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Screening and Brief Intervention for Unhealthy Drug Use in Primary Care Settings: Randomized Clinical Trials Are Needed

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Abstract

The efficacy of screening and brief intervention (SBI) for drug use in primary care patients is largely unknown. Because of this lack of evidence, US professional organizations do not recommend it. Yet, a strong theoretical case can be made for drug SBI. Drug use is common and associated with numerous health consequences, patients usually do not seek help for drug abuse and dependence, and SBI has proven efficacy for unhealthy alcohol use. On the other hand, the diversity of drugs of abuse and the high prevalence of abuse and dependence among those who use them raise concerns that drug SBI may have limited or no efficacy. Federal efforts to disseminate SBI for drug use are underway, and reimbursement codes to compensate clinicians for these activities have been developed. However, the discrepancies between science and policy developments underscore the need for evidence-based research regarding the efficacy of SBI for drug use. This article discusses the rationale for drug SBI and existing research on its potential to improve drug-use outcomes and makes the argument that randomized controlled trials to determine its efficacy are urgently needed to bridge the gap between research, policy, and clinical practice.

Keywords

addiction; drug use; primary care; drug screening; brief intervention

Unhealthy drug use is the spectrum from use that risks health consequences (also known as “at-risk use” or “risky use”) through dependence. It could be argued that all illicit drug use is unhealthy, since any drug use risks some health or legal consequences. Unhealthy drug use is

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prevalent in the United States and is associated with numerous health consequences. About 20.4 million Americans (8.3%) age 12 and older report past-month illicit drug use, and 2% have a current clinical disorder (i.e., abuse or dependence).[1,2] Drug use costs the United States $181 billion per year, primarily due to productivity loss, healthcare costs, and crime.[3]

Not all drug use is associated with substance dependence, the most severe disorder. However, for those who develop it, as with other chronic illnesses, substance dependence is associated with long-term physiologic changes, a relapsing course, variable adherence to care, and the need for ongoing care.[4,5] In addition to social and legal consequences, co-occurring medical and psychiatric disorders such as depression are common and can trigger relapse.[6–13] Patients with substance dependence are more likely than those without this diagnosis to have myriad conditions including injury, anxiety, psychosis, back pain, headache, arthritis, asthma, peptic disorders, chronic obstructive pulmonary disease, hepatitis C, hypertension, alcoholic gastritis, diseases of the pancreas, and cirrhosis.[1,14] In addition, the treatment of co-occurring medical and psychiatric conditions in patients with substance dependence is complicated by their risk of poor adherence to medication and other self-care.[15]

Drug use that does not meet criteria for abuse or dependence can also put people at risk for health consequences. Not only can it develop into dependence, but other medical complications (e.g., pneumothorax, myocardial infarction, accidents, and trauma) can result from such use. Unsafe sex practices and injection drug use are major routes of transmission for human immunodeficiency virus (HIV).[16,17] Mechanisms for increased risk include impaired judgment, increased sex drive, unsafe injection practices, and exchange of sex for drugs. Although risk-reduction interventions in addiction treatment settings and sexually transmitted disease clinics have been effective in decreasing these behaviors,[18-20] many people at risk, including those in primary care settings, do not receive such interventions.[21]

It is worth noting here, however, that a number of studies have failed to demonstrate health risks associated with drug use in some circumstances. One study found no association between marijuana use and declines in pulmonary function,[22] another found no association between cocaine use and a marker of coronary artery disease,[23] and a third found little evidence of psychological harm associated with drug use among young adults.[24] In circumstances where the risks associated with drug use are small or nonexistent, risk-reduction interventions have had no effect on outcomes.

Clearly, early detection and treatment of drug use that does risk harms could be important if efficacious, yet opportunities for early intervention are limited. To date, the primary focus of treatment has been on persons with more severe unhealthy use; i.e., those who meet criteria for substance abuse or dependence. Furthermore, most people with dependence do not seek treatment,[1,25] and detection and treatment efforts in medical care settings are limited. Thus, reliable methods to screen and treat people who use drugs in the primary care setting have the potential to dramatically improve care and patient outcomes.

