## Drug\* Screening & Brief Intervention Efficacy: the state of the science

**Nick Heather Lecture** 



### Richard Saitz MD, MPH

Chair, Department of Community Health Sciences Professor of Community Health Sciences & Medicine Schools of Public Health and Medicine Boston Medical Center

\*other than alcohol and tobacco







## 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, Senior Editor J Addiction Med)
- Elected member, INEBRIA Coordinating Committee
- No alcohol, tobacco or marijuana industry support
- I am interested in practice and policy being based on the best available evidence, whatever that evidence is



## **Prof Nick Heather**

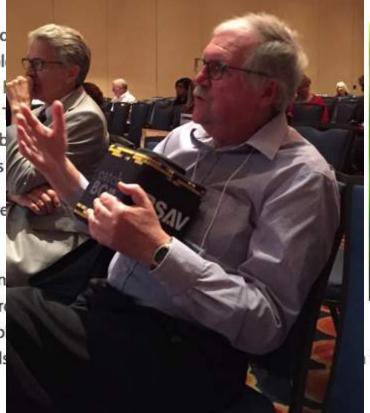
Emeritus Professor of Alcohol and Other Drug Studies Department: Psychology

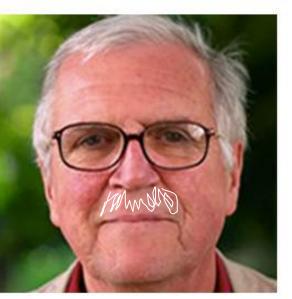
Nick is Emeritus Professor of Alcohol and Other Drug Studies within the Department of Psychology.

Nick is Emeritus Professor of the Department of Psychol following retirement from I with the Newcastle, North 7 Health NHS Trust but had b University for several years

He is actively engaged in re responsibilities.

Nick has a long-standing in with an emphasis on the tre accumulated over 450 pub articles in scientific journals





the field of addictions.

### 4th Conference of INEBRIA

The 4th Inebria Meeting "Putting theory into practice: Research, Training and Health Promotion Programmes in EIBI" took place in Brussels from 19 th to 20th November 2007 with the support of the Flemish Government and DOMUS MEDICA and the co-sponsorship of the World Health Organitzation and the Health Departament of the Government of Catalonia.

15.30 - 17.00	Workshop 3 (part 2) : EIBI in special groups. Chair: N Heather Workshop 4 (part 2) : Reframing understanding through internet. Chair: A Gual Workshop 5 (part 2) : EIBI in occupational health. Chair: B Garmyn
15.30	Emily Williams (USA): The Impact of Physical Health and Comorbidity on Drinking after Hospitalization among Inpatients with Unhealthy Alcohol Use
15.45	Richard Saltz (USA): Which Medical In patients With Unhealthy Alcohol Use Benefit From Brief Intervention?
16.00	Ana Bellen Martinez (Spain): Usefulness of AUDIT-C as screening tool in an opportunistic brief intervention program for alcohol problems in hospitalized patients.
16.30	Debate: Do effects between various BI's and among target groups differ? Should BI be adapted to target groups ?



## Objectives

- Drug screening and brief intervention: what it is
- Why do we think this might work?
- Review randomized controlled trial evidence
- Interpret the state of the science (speculation)
- Implications for policy, practice and research



# THINKING ABOUT CHANGING YOUR DRINKING?

Did you know that 75% of people change their drinking on their own?

CALL US for free materials you can complete at home.

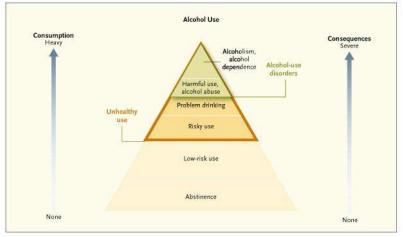
## (416) 595-6071

All calls are confidential Sponsored by the University of Toronto and the Addiction Research Foundation



## A few assumptions/definitions

- Screening (universal, brief); not treatment-seeking
- Brief intervention (in person)
- 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





Saitz R. New Engl J Med 2005;352:596.

### STEP 1 - Ask the NIDA Quick Screen Question

Instructions: Using the sample language below, introduce yourself to your patient, then ask about <u>past year</u> drug use, using the NIDA *Quick Screen*. For <u>each</u> substance, mark in the appropriate column. For example, if the patient has used cocaine monthly in the past year, put a mark in the "Monthly" column in the "illegal drug" row.

#### Introduction (Please read to patient)

Hi, I'm \_\_\_\_\_\_, nice to meet you. If it's okay with you, I'd like to ask you a few questions that will help me give you better medical care. The questions relate to your experience with alcohol, cigarettes, and other drugs. Some of the substances we'll talk about are prescribed by a doctor (like pain medications). But I will only record those if you have taken them for reasons or in doses other than prescribed. I'll also ask you about illicit or illegal drug use—but only to better diagnose and treat you.

<i>Quick Screen</i> Question: <u>In the past year</u> , how often have you used the following?	Never	Once or Twice	Monthly	Weekly	Daily or Almost Daily
Alcohol • For men, 5 or more drinks a day • For women, 4 or more drinks a day					
Tobacco Products					
Prescription Drugs for Non-Medical Reasons					
Illegal Drugs					



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

93% sensitive94% specificfor past year use

Alternatives: **ASSIST**-cutoff 4 or 2?; **DAST** (misses use; doesn't spec drug); **SoDU** 2-item (Tiet et al. JAMA Intern Med 2015; Aug 175:1371-7, misses use); **DUDIT** (Berman A et al., disorders)

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

Jennifer McNeely, MD, MS<sup>1,2,3</sup>, Charles M. Cleland, PhD<sup>3,4</sup>, Shiela M. Strauss, PhD<sup>3,4</sup>, Joseph J. Palamar, PhD, MPH<sup>1,3</sup>, John Rotrosen, MD<sup>5</sup>, and Richard Saitz, MD, MPH<sup>6,7</sup> J Gen Intern Med May 19, 2015



*Smith PC,* Schmidt SM, Allensworth-Davies D, Saitz R. *Arch Intern Med.* 2010;170(13):1155-1160. doi:10.1001/archinternmed.2010.140.

### Screening and Brief Intervention:

\*Screening \*Feedback w/-permission \*Advice \*Goal-setting \*Follow-up

\*assessment of severity and readiness \*non-confrontational, motivational interviewing-consistent/adaptations

HULPER S

# What the US thinks

About the promise of drug SBI





BOSTON

## Before-After study

- 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



#### Drug SBI: does it work?



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#### Screening, Brief Intervention, And Referral To Treatme (SBIRT)

SBIRT is a public health approach to the delivery of early intervention and treatment services with substance use disorders and those at risk of developing these disorders. Many different 1 community settings provide opportunities for early intervention with at-risk substance users b more severe consequences occur.



Screening, Brief Intervention, and Referral to Treatment (SBIRT) services are an evidence-based practice designed to identify, reduce, and prevent problematic use, abuse, and dependence on alcohol and illicit drugs. The SBIRT model calls for community-based screening for health

Please note: The information in this publication applies to the Medicare Fee-For-Service Program (also known as Original Medicare) and Medicaid. Unique requirements apply to each of these programs.

risk behaviors. SBIRT offers an opportunity to identify problem drinking and substance abuse, and trigger intervention.

This fact sheet provides health care professionals with an overview of Medicare and Medicaid coverage of SBIRT services, including who may perform the services. documentation requirements, billing and coding guidance, payment information, and resources for additional information.

