Linking alcohol- and drug-dependent adults to primary medical care: a randomized controlled trial of a multi-disciplinary health intervention in a detoxification unit

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ABSTRACT

Aim Pragmatic approaches to integration of medical care and substance abuse treatment are desired. We assessed the effectiveness of a novel multi-disciplinary clinic for linking patients in a residential detoxification program to primary medical care.

Participants We enrolled patients undergoing in-patient detoxification from alcohol, heroin or cocaine who had no primary care physician into a randomized controlled trial. The intervention consisted of a clinical evaluation at the detoxification unit in the health evaluation and linkage to primary care (HELP) clinic by a nurse, social worker and physician and facilitated referral to an off-site primary care clinic. The primary outcome of interest was attendance at a primary care appointment within 12 months. Secondary outcomes assessed over 24 months were addiction severity, health-related quality of life, utilization of medical and addiction services and HIV risk behaviors.

Findings Of the 470 subjects enrolled, 235 were randomized to the HELP clinic intervention. Linkage to primary medical care occurred in 69% of the intervention group compared to 53% in the control group ($P = 0.0003$). The clinic was similarly effective for subjects with alcohol and illicit drug problems. Randomization to the HELP clinic resulted in no significant differences in secondary outcomes.

Conclusions The HELP clinic, a multi-disciplinary clinic located in a detoxification unit, effectively linked alcohol- and drug-dependent individuals to primary medical care. This intervention utilized a 'reachable moment', the period of addiction care, as a window of opportunity for linking substance abusers to medical care.

KEYWORDS Access, alcohol dependence, alcoholism, drug abuse, injection drug user, linkage, primary care, randomized controlled trial.

INTRODUCTION

Linkage of alcohol and drug abusers to primary medical care is advocated currently as a means to reduce the human toll and enormous expense associated with addiction (Levin *et al.* 1993; Morris 1995; Samet, Friedmann & Saitz 2001). The consequences of substance abuse include increased morbidity and mortality (Michaud, Murray & Bloom 2001), medical expenditures for emergency department care and hospitalizations

(McGeary & French 2001) and transmission of HIV infection (Division of HIV/AIDS Prevention 2000). Despite an apparent need for medical services, patients with identified alcohol and drug abuse problems do not receive adequate medical care (D'Aunno & Vaughn 1995; D'Aunno 1997; Saitz *et al*. 1997). Ideally, primary care for this population provides comprehensive, continuous and preventive health care over time (Donaldson *et al*. 1996). The primary care model presents an opportunity to prevent or minimize substance abuse-related complications, to provide early treatment for medical problems and to address substance abuse issues. Systems for providing medical care for patients receiving substance abuse treatment include both linkage of patients to existing medical services (distributive models) and provision of medical services at the substance abuse treatment site (integrative models) (Selwyn *et al*. 1989; O'Connor *et al*. 1992; Schlenger *et al*. 1992; Umbricht-Schneiter *et al*. 1994; Samet, Saitz & Larson 1996; Willenbring & Olson 1999).

Achieving linkage of substance abusers to primary care has been elusive, unless an integrative approach was taken (e.g. medical care provided at a methadone treatment program). This integrative strategy has inherent practical limitations: expensive to implement, and medical care disruption if addiction treatment terminated. A distributive model approach whereby patients in substance abuse treatment are linked to existing off-site primary medical care sites is theoretically more replicable; however, not as yet demonstrated.

We attempted to test empirically a novel 'mixed integrative–distributive' approach to link patients undergoing residential detoxification for alcohol and drug problems to primary medical care by establishing a multidisciplinary medical clinic in a substance abuse treatment unit. This clinic was called the health evaluation and linkage to primary care (HELP) clinic. The purpose of the clinic was to perform a single comprehensive initial evaluation at the substance abuse treatment facility and then arrange subsequent follow-up with a primary care physician from whom the patient could receive ongoing health care. To assess the effectiveness of this model for linkage of substance abusers to primary medical care, we utilized a randomized controlled trial design. Our primary hypothesis was that alcohol and drug dependent people assigned to attend a multi-disciplinary health evaluation while undergoing residential detoxification would be more likely to link with primary medical care. Secondary hypotheses were that such an intervention would decrease addiction severity, improve health-related quality of life, optimize utilization of medical and addiction resources and minimize HIV risk behaviors. Planned subgroup analyses included these outcomes stratified by substances of choice.

