What we know and don't know about brief intervention effectiveness

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of the Boston University School of Medicine.

SCOPE OF TOPIC

EVIDENCE WE SHOULD HAVE

EVIDENCE WE DO HAVE

KNOWN UNKNOWNS

SCOPE OF TOPIC

SCOPE OF TOPIC

- General healthcare, not addiction specialty or referral center
  - Primary care
  - Hospital (general medical)
  - Emergency
    - Trauma
- Brief intervention among people identified by screening (SBI)
  - Screening=before symptoms are apparent
    - Not the same as asking about use to avoid medication interaction or as part of diagnostic evaluation of symptomatic disease
    - Goal is identification that would otherwise not be made, anticipating that brief intervention will improve health
- Alcohol and other drugs (except tobacco)

Primary care=Accessible longitudinal and continuous services provided by clinicians accountable for addressing a large majority of a person's health care needs

UNHEALTHY USE

The NEW ENGLAND JOURNAL of MEDICINE

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

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EVIDENCE WE SHOULD HAVE

What in heaven's name, for instance, is "evidence-based medicine''? Here is a quote from the august British Medical Journal that should set us straight: "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.'' And the opposite of this would be . . . divination? Are men and women trooping out of the nation's medical schools trained to flip coins or toss the I Ching on the floor of the intensive care unit if a diagnosis isn't quickly forthcoming?


alex beam

Knowledge-based gibberish

Those in politics, medicine, and business who rely on annoying verbal ties often don't have their facts straight

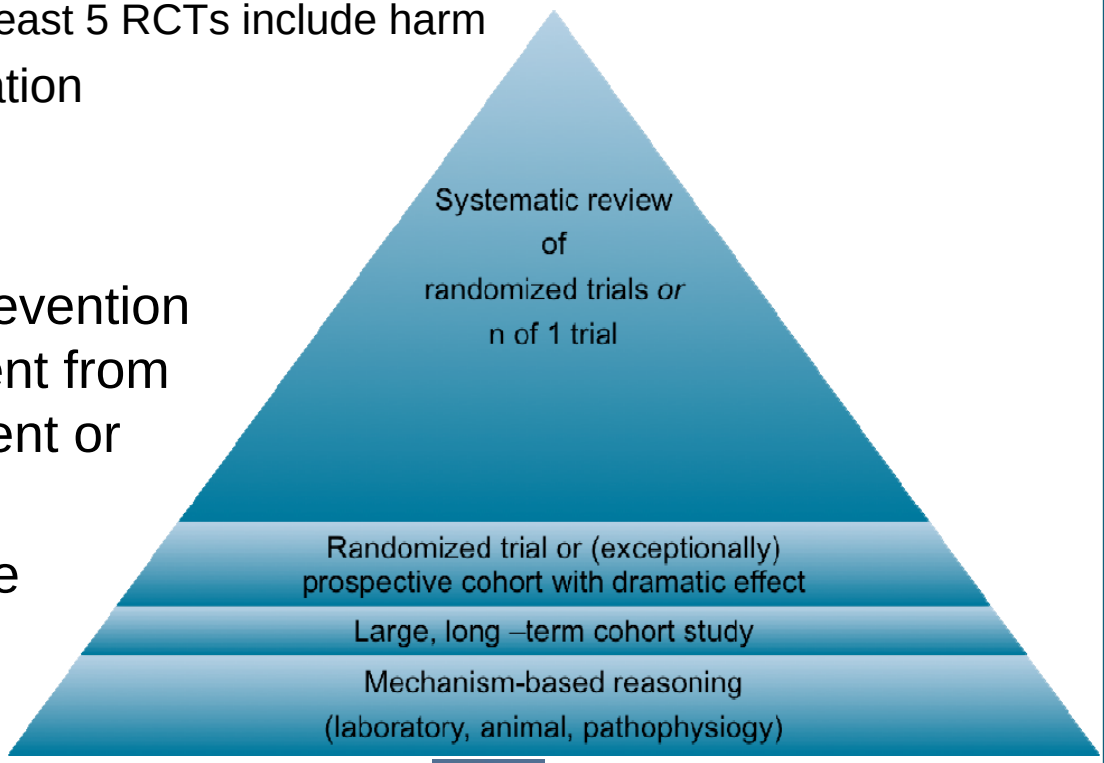
Boston Globe July 8, 2011

EVIDENCE…

- Do we have evidence?
  - What *exactly* is that evidence?
- Do we have enough, and good enough evidence?
  - How much and what type do we need?
- We don't need evidence?
  - We just know it will work.
  - It can't be bad.
  - Alcohol and drugs are important and ignored in healthcare; even if SBI doesn't work, its dissemination is a way to increase attention.