1

#### Benefits of SBIRT Services

SBIRT services aim to prevent the unhealthy consequences of alcohol and drug use among those who may not reach the diagnostic level of a substance use disorder, and helping those with the disease of addiction enter and stay with treatment. You may easily use SBIRT services in primary care settings, enabling you to systematically screen and assist people who may not be seeking help for a substance use problem, but whose drinking or drug use may cause or complicate their ability to successfully handle health, work, or family issues. For more information on the benefits of SBIRT services, refer to http://www.integration.samhsa. gov/SBIRT Issue Brief.pdf on the Internet.

#### ICN 904084 June 2014

What Is SBIRT?

SBIRT is an early intervention approach that targets individuals with nondependent substance use to provide effective strategies for intervention prior to the need for more extensive or specialized treatment. This approach differs from the primary focus of specialized treatment of individuals with more severe substance use, or those who meet the criteria for diagnosis of a substance use disorder.



About SBIRT

#### Coding for Reimbursement

Reimbursement for screening and brief intervention is available through comm

substance use and identifies the appropriate

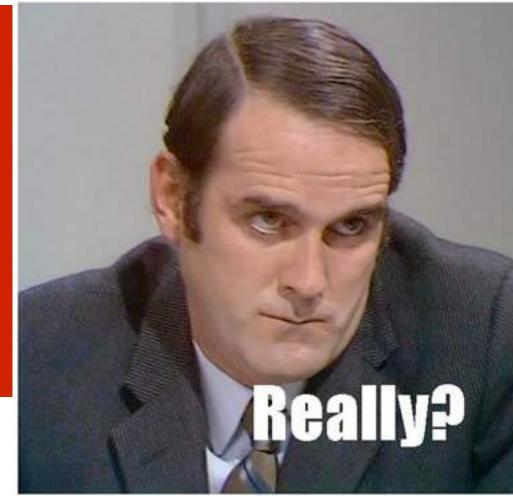
» Screening quickly assesses the severity of

# What the rest of the world thinks



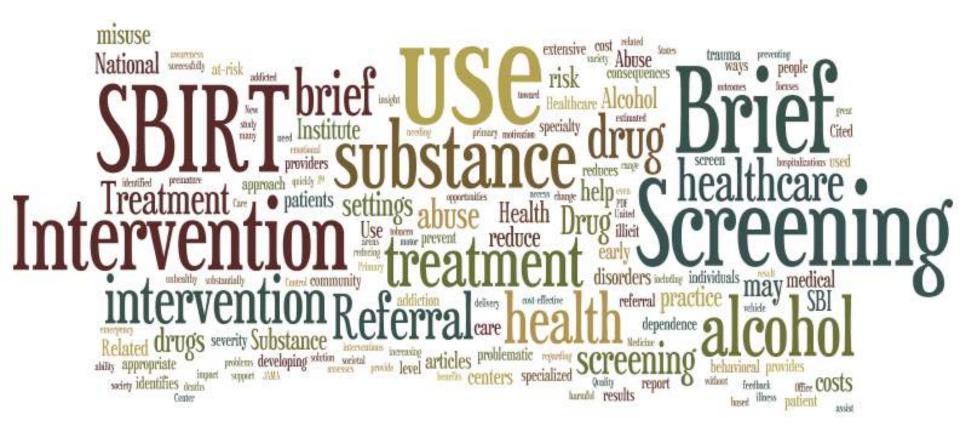
Saitz R. New Engl J Med 2005;352:596.

# **KEEP** CALM AND...ARE YOU KIDDING **ME??**









BOSTON

What happened to the evidence?





# UNKNOWN EFFECTIVENESS



# DOES NOT WORK



# Primary Medical Care Settings



- RCT in varied outpatient settings, 5 countries, n=731
  - Excluded mild and severe; 3-month follow-up
  - Small (clinically insignificant) decreases in drug use scores
    - Total score (range 0-338):
      - BI 36>30 vs Control 36>32 (7% diff)
      - In the US, Control was > effective (35>31 vs 39>31, 9% diff, p=0.11)
    - 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



Research

#### **Original Investigation**

### 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

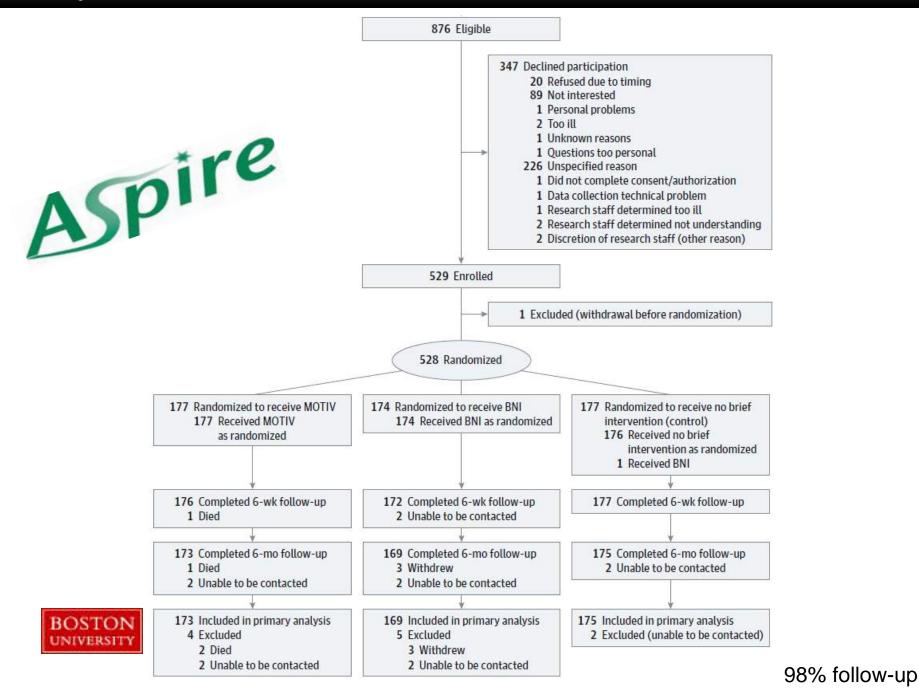
IMPORTANCE. The United States has invested substantially in screening and brief intervention for illicit drug use and prescription drug misuse, based in part on evidence of efficacy for unhealthy alcohol use. However, it is not a recommended universal preventive service in primary care because of lack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









	Study Entry (n = 528)								
Characteristic	Overall	BNI	MOTIV	Control					
Substance Use									
Main drug, No, (%) <sup>a</sup>	$\frown$								
Opioid (includes heroin, prescription, and others)	90 (17.1)	31 (17.8)	28 (15.8)	31 (17.5)					
Prescription opioid on y	30 (5.7)	8 (5.7)	10 (5.7)	12 (6.8)					
Cocaine	98 (18.6)	32 (18.4)	33 (18.6)	33 (18.6)					
Marijuana	331 (62.7)	109 (62.6)	111 (62.7)	111 (62.7)					
CIDI-SF positive <sup>b</sup>	245 (46.4)	80 (46.0)	83 (46.9)	82 (46.3)					
Tobacco use past year	403 (76.3)	142 (81.6)	130 (73.5)	131 (74.0)					