METHODS

Subject recruitment

All subjects were recruited from a single free-standing residential detoxification unit in Boston, MA between 1 June 1997 and 1 April 1999. They were screened for eligibility and enrolled on their second or later day in the detoxification unit. Inclusion criteria were the following: (1) alcohol, heroin or cocaine as the patient's first or second drug of choice; (2) age greater than 17 years; and (3) residence in proximity to the referral primary care clinic or homelessness.

The exclusion criteria were as follows: (1) an established primary care relationship that the patient intended to continue; (2) mental deficiencies making the subject unable to provide pertinent history or informed consent [score of less than 21 of 30 on the Mini-Mental State Examination (Folstein, Folstein & McHugh 1975)]; (3) specific plans to leave the Boston area in the next 12 months; (4) inability to provide three contact names for follow-up tracking; (5) pregnancy; and (6) not fluent in English or Spanish.

All subjects who met eligibility criteria and wished to participate in this study provided written informed consent prior to enrollment. The Institutional Review Board of Boston University Medical Center approved this study. Additional privacy protection was secured by the issuance of a Certificate of Confidentiality by the Department of Health and Human Services, to protect subjects from release of their research data even under a court order or subpoena.

Subject assessment at baseline

After enrollment, all subjects received an interviewer-administered baseline assessment prior to randomization into the control or intervention group. The baseline instrument included the following: demographics, Short-Form Health Survey (SF-36) (Ware 1993), Addiction Severity Index (medical, alcohol, drug and psychological subscales) (McLellan *et al*. 1992), medical and addiction care utilization (emergency department use, hospitalization, residential detoxification in the past 6 months), depressive symptoms [Center for Epidemiologic Studies Depression scale (CES-D)] (Radloff 1977), alcohol and drug quantity, Inventory of Drug Use Consequences (INDUC-2 L) (Tonigan & Miller 2002) and HIV risk behaviors [Risk Assessment Battery (RAB)] (Navaline, Snider & Petro 1994).

Randomization

Subjects were assigned randomly to control or intervention group using a blocked randomization pro-

cedure stratified by alcohol or drug abuse as drug of choice.

HELP clinic description

Using a design similar to a clinic engaging HIV-infected individuals into primary care (Samet *et al*. 1995), the HELP clinic met two afternoons each week in a dedicated sparsely equipped space at a residential detoxification unit. Its purposes were to provide multi-disciplinary assessment, individualized education that underscored the importance of primary medical care and referral for continuing care with a primary care provider.

The HELP clinical team was comprised of a physician trained in internal medicine, a nurse and a social worker. First, the nurse met the patient and obtained a structured history and vital signs. The physician reviewed and expanded upon the medical history as recorded by the nurse, and performed a physical examination. Identified medical issues were discussed with the patient, with particular emphasis on those related to addiction and/or requiring ongoing medical care. The social worker assessed the social support system and concrete needs of the patient. She also served in a case management role facilitating linkage of the patient to a specific primary care appointment with a named physician, including contacting the subject by phone after discharge from the detoxification unit. The appointment was made both with attention to the patient's preference regarding gender of the physician, particular expertise (e.g. homeless clinic, HIV clinic), time of day and language fluency. In all three separate patient HELP encounters, each lasting approximately 30 minutes, engagement of the patient in the medical care process was a key dimension of the clinical interaction. The physician prepared a letter detailing the subject's medical issues that was delivered to the new primary care physician. All members in the HELP multidisciplinary team were trained in a full day session about the principles of motivational interviewing (Miller & Rollnick 1991). The training was conducted by one of the study investigators with expertise in these methods (JHS, RS).

A small number of subjects randomized to the intervention left the detoxification unit prior to attending the HELP clinic. For these subjects, a 'partial' intervention was carried out: contact by the social worker or nurse to briefly assess needs, discuss the value of establishing primary care and provide a physician appointment. Control subjects did not attend the HELP clinic and were not referred to primary care by the study team. Detoxification unit staff made referrals to aftercare as appropriate but primary care referral was not part of standard or routine practice.