EVIDENCE WE SHOULD HAVE

- SBI is a population wide service
  - Need highest level of evidence
    - Small costs and harms multiply quickly
      - Unintended effects when (?poorly) done?
        - » 95% CIs of at least 5 RCTs include harm
      - Privacy/discrimination
      - Opportunity costs
  - Not demanded?
  - Evidence needed for prevention and performance different from care for clinically apparent or help-seeking
  - Need evidence when we think circumstances will alter effectiveness



CEBM, Oxford 2011
USPSTF 2011

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WHAT ABOUT OBSERVATIONAL STUDIES?

RED SOX LEAD FOR A PLAYOFF SPOT

HISTORIC CHOKES

If the Red Sox don't make the playoffs, they will join an ignominious group who collapsed after leading late in the season.

Boston Globe September 13, 2011
As of today, 6 games left…

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INFORMATIVE OBSERVATIONAL STUDIES

- Before-after study of a 10% sample of those who screened positive for heavy alcohol or any other drug use at 4 sites with good follow-up (n=3622). Of those using the drug at baseline, 6 month use:
  - 33% marijuana
  - 21% cocaine
  - 15% methamphetamine
  - 27% heroin
  - 16% other drugs

Madras B et al. Drug Alcohol Depend 2009

INFORMATIVE, BUT THEY SHOULDN'T REPLACE CONTROLLED TRIALS WHEN THE QUESTION IS EFFICACY OR EFFECTIVENESS

- Effect sizes usually overestimated
  - Natural history
  - Confounding
  - Assessment effects
    - Several RCTs in SBI>>no assessment effects
  - Regression to mean
  - Self-change ("learnable moments")

MISLEADING EVIDENCE IN MEDICINE
The list is long…

- Antioxidants for cancer in smokers
  - RCT: Vitamin E has no effect on lung or colon cancer or death
  - RCTs: Beta-carotene increases lung cancer and deaths
- Estrogen to prevent heart disease (Obs. studies RR 0.6)
  - RCT: No decrease
- Anti-arrhythmics for sudden death (surrogate outcomes)
  - RCTs: They increase mortality or at best have no effect

EVIDENCE FOR PREVENTIVE SERVICES

- Aspirin for coronary artery disease (CAD)->50,000 people, 5 RCTs, CAD and mortality outcomes
- Colon cancer screening-250,000 people, 4 RCTs, colon cancer mortality outcomes
- NB: Electrocardiogram screening for CAD, USPSTF review:
  - “"We cannot assume that because a clinical measurement predicts risk, incorporating it into clinical care will reduce risk." “…clinicians should not incorporate screening with resting or exercise electrocardiography into their practices except in the context of clinical trials.“ *Lauer MS*.

Ann Intern Med Sept 20, 2011

RANDOMIZED TRIALS OF SCREENING AND BRIEF INTERVENTION VS. NO SCREENING

NB: these studies *do* exist for other preventive interventions

- Colon cancer
- Breast cancer
- Prostate cancer

EVIDENCE WE DO HAVE

EFFICACY OF BRIEF INTERVENTION VS. NO BI: Alcohol, Low severity (e.g. not dependence or very heavy drinking), Primary care

- ≥22 original RCTs, 8 systematic reviews
  - Lower proportion of drinkers of risky amounts (n=2784)
    - 57% vs. 69% at 1 year
  - Lower consumption (n=5639)
    - by 15% (38 grams per week)
- Decreased hospital utilization (≥2 RCTs)
- Cost-effective (spend $166, save $546 medical)
- 4 RCTs (n=1640), BI decreased mortality (RR 0.47)

