, EAPs facilitate the identification of employees work-impairing problems that may (or may not) be related to alcohol or other substance abuses, assess the nature and severity of the problems, and make referrals for appropriate care (Walsh 1982). Yet, for the most part, the assessment and referral process has remained a black box, and the question of where to refer clients has been left for individual counselors to work out as best they can (Walsh, Hingson 1985). Those who look find little guidance from authoritative empirical research on alternative strategies for making referrals to alcoholism treatment. This is the case not only because generic treatment research leaves much yet to be resolved, but also (and importantly) because its application to decision-making in the workplace is at best limited. Treatment-comparison studies, typically, are carried out in clinical settings, divorced from the workplace. EAPs, which can back their referrals with "constructive confrontation," and the implicit or explicit threat of job loss, create a distinct incentive structure for patients entering alcoholism treatment (Trice, Beyer 1984). Consequently, the available research on treatment efficacy very likely does not apply directly to treatment initiated by an EAP, an increasingly common situation.

This paper describes the genesis, goals, implementation, and results of a study undertaken to address the question of where employers should refer workers for treatment of alcohol problems. Several features of the study make it unusual. It spanned a 10-year period, all told, from an original start-up grant to the publication of final results. It was located in a large corporation, the General Electric Company (GE), under joint sponsorship with the local and district council of the International Union of Electrical Workers (IUE), a major international union. In that action setting, the study succeeded in randomly assigning a sequential cohort of 227 new EAP clients to three alternative treatments, and following them prospectively for two years of observation. This was a rigorous design and its implementation demanded special attention to the protection of all participants. The project was funded jointly by the private and public sectors, initially with design and developmental support — together with substantial intellectual, technical and political guidance — from the Commonwealth Fund in New York, then with companion funding for a year from the Robert Wood Johnson Foundation, and, finally, with a sizable five-year investigator-initiated research grant from the National Institute on Alcohol Abuse and Alcoholism (NIAAA).

Some key results of the study have previously been published (Walsh, Hingson, Merrigan, Levenson, Cupples, Heeren, Coffman, Becker, Barker, Hamilton, McGuire, Kelly 1991). This report provides substantially more context and methodological detail, and presents entirely new findings on treatment compliance, and on participation in Alcoholics Anonymous as an important factor in treatment success.

### Context and Rationale

The alcoholism field has long been divided over how much treatment is enough, and specifically over whether and when inpatient care is justified to supervise alcohol withdrawal (Hayashida, Alterman, McClellan, 1989) and/or manage alcohol dependence (Chapman, Huygens 1988). The 1977 landmark English study in which Griffith Edwards and his colleagues found "treatment and advice" to be equally efficacious threw down a gauntlet for proponents of more intensive approaches to care (Edwards, Orford, Egert 1977). A whole line of related research, comparing inpatient treatment to a variety of alternatives [such as outpatient treatment (Wanberg, Horn, Fairchild 1974), partial hospitalization (Longabaugh, McCrady, Fink 1983), and day clinic settings (McLachlan, Stein 1982)], has rarely found significant differences in outcomes. More recently, government and private panels, (U.S. Office of Technology Assessment 1983; Institute of Medicine 1989; Institute of Medicine 1990; National Institute on Alcohol Abuse and Alcoholism 1990) and several

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academic reviewers, (Miller, Hester 1986; Eurich, 1975) have synthesized the accumulated evidence on alcoholism treatment efficacy, and have concluded that inpatient rehabilitation still awaits convincing justification, pending larger-scale studies, and research to develop procedures for matching patients to specific treatments that will best serve their particular needs (Institute of Medicine 1990, p. 406).