Subject assessment at follow-up

Follow-up was planned over 2 years at 6-month intervals and included reassessment of the domains covered at baseline. Alcohol breath tests were performed at all follow-ups to encourage truth telling (Welte *et al*. 1998). Interviews usually occurred at the General Clinical Research Center at Boston University School of Medicine.

For both intervention and control subjects, follow-up interviews assessed establishment of primary care using a series of questions. These included the following: 'Is there one particular doctor that you consider to be your regular personal doctor?'; 'Have you seen any doctors in the last 6 months (or since your last interview)?' If they did not report having a regular personal doctor but had seen a physician, they were asked: 'Would you call or go to one of these/this doctor(s) if you had a medical problem that was not an emergency?'; 'Do you think one of these doctors could be your regular doctor?' Subjects reporting either having or possibly having a regular personal doctor or that they would contact the doctor for non-emergent problems were asked 'What type of doctor is your regular personal/this doctor?' Response options included all generalist and specialist physician types.

Measures to achieve follow-up

Because we were working with a transient and hard-to-reach population, we employed exhaustive techniques to track subjects over the follow-up period. All subjects were required to give contact information about three close individuals in order to enroll in the study (e.g. case-workers, family members or friends). We attempted to contact all subjects at 2 months post-enrollment to verify contact information and remind them of their participation in the study and again at 5 months to confirm their 6-month appointment and 11 months for the 12-month appointment. Subjects were sent reminder letters and contacted before interviews to reconfirm. If needed, we offered van service to transport subjects. We allowed subjects to bring their children and had someone to watch the children while the interview was conducted. For subjects with whom contact was unsuccessful (i.e. did not respond to our calls and letters), we sent a reminder letter via Federal Express. Compensation in the form of supermarket certificates was given to subjects for their time, $20 for the initial interview and $30 for subsequent ones.

Primary outcome

The primary outcome was time to self-reported linkage to primary medical care. Linkage was defined as at least one visit to a primary care medical doctor (MD), nurse practitioner (NP), or physician assistant (PA) during the

12 months following enrollment. For the visit to be defined as 'primary care', two criteria needed to be met: (1) the subject reported having a regular personal doctor, would call the doctor for a non-emergent issue, or saw a doctor that could be their regular personal doctor; and (2) the doctor was in a specialty that could be considered primary care, including obstetrics and gynecology, family medicine, pediatrics, adolescent medicine, internal medicine, AIDS doctor, asthma doctor, pulmonary doctor, cardiologist, gastroenterologist or unknown specialty. The following specialties were not considered to be primary care: psychiatrist, dentist, dermatologist, orthopedic surgeon or bone doctor, emergency room doctor, surgeon, ophthalmologist or podiatrist.

Assessment of primary care linkage by administrative sources

In order to corroborate the primary outcome we searched the computerized administrative appointment and billing records of Boston Medical Center Ambulatory Care Clinics and those of the Boston Healthcare for the Homeless Program. These are the two programs to which subjects were referred for primary care and are also probable sources of primary care for this population. However, as only a minority of primary care providers in the City of Boston is in these programs, analysis of these data alone provided a partial but incomplete capture of possible appointments. Each appointment with an MD, NP or PA during the 12-month period of follow-up appearing in administrative record systems was recorded in a study database noting the date of the encounter. If a subject had a primary care visit during the 12-month follow-up window, then that subject was considered 'linked' to primary care in the administrative database. If the subject was found by name or social security number in one or the other of the administrative systems, but had no primary care appointments during the 12-month follow-up window, then the subject was 'not linked' to primary care in the administrative database. A subject not found for any services (e.g. emergency, specialty or primary care) in either administrative system was defined as 'missing'.

Secondary outcomes

Over 24 months we examined four secondary outcomes expected to improve with primary care linkage: addiction severity; health-related quality of life; utilization of medical and substance abuse services; and HIV risk behaviors. The specific outcome measures were alcohol and drug subscales of the Addiction Severity Index (ASI) (McLellan *et al*. 1992), the physical and mental component summaries of the SF-36 Health Survey (Ware 1993; Stein *et al*. 1998), HIV sex and drug use risk behaviors scale scores from the Risk Assessment Battery (RAB) (Navaline *et al*. 1994) and self-report of any emergency department visits, hospitalizations and detoxification episodes.