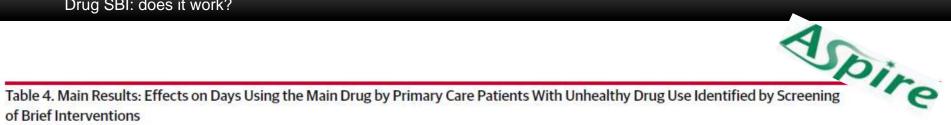




Days using main drug past 30 d	
Median (IQR)	12.0 (3.0-27.0)
Mean (SD)	14.4 (11.5)
Days >1 time using main drug past 30 d	
Median (IQR)	5.0 (0.0-18.0)
Mean (SD)	9.8 (11.1)
njection drug use past 8 mo, No. (%)	63 (12.1)
Jse of >1 drug past 90 d, No. (%)	167 (31.6)
Aisuse any prescription drug past 90 d, No. (%)	112 (21.2)
leavy alcohol or drug use bast 90 d, No. (%)	528 (100.0)
ny heavy drinking past nonth, No. (%)	254 (48.1)
lo. of heavy drinking days bast month	
Median (IQR)	0.0 (0.0-4.0)
Mean (SD)	4.5 (8.0)
SSIST Scores <sup>c</sup>	
SSIST score ≥27	97 (18.4)
ubstance-specific score	
Main drug, median (IQR)	15.0 (9.0-23.0)
Mean (SD)	16.8 (9.6)







		Predicte	ed Mean <sup>a</sup> No. of D in Past 30 Days	ays Usin <mark>g Main Drug<sup>b</sup> at 6 Months<sup>c</sup></mark>	BNI vs Contr	rol	MOTIV vs Co	ntrol
	No.	BNI	MOTIV	Control	IRR (95% CI)	P Value <sup>d</sup>	IRR (95% CI)	P Value <sup>d</sup>
Overall analysis <sup>e</sup>								
Unadjusted	517	14.2	14.1	13.8	1.03 (0.80-1.34)	.85	1.03 (0.79-1.33)	.85
Adjusted <sup>f</sup>	516	11.2	12.1	11.5	0.97 (0.77-1.22)	.81	1.05 (0.84-1.32)	.81
Stratified by Main	Drug <sup>b</sup>							
Opioids								
Unadjusted	88	7.0	8.0	8.8	0.80 (0.33-1.92)	.84	0.91 (0.38-2.21)	.84
Adjusted <sup>g</sup>	88	6.4	7.4	7.6	0.85 (0.35-2.07)	.96	0.98 (0.41-2.34)	.96
Cocaine								
Unadjusted	97	8.0	7.4	5.3	1.51 (0.78-2.91)	.31	1.41 (0.73-2.72)	.31
<b>Adjusted</b> <sup>g</sup>	97	5.7	7.2	5.0	1.15 (0.62-2.14)	.66	1.44 (0.78-2.65)	.48
Marijuana								
Unadjusted	323	18.3	18.2	18.0	1.02 (0.80-1.31)	.91	1.01 (0.79-1.30)	.91
Adjusted <sup>g</sup>	322	16.7	17.1	16.7	1.00 (0.80-1.25)	.99	1.02 (0.82-1.28)	.99
Stratified by ASSIS	T Score <sup>h</sup>							
ASSIST<27								
Unadjusted	424	14.3	14.3	14.2	1.01 (0.76-1.33)	.96	1.01 (0.76-1.33)	.96
Adjusted <sup>f</sup>	423	11.1	11.7	11.5	0.97 (0.76-1.23)	.86	1.02 (0.80-1.30)	.86
ASSIST≥27								
Unadjusted	93	13.5	13.1	12.2	1.11 (0.55-2.23)	.84	1.07 (0.54-2.12)	.84
Adjusted <sup>f</sup>	93	10.7	12.6	10.6	1.01 (0.52-1.98)	.97	1.19 (0.63-2.26)	.97

		Study Ent	try (n = 528)			6 Month	As (n = 517)	C
	Overall	BNI	MOTIV	Control	Overall	BNI	MOTIV	Control
SIP-D score, median (IQR) <sup>a</sup>	6.0 (1.0-21.0)	6.0 (1.0-19.0)	7.0 (1.0-23.0)	5.0 (1.0-18.5)	3.0 (0.0-16.0)	4.0 (0.0-14.0)	3.0 (0.0-16.0)	3.0 (0.0-16.0)
Mean (SD)	12.0 (13.6)	12.1 (13.8)	12.7 (13.7)	11.3 (13.3)	9.3 (11.7)	9.3 (11.8)	9.2 (11.3)	9.4 (12.1)
Unsafe sex past 3 mo, No. (%)	277 (57.6)	95 (59.0)	94 (58.0)	88 (55.7)	263 (55.8)	88 (55.4)	82 (51.9)	93 (60.4)
No. of unsafe sex encounters past 3 mo, median (IQR)	3.0 (0.0-13.5)	3.0 (0.0-17.0)	2.0 (0.0-10.0)	2.0 (0.0-13.0)	2.0 (0.0-15.0)	2.0 (0.0-10.0)	1.0 (0.0-12.0)	4.0 (0.0-15.5)
Mean (SD)	16.1 (39.7)	13.9 (24.2)	17.6 (46.7)	16.7 (44.5)	13.2 (29.0)	12.7 (26.0)	14.0 (38.0)	12.9 (19.9)
Unsafe sex with nonprimary or transactional partners past 3 mo, No. (%)	50 (10.3)	14 (8.6)	19 (11.7)	17 (10.6)	65 (13.5)	21 (13.1)	19 (11.7)	25 (15.6)
Hair Testing, No. (%) <sup>b</sup>								
Any drug use	475 (96.2)	160 (97.0)	158 (95.8)	157 (95.7)	422 (92.8)	142 (94.7)	142 (92.8)	138 (90.8)
Any drug use (missing as positive)	490 (96.3)	164 (97.0)	163 (95.9)	163 (95.9)	452 (93.2)	150 (94.9)	152 (93. <mark>2</mark> )	150 (91.5)
Any opioids	86 (18.4)	34 (22.2)	19 (12.2)	33 (20.1)	67 (16.3)	28 (20.9)	21 (15.6)	18 (12.6)
Any cocaine or benzoylecgonine	249 (53.4)	81 (52.9)	89 (56.7)	79 (50 5)	199 (49.1)	62 (45.9)	70 (52.2)	67 (49.3
Any carboxy-tetrahydrocannabinol	366 (75.6)	120 (75.9)	125 (77.2)	121 (73 8)	328 (74.7)	106 (73.1)	117 (79.6)	105 (71.4
Days using main drug past 30 d								
Median (IQR)	12.0 (3.0-27.0)	14.0 (3.0-28.0)	10.0 (3.0-27.0)	12.0 (3.0-28.0)	11.0 (2.0-29.0)	11.0 (2.0-29.0)	11.0 (2.0-28.0)	9.0 (2.0-29.0
Mean (SD) 1	14.4 (11.5) 1	6.1 (11.7)	13.8 (11.2)	14.3 (11.4)	14.0 (12.2)	14.2 (12.5)	14.1 (12.1)	13.8 (12.1)

#### **Original Investigation**

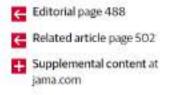
### Brief Intervention for Problem Drug Use in Safety-Net Primary Care Settings A Randomized Clinical Trial

Peter Roy-Byrne, MD; Kristin Burngardner, BS; Antoinette Krupski, PhD; Chris Dunn, PhD; Richard Ries, MD; Dennis Donovan, PhD; Imara I. 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).