In striking contrast, at the same time that this note of caution was building resonance in the research literature, inpatient rehabilitation programs for alcoholism were expanding sharply. The growth was most pronounced during the 1970s and 1980s, (Goldbeck, Walsh, Egdahl 1981) and was supported to a great extent by decisions and incentives in private-sector employment. With more EAPs in place, more problem-drinking employees would be identified and referred out for care. A four-element incentive structure within most EAPs tended, other things being equal, to favor making that referral to an inpatient setting. First, most medical insurance provided much fuller — and sometimes exclusive — coverage for in-hospital care. Second, sickness and accident plans ensured wage replacement during the employee's time away from work. Third, an inpatient referral simplified the EAP administrator's life. Managing the entry into treatment of a problem-drinking employee was often a difficult, time-consuming, and emotionally-charged task. For a busy administrator facing a choice between transferring that responsibility to an inpatient program, or personally having to orchestrate and monitor the client's successful integration into a non-residential alternative, the inpatient route clearly was the path of least resistance. Fourth, the financial impact of these decisions was imperceptible and inconsequential to the administrator making them. The costs of both the inpatient stay and the wage replacement were buried elsewhere in experience-rated health benefit and insurance plans, under a jurisdiction that was generally quite separate from the EAP. From a policy perspective, this combination — growing numbers of EAPs, with built-in forces to fuel an expansion of inpatient capacity and with little financial control or accountability — was occasion for concern in the absence of scientific evidence to justify increasing investments into inpatient rehabilitation programs for alcohol dependence and abuse.

By the early 1990s, the pendulum was swinging back. Alarmed at their inability to contain rising health care costs, the nation's large employers were beginning to reduce their coverage for alcoholism treatment. Many corporations took steps to limit coverage to a specified number of treatments over a year and/or a lifetime, to increase copayment fees, and/or to impose incentives that would channel employees into a variety of managed care programs whose mission it was to reduce admissions and lengths of stay for health care in general and, often, for chemical dependency treatment in particular.

Over this three-decade span, then, the pendulum swung back and forth — from more to less enthusiasm and coverage for inpatient treatment of workers' alcohol problems — with very little convincing data on either side of the arc, and with no basis on which decision makers could gauge realistically what effect the changes might have on the health of workers, and/or on the smooth functioning of the work organization. Virtually all investigations into the question of how much alcoholism rehabilitation is enough had posed it in orthodox clinical settings, removed from force fields and decision rules operating within the workplace.

With a start-up grant from the Commonwealth Fund, we set out in February



1981 to conduct a study that would change the venue and examine the question of alcoholism treatment efficacy in the corporate setting, where key decisions were daily being made that were shaping the treatment system. In doing so, we had two additional goals in mind. First, we felt it crucial to try to move the methodology forward, so we established as a *sine qua non* that the study be a randomized controlled trial. It seemed to us that a condition officially designated a disease ought to be studied using state-of-the-art research methodology for comparing alternative therapies. Particularly in the case of behavioral disorders such as alcohol abuse, the patient's motivation is such a powerful confounder — and so elusive of measurement — that quasi-experimental study designs can never adequately deal with selection bias. Second, in line with the Edwards study, it seemed important to endeavor to push the treatment efficacy question as far as we could, in search of something that would approximate an effective *minimum* treatment package for problem-drinking workers. Other investigators were studying the effects of removing the hotel function from the standard inpatient protocol; our goal was to compare treatments that were more widely spaced along a continuum of intensity, expense and intrusiveness into employees' lives.

### Practicalities of Launching the Study

The first year was spent soliciting companies to participate in the trial. All told, these and later efforts to enlist participants involved contacts with 58 large corporations in which we had a personal entree or an introduction to an individual who could broker a partnership. Although we found these business managers unanimously supportive of the need for systematic research comparing treatment alternatives (and eager to hear about the results of the study we were setting out to do), we had little success persuading them to consider participating in a study using a randomized trial design. The resistance we encountered echoed experiences that have been discussed in the literature on logistical challenges associated with the conduct of randomized trials. Some managers viewed randomization as inevitably "unethical," or ethical but "impossible" because they were unionized or because they were non-union and could not risk labor unrest. Some said their programs were not "formal" or "structured" enough, or were "too new to be subjected to this kind of experimentation," while others were "too well established," or "too successful" to be "tampered with." Many said that they had too few employees with drinking problems to support the proposed research and one expressed willingness to participate provided that we not tell the involved employees that they were being assigned randomly to alternative treatments, an approach that we knew would (and should) not clear a human subjects committee. Other variations on the "prerandomization" (Zelen 1979) theme also surfaced in the form of suggestions that we ascertain every subject's random assignment before inviting him/her to participate in the study, a tactic that could have compromised the randomized trial design with a serious selection bias. Some companies were hospitalizing so few of their problem-drinking employees that participation in the study would have increased their inpatient costs substantially (and unacceptably), while others were hospitalizing so many that withholding their most intensive treatment from some employees seemed unconscionable to them.