RCT=Randomized controlled trial

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
Fleming MF et al. Alcohol Clin Exp Res. 2002;26(1):36-43.
Cuijpers et al. *Addiction* 2004;99: 839–845

TREATMENT “WORKS”

KNOWN UNKNOWNS

- Absence of evidence (a known unknown; evidence needed)
- Evidence of absent effect (something known; shouldn’t ignore)

KNOWN UNKNOWNS

As we know,
There are known knowns.
There are things we know we know.
We also know
There are known unknowns.
That is to say
We know there are some things
We do not know.
But there are also unknown unknowns,
The ones we don't know
We don't know.

US Secretary of Defense Donald Rumsfeld —Feb. 12, 2002, Department of Defense news briefing transcript http://dod.gov The Poetry of D.H. Rumsfeld, http://www.slate.com/id/2081042/

OTHER DRUGS

- Should data on nondependent/low severity alcohol use apply?

Other drugs: We don't know

- 5 controlled studies in people *identified by screening*
- None exclusively in primary care setting for adults
  - 1. Less MJ and ecstasy use + problems (n=59 adolescents, PC)
  - 2. Less MJ use at 12 (not 3) months (n=210 adolescents, ED)
  - 3. No difference in daily dose or discontinuation, but less use of addictive prescription drugs at 3 (not 12) months (n=126, hospital)
  - 4. More abstinence from heroin (9%) and cocaine (5%)(n=1175, urgent care)
  - 5. 3 points better (on 336 pt use score)(n=731, outpatients)

DeMicheli D et al. Rev Assoc Med Bras 2004; 50(3): 305-13
Bernstein et al. Acad Emerg Med. 2009 Nov;16(11):1174-85
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
Humeniuk R, et al. *Technical Report,* WHO, 2008

DURATION, CLINICIAN, TRAINING/SKILL/REAL WORLD?

- What is required to get the effects seen in RCTs?

Duration may matter

"Longer counselling has little additional effect"