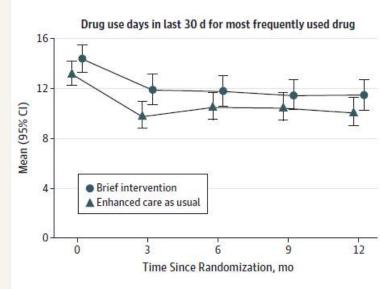
MAIN OUTCOMES AND MEASURES The primary outcomes were self-reported days of problem drug use in the past 30 days and Addiction Severity Index–Lite (ASI) Drug Use composite score. Secondary outcomes were admission to substance abuse treatment; ASI composite scores for medical, psychiatric, social, and 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,  $\beta$  = 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 not significantly different 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,  $\beta$  = 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

"This finding suggests a need for caution in promoting widespread adoption of this intervention for drug use in primary care."



BI 14 >>12 d/30, ASI 0.11>>0.10 UC 13 >>10 d/30, ASI 0.11>>0.09 Favors control group

JAMA. 2014;312(5):492-501. doi:10.1001/jama.2014.7860

Drug SBI: does it work?

### ASPIRE secondary and subgroup analyses

\*\*No differences in drug use consequences (SIP-D), injection drug use, unsafe sex, hospitalizations, ED visits, or for mutual help group attendance.

\*\*No effects in ASSIST 4-15, 16-26 No effects in ≥5 vs <5 days use

\*\*No interactions with significant interactions with readiness, anxiety, depression, pain.

\*\*No effect for daily marijuana (Fuster D et al. in press)

\*\*Among a subgroup of 23 participants who also had marijuana consequences AND ASSIST scores of 27 or greater, MI was associated with fewer days of marijuana use (mean, 8 vs 20 for BNI, 21 for control; P = .06)

### **ROY-BYRNE Study secondary and subgroup analyses**

\*\*No differences in any ASI severity (drug, med, psych, social, legal), arrests, HIV risk behaviors, hospital and ED utilization, mortality

\*\*BI group with high drug problem severity more likely to enter specialist drug treatment (26% vs 16%) and more likely to reduce ED use (2.6 vs. 4 visits/yr among those w/>1 visit)







JAMA. 2014;312(5):502-513. doi:10.1001/jama.2014.7862. JAMA. 2014;312(5):492-501. doi:10.1001/jama.2014.7860

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

ASSIST scores 2,3 only. Adjusted for baseline use. Baseline unadj. mean=3.4 days

		No BI	BNI	MOTIV	BNI vs. r	no Bl	MOTIV v BI	s. no
	Ν	Ad	justec	d Means	IRR (95% CI)	p- value	IRR (95% CI)	p- value
Days used main drug	57	6.4	2.1	2.3	0.33 (0.15,0.74)	0.01	0.36 (0.15,0.85)	0.02
Explorato	ory	anal	yses	stratifie	d by main	drug	<b>A</b> 5	bire
Days used main drug (Cocaine, Opioids, and Other)	17	2.3	0.3	1.9	0.12 (0.03,0.43)	0.003	0.81 (0.17,3.91)	0.79
Days used main drug -Marijuana	40	7.4	3.6	3.1	0.49 (0.19,1.25)	0.13	0.42 (0.15,1.14)	0.13

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" druguse health education/reinforcement telephone sessions. CONTROL: information on cancer screening.

PARTICIPANTS: n=334, 3 mo. follow-up 78%.

RESULTS: Reduction in days use of the highest scoring drug 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



# Other Settings



#### Drug SBI: does it work?

#### **Original Investigation**

#### Brief Intervention for Patients With Problematic Drug Use Presenting in Emergency Departments A Randomized Clinical Trial

Michael P. Bogenschulz, MD: Dennis M. Donovan, PhD: Raul N. Mandler, MD: Hanold L. Pert, PHD: Alysia A. Foroshimes, PhD: Camerion Crandall, MD, PhD: Robert Lindblad, MD: Neal L. Oden, PhD: Sarara Sharma, PhD: Lina Metsch, PhD. Michael S. Ljusin, MD, MPH: Ryan McConnack, MD; Wendy Micciael Konstantopodes, MD, MPH: Antonie Douality, MD.

INPORTANCE Medical treatment settings such as emergency departments (EDs) present important opportunities to address problematic substance use. Currently, EDs do not typically intervene beyond acute medical stabilization.

ORIECTIVE. To contrast the effects of a brief intervention with telephone boosters (8I-8) with those of screening, assessment, and referral to treatment (SAR) and minimal screening only (MSO) among fung using ED patients.

DESIGN, SETTING, AND PARTICUMENTS: Between October 2010 and February 2012, 1285 adult ID patients from 6 US academic hospitals, who scored 3 or greater on the 10-term Drug Abure Screening Test Undicating moderate to servere problems related to drug use) and who were currently using drugs, were randomized to MSO (n = 431), SAR (n = 427), or Bi-8 (n = 427), Follow-up assessments were conducted at 3, 6, and 12 months by blended interviewers.

INTERVENTIONS Following screening, MSO participants received only an informational pamphiet. The SAR participants received assessment plas referral to addiction treatment if indicated, and the BI-B participants received assessment and referral as in SAR, plus a manual-guided counseling session based on motivational interviewing principles and up to 2 "booster" sessions by telephone during the month following the ED visit. N=1,284 Mean age 36 44% cannabis 16 days use/mo

	Da	Days of Use of the Primary Drug of Abuse in the Past 30 d at the 3-mo Visit									
	Normal	Model	β-Binom	β-Binomial Model							
	Hair drug test	Primary	drug	Any drug		lue Adjusted					
MSO vs BI-B SAR vs BI-B	Baseline	93%		98%		.63					
SAR vs MSO Baseline us. Jays	3 months	90%		96%		.36 NA*					
DAST-10 score	-0.5581 (-0.8525 to -0.2657)	.001	1111	0.0000 (0.0044 to 0.9278)	<.001	NA*					
AUDIT-C score	-0.1811 (-0.3520 to -0.01019)	.04	NA*	0.9702 (0.9501 to 0.9907)	.02	NA*					
Site (variance)	3.99	.08	NA <sup>a</sup>	NA <sup>b</sup>	NA	NA <sup>a</sup>					
Error (variance)	113.62	<.001	NA*	NA <sup>b</sup>	NA	NA*					

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.

<sup>a</sup> Not adjusted for multiple testing in the model.

<sup>b</sup> The β-binomial model does not include an error term, and site was not included in this model because the β-binomial model does not allow a random site effect.

JAMA Intern Med. 2014;174(11):1736-1745. doi:10.1001/jamainternmed.2014.4052 Published online September 1, 2014.

#### Blow et al. 2015 (June)

RCT computer v. in person BI v. UC; n=780 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 (not computer) reduced self-reported days drug use over 6-12 mo (effect size 0.2; by approx. 13/90 days, from 46 to 33) Booster did not add

Blow FC et al. Poster, and Abstract book p.14 CPDD 77th Annual Meeting • Arizona Biltmore, Phoenix, Arizona



Woodruff SI et al. *Addict Sci Clin Pract* (2014) 9:8.doi: 10.1186/1940-0640-9-8

RCT in person BI n=700 ED patients --42% follow-up at 6 months. Hair testing.

