What is the evidence for drug SBIRT in general health settings and what does it mean?

July 1, 2015

IRETA Webinar

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Boston Medical Center

Senior Editor, Journal of Addiction Medicine
Disclosures of potential conflicts of interest

- Grants to the institution that employs me, from the US government (National Institutes of Health) to study this topic
- Payments to me as editor of publications on this topic (e.g. UpToDate)
- I am interested in practice and policy being based on the best available evidence, whatever that evidence is
Objectives

- Review randomized controlled trial evidence in the peer-reviewed literature that addresses whether or not drug SBIRT is efficacious for adults in general health settings
- Interpreting such trials
- Implications for clinical practice and SBIRT programs
A few assumptions/definitions

- Screening (universal, brief); not treatment-seeking
- General health setting
- Evidence for efficacy IN SUCH PEOPLE AND SETTINGS (CONTEXT) is required (randomized trials)
  - Well-agreed upon by bodies that recommend preventive interventions in general health
  - Precautionary principle: action in face of uncertainty is not without consequences

- Adults
- Unhealthy use
UNHEALTHY USE

SBI: does it work?

Risky use, at-risk, hazardous

Mild AUD

Harmful use, alcohol dependence

Alcohol-use disorders

Consequence/problem

Low-risk use

Abstinence

None

Heavy Consumption

Severe Consequences
Screening, Brief Intervention, And Referral To Treatment (SBIRT)

SBIRT is a public health approach to the delivery of early intervention and treatment services for people with substance use disorders and those at risk of developing these disorders. Many different types of community settings provide opportunities for early intervention with at-risk substance users before more severe consequences occur.

A Step-by-Step Implementation Guide for Trauma Centers

At least 38 million adults drink too much and most are not alcoholics. Drinking too much includes binge drinking, high weekly use, and any alcohol use by pregnant women or those under age 21. It causes about 80,000 deaths in the US each year, and costs the economy about $224 billion. Alcohol screening and brief counseling can reduce drinking on an occasion by 25% in people who drink too much, but only 1 in 6 people have ever talked with their doctor or other health professional about alcohol use. Talking with a patient about their drinking is the first step of screening and brief counseling, which involves:

1 Using a set of questions to screen all patients for how much and how often they drink.
2 Counseling patients about the health dangers of drinking too much, including women who are (or could be) pregnant.
SBI: does it work?
Physician Unawareness of Serious Substance Abuse

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Kevin P. Mulvey, Ph.D.²,⁵
Alonzo Plough, Ph.D., M.P.H.²,³,⁵
Jeffrey H. Samet, M.D., M.A., M.P.H.¹,²,⁴

¹Clinical Addiction, Research and Education Unit
Section of General Internal Medicine
Boston Medical Center
Boston University School of Medicine
Ask the screening question about heavy drinking days:

How many times in the past year have you had...

5 or more drinks in a day? (for men)
4 or more drinks in a day? (for women)

One standard drink is equivalent to 12 ounces of beer, 5 ounces of wine, or 1.5 ounces of 80-proof spirits.

82% sensitive
79% specific
for unhealthy use

“How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?”

93% sensitive
94% specific
for past year use

Validation of Self-Administered Single-Item Screening Questions (SISQs) for Unhealthy Alcohol and Drug Use in Primary Care Patients

Jennifer McNeely, MD, MS1,2,3, Charles M. Cleland, PhD3,4, Sheila M. Strauss, PhD3,4, Joseph J. Palamar, PhD, MPH1,3, John Rotrosen, MD5, and Richard Saitz, MD, MPH6,7

J Gen Intern Med May 19, 2015
Screening and Brief Intervention:
* Feedback w/-permission
* Advice
* Goal-setting
* Follow-up

*other alcohol screening tools (e.g. AUDIT-C)
* assessment of severity and readiness
* non-confrontational, motivational interviewing-consistent/adaptations

SBI: does it work?
RANDOMIZED TRIALS OF SCREENING AND BRIEF INTERVENTION VS. NO SCREENING

NONE
EFFICACY of BI among screen-identified patients with non-dependent unhealthy alcohol use

- Efficacious: 10-15” multi-contact
  - >23 original RCTs,* many systematic reviews, primary care
  - Lower proportion of drinkers of risky amounts
    - 57% vs. 69% at 1 year (n=2784)**; 11% risk diff (n=5973)*
  - Lower consumption (n=5639)
    - by 15% (38 grams per week)(n=5639)***; 3.6 drinks/wk (n=4332)*
  - Accidents, injuries, liver problems, hospital/ER/primary care use, legal problems, quality of life: insufficient evidence*
    - Decreased hospital utilization (≥2 RCTs)
    - Cost-effective (spend $166, save $546 medical, $7780 society)
    - Decreased mortality (RR 0.47)(4 RCTs (n=1640)

**Beich et al. BMJ 2003;327:536
SBI: does it work?
MODIFIERS OF EFFICACY

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- Frequency (alcohol)
  - Brief multi-contact, 6/7 trials find efficacy
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  - No effect on use (or mental health)