Statistical analyses

We conducted all analyses based on an intention-to-treat basis. Analyses of the primary and secondary outcomes were also performed separately for subjects who identified alcohol as their first or second drug of choice and subjects who identified heroin or cocaine as first or second drugs of choice. Reported *P*-values are two-tailed, and a *P*-value of less than 0.05 was considered statistically significant. Analyses were carried out using SAS/STAT software.

To test for differences between the baseline characteristics between treatment and control groups, we carried out two-sample *t*-tests for continuous variables and χ^2 tests for categorical variables. We also used χ^2 tests to compare whether the proportion of subjects with follow-up differed between treatment and control groups.

Time to first linkage to primary care was the primary end-point of the study, where linkage could occur at 6 or 12 months. Survival analysis, specifically the log rank test, was used to compare randomization group differences in time to linkage and the Cox proportional hazards model was used to estimate the hazard ratio. Subjects observed at 6 months but not at 12 months who had not linked were censored after 6 months. Estimates of linkage were calculated using the Kaplan–Meier method.

In analyses of secondary outcomes, longitudinal regression models for correlated data were used to test for intervention effects controlling for baseline measurements, and time points (6, 12, 18, and 24-months). The model provides a test of group differences, averaged over the follow-up period, and accounts for repeated observations on the same subject. For analyses involving continuous measures (e.g. HIV risk behaviors and quality of life) models were fit using the generalized linear model for correlated data (Laird & Ware 1982; Cnaan, Laird & Slasor 1997) using PROC MIXED. An unstructured working covariance matrix was used to account for the correlation between repeated measures on the same subject. The Wilcoxon rank sum test was used to compare annual rates of utilization (i.e. emergency department visits, hospitalizations and detoxifications) between randomization groups.

RESULTS

Enrollment and follow-up

Of 2062 clients screened at the detoxification unit, 1420 people did not meet study eligibility criteria. Major rea-

sons for ineligibility included: already had established primary care physician ($n = 980$, 69%); residence not in proximity to the referral primary care clinic area ($n = 204$, 14%); did not have three contacts ($n = 91$, 6%); did not pass the Mini-Mental State Examination ($n = 58$, 4%); and pregnancy ($n = 51$ 4%). Of the 642 eligible subjects, 470 (73%) provided informed consent and agreed to participate in this study. Of the 235 subjects in the intervention group, 178 (76%) received the full intervention, 42 (18%) received a partial intervention and 15 (6%) left the detoxification unit prior to receiving any intervention.

Baseline characteristics of the study subjects did not differ by randomization group. Subjects were generally young (mean age 35.8 years, ranging from 18 to 60), 76% male and ethnically diverse (46% black, 37% white, 11% Hispanic and 6% other). The majority [56% (263/470)] identified more than one drug of choice, 63% alcohol, 31% heroin and 51% cocaine. Of all subjects, 40% reported having health insurance, 47% reported at least one chronic medical condition and 47% were homeless, defined as one night in a shelter or on the streets in the past 6 months.

Two subjects died prior to the first available interview; 468 subjects were eligible for follow-up, which was achieved in 54% at 6 months, 46% at 12 months, 54% at 18 months and 59% at 24 months. Follow-up interviews at either 6 or 12 months occurred for 68% (317/468) of the sample. During this period there was no differential follow-up between intervention [69% (163/235)] and control [66% (154/235)] subjects ($P = 0.38$). Follow-up interviews occurred at least once in 85% of subjects (400/468).

Linkage to primary care

Based on subject self-report, linkage to primary medical care within 12 months occurred in 69% of the intervention group compared to 53% of the control group ($P = 0.0003$); the hazard ratio for linkage was 1.8 (95% CI = 1.3–2.4). Among control and intervention subjects who linked, there was no significant difference between the mean number of visits in the 12-month follow-up period, 4.9 versus 4.7, respectively ($P = 0.86$).

Administrative data from at least one of two primary care sites were obtained on 95% of subjects (447/470). First, linkage to primary care was examined by using the administrative data in those for whom follow-up was not obtained by self-report. This includes 140 subjects who were not assessed at the 6- and 12-month follow-up. Among those subjects for whom administrative data only were available, 46% (33/72) of the intervention group linked to primary care and 10% (7/68) of the control subjects linked. Secondly, administrative data were used to corroborate self-report data. Among subjects with self-report data who were determined by administrative data to have linked, 81% reported linkage (kappa = 0.41).