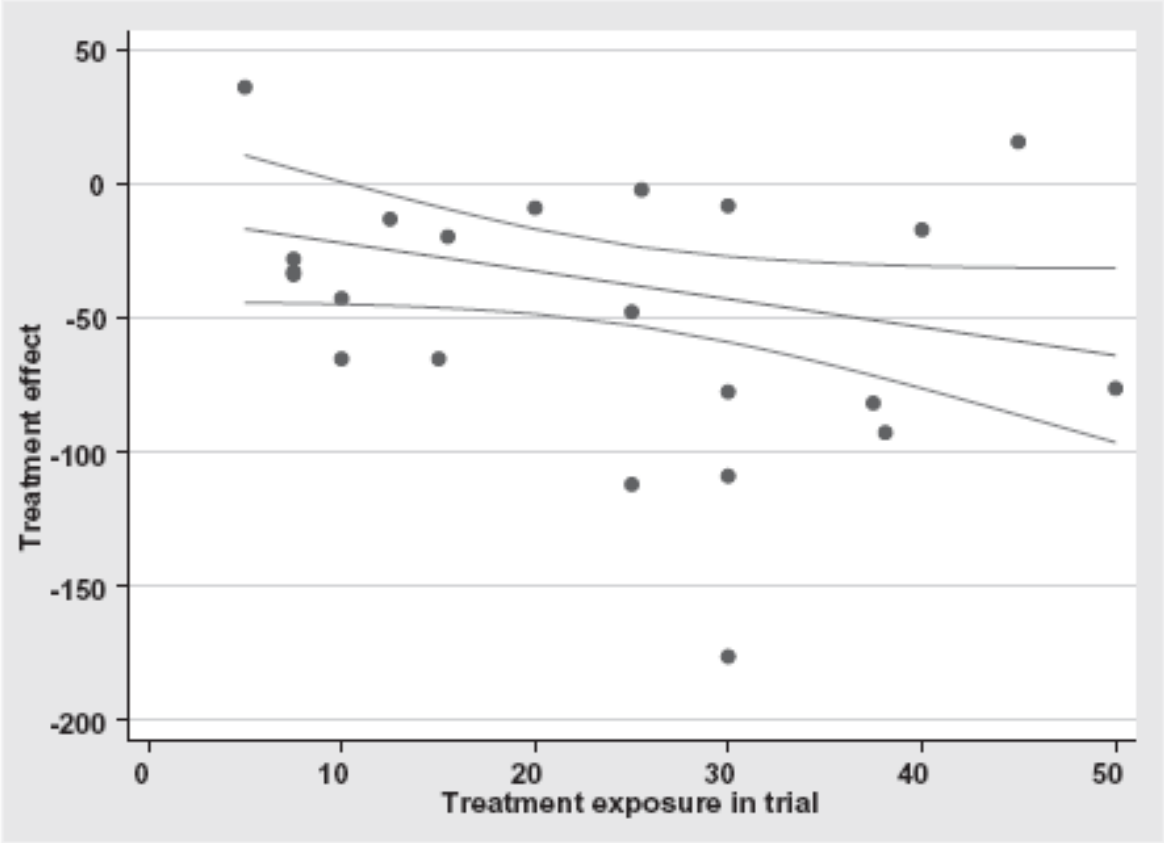

Figure 4. *Estimated treatment effect versus treatment exposure for trials comparing brief intervention with control: the predicted meta-regression line and its 95%CI. The treatment effect is the net reduction in alcohol intake in g week^{-1}; the treatment exposure is the estimated duration of the brief intervention in minutes.*

Kaner EFS et al. *Drug and Alcohol Review* 2009;28:301–323

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Duration and frequency may matter:
Brief and Very Brief (VB) vs. Brief Multi-contact

Brief and very brief

Author(s)	N	Difference	Comment
Richmond et al. (VB)	378	-	Nonrandom
WHO (VB)	1559	+ B & VB	NS for women
Anderson & Scott	154	+	Men
Nilssen	338	+	
Senft et al.	516	Borderline	
Maisto et al.	301	-	Outside clinic
Scott & Anderson	72	-	Women

RED=no diff
GREEN= + study

Brief multi-contact

Author(s)	N	Difference	Comment
Maisto et al.	301	-	Decrease but NS
Curry et al.	307	+	Good quality
Fleming et al.	774	+	Good quality
Fleming et al.	158	+	Good quality; Elderly
Nilssen	338	+	
Ockene	530	+	Good quality
Wallace	909	+	Good quality

Whitlock et al. Ann Intern Med 2004; 140:557-68.

Clinician may not matter:
but little evidence

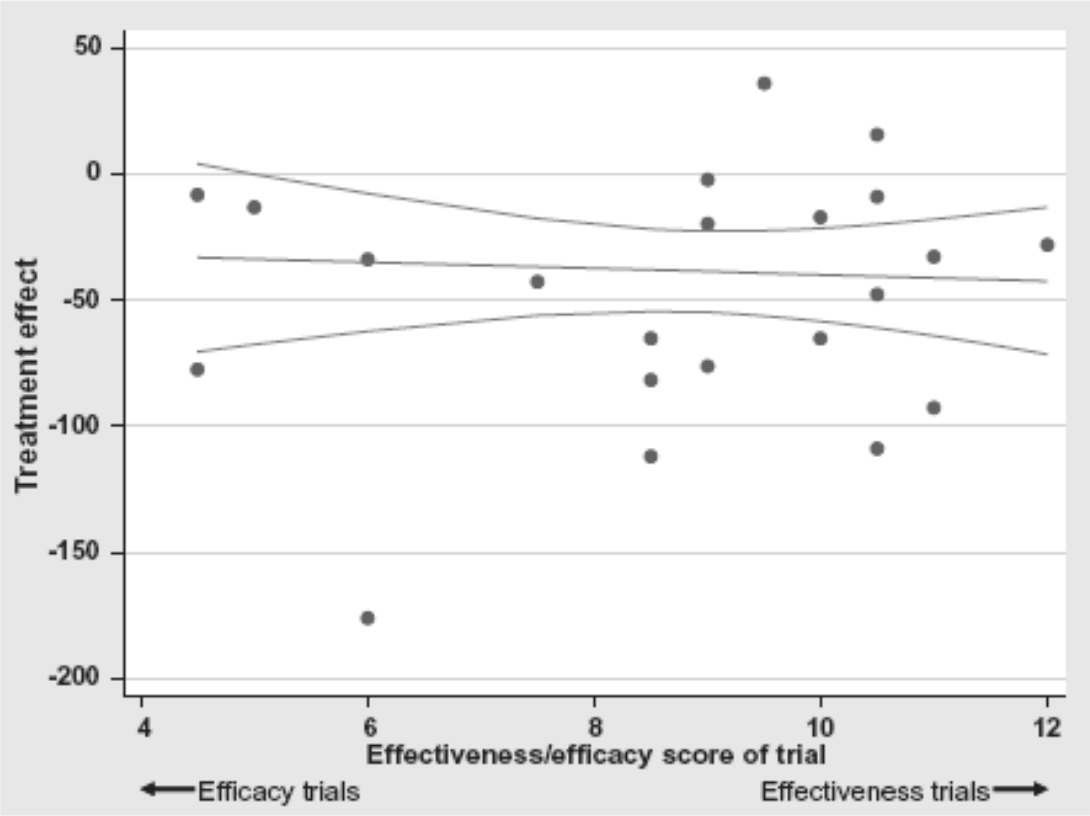
- Systematic review of “nonphysician” (NP) interventions
  - Studies of fair to poor methodological quality