Screening and Brief Intervention

Screening and brief intervention (SBI) is a comprehensive, integrated, public-health approach to the delivery of early intervention and treatment services for people with the full spectrum of unhealthy substance use. Screening identifies people with unhealthy use and, when followed by an assessment of the severity of substance use, can identify the treatment goal (i.e., cutting down or abstinence). Brief intervention generally involves 1 or 2 counseling sessions of 10–30 minutes each, although sessions may be as short as 5 minutes (generally referred to as brief advice) or as long as 1 hour for 4 sessions. Referral may be provided for those identified as needing more extensive specialized treatment.

Primary care centers, hospital emergency departments, and other community health settings see the broadest number and range of patients and thus provide ideal opportunities to screen for and address drug use before more severe consequences occur. Primary care settings provide the best context and opportunities for change over time, since patients have an expectation of preventive care and often have a longitudinal trusting relationship with a clinician.

Conceptual Framework

Although brief intervention includes clear directive advice, focus is primarily on increasing patient insight and awareness regarding substance use and encouraging behavioral change through motivational interviewing (MI) and self-management approaches.[26–28] Motivational interviewing is based on psychological theories of attitude and behavior change,[27–32] addressing the fact that patients frequently do not recognize their health behaviors as hazardous, nor do they acknowledge a desire to change.[33] Factors that enhance willingness and ability for behavior change have roots in self-management,[34] self-control,[35] and self-regulation[36] theories that describe how individuals plan, guide, and monitor behavior. A number of these factors have been used successfully in interventions for unhealthy alcohol use, such as altering norms and standards,[37] specifying change plans,[38] and increasing the probability of action by helping the patient take the first step, such as facilitating referral to treatment.[26]

Elements of effective brief interventions include **F**eedback on personal risk, emphasis on **R**esponsibility, clear **A**dvice, a **M**enu of change options, clinician **E**mpathy, and facilitation of patient **S**elf-efficacy (FRAMES).[39] Brief intervention models tested in primary care have been delivered by physicians, nurses, health educators, advocates, computer, or pamphlet. Each involved feedback, advice, goal-setting, and follow-up. Models may differ by how, by whom, and in what context they are delivered; therefore, different training, supervision, and quality monitoring are required.[40] Although patient and interventionist characteristics are important, feasibility and cost are particularly relevant to effective implementation in (usually) busy general health settings with numerous other priorities.

Screening and Brief Intervention for Unhealthy Alcohol Use

Screening and brief intervention for unhealthy alcohol use has been described in the scientific literature for nearly 50 years. In 1961, Chafetz[41] found that subjects with alcoholism in an emergency department were significantly more likely to follow up in an alcohol clinic after brief advice from a psychiatrist than after no advice (42% versus 1%). Later studies[42,43] found that brief intervention was as efficacious as more intensive treatment (although this finding was likely attributable to studying treatment-seeking patients rather than those identified by screening—a critical distinction). Thirty years after Chafetz published his findings, Bien et al.[39] reviewed 32 studies that showed brief intervention effectively reduced unhealthy alcohol use, and meta-analyses have confirmed its efficacy for non-dependent unhealthy alcohol use in primary care settings leading to a universal screening practice guideline in the United States.[44–50]

Such evidence-based guidelines, as is appropriate for universal preventive services, only appeared after randomized trials provided supportive evidence. These trials most often involved primary care clinicians delivering brief interventions, although in some cases, interventions were conducted by other healthcare professionals hired specifically to deliver them. Some of the most notable studies found that more than 1 contact improved efficacy.[51–54]

Despite this relatively robust evidence, several studies show that brief intervention was not effective in hospitalized patients,[55,56] in largely alcohol-dependent patients with prevalent use of other drugs,[57] in emergency departments,[58–61] and in some general practice settings.[62,63]

Factors such as sex, age, homelessness, and cognitive status influence effectiveness,[64] and SBI has not been effective in linking medical inpatients with treatment for alcohol dependence after discharge.[57] The best evidence for alcohol brief intervention is for reductions in consumption (in contradistinction to consequences) among patients in the primary care setting who have unhealthy use that is not severe.[44]