### The Host Site

Ultimately, in April 1981, the president of District Council II of the IUE arranged a meeting for us with representatives of

both union and management administrators of a joint EAP that had been in place for more than 15 years at a sizable (10,000-employee) GE manufacturing plant north of Boston, Massachusetts. Numerous discussions and meetings, during May and June of 1981, finally brought us to the point where all parties — the company, the union, the research team, and the initial funder — were satisfied that we had worked out the essential contours of a study that could be carried out in that setting in such a way that it would be in everyone's interest to proceed.

From the outset, we looked to our hosts at the research site to identify both a general question whose resolution would be of value to them and the specific alternatives around which to structure the study. Securing their cooperation, we felt, required that we craft the study to meet their perceived needs. We were fortunate that one of the questions that was very much on their minds — what is the appropriate role of inpatient treatment? — dovetailed with our interest in the fundamental and unresolved question of how much alcoholism treatment is enough. Even better, for our purposes, the treatment alternatives they were offering were distinct and quite far apart on a continuum of intensity and expense. From their perspective, the most immediate issue needing research was the question of whether or not, as an initial treatment strategy, they should hospitalize a new client in their program, and how to make that decision on case-by-case basis. Those they did not hospitalize they usually sent directly to Alcoholics Anonymous. All clients of the EAP received a stern admonition to stay off alcohol and all were required, during a probationary year, to report back to the EAP on a regular basis or else risk the loss of their jobs.

At this time, the host company ranked among the top 10 American industrial firms in dollar sales and among the top five in number of employees and number of stockholders. Founded in 1878, the firm was a leading manufacturer of electrical products, small and large appliances for the home, equipment used by utility companies in the generation and transmission of electricity, steam turbine and jet engines for ships and aircraft, X-ray machines and CAT-scanners, missile launch systems, and a variety of other consumer and industrial products. "Widely regarded in business circles as one of the best managed companies in America," (Moskowitz, Katz, Levering 1980) the huge and diverse firm had a reputation for tough-minded employee relations, and was famous for having pioneered a decentralized form of management in which major manufacturing installations and even subdivisions of a single plant functioned as virtually autonomous businesses. This meant that the decision to go forward with the study was entirely in the hands of local management at the original site. Conversely, access to additional sites in the same company had to be negotiated individually.

The Massachusetts installation was the fourth largest of the company's facilities and one of the oldest. It was a sprawling smokestack plant engaged in the manufacture of jet engines, engine parts, and other units for aircraft and marine propulsion. Of the 10,941 employees in the plant in 1981, 4,005 (37 percent) were "exempt" workers or managers, 9,249 (84 percent) were male, and 10,706 (98 percent) were white. Two satellite plants, also in eastern Massachusetts, reported up through the host site and participated in the study; one had 1,600 employees, the other 1,450.

Management and union at this location began to address alcohol problems earlier than did their peers elsewhere in the company and in many other firms. In 1962, the union joined with management to sponsor an alcohol rehabilitation program. In time that program became a bone of political contention between management and labor and was disbanded until 1966, when the union's district council elected as president the officer who brokered the meeting that led to the agreement to go forward with this trial. He appointed Cecil A. Kelly, a 37-year veteran of the plant, to represent the union, work with management to reinstate the alcohol program, and administer it from the union's side. Shortly thereafter, Mr. Kelly was asked to take over the management of the program for the company, which he was doing when we first met him and through most of the life of the study, until his retirement in 1987. In July, 1981 management and labor signified formally their intention to participate in the study. In February, 1982 the first subject was enrolled.