Table 1 Kaplan–Meier estimates of the proportion of subjects linking to primary care at 12-months after randomization to the HELP clinic or control group—overall results and stratified by drug of choice.

*Subjects**	*Intervention linked*	*Control linked*	P-*value***
All ($n = 317$)	69%	53%	0.0003
Alcohol† ($n = 199$)	72%	52%	0.0006
Cocaine or Heroin† ($n = 247$)	67%	54%	0.006

*Study subjects with follow-up at 6 or 12 months. **Log rank test. †Subjects reporting this substance as their first or second drug of choice (alcohol and drug groups are not mutually exclusive).

Pre-specified analyses examining subjects with alcohol as first or second drug of choice and those with heroin or cocaine as drugs of choice showed similar impact of the intervention on linkage to primary care (Table 1). For the alcohol group receiving the intervention, 72% of subjects linked to primary care versus 52% of the controls ($P = 0.0006$). Similarly, 67% of the cocaine or heroin group receiving the intervention linked versus 54% of controls ($P = 0.006$).

The secondary outcomes of HIV sex risk behaviors and drug risk behaviors, alcohol and drug abuse severity, health-related quality of life and utilization of medical and addiction services were not significantly different between intervention and control subjects over the 24-month follow-up period, based on intention-to-treat analyses (all P-values > 0.20, Table 2).

DISCUSSION

Collaborative efforts between substance abuse treatment providers and primary medical care clinicians have theoretical and empirical benefits. Theoretical benefits of primary care for individuals with alcohol and drug problems encompass improved medical, addiction and HIV risk behavior outcomes, as well as more efficient utilization of medical and substance abuse services (Samet *et al.* 2001). In a recent examination of New York Medicaid records, drug users who had seen a primary care physician in the past year had less addiction severity (Laine *et al.* 2001). In a staff model California Health Maintenance Organization (HMO), alcohol and drug users with substance abuse-related medical conditions randomized to an integrated primary care and substance abuse treatment model showed improved addiction outcomes at 6-month follow-up (Weisner *et al.* 2001). These findings suggest that efforts to establish primary care for sub-

Table 2 HELP study secondary outcomes at follow-up over 24 months*.

Characteristic *Mean (SD)*	*6 months* n = *254*	*12 months* n = *217*	*18 months* n = *254*	*24 months* n = *277*
SF-36				
PCS**				
Intervention	50.3 (10.8)	49.8 (11.1)	50.6 (11.2)	50.3 (10.3)
Control	50.1 (9.7)	50.3 (9.5)	47.5 (10.9)	48.9 (9.8)
MCS***				
Intervention	41.4 (14.2)	41.1 (13.6)	41.4 (13.4)	44.4 (13.2)
Control	40.4 (13.2)	39.3 (13.9)	42.3 (13.2)	41.9 (14.3)
RAB†				
Sex				
Intervention	3.6 (2.5)	3.5 (2.5)	3.6 (2.3)	3.5 (2.6)
Control	3.5 (2.9)	3.5 (2.8)	3.8 (2.8)	3.3 (2.6)
Drug				
Intervention	1.1 (3.4)	1.8 (4.4)	1.3 (3.9)	1.2 (3.9)
Control	1.1 (3.4)	1.1 (3.6)	1.2 (3.5)	1.0 (3.0)
ASI‡				
Alcohol				
Intervention	0.21 (0.24)	0.26 (0.26)	0.23 (0.26)	0.23 (0.26)
Control	0.22 (0.26)	0.29 (0.29)	0.26 (0.29)	0.21 (0.25)
Drug				
Intervention	0.14 (0.12)	0.14 (0.13)	0.12 (0.12)	0.12 (0.13)
Control	0.10 (0.11)	0.14 (0.13)	0.11 (0.12)	0.11 (0.13)

*All *P*-values > 0.20. ** Physical component summary measures. *** Mental component summary measures. †Risk Assessment Battery. ‡Addiction Severity Index.

stance abusers may yield improved clinical outcomes and merit efforts to implement such innovations in substance abuse services.