References:
MODIFIERS OF EFFICACY

- Frequency (alcohol)
  - Brief multi-contact, 6/7 trials find efficacy
  - Very brief or brief single contact, 3/7 trials find efficacy
- Comorbidity (BI among those with mental health condition or use of >1 substance)
  - No effect on use (or mental health)
- Severity (alcohol)
  - Little evidence for effect (use/consequences) on those with very heavy use or dependence

Specialty substance use disorder services following brief alcohol intervention: a meta-analysis of randomized controlled trials

Joseph E. Glass, Ashley M. Hamilton, Byron J. Powell, Brian E. Perron, Randall T. Brown and Mark A. Ilgen

DOI: 10.1111/add.12950

Accepted Article (Accepted, unedited articles published online and citable. The final edited and typeset version of record will appear in future.)
Systematic review, 13 RCTs, 1 excluded due to high risk of bias (results unchanged if included), 9 with sufficient data meta-analyzed

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  - 6 studies had referral-specific interventions in the intervention group only; 2 in both groups; rest motivational but not specific referral description
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- 6 studies had referral-specific interventions in the intervention group only; 2 in both groups; rest motivational but not specific referral description
- Specialty care 2%-56% over next 3-18 mo (1 was 10 y)
- RR 1.08 (95% CI: 0.91-1.29)
LACK OF FOR THE RT IN SBIRT

EFFICACY
Evidence that SBI prevents dependence (disorder)
SETTING

- Most people identified by screening in hospitals have *dependence* (57-79%)
- Different expectations and goals
  - Comprehensive preventive longitudinal care?
  - Long-term therapeutic alliance?
  - Teachable vs. learnable moments?

4 hosps in Germany, Spain, US
Belen Martinez et al INEBRIA 2007
Bischof et al. Int J Pub Health 2010
Saitz et al. Int J Pub Health 2010
Cochrane Review: General Hospital

- 4 RCTs studied effects on drinking
- No effect on drinking when trial with high risk of bias excluded (and 3 trials excluded dependence*)

*or more severe drinking or treatment
SBI: does it work?

Trauma centers-hospitalized patients

- 1999, n=762
  NS reduction in injury HR 0.52, CI 0.21-1.29
  - decreased consumption in 54% sub-sample located in follow-up, among those with intermediate but not high, or low, SMAST scores, evident at 12 but not 6 months

- 2006, n=126: no decrease in DWI
  except in adjusted analyses

- 2006, n=187: no differences

- 2007, n=497: no differences

- 2010, n=1336: effect among dependent
  % hospitalized not reported

Schermer CR et al. J Trauma. 2006;60:29-34
Sommers MS et al. J Trauma. 2006;61:523-31
Soderstrom CA et al. J Trauma. 2007;62:1102-11
Field & Caetano Drug Alcohol Dep 2010;111:13-20
A (small) bit of good news

- 20 sites-enhanced training MI (10 hrs); 878 patients
  - +BACs (but AUDIT <20)

- Providers: greater MI skills and time at bedside on SBI
  - RR 0.88 (95% CI 0.79-0.98) for unhealthy alcohol use,*
  - 3 more abstinent days/90
  - No difference in heavy drinking days or alcohol-related consequences
  - No effect on the 50% who had traumatic brain injury

*AUDIT >8 (men) >5 (women)
Two systematic reviews

MAIN RESULT: Most studies-no impact on drinking; mixed effects on other outcomes (e.g. injuries)
(some, not all, with injured patients)

Two later RCTs
- 2008: risky use or alcohol+injury, n=500, no effect
- 2012: risky use, n=899, BI reduced drinking, driving p drinking
  - No assessment effects (see also Daeppen et al 2007)

6 studies are included in both reviews
Havard A et al. Addiction 2008; 103:368-76
SBI: does it work?
SBI: does it work?

UNKNOWN EFFECTIVENESS ≠ DOES NOT WORK
Before-After study of alcohol/drug SBIRT

- 10% sample of >450,000 screened + heavy alcohol or any drug use
  - The 3622 at 4 sites with good follow-up (<10% of initial 10% sample)
- Of those using the drug at baseline (100%), 6 month use was:
  - 100%>>33% marijuana
  - 100%>>21% cocaine
  - 100%>>15% methamphetamine
  - 100%>>27% heroin
  - 100%>>16% other drugs

Madras B et al. Drug Alcohol Depend 2009;99:280-95
Small or focused studies of drug SBI

- n=59 adolescents in primary care in Brazil-decreased MJ and stimulant use and problems
- Short-term decrease in addictive prescription drug use by hospitalized patients
- Decreased marijuana use by adolescents in the emergency department in a randomized pilot study

RCT in urgent care
- 5-9% increase in cocaine/heroin abstinence
- No difference in linkage to treatment

RCT in varied outpatient settings, 5 countries
- Excluded mild and severe; 3-month follow-up
- Small (clinically insignificant?) decreases in drug use scores
  - US findings negative (trend towards worse in BI group, 9% diff, p=0.11)
    - Total score (range 0-338):
      - BI 36>30 vs Control 36>32 (7% diff)
    - Cannabis (range 0-39)
      - BI 18>14 vs Control 17>15 (8% diff)
    - Stimulant (range 0-39)
      - BI 17>12 vs Control 15>12 (14% diff)
    - Opioid (Studied in India only)
      - BI 23>13 vs Control 23>18