## THE STUDY DESIGN

The study that emerged from those negotiations involved randomly assigning a series of newly-identified alcohol-abusing EAP clients to three alternative alcoholism rehabilitation regimens as initial strategies. The design is represented schematically in Figure 1. The first alternative commenced with a roughly three-week period of mandatory inpatient rehabilitation in facilities that the EAP had been using for years. The second involved a mandate only that the employee attend Alcoholics Anonymous (AA) meetings, which was the principal alternative to hospitalization the EAP had available at the time. The third, developed explicitly for purposes of the study, offered subjects a choice among intervention modalities, with non-directive advice from the EAP administrators.

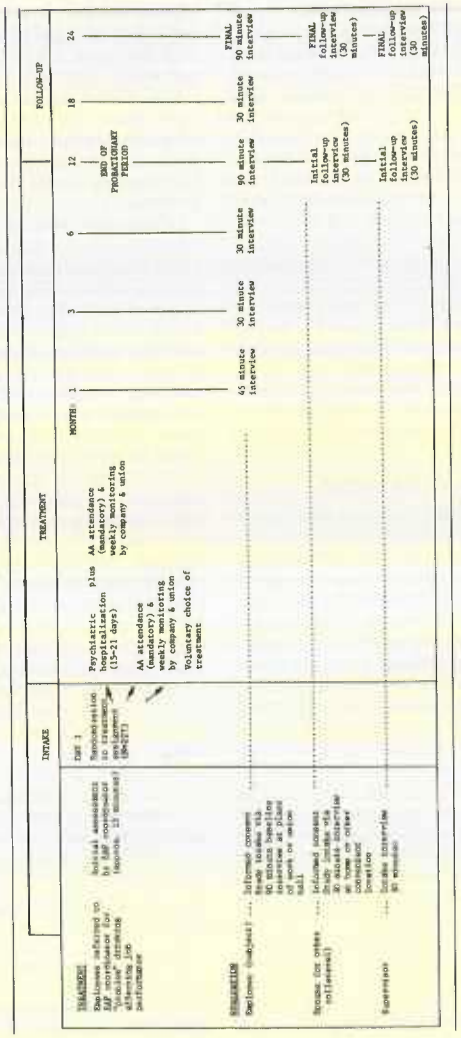
Employees in all three groups were monitored by the company for a probationary year, a procedure the EAP already had in place. All EAP clients were required to report to the administrator's office before work every Monday morning and to leave a slip of paper indicating that they had been attending AA meetings, and which ones they had attended. The informal network of recovering alcoholics with whom the company and union administrators had relationships unofficially served a sentinel function for the EAP, keeping clients "honest" and under scrutiny.

During that year of probation, and through a second follow-up year, additional inpatient treatment was available to study subjects who, in their own view or that of the EAP staff, were in sufficient trouble with their drinking, after the randomly assigned referral, to place them or their jobs in jeopardy. This was necessary to ensure that participation in the research would entail no extra risk. Thus, the study compared three distinct *initial* referral strategies, each with a hospital back up if needed. All three strategies included AA as an integral component or option, so the study was, in effect, examining alternative *pathways* into AA. Yet the three strategies were fundamentally different — in their underlying philosophies, in their costs, and in the manner and degree in which they intruded into patients' lives. We compared the three protocols on a number of outcome measures collected over a two-year period after the intake interview. For conceptual and analytic simplicity, the various outcome measures were collapsed into two major domains of treatment success: job performance indicators, and indicators related to continued drinking and drug use.

### Recruitment, Eligibility Assessment, and Randomization

Subjects were recruited for the study between 1982 and 1987 as they entered the EAP with an alcohol problem that was interfering with their work. Many (46

**Figure 1**
**Schematic Representation of Study Design**






percent) said they referred themselves to the EAP, while others reported having been sent by job supervisors (25 percent), coworkers or family members (14 percent), or by shop stewards or other representatives of the union (15 percent). Irrespective of referral source, it was the EAP's policy to apply uniform procedures to all alcohol-abusing clients, once identified.