Screening and Brief Intervention for Unhealthy Drug Use

Although randomized controlled trials have proven the efficacy of SBI for non-dependent unhealthy alcohol use in primary care settings,[44,45] the evidence is much more limited regarding its effectiveness for other drug use. Although the prevalence of drug use in primary care is variable, it is much lower than that of unhealthy alcohol use. Estimates range from 3% of adults reporting past-year use in a Health Maintenance Organization setting,[65] to 5% reporting past 90-day use in practices in Wisconsin,[66] to 8% reporting past-year use in an urban practice (among whom only 22% received treatment).[25] Marijuana use is especially common: in 1 study, 8% of young women used marijuana monthly[67] in another, 9–17% of adults report past 6-month use.[68]

Because most US adults (83%) report having an outpatient visit in the past year,[69] primary care settings provide a natural setting to pursue health behavior change, including unhealthy drug use. Because of this, US policymakers have sought to make SBI, referral, and treatment[70] an important part of addressing the nation's drug problems, and reimbursement codes for insurers to compensate clinicians for these activities have been approved by the American Medical Association.[71] However, scarcity of evidence from controlled clinical trials in the primary care setting (or in any setting among those identified by screening in contradistinction to those seeking help) has prevented the inclusion of drug SBI in preventive service recommendations.[72] No major professional organizations recommend universal drug SBI in primary care settings, and its dissemination has been limited mainly to externally funded programs that specifically support the activity. To date, few randomized trials have addressed the question of whether SBI reduces illicit drug use and its consequences by identifying patients who need treatment before they seek it, nor have they adequately explored whether the benefits of SBI outweigh potential harms such as increased use, consequences of breached confidentiality, or stigma.

Screening Tools for Unhealthy Drug Use

One reason for the scarcity of SBI research in primary care may be the lack (perhaps until recently) of brief and valid screening instruments for substances other than alcohol or tobacco. Screening tests have been used for unhealthy drug use, however, most have been alcohol tests modified for drug use, have focused on dependence, or have not been validated extensively. For example, the Drug Abuse Screening Test (DAST) detects drug use problems and has been widely used in federal SBI programs, but it was not validated in primary care until recently.[73,74]

In recent years, screening instruments for drug use have been developed and validated in primary care settings. The Alcohol Smoking and Substance Involvement Screening Test (ASSIST)[75] tests for tobacco, alcohol, cannabis, cocaine, stimulants, sedatives, hallucinogens, opioids, and several other drugs. Although it does not directly identify risky amounts of alcohol consumption (a substantial clinical limitation), it has excellent concurrent validity compared with the Addiction Severity Index (ASI)-Lite version, the Severity of Dependence Scale (SDS), and the Alcohol Use Disorders Identification Test (AUDIT)[76] as well as construct validity, test-retest reliability, discrimination of severity, and sensitivity and specificity for a drug use disorder and, in some cases, any drug use (cocaine, amphetamine, benzodiazepines, opioids).[76,77] In a Brazilian study of the ASSIST that included 99 patients from mostly primary care

settings and 48 patients in drug treatment, sensitivity and specificity for a cocaine use disorder were 84% and 98%, respectively, and 87% and 95%, respectively, for a marijuana disorder.[78] An important drawback of the ASSIST, however, is that it may be too lengthy to be feasible in busy primary care settings.

In addition to the ASSIST, Smith et al.[74] evaluated a single-item screening tool—"How many times in the past year have you used an illegal drug or used a prescription medication for nonmedical reasons?"—among 286 primary care patients in a large urban hospital-based setting. Thirty-five percent screened positive for any drug use, and 13% (more than one-third of those who screened positive) met criteria for a current drug use disorder. A response of "1 or more" was 100% sensitive and 74% specific for a drug use disorder, 94% sensitive and 91% specific for use with consequences, and 93% sensitive and 94% specific for any drug use. This single item tool has promise, although it has been validated in only 1 primary care practice. Other brief tools with limited validation have generally focused on disorders and not the spectrum of unhealthy use[79,80] and often combine both alcohol and drugs. The availability of brief validated screening tools is an important foundation for increased research on SBI's effectiveness for drug use in primary care.

Efficacy of Drug SBI: Current Evidence

Substantial evidence in non-primary health care settings and under different circumstances (e.g., among people actively seeking help) informs the question of whether drug SBI has efficacy in primary care but does not establish definitive answers.[81–92] To our knowledge, no randomized controlled trials of drug SBI in adult primary care settings have been published in the peer-reviewed literature.