Bernstein et al. Drug Alcohol Depend 2005;77:49
Original Investigation

Screening and Brief Intervention for Drug Use in Primary Care
The ASPIRE Randomized Clinical Trial

Richard Saltz, MD, MPH; Tibor P. A. Palfai, PhD; Debbie M. Cheng, ScD; Daniel P. Alford, MD, MPH;
Judith A. Bernstein, PhD, RN, MSN; Christine A. Lloyd-Travaglini, MPH; Seville M. Meli, MPH;
Christine E. Chaisson, MPH; Jeffrey H. Samet, MD, MPH, MA

IMPORTANCE The United States has invested substantially in screening and brief intervention for illicit drug use and prescription drug misuse, based in part on evidence of efficacy for unhealthy alcohol use. However, it is not a recommended universal preventive service in primary care because of lack of evidence of efficacy.

OBJECTIVE To test the efficacy of 2 brief counseling interventions for unhealthy drug use (any illicit drug use or prescription drug misuse)—a brief negotiated interview (BNI) and an adaptation of motivational interviewing (MOTIV)—compared with no brief intervention.
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study Entry (n = 528)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
</tr>
<tr>
<td>Substance Use</td>
<td></td>
</tr>
<tr>
<td>Main drug, No, (%)a</td>
<td></td>
</tr>
<tr>
<td>Opioid (includes heroin, prescription, and others)</td>
<td>90 (17.1)</td>
</tr>
<tr>
<td>Prescription opioid only</td>
<td>30 (5.7)</td>
</tr>
<tr>
<td>Cocaine</td>
<td>98 (18.6)</td>
</tr>
<tr>
<td>Marijuana</td>
<td>331 (62.7)</td>
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<tr>
<td>CIDI-SF positiveb</td>
<td>245 (46.4)</td>
</tr>
<tr>
<td>Tobacco use past year</td>
<td>403 (76.3)</td>
</tr>
<tr>
<td>Days using main drug past 30 d</td>
<td>12.0 (3.0-27.0)</td>
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<tr>
<td>-------------------------------</td>
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<tr>
<td>Mean (SD)</td>
<td>14.4 (11.5)</td>
</tr>
<tr>
<td>Days &gt;1 time using main drug past 30 d</td>
<td>5.0 (0.0-18.0)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>9.8 (11.1)</td>
</tr>
<tr>
<td>Injection drug use past 3 mo, No. (%)</td>
<td>63 (12.1)</td>
</tr>
<tr>
<td>Use of &gt;1 drug past 90 d, No. (%)</td>
<td>167 (31.6)</td>
</tr>
<tr>
<td>Misuse any prescription drug past 90 d, No. (%)</td>
<td>112 (21.2)</td>
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<tr>
<td>Heavy alcohol or drug use past 90 d, No. (%)</td>
<td>528 (100.0)</td>
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<tr>
<td>Any heavy drinking past month, No. (%)</td>
<td>254 (48.1)</td>
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<tr>
<td>No. of heavy drinking days past month</td>
<td>0.0 (0.0-4.0)</td>
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<tr>
<td>Mean (SD)</td>
<td>4.5 (8.0)</td>
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<tr>
<td>ASSIST Scores(^c)</td>
<td></td>
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<tr>
<td>ASSIST score ≥27</td>
<td>97 (18.4)</td>
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<tr>
<td>Substance-specific score</td>
<td></td>
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<tr>
<td>Main drug, median (IQR)</td>
<td>15.0 (9.0-23.0)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>16.8 (9.6)</td>
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</table>
Table 4. Main Results: Effects on Days Using the Main Drug by Primary Care Patients With Unhealthy Drug Use Identified by Screening of Brief Interventions