RESULTS

- NP vs. usual care: 7 studies (2110 patients), 1.7 drinks/week lower
- P+NP vs. P: 1 study, no difference; 1 study, reduced drinking
- P vs. NP: 3 studies: no difference in drinking outcomes

P=Physician, NP=Non-physician
Nurses, nurse practitioners, health educators,counselors, psychologists, therapists, “trained interventionists”
Sullivan LE et al. Am J Addictions 2011;20:343-56

In real-world practice? Unclear if practices proven efficacious in RCTs can be disseminated widely



"The lack of differences in outcomes between efficacy and effectiveness trials suggests that the current literature is relevant to routine primary care."

Figure 3. *Estimated treatment effect versus effectiveness/efficacy score for trials comparing brief intervention with control: the predicted meta-regression line and its 95%CI. The treatment effect is the net reduction in alcohol intake in g week^{-1}; the effectiveness/efficacy score was estimated as described in Appendix 3.*

Kaner EFS et al. *Drug and Alcohol Review* 2009;28:301–323

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Severity

Most trials exclude people with very heavy drinking or dependence

Moyer A. Addiction 2002;97:279

Severity: Alcohol dependence in primary care
—Absence of evidence of efficacy

- Systematic review, primary care alcohol SBI
  - 16 RCTs (6839 patients); 14 excluded some or all persons with very heavy alcohol use or dependence
    - 1 study: 35% of 175 patients had dependence
      - no difference in an alcohol severity score between groups
    - 1 study of 24 women, 58% with dependence
      - no efficacy

Saitz R. Drug Alcohol Rev 2010; 29:631-640.

Severity: Alcohol dependence, primary care

- Systematic screening followed by computer and telephone interventions for range of unhealthy use
  - No difference in drinking or help seeking (n=408)
- Systematic screening followed by telephone and mail interventions for alcohol abuse and dependence (n=897)
  - Intervention decreased consumption for those with abuse and dependence

Bischof G et al. Drug Alcohol Depend 2008;93:244-51
Brown RL et al. Alcohol Clin Exp Res 2007;31:1372-9

Severity: Alcohol dependence in other settings

Little/some evidence for efficacy for use and consequences

- 3 RCT subgroup analyses (2 hospital, 1 trauma)
  - 2 found less drinking; 1 of those fewer problems, 1 no differences
- 1 quasi-experimental study found less drinking (ED)

Little/some evidence for efficacy for increasing receipt of treatment

- 2 RCT subgroup analyses, 1 RCT few dependence (hospital), 1 observational study (system of care)
  - 6-11% increases noted but majority do not go (~60-90%)
- Bernstein et al (drug): no difference in treatment

Few people in addiction specialty care are referred there by physicians. In part this is due to physicians not referring. HOWEVER, completion of referrals is very low after BI and little evidence BI affects it.