Madras et al.[93] conducted a before/after retrospective uncontrolled study to evaluate the Center for Substance Abuse Treatment's 6-state SBI referral and treatment initiative. Settings were diverse, including trauma centers, emergency departments, primary and specialty care sites, and hospitals. Of the 459,599 patients screened for the study, 23% tested positive for risky or problematic alcohol or drug use. Of these, 70% had screening results that suggested brief intervention would be a reasonable course of action, 14% were recommended for brief treatment, and 16% had screening results that suggested they should be referred to specialty substance dependence treatment. How many patients actually received intervention or treatment is unknown. Ten percent of patients who screened positive were randomly selected for reassessment 6 months later, at which time self-reported rates of heavy alcohol use and illicit drug use had decreased by 39% and 68%, respectively. Self-reported rates of overall health, employment, housing status, and criminality among persons who were in categories in which they should have been offered brief treatment or referral had also improved significantly.

In a landmark randomized controlled study of brief intervention in adult outpatients with cocaine or heroin use identified by screening, Bernstein et al.[94] screened 23,660 patients from women's health, homeless, and urgent care clinics and randomized those who screened positive for risky cocaine or heroin use (N = 1175) to a brief negotiated interview or to receipt of a referral list and written advice. Although a homeless clinic and women's health clinics could be considered primary care settings, urgent care settings are quite different from primary care, and subgroup analyses by site are not available. Ninety-five percent of eligible subjects were enrolled, and 82% were available for follow-up. Post-hoc, 19% of those followed up were excluded because baseline drug use was not confirmed biochemically. At 6 months, abstinence was documented among 40% of the intervention subjects and 31% of control subjects who used opiates at baseline, and 22% of the intervention subjects and 17% of the control subjects who used cocaine at baseline (statistically significant differences). No difference in receipt of help (90% of which was detoxification) was observed between groups.

In an uncontrolled study by Bernstein et al.,[95] patients who screened positive for substance problems in the emergency department were given a brief negotiated interview (BNI). At 60–90 day follow-up (completed by 8% of those who screened positive for alcohol or drugs), patients who received the BNI had significant reductions in substance use, including a 45% reduction in drug-problem severity. The number of referrals and receipt of addiction treatment also quadrupled from 6% to 23% after a BNI.

The Health Evaluation and Linkage to Primary Care (HELP) study linked 470 drug and alcohol abusers at a detoxification unit to primary medical care and assessed the effect over a 2-year period, during which 85% completed at least 1 follow-up assessment.[96,97] Results showed that a brief multidisciplinary intervention could link people with primary medical care, and that primary care exposure was associated with greater drug abstinence.[98] What component led to improvement, and whether brief intervention was a factor, is not known.

Finally, a number of studies have suggested brief intervention may decrease substance use among teens. In a randomized trial of adolescents with recent drug use (N = 59) in a primary care setting in Brazil, brief intervention decreased ecstasy and marijuana use and related drug problems.[99] In the United States, Project CHAT examined the impact of a brief MI intervention on alcohol consumption and drug use for high-risk teens in a primary care clinic.[100] Teens who screened positive for negative consequences related to substance use were randomized to receive either a brief MI intervention or to a control group (care as usual). Participants in the intervention group reported less marijuana use, lower perceived prevalence of marijuana use, fewer friends who used marijuana, and decreased intent to use marijuana in the next 6 months compared with controls.

In 2 randomized controlled trials by Tait et al.,[101,102] brief intervention among adolescents in an emergency department increased drug-treatment attendance and reduced return visits for consequences related to substance use. In another study, a single MI-style feedback session decreased some drug use (but not alcohol or marijuana use) among homeless adolescents,[103] and additional studies have shown its efficacy for youth in mandated treatment and in high schools.[104–106] In a pediatric emergency department, brief intervention for marijuana use resulted in greater levels of abstinence at 1 year compared with controls who received only written advice.[107] A randomized trial in a hospital assessed effects of 2 counseling sessions on psychoactive prescription drug use and found that intervention was associated with decreased use. However, some of the subjects had regular use but not abuse, and it is not clear whether the decrease was beneficial since some patients were taking pain medication regularly for pain.[108]

Reasons for Caution

Although SBI has proven efficacy for nondependent unhealthy alcohol and drug use in some health care settings and populations, this benefit may not translate to drug users identified by screening in primary care (or elsewhere) due to a number of clinical concerns and challenges. BI for drug use in a general health setting is likely to be more complicated than BI for alcohol use and is likely to involve a greater proportion of patients with dependence than is BI for screen-identified unhealthy alcohol use.