<table>
<thead>
<tr>
<th></th>
<th>Predicted Mean No. of Days Using Main Drug in Past 30 Days at 6 Months</th>
<th>BNI vs Control</th>
<th>MOTIV vs Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BNI</td>
<td>MOTIV</td>
<td>Control</td>
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<tr>
<td>Overall analysisa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unadjusted</td>
<td>517</td>
<td>14.2</td>
<td>14.1</td>
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<tr>
<td>Adjusteda</td>
<td>516</td>
<td>11.2</td>
<td>12.1</td>
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<tr>
<td></td>
<td>1.03 (0.80-1.34)</td>
<td>.85</td>
<td>1.03 (0.79-1.33)</td>
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<tr>
<td>Stratified by Main Drugb</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Opioids</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Unadjusted</td>
<td>88</td>
<td>7.0</td>
<td>8.0</td>
</tr>
<tr>
<td>Adjustedb</td>
<td>88</td>
<td>6.4</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>0.80 (0.33-1.92)</td>
<td>.84</td>
<td>0.91 (0.38-2.21)</td>
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<tr>
<td></td>
<td>0.85 (0.35-2.07)</td>
<td>.96</td>
<td>0.98 (0.41-2.34)</td>
</tr>
<tr>
<td>Cocaine</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Unadjusted</td>
<td>97</td>
<td>8.0</td>
<td>7.4</td>
</tr>
<tr>
<td>Adjustedc</td>
<td>97</td>
<td>5.7</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td>1.51 (0.78-2.91)</td>
<td>.31</td>
<td>1.41 (0.73-2.72)</td>
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<td></td>
<td>1.15 (0.62-2.14)</td>
<td>.66</td>
<td>1.44 (0.78-2.65)</td>
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<tr>
<td>Marijuana</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Unadjusted</td>
<td>323</td>
<td>18.3</td>
<td>18.2</td>
</tr>
<tr>
<td>Adjusteda</td>
<td>322</td>
<td>16.7</td>
<td>17.1</td>
</tr>
<tr>
<td></td>
<td>1.02 (0.80-1.31)</td>
<td>.91</td>
<td>1.01 (0.79-1.30)</td>
</tr>
<tr>
<td></td>
<td>1.00 (0.80-1.25)</td>
<td>.99</td>
<td>1.02 (0.82-1.28)</td>
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<tr>
<td>Stratified by ASSIST Scoreh</td>
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<tr>
<td>ASSIST&lt;27</td>
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<td></td>
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<tr>
<td>Unadjusted</td>
<td>424</td>
<td>14.3</td>
<td>14.3</td>
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<tr>
<td>Adjustedf</td>
<td>423</td>
<td>11.1</td>
<td>11.7</td>
</tr>
<tr>
<td></td>
<td>1.01 (0.76-1.33)</td>
<td>.96</td>
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<td>ASSIST≥27</td>
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<td>1.11 (0.55-2.23)</td>
<td>.84</td>
<td>1.07 (0.54-2.12)</td>
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<td></td>
<td>1.01 (0.52-1.98)</td>
<td>.97</td>
<td>1.19 (0.53-2.26)</td>
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</tbody>
</table>
SBI: does it work?

<table>
<thead>
<tr>
<th></th>
<th>Study Entry (n = 528)</th>
<th>6 Months (n = 517)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall</td>
<td>BNI</td>
</tr>
<tr>
<td>SiP-D score, median (IQR) ^a</td>
<td>6.0</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>(1.0-21.0)</td>
<td>(1.0-19.0)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>12.0</td>
<td>12.1</td>
</tr>
<tr>
<td></td>
<td>(13.6)</td>
<td>(13.8)</td>
</tr>
<tr>
<td>Unsafe sex past 3 mo, No. (%)</td>
<td>277 (57.6)</td>
<td>95 (59.0)</td>
</tr>
<tr>
<td></td>
<td>(20.0-44.0)</td>
<td>(20.0-40.0)</td>
</tr>
<tr>
<td>No. of unsafe sex encounters past 3 mo, median (IQR)</td>
<td>3.0</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>(0.0-13.5)</td>
<td>(0.0-17.0)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>16.1</td>
<td>13.9</td>
</tr>
<tr>
<td></td>
<td>(39.7)</td>
<td>(24.2)</td>
</tr>
<tr>
<td>Unsafe sex with nonprimary or transactional partners past 3 mo, No. (%)</td>
<td>50 (10.3)</td>
<td>14 (8.6)</td>
</tr>
<tr>
<td></td>
<td>(5.0-15.5)</td>
<td>(5.0-12.0)</td>
</tr>
<tr>
<td>Hair Testing, No. (%) ^b</td>
<td>475 (96.2)</td>
<td>160 (97.0)</td>
</tr>
<tr>
<td></td>
<td>(94.0-98.0)</td>
<td>(94.0-98.0)</td>
</tr>
<tr>
<td>Any drug use</td>
<td>490 (96.3)</td>
<td>164 (97.0)</td>
</tr>
<tr>
<td></td>
<td>(94.0-98.0)</td>
<td>(94.0-98.0)</td>
</tr>
<tr>
<td>Any opioid</td>
<td>86 (18.4)</td>
<td>34 (22.2)</td>
</tr>
<tr>
<td></td>
<td>(15.0-21.5)</td>
<td>(15.0-21.5)</td>
</tr>
<tr>
<td>Any cocaine or benzoylecgonine</td>
<td>249 (53.4)</td>
<td>81 (52.9)</td>
</tr>
<tr>
<td></td>
<td>(49.0-58.0)</td>
<td>(49.0-58.0)</td>
</tr>
<tr>
<td>Any carboxy-tetrahydrocannabinol</td>
<td>366 (75.6)</td>
<td>120 (75.9)</td>
</tr>
</tbody>
</table>

92% used any drug by self-report, 3 mo
ASSIST scores 2,3 only. Adjusted for baseline use