Liu et al. Addiction 2011;106:928-40
Saitz et al. Ann Intern Med 2007;146:167-76
Field & Caetano. Drug Alcohol Depend 2010; 111:13-20
Cobain et al. 2011;46:434-40
Krupski et al. 2010;110:126-36
Elvy et al. Addiction 1988;83; 83-9
Bernstein et al. Drug Alc Dep 2005

SETTING

- Related to severity but not the same
- Different expectations and goals
  - Comprehensive including preventive care?
  - Longitudinal? Long-term therapeutic alliance?
  - Teachable vs. learnable moments?

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General hospital:
High prevalence of dependence

- Most patients identified by screening have <u>dependence</u>
  - 57%-79% across >4 hospitals in Germany, Spain, US

Thanks to Ana Belen Martinez for the photo at INEBRIA 2007, Brussels, Parliament

Belen Martinez et al INEBRIA 2007
Saitz et al. Ann Intern Med 2007;146:167-76
Freyer-Adam J et al. Drug Alcohol Depend 2008
Bischof et al. Int J Pub Health 2010 Saitz et al. Int J Pub Health

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Cochrane Reviews: General Hospital

- "The evidence for brief interventions delivered to heavy alcohol users admitted to general hospital is still inconclusive." *McQueen et al, 2009*
- "The main results of this review indicate that there are benefits to delivering brief interventions to heavy alcohol users in general hospital." *Mc Queen et al, Aug 10, 2011*
  - 14 trials, n=4041 (mostly men)
    - 69g lower weekly consumption compared with control (4 studies)
      - Not significant when study with greatest risk of bias excluded
      - No difference in drinking decreases, # binges, GGT
    - Fewer deaths at 6 months (RR 0.42)(4 studies)
  - Worries
    - Trauma mixed with other settings
    - Inability to combine results across varied outcome measures
    - Main findings based on studies rated lower methodologically
    - Inaccuracies ('no study considered quality of life')

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

Setting: Emergency
First RCT of brief intervention

- Patients with alcoholism in the emergency department (MGH, Boston)
- Brief advice by a psychiatrist
- More likely to report to an alcohol clinic (42% vs. 1%)

Chafetz M et al. Q J Stud Alcohol 1961;22:325

Setting: Emergency

Evidence mixed

- Two systematic reviews
  - Nilssen et al, injured patients
    - 6 studies—no difference in drinking
    - 5 studies—decrease in consumption
    - Mixed effects on other outcomes (e.g. completion of referral to treatment, injuries)
  - Havard et al, injured and non-injured patients
    - 11 studies (n=1174)—no difference in drinking
    - 3 studies (n=785)—decreased injuries (OR 0.59)

*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

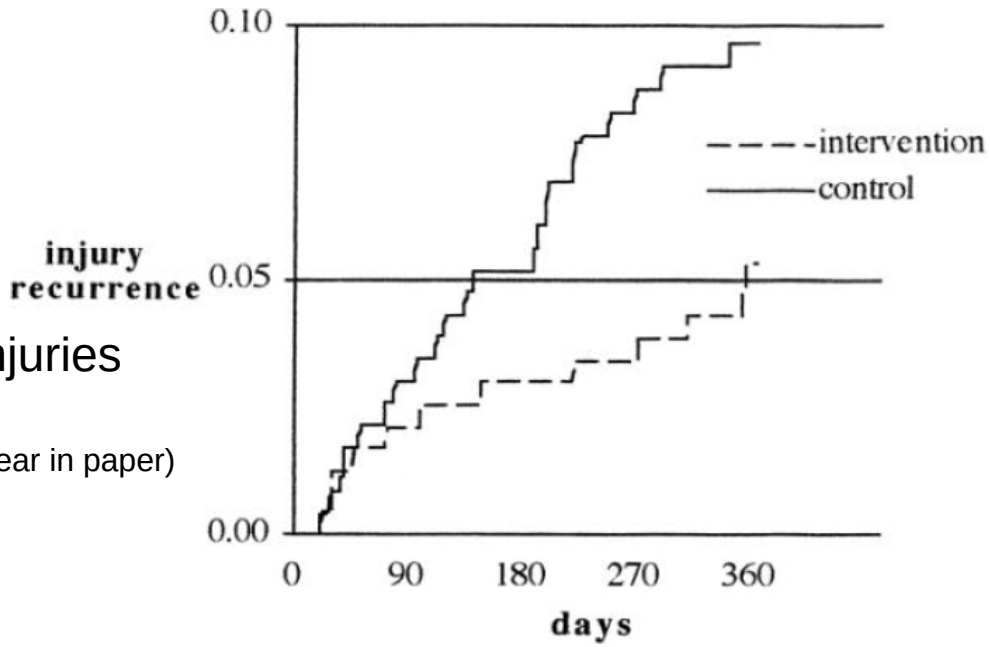
More recent emergency department studies