No difference in abstinence or ASI-Lite drug use score



# Other RCTs

- Short-term decrease in addictive prescription drug use by adult hospitalized patients (n=126)
- 2 RCT in adults in urgent care (n=1175)
  - 5-9% increase in cocaine/heroin abstinence
  - No difference in linkage to treatment



Zahradnik A, et al. Addiction. 2009;104(1):109–117 Otto C, et al. Drug Alcohol Depend 2009;105:221-6 Bernstein et al. Drug Alcohol Depend 2005;77:49

		Example: "Heart attack" AND "Los Angeles"				
ClinicalTrials.gov	s	Search for studies:				Search
A service of the U.S. National Institutes of Health			Advanced Search	Help	Studies by Topic	Glossary
Find Studies About Clinical Studies Submit St	udies Resources About This Site					
Home > Find Studies > Study Record Detail					т	ext Size 🔻
Multidisciplinary Approach to Reduce Injury a	nd Substance Abuse					
This study is ongoing, but not recruiting participants.	ClinicalTrials.gov Identifier: NCT01048359					
Sponsor: University of Texas at Austin	First received: January 11, 2010 Last updated: June 23, 2015					
Collaborator: National Institute on Drug Abuse (NIDA)	Last verified: June 2015 History of Changes					
Information provided by (Responsible Party): University of Texas at Austin						
Full Text View Tabular View No Study Results	Posted Disclaimer I How to Read a Study Record	t				

#### Purpose

BO

The primary purpose of the project entitled: Multidisciplinary Approach to Reduce Injury and Substance Abuse, which is funded by the National Institute on Drug Abuse (5R01DA026088-02), is to compare the effectiveness of brief intervention, brief intervention plus a booster, and brief advice for adult patients who abuse drugs and present to a trauma department for treatment of an injury.

Condition	Intervention Phase						
Drug Abuse	Behavioral: Brief advice     Phase 3       Behavioral: Brief Intervention plus Booster     Phase 3       Behavioral: Brief Intervention     Phase 3						
	Estimated Enrollment: 930						
OSTON NIVERSITY	Primary Completion Date: April 2014						
	(Final data collection date for primary outcome measure)						
	Velasquez MM, Field CA co-P	'ls					
	Von Sternberg K Co-I						

SBI: does it work?	Original Investigation
	Emergency Department-Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence A Randomized Clinical Trial
	Gail D'Onofrio, MD, MS; Patrick G. O'Connor, MD, MPH; Michael V. Pantalon, PhD; Marek C. Chawarski, PhD; Susan H. Busch, PhD; Patricia H. Owens, MS; Steven L. Bernstein, MD; David A. Fiellin, MD
	IMPORTANCE OploId-dependent patients often use the emergency department (ED) for medical care.
(screen), TRE	A Community-based treatment services (brief intervention); and (3) screening, brief intervention, ED-initiated treatment with buprenorphine/haloxone, and referral to primary care for 10-week follow-up (buprenorphine).
✓ increased e	ngagement in addiction treatment (78% vs 41%),
✓ reduced sel	f-reported illicit opioid use (5 to 1 vs 2 days/wk)
✓ decreased ι	use of inpatient addiction treatment services
	treatment services were the secondary outcomes. <b>rease the rates of urine samples positive for opioids</b> 70%-85%] vs 37% in the referal group (38 of 102 [95% CL, 28%-47%]) and 45% in the brief Intervention group (50 of 111 [95% CL, 36%-54%]) were engaged in addiction treatment on the 30th day after randomization (P< .001). The buprenorphine group reduced the number of days of illect opioid use per week from 5.4 days (95% CL, 5.1-5.7) to 0.9 days (95% CL, 0.5-1.3) vs a
	treatment, 9% overdose, 73% past drug treatment une samples that tested negative for opiolds did not differ statistically across groups, with 53.8% (95% Cl. 42%-65%) in the referral group, 42.9% (95% Cl. 31%-55%) in the brief intervention group, and 57.6% (95% Cl. 47%-68%) in the buprenorphine group (P = 17). There were no statistically significant differences in HU tok across groups (P = 66). Eleven percent of
(*e.g. Terrific	Author Affiliations: Department of Emargency Medicine, Vala School of Medici



TRIAL REGISTRATION dinicaltrials.gov identifier: NCT00913770

JAMA. 2015;313(16):1636-1644. doi:10.1001/jama.2015.3474

In other centers before widespread adoption.

Medicine, Yale School of Madicine, New Harven, Connecticut (O'Connor, Fiellin): Department of Psychiatry, Yale School of Medicine, New Haven, Connecticut (Chawarski): Yale School of Public Health, New Haven, Connecticut (Basch, Fiellin). Corresponding Author: Gall D'Onofrio, MD, MS, Department of Emergency Medicine, Yale School of Medicine, 464 Congress Are, Sta 260, New Haven, CT OSIS9

(gail.donofrio@yale.edu).

















"If it's all the same to you, I'd rather eat this not knowing what the latest science suggests."

# Counting Drug SBI RCTs and n's

- Primary care
  - 2 null, n=1,396
  - 1 positive, n=334 (abstract; publication imminent)
  - 1 positive pilot for low risk (n=61)(abstract; publication not imminent)
- Emergency Department
  - 1 null, n=1,285 (multi-site)
  - 1 null, n=700 (58% loss to follow-up)
  - 1 ?null, n (projected)=930 (trauma; not presented)
  - 1 positive, n=780 (abstract; publication pending)
- Various sites
  - 1 mixed results, mixed sites, n=731, clinically insignificant
  - 1 positive, mixed sites (urgent, ortho, women's) n=1,175



# Summarizing Drug SBI RCTs

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

Adding methodological differences: may favor null studies.

But can/should SBI studies be combined? \*Electronic (computer, video) components \*Involvement of physician (Gelberg et al advice, video)





Richard Saitz 12 \*

#### frontiers in PSYCHIATRY

REVIEW ARTICLE published: 16 July 2014 doi: 10.3389/fpsyt.2014.00085

#### Interpreting null findings from trials of alcohol brief interventions

#### Nick Heather \*

Department of Psychology, Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne, UK

- Null hypothesis significance testing—limited
  - Effects of control group procedures
  - Regression to the mean
  - Research participation effects
    - Assessment reactivity
  - Historical/secular/time/natural history trends
    - Note: in Saitz et al use did not decrease, differences 0; in Roy-Byrne et al effect estimates favored *control*; thus unlikely due to any of above

#### Bayesian approach

 e.g. prior to doing the study, how likely is it that a brief conversation with someone newly identified as at risk from drug use will in response, reduce or stop their use?



#### DISTINGUISHING BETWEEN ABSENCE OF EVIDENCE + EVIDENCE OF ABSENCE

#### What do I think we know?

- Evidence of absent effect: 1-2 brief motivational counseling sessions by counselors not previously known to the patient (identified by universal screening), in primary care, has no efficacy for reducing drug use or consequences
- Probably evidence of absent effect: emergency department

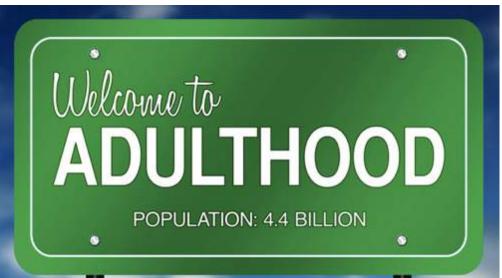


### Not surprising, we are not alone.

- RCT of BI for intimate partner violence and alcohol
  - Null (for IPV incidents and days heavy drinking)
- RCT of BI for intimate partner violence
  - Null
- Life is too complicated for BI







Rhodes KV et al. *JAMA* 2015;314:466-77

Klevens J et al. *JAMA* 2012;308;681-9

Klevens J et al. *JAMA* 2015;314;515-6

- When you identify someone, treat them! And don't make it so difficult! (D'Onofrio et al, 2015)
- Corollary: RT as currently done as part of "SBIRT" doesn't work
  - Evidence: very few go; no more go as a result of 'BIRT'



#### LACK OF, FOR THE RT IN SBIRT

Addiction



SSA

#### Addiction

#### Commentaries on Glass et al. (2015)

#### 'SBIRT' IS THE ANSWER! PROBABLY NOT

Screening, brief intervention and referral to treatment (SBIRT) addresses the full spectrum of unhealthy substance use [1]. It sounds like the answer to the question: 'how can we reduce substance use and disorders?' by addressing everything except the delivery of specialized treatment itself. The best evidence suggests that brief evidence-based services). A tail order. The second question is how to best treat people with a disorder (e.g. dependence) who come to treatment having been identified by screening, who may be even more ambivalent about change than seekers of treatment. Treating them with a referral to treatment assumes that treatment will be received and have efficacy: but efficacy of treatment is only known for treatment seekers (or when mandated), not people identified by



Glass JE et al. *Addiction* 2015; 110:1404–15. Saitz R. *Addiction* 2015;110:1416–17.