<table>
<thead>
<tr>
<th></th>
<th>No BI</th>
<th>BNI</th>
<th>MOTIV</th>
<th>BNI vs. no BI</th>
<th>MOTIV vs. no BI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Adjusted Means</td>
<td>IRR (95% CI)</td>
<td>p-value</td>
<td>IRR (95% CI)</td>
</tr>
<tr>
<td>Days used main drug</td>
<td>57</td>
<td>6.4</td>
<td>2.1</td>
<td>2.3</td>
<td>0.33 (0.15,0.74)</td>
</tr>
<tr>
<td>Exploratory analyses stratified by main drug</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Days used main drug (Cocaine, Opioids, and Other §)</td>
<td>17</td>
<td>2.3</td>
<td>0.3</td>
<td>1.9</td>
<td>0.12 (0.03,0.43)</td>
</tr>
<tr>
<td>Days used main drug -Marijuana</td>
<td>40</td>
<td>7.4</td>
<td>3.6</td>
<td>3.1</td>
<td>0.49 (0.19,1.25)</td>
</tr>
</tbody>
</table>
Original Investigation

Brief Intervention for Problem Drug Use in Safety-Net Primary Care Settings
A Randomized Clinical Trial

Peter Roy-Byrne, MD; Kristin Bumgardner, BS; Antoinette Krupski, PhD; Chris Dunn, PhD; Richard Ries, MD; Dennis Donovan, PhD; Imara L. West, MPH; Charles Maynard, PhD; David C. Atkins, PhD; Meredith C. Graves, PhD; Jutta M. Joesch, PhD; Gary A. Zarkin, PhD

IMPORTANCE Although brief intervention is effective for reducing problem alcohol use, few data exist on its effectiveness for reducing problem drug use, a common issue in disadvantaged populations seeking care in safety-net medical settings (hospitals and community health clinics serving low-income patients with limited or no insurance).

OBJECTIVE To determine whether brief intervention improves drug use outcomes compared with enhanced care as usual.

DESIGN, SETTING, AND PARTICIPANTS A randomized clinical trial with blinded assessments at baseline and at 3, 6, 9, and 12 months conducted in 7 safety-net primary care clinics in Washington State. Of 1621 eligible patients reporting any problem drug use in the past 90 days, 868 consented and were randomized between April 2009 and September 2012. Follow-up participation was more than 87% at all points.

**INTERVENTIONS** Participants received a single brief intervention using motivational interviewing, a handout and list of substance abuse resources, and an attempted 10-minute telephone booster within 2 weeks (n = 435) or enhanced care as usual, which included a handout and list of substance abuse resources (n = 433).

**MAIN OUTCOMES AND MEASURES** The primary outcomes were self-reported days of problem drug use in the past 30 days and Addiction Severity Index-Lite (ASI) Drug Use composite score. Secondary outcomes were admission to substance abuse treatment; ASI composite scores for medical, psychiatric, social, and legal domains; emergency department and inpatient hospital admissions, arrests, mortality, and human immunodeficiency virus risk behavior.

**RESULTS** Mean days used of the most common problem drug at baseline were 14.40 (SD, 11.29) (brief intervention) and 13.25 (SD, 10.69) (enhanced care as usual); at 3 months postintervention, means were 11.87 (SD, 12.13) (brief intervention) and 9.84 (SD, 10.64) (enhanced care as usual) and not significantly different (difference in differences, β = 0.89 [95% CI, −0.49 to 2.26]). Mean ASI Drug Use composite score at baseline was 0.11 (SD, 0.10) (brief intervention) and 0.11 (SD, 0.10) (enhanced care as usual) and at 3 months was 0.10 (SD, 0.09) (brief intervention) and 0.09 (SD, 0.09) (enhanced care as usual) and not significantly different (difference in differences, β = 0.008 [95% CI, −0.006 to 0.021]). During the 12 months following intervention, no significant treatment differences were found for either variable. No significant differences were found for secondary outcomes.

**CONCLUSIONS AND RELEVANCE** A one-time brief intervention with attempted telephone booster had no effect on drug use in patients seen in safety-net primary care settings. This finding suggests a need for caution in promoting widespread adoption of this intervention for drug use in primary care.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT00877331

Gelberg et al. 2014 abstract

DESIGN: RCT, primary care, drug ASSIST scores 4-26

INTERVENTION: brief clinician advice, a video doctor, and 2 30-40” drug-use health education/reinforcement telephone sessions.
CONTROL: information on cancer screening.

RESULTS: n=334, 3 mo. follow-up 78%.
Reduction in highest scoring drug use days was 3.9 days larger in the intervention than in the control group, larger in patients with high baseline drug use, and with 2 or more contacts.

Laboratory testing (urine) in a subset
## SBI: does it work?

### Screening and brief intervention for unhealthy drug use: little or no efficacy

*Richard Saitz*

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#### Table 1 | Randomized trial evidence regarding drug screening and brief intervention in adult general health settings that include at least some primary care patients.