- 2010: risky use
  - 900 randomized
  - BI reduced weekly and heavy episodic drinking, though not problems
- 2008: risky use or alcohol-related injury
  - 500 randomized
  - No differences in drinking

D'Onofrio G et al. Oral abstract presentation at ISBRA, Paris 2011
D'Onofrio G et al. Ann Emerg Med. 2008; 51(6):742-750

Trauma centers

- 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
  (despite no baseline differences)
- 2006, n=187: no differences
- 2007, n=497: no differences



Represents a difference of 15 injuries (approx. 35 vs. 20)
(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

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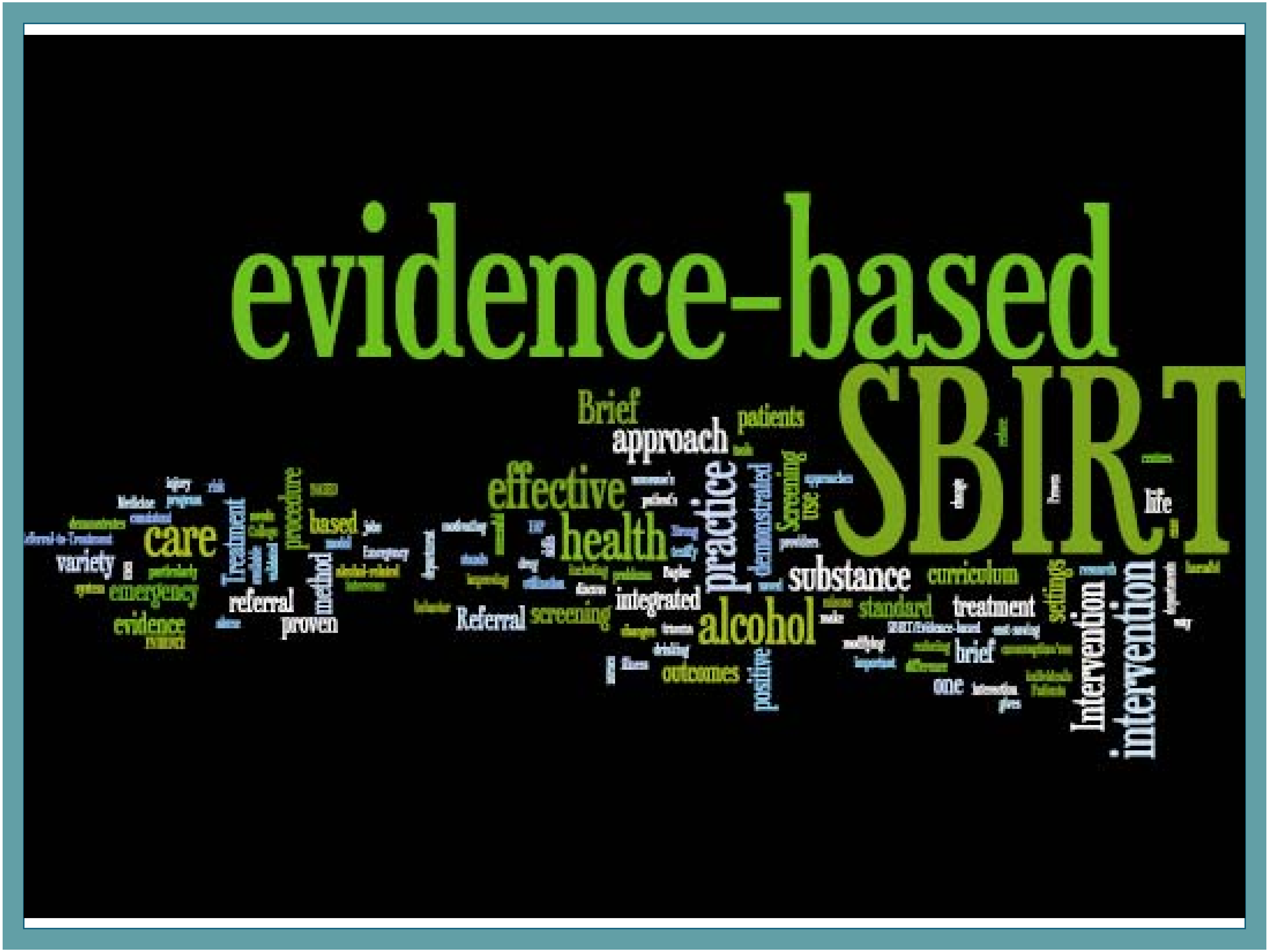
Comorbidity