- Biological testing may be very important, especially testing that covers the self-report period
- D'Onofrio 2015: Intervention affected self-report, not urine results
- Studies using hair testing (90 day)>>null and consistent
  - Bogenschutz, Saitz, Woodruff
- Alcohol SBI consistently yields modest effects on self report use (among those with risky, not heavy disordered use, in PC)
  - In systematic reviews, no consistent effects on biological measures, alcohol consequences (including medical), hospitalizations, emergency department visits...
  - So, does *alcohol* SBI "work"?



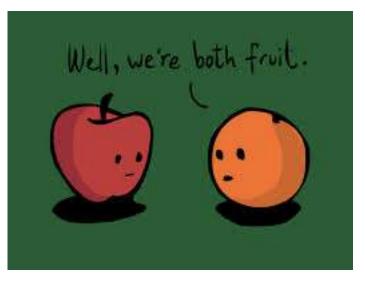
- Context/setting matter
  - PC: consistent modest effects (alcohol consumption)
  - ED: good place to start urgent drug Rx (D'Onofrio); mixed findings for alcohol (signal for more severe? Field C et al 2010 alc-rel injury+dep)
  - Hospital: Difficult to detect efficacy (4 RCTs find effects on selfreport alcohol use but no other outcomes; null when study with highest risk of bias excluded (McQueen Cochrane review 2011)
    - Keep an eye out for J Freyer-Adam ELECTRONIC alcohol SBI hospital—presented at ICTAB 2015 Odense
  - Drug: Will it work anywhere? Skip SBI and go to Rx directly?





#### Severity and nature of risk

- Illicit/illegal nature? Perceived risk? Disorder severity?
- Alcohol SBI lit suggests 'narrow band' for efficacy; translatable to drug? Is the band so narrow as to not be clinically useful?
- Intervention details may matter
  - Confounded (i.e. duration and motivational)





## Maybe computer?

- Gelberg et al had electronic components
  - Fidelity advantages
  - Longitudinal therapeutic alliance disadvantages?
- Ondersma et al. 2014
  - eSBI drug n=143 postpartum women.
  - OR 3 for abstinence at 3 mo, OR 4 for neg hair test at 6 mo.
- But...alcohol eSBI null (systematic review 2015)?
  - Decrease 1 drink per week at 6 but not 12 mo (self-report); no difference in risky drinking)



Ondersma et al. J Subst Abuse Treat 2014;46:52-9 Dedert EA et al. Ann Intern Med 2015;163:205-14

### **Research implications**

 Findings are generally null. Will funders and peers be convinced that further efficacy testing is warranted? Will policy-makers and SBIRT implementers continue to disseminate it without or until further research?

#### Needed (?) studies

- Meta-analysis
- Biological testing
- Clinically important outcomes, combined pre-specified outcomes (e.g. coc, alcohol)
- Interventions that are integrated into general health care, repeated and not so brief
- Electronic components with human touch, other clinicians
- Interventions for multiple risks
- Clarify intervention components, details (more reviews may help)
- Ever more focused subgroups? Even greater attention to fidelity? Focus on more advantaged populations?





# WHY ARE WE (MOSTLY) STUDYING PREVENTION OF A RISK THAT BEGINS IN YOUTH, IN ADULTS? AND (MOSTLY) NOT STUDYING YOUTH?

# Some youth drug SBI RCTs

- n=59 adolescents in primary care in Brazil-decreased MJ and stimulant use and problems
- ② Decreased marijuana use by adolescents in the emergency department in a pilot study (n=210)
- ③ Decreased cannabis problems and drug use (computer BI) and cannabis DUI (therapist) by adolescents in primary care (n=328)
- ④ Computer (but not therapist) BI prevented cannabis (17% vs 24%, 1 yr) use in adolescents in primary care (n=714)

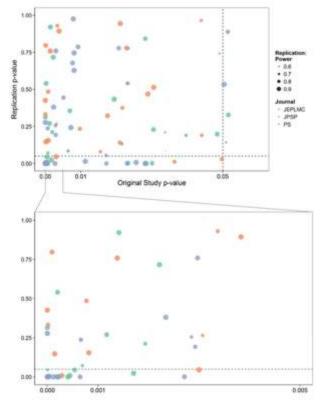


DeMicheli D et al. Rev Assoc Med Bras 2004; 50(3): 305-13 Bernstein E et al. Acad Emerg Med 2009; 16: 1174-85 Walton MA (Blow) et al. Drug Alcohol Dependence 2013;132;646-53. Walton MA (Blow) et al. Addiction 2013;109:786-97.

# We spend lots of time and effort with critical appraisal of null studies. But...

Addiction	SSA incorrent
EDITORIAL	doi:10.1111/add.12954
	to address confirmation bias prevention interventions for
adolescents	

The evidence base of prevention research appears to comprise predominantly chance findings that emerge from flexible data analysis practices motivated by confirmation bias. This area needs to urgently adopt the kinds of mandatory pre-registration practices required of clinical trials as a first step to creating a credible evidence base. constitutes statistical significance or a primary outcome variable [13,14]. The latter argument would be more compelling were it not for the fact that use of flexible data analytical practices frequently results in minute differences between intervention and control groups being statistically significant and then program developers pre-





Gorman DM. Addiction 2015;110;1539-40. Aarts AA et al. Science 28 August 2015: Vol. 349 no. 6251

#### EVIDENCE BASED MEDICINE (EBM)

#### Evidence-informed person-centered healthcare (part I): Do 'cognitive biases plus' at organizational levels influence quality of evidence?

Shashi S. Seshia MD FRCP,<sup>1</sup> Michael Makhinson MD PhD,<sup>23</sup> Dawn F. Phillips PhD<sup>4</sup> and G. Bryan Young MD FRCP<sup>56</sup>

- Self-serving (e.g. COI) Anchoring (focus) Confirmation In group conformity Affect heuristic (feel good) Framing effects (of evidence) Search satisficing (satisfy and suffice) Consistency tendency Reductionism Overconfidence Automation Novelty
- Optimism Intellectual/belief/advocacy Halo effect Groupthink Inside the box Herd effect Specialty bias Scientific inbreeding Sunk cost fallacy Fallacy of silence Planning fallacy