Many patients who use drugs use more than 1 drug or use alcohol and another drug, making brief intervention more complicated than it is for alcohol alone.[109,110] These drugs have variable forms, costs, risks, consequences, and ways for clinicians to identify use. For example, in our experience implementing drug SBI clinically, a brief intervention for dependent injection heroin use, with its attendant risks of overdose and HIV infection, is quite different from a brief intervention for occasional users of marijuana who perceive their use to be without risk or even beneficial to their health. Most abused drugs are illegal or used illegally, which can complicate

addressing their use in medical settings by raising patient and physician concerns about confidentiality and medical record documentation. Prescription drug abuse presents additional challenges as clinicians struggle to distinguish between appropriate and inappropriate use.

Another clinical concern is that a larger proportion of patients with drug use identified by screening will have dependence compared with those identified as having unhealthy alcohol use.[70] Brief intervention, even with a goal of referral, has not been proven even for alcohol in such circumstances, and is not widely recommended as the sole intervention for dependence.[48,56]

In addition to the aforementioned clinical concerns, the state of the evidence regarding screening is an additional reason for caution. Limited availability of feasible brief screening tools present a significant barrier to implementation. Few validation studies have been conducted in general health settings on the screening tools discussed herein, and the DAST and ASSIST cannot be considered brief, having 10 to 80 or more items. Given the known challenges to implementing SBI for alcohol with 1–3 item screening tests, the DAST and ASSIST are not likely to be disseminated widely, even if extensively validated. Although the single-item screening tool discussed earlier has the potential to minimize this barrier to implementing drug BI, further validation is needed.

With regard to BI, the lack of randomized trial evidence along with the inability to generalize results among treatment seekers compared with those identified by screening are additional concerns surrounding universal drug SBI. The assumption that drug-treatment efficacy among those seeking help will apply to people identified by screening and not necessarily seeking treatment is likely inaccurate. Assessing whether brief intervention has efficacy among people identified by screening—the common situation in primary care—is important, since these patients present with varying levels of readiness to change and a range of drug-use severity. Unfortunately, this distinction is challenging to test empirically since randomizing these two patient populations to the same treatment and control groups and comparing the effects would prove difficult, and people with less severe unhealthy use are not likely to be well represented in treatment-seeking populations. For a condition such as drug use in which motivation plays an important role, it seems logical that brief intervention (i.e., counseling that addresses motivation to change) would have different outcomes among those seeking help versus those not seeking it.

Aside from the challenge of translating study results from patients seeking help to those identified by screening, the absence of randomized trial evidence for drug SBI among adults in the primary care setting is a major concern. Observational studies and uncontrolled trials have limited ability to establish causality and thus cannot provide sufficient evidence to support recommendations for universal implementation of drug SBI. Improvements in the range of 40–70% seen in such studies[93,95] may be the result of many factors besides brief intervention, including regression to the mean, natural history of drug use after a patient-initiated voluntary healthcare contact, and confounding by prognostic factors that change across time. Effects seen in randomized trials are much more modest (about one-tenth of the magnitude).