Formal exclusion criteria for the study were developed at a weekend retreat to which we brought company and union managers of the firm's EAPs at its large facilities in Massachusetts, New York, and Kentucky. Subsequent meetings were held to review these criteria with other experts in the field (including internists and psychiatrists, other alcohol and EAP researchers, and other methodologists) as well as with medical, human resource, legal and administrative staff at the host plant and at corporate headquarters. To be eligible, an EAP client was required: (1) to be a new case (without prior EAP contact), (2) to present with alcohol abuse as the primary manifestation of problems, and (3) to fall within a gray zone where the company and/or union EAP administrators were uncertain whether hospitalization was the appropriate treatment.

Employees were excluded from the study and referred directly to a hospital if they: (1) required medically supervised detoxification, owing to: (a) a blood alcohol concentration (BAC) of 0.2 or higher on an alcohol breath test administered by a study interviewer; (b) a definite, recent history of delirium tremens or grand mal seizures during alcohol withdrawal, or (c) clear signs and symptoms premonitory to delirium tremens (acute tremulousness, excessive sweating, overwhelming anxiety, hallucinations, extreme disorientation); (2) required medical attention for serious illness, such as extreme malnutrition, edema with ulcerous wounds, yellow discoloration of eyes and skin suggesting serious jaundice; (3) had to be removed from their environment because of imminent danger to themselves or others; (4) needed psychiatric care, as evidenced by signs, during the interview, of delusions or other gross impairments of mood, language, memory or perception of reality; (5) would likely be lost to follow-up because they were: (a) embroiled in legal proceedings that could result in protracted imprisonment or (b) imminently going to resign or be fired from the firm.

To ensure adherence to the protocol, the research and program staffs met monthly to review and document the eligibility determination for each individual case enrolled into the EAP. Between February 1, 1982 and June 30, 1987 every newly identified alcohol-abusing EAP client was screened for eligibility. A total of 371 potentially eligible subjects came to the attention of the EAP before being hospitalized, and another 76 (17 percent) who would have been eligible were lost to the study because they had already been admitted to the hospital when the EAP first encountered them, too late for random assignment to treatment. This was an unanticipated problem. The power calculations for the study had been based on estimates, from EAP logs, of all new cases. That some were entering the EAP from a "back door" through the hospital did not become evident until the study was underway. This reduced the number of cases available for randomization into the trial and slowed the accrual process.

We were able to obtain complete intake interviews with about half (40) of the 76 employees who entered the EAP through the hospital and to compare those with study subjects. The two groups were similar with respect to age, marital status, family income and education, and on a long list of drinking and job-related variables. Not surprisingly, however, there were significant differences in some drinking measures, in beliefs and attitudes about the potential demands and

benefits of treatment, and in the perceived severity of drinking problems. Workers who sought treatment prior to EAP contact were drinking more (9.3 drinks a day, compared to 6.3), were more likely to define their drinking problem as "very serious" (85 percent v. 73 percent), themselves as "alcoholic" (85 percent v. 70 percent) and their drinking as "out of control" (50 percent v. 11 percent). Significantly fewer of them (26 percent v. 52 percent) concurred with the statement that "a drinking problem can be overcome with no treatment." Otherwise, the two groups were substantially similar.

Of the 371 new cases who came through the EAP, 128 (35 percent) were ruled ineligible; the remaining 243 (65 percent) were escorted by the EAP staff to a study interviewer, who outlined the purposes, procedures and sponsorship of the research project, explained mechanics of the randomization and study protocol, stressed that enrollment was entirely voluntary, and discussed alternatives to participation, possible risks and benefits, assurances of confidentiality, plans to interview a spouse or close collateral and a job supervisor, and to examine company and hospital records. The alcohol breath test was administered at this time, to ascertain eligibility (BAC <0.2), to assess competence to give informed consent (O'Farrell, Maisto 1987) (BAC <0.1) and to enhance the reliability of self-reported data (BAC <0.1). Altogether, 227 subjects (94 percent of all eligible) consented to participate and were randomized into the trial. Each was given an intake packet that included a copy of the signed consent form, listings of the categories of questions they, their spouses and supervisors would be asked in follow-up interviews, a summary of the goals of the study, and detailed information on how to contact the principal and co-principal investigators, the project director, and the study interviewers, in the event of problems or questions. Subjects were partially compensated for their time (at a rate of $10 per hour) in a lump- sum payment at the close of their participation in the study.