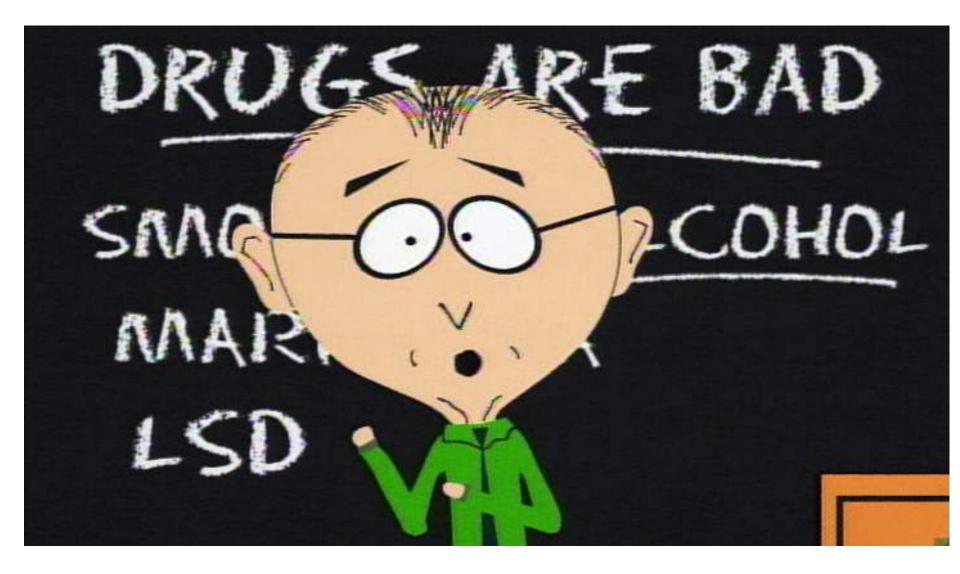
### Thoughts.

 Even positive SBI studies find small effects, on use (only, and, maybe). Difficult to maintain fidelity, clinical effects, in real practice.

"A leading hypothesis to explain the null findings of the SIPS and PRE-EMPT trials is that they are due to lack of fidelity in the implementation of BI in large, complex, cluster randomized trials" Heather N.

> Kaner E et al (Heather). (SIPS) *BMJ* 2013;346:e8501 Van Beurden I et al (Anderson) *Addiction* 2012 107:1601–1611 Butler CC (McCambridge, Rollnick)(PRE-EMPT) *BMJ* 2013, 346:f1191. Williams EC et al. *Addiction* 2014;109(9):1472–1481 Zatzick D et al. *Addiction* 2014;109: 754–765 Bendtsen P et al. ODHIN study. *Alcohol* Alcohol 2015 (5% screened) Heather N. *Addiction Sci Clin Prac* 2014, 9:13





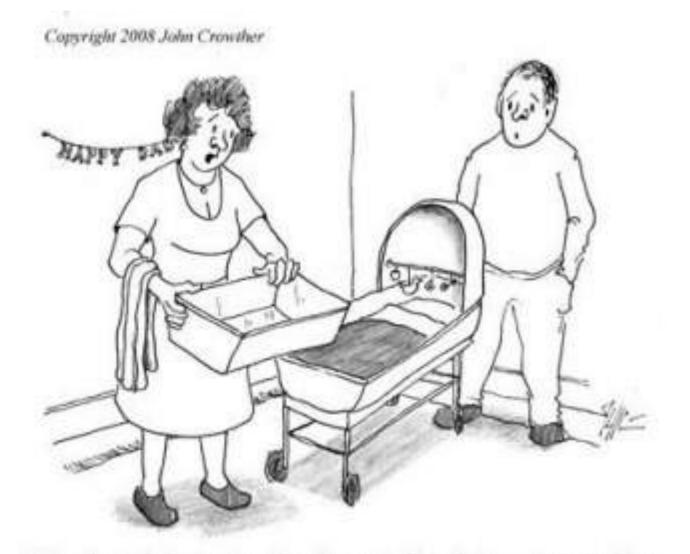


## Thoughts.

- Extended Precautionary Principle:
  - "Substance use is a big problem; we have to do something about it"
  - SBIRT is "cheap" (not really)
    - Itself.
    - Opportunity costs.
    - Adverse effects (confidentiality; of BI done poorly).
  - Action in face of uncertainty is not without consequences

Precautionary principle (i.e. not extended): if an action or policy has a suspected risk of causing harm to the public or to the environment, in the absence of scientific consensus that the action or policy is not harmful, the burden of proof that it is not harmful falls on those taking an action. (primum non nocere)





"I've heard the saying, but I never thought it was something that could actually happen."



## Thoughts.

- Policymakers believe in this; practitioners, researchers and patients have known all along it is more complicated
- Evidence does not make decisions; it informs us what to expect from our actions
  - Don't expect much in terms of less use from SBI (alcohol or drug)
    - Even best evidence for alcohol SBI in PC, >50% still drinking too much
- 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...)
  - To get staff in clinics to address substance disorders
  - To get substance use considered a health risk and condition
- Better approaches are needed. Really.



rsaitz@bu.edu @unhealthyalcdrg @JAM\_lww @EvidBaseMed\_BMJ http://www.bumc.bu.edu/care/ http://www.bu.edu/sph/academics/departments/community-health-sciences/













#### Drug SBI: does it work?

### 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



Kaner et al. BMJ 2013;346:e8501 doi: 10.1136/bmj.e8501

Effectiveness of screening and brief alcohol intervention in primary care (SIPS trial): pragmatic cluster randomised controlled trial

ING:

Alcohol Screening and Brief Interventions From Research Into Dractice A one day conference including findings from the SIPS Alcohol Screening and Brief Intervention Trials and the launch of SIPS Junior

Institute of Psychiatry, King's College London

Outline programme and application details on reverse

1.1. Int OLD KINDS HEATH MATNERS



8MJ 2013:346 elt601 por: 10.1136 brig elt601 (Published 9 January 20

RESEARCH

#### Cautions for the real world

alcohol problems: a randomized controlled trial of a tailored improvement programme RCT of extensive implementation effort led to no increase and between group differences in screening of (10%) and advice to atrisk drinkers (3%) •(No effect on drinking)

Ivonne van Beurden<sup>1</sup>, Peter Anderson<sup>2,1</sup>, Reinier P. Akkermans<sup>1</sup>, Richard P. T. M. Grol<sup>1</sup>, Hammings I hadro of Hadro Produces and Life Guideline provided Reminder card on desk 2-3 hr. evening training with dinner Feedback re: their own patients screened Facilitated linkage to local addiction treatment programs Outreach by trained facilitator Provision of self-help materials for distribution Waiting room poster

ANTERIETERORIETERTISTICS

Involvement of general practitioners in managing

SEARCH REPORT



van Beurden, Anderson et al. Addiction 2012 DOI: 10.1111/j.1360-0443.2012.03868.x 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)





#### What happens in real life screening and brief intervention EVEN WHEN PRACTITIONERS KNOW THEY ARE BEING OBSERVED?

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

Audiotaped encounters with clinicians who were aware they were being recorded

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 Bradley KA and Williams EC. Principles of Addiction Medicine. 2009. Lapham et al, Med Care, 2012 Williams EC et al. abstract presentations INEBRIA 2011, 2012

	Study Entry (n = 528)			
<b>Characteristic</b>	Overall	BNI	MOTIV	Control
Male sex, No. (%)	369 (69.9)	124 (71.3)	126 (71.2)	119 (67.2)
Race/ethnicity, No. (%) <sup>a</sup>				
Black	357 (68.8)	116 (68.2)	126 (72.4)	115 (65.7)
Hispanic	50 (9.6)	18 (10.6)	11 (6.3)	21 (12.0)
White	105 (20.2)	32 (18.8)	37 (21.3)	36 (20.6)
Other	7 (1.4)	4 (2.4)	0	3 (1.7)
Age, mean (SD), y	41.3 (12)	40.0 (12.2)	42.6 (12.2)	41.3 (12.5)
High school graduate or equivalent, No. (%)	369 (69.9)	119 (68.4)	127 (71.8)	123 (69.5)
Never married, No. (%)	328 (62.1)	105 (60.3)	108 (61.0)	115 (65.0)
Health insurance, No. (%)				
Private/commercial <sup>b</sup>	69 (13.1)	24 (13.8)	18 (10.2)	27 (15.3)
Medicaid/Medicare <sup>c</sup>	429 (81.3)	138 (79.3)	153 (86.4)	138 (78.0)
None	30 (5.7)	12 (6.9)	6 (3.4)	12 (6.8)

70.3 (20.4)
189 (35.8)
176 (33.3)
75 (14.2)
29 (5.5)
189 (35.8)
47 (8.9)
93 (17.6)
43 (8.1)
119 (22.6)



Drug SBI: Does it work?