Although primary medical care for alcohol- and drug-dependent people does not guarantee improved outcomes, such linkage is a necessary first step to derive potential benefits. Once linked, the following question can be addressed: 'Do relationships with primary care providers improve the overall care of drug and alcohol dependent patients?' Because substance abusers are not commonly receiving primary medical care, linking the most severely affected individuals to these services is an important task and represents a perplexing pragmatic hurdle. The HELP study used randomized controlled trial methodology to test a specific intervention placed in a detoxification unit and found significantly improved linkage of alcohol and drug dependent subjects to off-site primary medical care. Detoxification patients randomized to the HELP clinic were more likely to establish primary care than control subjects. The fact that more than two-thirds of alcohol- and drug-dependent people were linked to primary care after a single intensive intervention in the substance abuse treatment setting is notable. As the intervention was multi-dimensional, attributing its efficacy to any one of its particular dimensions alone (e.g. appointment, physician examination, motivational enhancement) is not possible.

Possible patient motivations to link to primary care may have included the need to address previously unrecognized medical problems or to obtain access to dental care, psychiatric and other subspecialty treatments (DeAlba *et al.* 2003).

The relative magnitude of the impact of the HELP clinic intervention may be underestimated for at least two reasons. First, not all subjects randomized to the intervention group were exposed to the HELP clinic. Secondly, we found an unexpectedly high percentage of the control group (53%) linked to primary care. During the follow-up period 1997–2000, Massachusetts was actively enrolling eligible indigent people into a publicly funded health insurance program and assigning them primary care physicians. This temporal phenomenon may have resulted in some control subjects receiving more than the usual assistance to engage them in primary care.

Subject indifference to engage in primary care was the focus of the intervention by the multi-disciplinary staff trained in the principles of motivational interviewing. This client-centered and directive therapeutic approach designed to build commitment-to-change behavior was developed for providers working with patients with addictive disorders to help elicit behavior change by helping clients to explore and resolve ambivalence (Rollnick & Miller 1995). In this study, the motivational interviewing

approach was focused on motivating the addicted patient to pursue primary care.

Simultaneously, the medical care system was redesigned to facilitate engagement of the alcohol- and drug-dependent patients. Subjects were approached at a 'reachable moment' while undergoing detoxification. This design enabled medical providers to meet face to face with patients at a time of relatively improved mental clarity, albeit still complicated by withdrawal symptoms. The HELP clinic design also facilitated subject linkage to primary medical care by assessing preferred physician characteristics and providing an appointment date, time, site and physician name to subjects before leaving the substance abuse treatment setting. Additionally, the social worker fulfilled the role of case manager to facilitate linkage.

Another encouraging finding is that the effective linkage result of the HELP clinic occurred among both alcohol- and drug-dependent people alike. As medications to prevent relapse for these chronic diseases become available and increasingly utilized, linkage to a source of pharmacological treatment will take on more urgency (Fiellin, Reid & O'Connor 2000; O'Connor & Fiellin 2000).

The secondary outcomes concerning addiction severity, health-related quality of life, utilization of medical and addiction services and HIV risk behaviors did not reveal any significant differences between the control and intervention groups over 24 months. Improvements in these outcomes were hypothesized on the basis of receipt of ongoing primary care. As a substantial percentage of both groups received primary care, this study's ability to detect any benefits of addressing these areas is limited.

This study has a number of additional limitations. Important factors not addressed are the duration and quality of the patient–physician relationship, critical components of primary care's effectiveness. Our primary outcome was based on subject self-report at follow-up. Despite our extensive efforts at tracking this challenging population, we achieved follow-up in only 68% in the initial 12 months. However, for assessment of secondary outcomes over 2 years, we did interview 85% of subjects over 2 years. We also had administrative information on 95%, which corroborated our findings. Combined with the fact that we found no differential loss to follow-up, these results minimize the possibility that missing data biased our results. Finally, we recognize generalizability limitations, as our intervention was performed at a single site and relied on a primary care system that cares for patients who may be uninsured or underinsured.

In conclusion, a novel multi-disciplinary intervention, the HELP clinic, established in a detoxification unit for alcohol- and drug-dependent people improved linkage substantially to primary medical care. Engaging addicted patients at a 'reachable moment' and providing pragmatic help within the framework of a therapeutic alliance can achieve the first step in the process of deriving the benefits from the collaboration of substance abuse treatment and primary care medical systems.

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