<table>
<thead>
<tr>
<th>Citation</th>
<th>Intervention</th>
<th>Result (between group differences at follow-up)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gelberg et al. (34)</td>
<td>Very brief advice, video doctor, and two booster sessions</td>
<td>Less frequent (4 days) drug use at 3 months; effect larger among more severe</td>
<td>78% Follow-up; attention control; no biological testing; excluded those with likely moderate to severe disorder</td>
</tr>
<tr>
<td>Roy-Byrne et al. (35, 40)</td>
<td>Single Bi with 1 week phone booster done by social workers</td>
<td>3, 6, 9, and 12 months outcomes. No significant differences in days drug use or drug use severity</td>
<td>Biological testing; 67% follow-up</td>
</tr>
<tr>
<td>Saitz et al. (36, 37)</td>
<td>Single 10–15 min health promotion advocate/health educator Bi 45-min psychologist Bi with one booster</td>
<td>6-month outcomes. No differences in days drug use or drug use severity, health-related quality of life, emergency department or hospital utilization or HIV risk behaviors</td>
<td>Biological testing; 98% follow-up</td>
</tr>
<tr>
<td>Humeniuk et al. (38)</td>
<td>Single Bi largely done by clinic staff (some by researchers in Brazil)</td>
<td>Seven points or smaller difference in drug use risk scale with 338 points theoretical maximum at most sites except US where control group had greater decrease in the score</td>
<td>86% Follow-up; no biological testing; excluded those likely to have moderate to severe disorder*</td>
</tr>
<tr>
<td>Bernstein et al. (39)</td>
<td>Single Bi done by health promotion advocate</td>
<td>5% Absolute risk increase in cocaine abstinence; 9% risk increase in opioid abstinence</td>
<td>Biological testing; 62% follow-up*</td>
</tr>
</tbody>
</table>

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*Two additional studies have been done exclusively in emergency department settings. One had 58% loss to follow-up and found no benefit of SBI (40). The other, a multi-site trial, has not yet had results published (41).* 

*Some participants in primary care (see text for details).
Screening and Brief Intervention for Drug Use in Primary Care
The ASPIRE Randomized Clinical Trial

Richard Saitz, MD, MPH; Tibor P. A. Palfai, PhD; Debbie M. Cheng, ScD; Daniel P. Alford, MD, MPH;
Judith A. Bernstein, PhD, RN, MSN; Christine A. Lloyd-Travaglini, MPH; Seville M. Meli, MPH;
Christine E. Chaisson, MPH; Jeffrey H. Samet, MD, MPH, MA

**IMPORTANCE** The United States has invested substantially in screening and brief intervention for illicit drug use and prescription drug misuse, based in part on evidence of efficacy for unhealthy alcohol use. However, it is not a recommended universal preventive service in primary care because of lack of evidence of efficacy.

**OBJECTIVE** To test the efficacy of 2 brief counseling interventions for unhealthy drug use (any illicit drug use or prescription drug misuse)—a brief negotiated interview (BNI) and an adaptation of motivational interviewing (MOTIV)—compared with no brief intervention.
Original Investigation

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SBI: does it work?

Original Investigation

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Richard Giltner, MD, MPH; Tiffany P. A. Palfai, MD; Debbie N. Cheng, ScD; Daniel F. Alfonse, MD, MPH; Judith A. Benson, MD, RN, MSN; Christopher A. Lloyd-Tramaglini, MPH; Sevill M. Med, MPH; Christine C. Chabot, MPH; Jeffrey H. Sedor, MD, MPH; DA

IMPORTANCE The United States has invested substantially in screening and brief intervention for illicit drug use and prescription drug misuse, based in part on evidence for its effectiveness in reducing unhealthy alcohol use. However, it is not a recommended universal screening tool for substance use in primary care because of lack of evidence of efficacy.

OBJECTIVE To test the efficacy of 2 brief counseling interventions for reducing illicit drug use or prescription drug misuse—a brief negotiated interview with primary care providers (SBI)—compared with usual care, in a randomized clinical trial.

Results In the ASPIRE Randomized Clinical Trial, 1000 patients with a current problem of drug use were randomized to the SBI condition (n = 499) or control (n = 501). The SBI condition included 2 counseling sessions with a nurse or pharmacist (in the primary care setting) and drug and alcohol counselor (in a substance use treatment setting). The results demonstrated no differences between the SBI condition and control condition in reducing drug use among patients after 6 months of follow-up. The results were consistent across drug types, sex, and substance use treatment settings. The SBI condition was associated with a 5.4% increase in诃

Boston University

Screening and Brief Intervention and Referral to Treatment for Drug Use in Primary Care
Back to the Drawing Board

Ralph Hingson, ScD, MPH, Wilson M. Compton, MD, MPE

IMPOR TANCE Although brief intervention is effective for reducing problem alcohol use, few data exist on its effectiveness for reducing problem drug use, a common issue in disadvantaged populations seeking care in safety-net medical settings (hospitals and community health clinics serving low-income patients with limited or no insurance).