In the only randomized controlled trial of SBI in a primary care setting (aside from the Brazilian study involving adolescents described earlier[99]), World Health Organization researchers who developed the ASSIST screening test conducted a 5-country Phase III randomized trial of brief intervention among 731 persons who screened positive on the ASSIST for risky cannabis, cocaine, amphetamine, or opioid use. The results appear in a technical report[75] not yet published in a peer-reviewed journal. Patients recruited from sexually transmitted disease clinics, walk-in clinics, a dental clinic, and community medical care sites (only some of which could be considered primary care) were randomly assigned to either brief intervention or no

counseling. Although brief intervention reduced substance-use scores in a preliminary single-site subgroup in the study,[77] results of the larger trial were less conclusive.[75] Differences between the 2 groups were small and of unknown clinical importance (3 points on a scale with a maximum value of 336 points), effects were seen for cannabis and stimulants but not for opioids, and substance use was not significantly impacted at the US site. Although the authors speculate that the lack of efficacy in the US was due to informed-consent procedures having an intervention effect, numerous alcohol SBI studies in the US that had informed-consent procedures have found SBI effects.[111] In sum, intervention effects in this study were not convincingly significant, nor were most patients recruited from settings that could be considered primary care (i.e., longitudinal, continuous, comprehensive care). As such, the study does not settle the question of whether SBI for drug use is of clinical benefit in primary care.

In addition, effects seen in trials that involve substantial training and effort to maintain intervention fidelity may not translate into real-world clinical practice. Effects in practice are likely to be smaller than those seen in research studies, which are small to begin with. Brief intervention for alcohol, a less complex clinical problem than drug use, among those identified by screening is associated with a 10–12% absolute decrease in risky use.[44,46,111] In Bernstein et al.'s randomized trial among outpatients who screened positive for cocaine or heroin use, [94] BI was associated with a 5–9% increase in abstinence. These small effects could be wiped out in practice if training and fidelity maintenance are not as good as in controlled trials, where clinicians or other interventionists are trained by study personnel for study purposes. The issue of translating efficacious interventions into practice also raises feasibility concerns if the commitment of clinical staff to delivering BI is uneven or inadequate.

Conversely, results in controlled research settings could be smaller than those observed in clinical practice because of assessment effects (i.e., the notion that research assessments alone may lead to behavioral change much as an intervention might) among control group patients. However, assessment effects are unlikely to explain the large improvements shown in some nonrandomized studies for such a recalcitrant clinical condition as a drug use disorder. In fact, no assessment effects were found in at least some brief intervention studies that tested for them. [58]

Conclusion

Although SBI can occur in many settings, and can target alcohol, drugs, or both, determining its efficacy and feasibility in primary care requires rigorous testing of brief screening tools and of different models of SBI. This issue, at a key clinical and policy crossroads, is of great importance given the severity and cost of the drug problem in the United States. The discrepancy between policy developments (reimbursement codes for drug SBI and a large federal SBI grant-funded program that includes drugs) and the existing evidence base for drug SBI underscore the need for randomized clinical trials to determine its effectiveness in primary care. Taking into consideration the perspectives of national professional societies, quality measurement groups, and practice guideline developers (none of which has come out in support of drug SBI), current policy and practice—at least as part of federally funded SBI programs—have gone well beyond the evidence base. Existing studies are insufficient to justify changes in clinical practice, just as decades of alcohol SBI data did not move practice guidelines in the United States until the completion of two large randomized controlled trials.[45,51,112] Validated screening tools exist and can be further tested, and most adults visit primary medical care settings where drug problems can be identified and where brief intervention can be conducted.

Although randomized clinical trials are challenging to implement, particularly with drug-using persons and those of lower socioeconomic status, including homelessness, high follow-up rates

can be achieved.[94,96–98,113] Findings from a pragmatic trial in primary care, enrolling people who use drugs and who are at risk for or have experienced related consequences, are necessary to determine whether brief intervention should be widely disseminated to reduce the national burden of drug-related illness and other negative effects, including the spread of HIV. Efficacious brief intervention models with favorable economic characteristics have the potential to significantly reduce the national burden of drug use and consequences. Conversely, lack of efficacy or excessive cost would force reconsideration of drug SBI as a broadly applicable strategy and would, appropriately, redirect efforts to address the problem.

Given that even proven strategies of SBI (e.g., SBI for alcohol in primary care settings) have not been widely implemented in practice, efficacy studies should include elements that can inform real-world effectiveness and implementation. Features might include minimizing restrictive entry criteria, recruiting subjects from diverse populations, minimizing intensity of study procedures to improve retention, and testing strategies that can be reproduced and financed in clinical practice settings. It is time for US efficacy studies of drug SBI in primary care settings that test models feasible in the real world and consider costs, sustainability, and outcomes.

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