AM. J. DRUG ALCOHOL ABUSE, 23(3), pp. 343-354 (1997)

#### Physician Unawareness of Serious Substance Abuse

Richard Saitz, M.D., M.P.H.<sup>1\*</sup> Kevin P. Mulvey, Ph.D.<sup>2,5</sup> Alonzo Plough, Ph.D., M.P.H.<sup>2,3,5</sup> Jeffrey H. Samet, M.D., M.A., M.P.H.<sup>1,2,4</sup>

<sup>1</sup>Clinical Addiction, Research and Education Unit Section of General Internal Medicine Boston Medical Center Boston University School of Medicine





## RANDOMIZED TRIALS OF <u>SCREENING AND BRIEF</u> INTERVENTION VS. <u>NO SCREENING</u>

#### NONE



## EFFICACY of BI among screen-identified patients with non-dependent unhealthy alcohol use

- Efficacious: 10-15" multi-contact
  - >23 original RCTs,\* 9 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 (<u>></u>2 RCTs)
      - Cost-effective (spend \$166, save \$546 medical, \$7780 society)
      - Decreased mortality (RR 0.47)(4 RCTs (n=1640)

\*Jonas DE et al. Ann Intern Med 2012 Kaner et al. Drug and Alcohol Review 2009;28:301–23 \*\*Beich et al. BMJ 2003;327:536 \*\*\*Bertholet et al. Arch Intern Med. 2005;165:986 Kristenson H, et al. Alcohol Clin Exp Res 1983;7:203 (mortality) Fleming MF et al. Alcohol Clin Exp Res. 2002;26(1):36-43 (cost) Cuijpers et al. Addiction 2004;99: 839–845 (mortality)



## 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



Whitlock et al. Ann Intern Med 2004;140:557-68 Kaner EFS et al. Ment Health Subst Use. 2011;4(1):38–61 Saitz R. Drug Alcohol Rev 2010; 29:631-640. Jonas DE et al. Ann Intern Med 2012;157(9):645-654. Kaner et al. Drug and Alcohol Review 2009;28:301–23



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

Richard Saitz 12 \*

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

Citation	Intervention	Result (between group differences at follow-up)	Comment
Gelberg et al. (34)	Very brief advice, video doctor, and two booster sessions	Less frequent (4 days) drug use at 3 months; effect larger among more severe	78% Follow-up; attention control; no biological testing; excluded those with likely moderate to severe disorder
Roy-Byrne et al. (35, 48)	Single BI with 1 week phone booster done by social workers	3, 6, 9, and 12 months outcomes. No significant differences in days drug use or drug use severity	Biological testing; 87% follow-up
Saitz et al. (36, 37)	Single 10–15 min health promotion advocate/health educator BI 45-min psychologist BI with one booster	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	Biological testing; 98% follow-up
Humeniuk et al. (38)	Single BI largely done by clinic staff (some by researchers in Brazil)	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	86% Follow-up; no biological testing; excluded those likely to have moderate to severe disorder <sup>b</sup>
Bernstein et al. (39)	Single BI done by health promotion advocate	5% Absolute risk increase in cocaine abstinence; 9% risk increase in opioid abstinence	Biological testing; 82% follow-up <sup>b</sup>

"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).

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Gelberg et al. APHA abstract 2014. Community health center primary care. Bernstein et al. Drug Alcohol Depend 2005;77:49. Urgent care. Humeniuk R, et al. Addiction 2012;107:957-66. Diverse outpatient settings.

# 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?





### **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 McQueen J et al. *Cochrane Database Syst Rev* 2011;8:CD005191. DOI: 10.1002/14651858.CD005191.pub3. NB 2009 "inconclusive"





#### Trauma centers-hospitalized patients

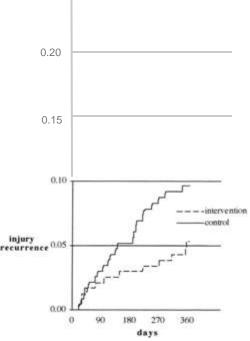
#### 1999, n=762

#### 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

Represents a difference of 15 injuries (approx. 35 vs. 20 injuries) (approximated from figure; numbers do not appear in paper)





Gentilello LM et al. Ann Surg 1999;230:473 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

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RESEARCH REPORT

doi:10.1111/add.12492

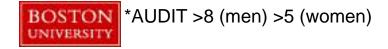
Disseminating alcohol screening and brief intervention at trauma centers: a policy-relevant cluster randomized effectiveness trial<sup>\*</sup>

Douglas Zatzick<sup>1</sup>, Dennis M. Donovan<sup>2</sup>, Gregory Jurkovich<sup>3</sup>, Larry Gentilello<sup>1</sup>, Chris Dunn<sup>4</sup>, Joan Russo<sup>4</sup>, Jin Wang<sup>1</sup>, Christopher D. Zatzick<sup>5</sup>, Jeff Love<sup>4</sup>, Collin McFadden<sup>4</sup> & Frederick P. Rivara<sup>6</sup>



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



#### **Emergency Departments**

- 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: <u>risky</u> use or alcohol+injury, n=500, no effect
  - 2012: <u>risky</u> 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



Nilsen P et al. J Subst Abuse Treat 2008; 35:184-201 Havard A et al. Addiction 2008; 103:368-76 D'Onofrio G et al. Ann Emerg Med. 2008; 51(6):742-750 D'Onofrio G et al. Ann Emerg Med 2012;60(2):181-92.

HEAVIER 20-21drks/wk, 7-8 HDDs/mo; mean AUDIT 11-12

LIGHTER

DRINKING

2/3rds AUDIT<8

12-14 drks/wk, 5-6 HDDs/mo;

### 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
  - Meta-analysis will likely yield null findings



Table 4. Hair Analysis Results

Bas <mark>eline and Follow-up</mark> Visit	Positive Hair Sample, No./Total (%)				
	BI-B	SAR	MSO	Total	
Primary drug					
Baseline	332/352 (94)	313/338 (93)	325/354 (92)	970/1044 (93)	
3 mo <sup>a</sup>	244/275 (89)	265/280 (95)	253/287 (88)	762/842 (90)	
6 mo	244/282 (87)	255/282 (90)	257/294 (87)	756/858 (88)	
12 mo	220/265 (83)	222/268 (83)	229/269 (85)	671/802 (84)	
Any drug					
Baseline	358/367 (98)	334/ <mark>3</mark> 43 (97)	353/360 (98)	1045/1070 (98)	
3 mo	263/274 (96)	278/285 (98)	266/282 (94)	807/841 (96)	
6 mo	267/275 (97)	276/282 (98)	277/290 (96)	820/847 (97)	
12 mo	241/260 (93)	251/264 (95)	256/268 (96)	748/792 (94)	