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### Table 2. Primary Outcome Analyses

<table>
<thead>
<tr>
<th>Drug of Abuse</th>
<th>Days of Use in Past 30 d</th>
<th>Normal Model</th>
<th>Beta-Binomial Model</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimate (95% CI)</td>
<td>Unadjusted</td>
<td>Adjusted</td>
</tr>
<tr>
<td><strong>MSO vs BI-B</strong></td>
<td>0.7174 (−0.8044 to 2.2391)</td>
<td>.36</td>
<td>.57</td>
</tr>
<tr>
<td><strong>SAR vs BI-B</strong></td>
<td>0.7003 (−0.8254 to 2.2261)</td>
<td>.37</td>
<td>.57</td>
</tr>
<tr>
<td><strong>SAR vs MSO</strong></td>
<td>−0.01701 (−1.5327 to 1.4987)</td>
<td>.98</td>
<td>.98</td>
</tr>
<tr>
<td>Baseline use days</td>
<td>0.4287 (0.3740 to 0.4834)</td>
<td>&lt;.001 NA</td>
<td>NA</td>
</tr>
<tr>
<td>DAST-10 score</td>
<td>−0.5581 (−0.8525 to −0.2637)</td>
<td>.001 NA</td>
<td>NA</td>
</tr>
<tr>
<td>AUDIT-C score</td>
<td>−0.1811 (−0.3520 to −0.01019)</td>
<td>.04 NA</td>
<td>NA</td>
</tr>
<tr>
<td>Site (variance)</td>
<td>3.99</td>
<td>.08 NA</td>
<td>NA</td>
</tr>
<tr>
<td>Error (variance)</td>
<td>113.62</td>
<td>&lt;.001 NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Abbreviations:** AUDIT-C, Alcohol Use Disorders Identification Test; BI-B, brief intervention with telephone booster sessions; DAST, 10-item Drug Abuse Screening Test; MSO, minimal screening only; NA, not applicable; SAR, screening, assessment, and referral.

*Not adjusted for multiple testing in the model.*
Blow et al. 2015 (June)

RCT computer v. in person BI; in ED patients
ASSIST 4+, 90% MJ, mean age 31, low SES, 1/5 suicidal thoughts
81% 3 mo. F/U, urine testing in some (?)

In-person BI reduced self-reported days drug use over 6-12 months
(effect size 0.2; by approx. 13/90 days, from 48 to 35)
SBI: does it work?
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"I've heard the saying, but I never thought it was something that could actually happen."
SBI: does it work?
"If it's all the same to you, I'd rather eat this not knowing what the latest science suggests."
Counting Drug SBI RCTs

- Primary care
  - 2 null
  - 1 positive (abstract; unpublished)
- Emergency Department
  - 1 positive
  - 1 null (abstract; unpublished)
- Various sites
  - 1 mixed, clinically insignificant
  - 1 positive
Summarizing Drug SBI RCTs

Many more patients in null studies; effect size in positive study small $->$ summary likely null

Adding methodological differences: will favor null studies

But can/should SBI studies be combined if BIs are different? Maybe not
Adolescents: promising? Need study

- If this is a preventive service, and most people who will ever develop an SUD do so by age 25, why are we studying and doing SBIRT for middle-aged/older adults?

- Decreased MJ use (pilot, ED) (Bernstein E et al. Acad Emerg Med 2009;16:1174-85)

- Walton et al: n=328 adolescents with MJ use in PC
  - Computer intervention decreased consequences but not use
  - Therapist intervention decreased DUI but not use or consequences

- Walton et al: n=714 adolescents with NO MJ use
  - Computer intervention decreased any MJ use (17% vs 24%) and frequency of use
  - Therapist intervention did not

*Drug Alcohol Depend 2013;132:646-53
Addiction 2013;109:786-97*
What does the evidence mean?

- SBI for alcohol: non-dependent, primary care, multiple
  - Positive findings may be due to self-report bias
  - What about meaningful outcomes?
  - What should we do about more severe?
  - Role for one-time advice?
  - Any chance it can be implemented and retain effectiveness?

- SBI for drug: little evidence for efficacy; evidence it does not work in primary care; similar for emergency departments

- At the very least it is possible to do SBI very well and have it yield no benefit
What does the evidence mean?

- Does SBI drug work for anyone? Who?
  - Studies that suggest efficacy are inconsistent—why?
    - Methods? (e.g. not truth)
      - Need biological testing, outcomes that matter to people (utilization, consequences of use)
    - Different interventions? (video, computer, repeated)
    - Setting? It does matter
    - Main drug? Probably matters (e.g. Rx drug and pain…)
  - Inefficacy still more probable than not
    - At best, it can be done but how, and how to replicate? What is it that is essential to make it work? And what is “it”? 

SBI: does it work?
What does the evidence mean?

We may decide to do something regardless of evidence for efficacy, for other reasons

- Be clear and honest about that
- SBI may be the entrée for beginning to address substance use in healthcare

Precautionary principle:

- “Substance use is a big problem; we have to do something about it”
- SBIRT is “cheap” (not really)
- Action in face of uncertainty is not without consequences (opportunity costs, “problem solved,” stigma/medical records, increased use if done poorly?)
What does the evidence mean?

- Policymakers believe in this; practitioners and patients have known all along it is more complicated.
- Evidence does not make decisions; it informs us what to expect from our actions.
- There are reasons to identify, assess and manage:
  - To diagnose symptoms (e.g. insomnia, anxiety, tremor, heartburn, chest pain…)
  - To treat, e.g. with medications (…opioids…)
  - Screening tools aimed at supporting BI don’t provide what is needed for Dx and Rx
- Better approaches in general healthcare needed.
SBI: does it work?