Participants were allocated into one of the three initial rehabilitation protocols, using simple randomization and a system of sequentially-numbered, opaque envelopes, brought individually from the university-based research office by a project interviewer. The sealed envelope was left with the EAP administrator while the interviewer and subject went to a private room in the plant or union hall for the informed consent and 90-minute intake interview, conducted on company time. The subject then returned to the EAP office and met privately with the EAP administrator for the assignment and referral.

The intake procedures, intended to maximize both the protection of subjects and the integrity of the study design, sought to ensure: (1) that the interviewer and subject were blind to the (as yet unrevealed) group assignment during the intake interview; (2) that study (not EAP) staff controlled the informed consent and random allocation process; (3) that EAP (not study) staff told clients of their referral assignments and provided the necessary information and counseling; (4) that a sharp separation was maintained between research and program staffs, so subjects could see for themselves that nothing they revealed in any of the interviews would have any bearing on their treatment or job prospects.

In summary, five specific mechanisms were put in place to protect participating employees. First and foremost, confidentiality of individual participants was scrupulously maintained throughout the course of the study, and, as an extra precaution, a federal writ of confidentiality was obtained to protect the research files from subpoena. Second, participation was always voluntary and fully informed; employees were reminded at the beginning of each interview that they were free to refuse to answer any questions, to end the interview at any point, or to withdraw from the study at any time. Third, specific provisions were established to ensure that both job and treatment status were unaffected by participation in the study. The retreatment option was established to secure employees another chance to save their jobs, should they relapse after the randomly-assigned treatment. When the benefit plan was renegotiated, several years into the study, the company agreed to waive a new restriction on inpatient alcoholism treatment so that employees in the study who had been randomized to the hospital would be covered for a rehospitalization if needed. Fourth, the exclusion criteria were designed to satisfy the cardinal ethical prerequisite to any randomized trial, namely that random assignment be applied only in situations where it is unclear which treatment alternative will be most efficacious. Fifth, stopping rules and a periodic review were instituted to provide for the cessation or modification of the trial as soon as a clear pattern emerged indicating that one of the treatments was significantly superior or inferior to one or both of the other two.



### Alternative Rehabilitation Strategies

The study compared three alternative packages of initial rehabilitation — "compulsory hospital" "compulsory AA only" and "choice" — each with inpatient back-up if needed. All three protocols consisted of a one-year period of job probation; the study continued to follow subjects for a second observational year. Information on treatment compliance is summarized in the findings section, below.

Of the 227 subjects, 73 were assigned to the "hospital" group. They were required to receive inpatient rehabilitation of approximately three weeks' duration. The average length of stay of subjects at the 10 participating hospitals was 23 days; range: 10-37 days, standard deviation: 6 days. Two inpatient facilities accounted for 86 percent of hospital assignments: 61 percent of hospital-group subjects were treated at a private psychiatric hospital, in northern Massachusetts, that specialized in mental health and substance abuse treatment, and 25 percent were treated at a freestanding adult alcohol and drug abuse treatment facility in southern New Hampshire. One other facility (also a freestanding chemical dependency treatment unit) accounted for two admissions, and the remaining seven each for one. Of those seven, two were acute general hospitals and six were specialty chemical dependency treatment facilities.

Participating hospitals described their programs in similar terms. All were JCAH accredited, had detoxification capabilities and prescribed medications as warranted, diagnosed and treated medical and psychiatric comorbidities, offered individual and group psychotherapy at least once a week, provided education about alcohol and drugs, arranged for AA meetings on site, encouraged family involvement in treatment, and coordinated with EAPs during the inpatient stay, and in planning and carrying out a program of aftercare. All cited abstinence as their treatment goal. In our special one-month follow-up interview exploring subjects' experiences in treatment, we found significant differences among the facilities on two of the six dimensions of the Moos treatment environment scale ("involvement" and "support") (Moos 1974). The mandatory hospitalization was followed by a year of job probation, required attendance at AA meetings on a regular basis (at least three times a week), sobriety at work, and weekly accountability to the EAP.

The 83 subjects assigned initially to the "compulsory AA-only" group were referred, and (if they wished) escorted, directly to a local meeting of AA, which