What works?
Clinical effectiveness.
Cautions for the real world

● 29 GP practices were given training, newsletters, progress reports, and paid to screen for unhealthy alcohol use, and provide advice and counselling (cluster RCT of leaflet, advice, counselling)
  ● 40% needed the research team to come and do it
  ● Even then, 43% of patients did not receive brief counselling to which they were assigned
● No differences in consumption, problems or quality of life
Cautions for the real world

- RCT of extensive implementation effort led to no increase and between group differences in screening of (10%) and advice to at-risk drinkers (3%)
- *(No effect on drinking)*

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Hilbink et al JABFM 2012;25:712-22. (contamination was an issue-controls got feedback 0-8 months into recruitment)
Failures of implementation even with Herculean efforts
Failures to effect change in drinking, consequences

746 clinicians in 120 European primary care practices AGREED to be in a trial of alcohol SBI implementation.

They screened FIVE PERCENT of 180,000 patients (most of whom were positive)

Audiotaped encounters with clinicians who were aware they were being recorded

VA: receipt of BI not associated with less drinking
VA: “do you drink?” “VA wants to know about it”

Patient A: “Six beers . . . or maybe even 8 sometimes”
Provider 1: “Okay. Okay. Have you been able to take your medication on a regular basis?”
No further exploration of patient’s drinking during this visit

Patient B: “Well, I’ve been boozing”
Provider 2: “I know. I’m more concerned about your kidney function . . .”
Only reference to alcohol during this visit

McCormick K et al., J Gen Intern Med. 2006; 21(9): 966–972.
Bradley KA, et al. Am J Managed Care, 2006
Lapham et al, Med Care, 2012
Williams EC et al. abstract presentations INEBRIA 2011, 2012
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (n = 528)</th>
<th>BNI (n = 124)</th>
<th>MOTIV (n = 126)</th>
<th>Control (n = 119)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%)</td>
<td>369 (69.9)</td>
<td>124 (71.3)</td>
<td>126 (71.2)</td>
<td>119 (67.2)</td>
</tr>
<tr>
<td>Race/ethnicity, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>357 (68.8)</td>
<td>116 (68.2)</td>
<td>126 (72.4)</td>
<td>115 (65.7)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>50 (9.6)</td>
<td>18 (10.6)</td>
<td>11 (6.3)</td>
<td>21 (12.0)</td>
</tr>
<tr>
<td>White</td>
<td>105 (20.2)</td>
<td>32 (18.8)</td>
<td>37 (21.3)</td>
<td>36 (20.6)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (1.4)</td>
<td>4 (2.4)</td>
<td>0</td>
<td>3 (1.7)</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>41.3 (12)</td>
<td>40.0 (12.2)</td>
<td>42.6 (12.2)</td>
<td>41.3 (12.5)</td>
</tr>
<tr>
<td>High school graduate or equivalent, No. (%)</td>
<td>369 (69.9)</td>
<td>119 (68.4)</td>
<td>127 (71.8)</td>
<td>123 (69.5)</td>
</tr>
<tr>
<td>Never married, No. (%)</td>
<td>328 (62.1)</td>
<td>105 (60.3)</td>
<td>108 (61.0)</td>
<td>115 (65.0)</td>
</tr>
<tr>
<td>Health insurance, No. (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private/commercial(^b)</td>
<td>69 (13.1)</td>
<td>24 (13.8)</td>
<td>18 (10.2)</td>
<td>27 (15.3)</td>
</tr>
<tr>
<td>Medicaid/Medicare(^c)</td>
<td>429 (81.3)</td>
<td>138 (79.3)</td>
<td>153 (86.4)</td>
<td>138 (78.0)</td>
</tr>
<tr>
<td>None</td>
<td>30 (5.7)</td>
<td>12 (6.9)</td>
<td>6 (3.4)</td>
<td>12 (6.8)</td>
</tr>
<tr>
<td>Measure</td>
<td>Value</td>
<td></td>
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<tr>
<td>----------------------------------------------------------------</td>
<td>-------</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Health-related quality of life, mean (SD)(^f)</td>
<td>70.3 (20.4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depressive symptoms (PHQ-9 (\geq 10), No. (%))(^g)</td>
<td>189 (35.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety symptoms (OASIS (\geq 8), No. (%))(^h)</td>
<td>176 (33.3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization past 3 mo, No. (%)</td>
<td>75 (14.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization, addiction or mental health related past 3 mo, No. (%)</td>
<td>29 (5.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED visit past 3 mo, No. (%)</td>
<td>189 (35.8)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ED visit for addiction or mental health past 3 mo, No. (%)</td>
<td>47 (8.9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutual help group participation past 3 mo, No. (%)</td>
<td>93 (17.6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residential stay for addiction or mental health past 3 mo, No. (%)</td>
<td>43 (8.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient addiction or mental health treatment or counseling past 3 mo, No. (%)</td>
<td>119 (22.6)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>