- Systematic review: comorbid physical, mental health or use of >1 drug
  - 14 trials, heterogeneous in design and quality
- 8 trials MH/SA:
  - Most reported no effect on substance use
  - No effects on MH
- 3 trials physical (hypertension or tuberculosis) and SA
  - Improvements in both SA and physical conditions
- 3 trials > 1 substance
  - Negative

Kaner EFS et al. Ment Health Subst Use. 2011;4(1):38–61

CONTEXT (in the US)

- LARGE national efforts in the US to deliver SBI, all settings
- LARGE national training efforts
- Codes that allow billing for SBI
- Accreditation standards (trauma centers)
- Performance measures tied to incentives (ambulatory, hospital)


evidence-based
SBIRT
Brief
approach
patients
effective
health
practice
demonstrated
Screening
use
care
Treatment
procedure
based
variety
emergency
evidence
referral
method
proven
Referral
screening
integrated
substance
alcohol
curriculum
standard
treatment
settings
Intervention
intervention
life
brief
one
outcomes
positive

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Efficacy, and will it translate into practice

- Efficacy
  - Brief multi-contact intervention for nondependent unhealthy alcohol use in primary care
  - Duration and frequency
  - Clinician
  - Severity
  - Context/setting (ED, trauma, hospital)
  - Drugs
- Effectiveness
  - Hard outcomes (or clear links between changes and outcomes)
  - Works in real practices when research protocols implemented. Feasible?
  - Will findings from efficacy studies translate into practice beyond research studies?
    - How much training?
    - How much skill for BI?
  - Dependence identified by screening

Thoughts

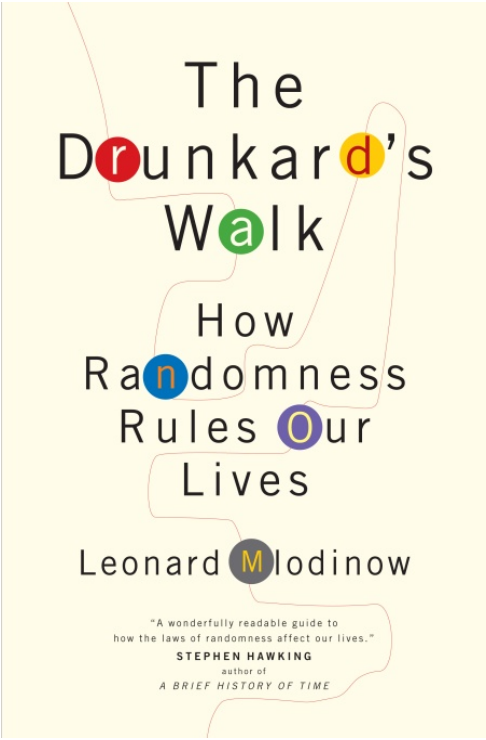
- “Because the evidence for BI comes from different types of investigation, with different samples, generalization should be restricted to the populations, treatment characteristics and contexts represented in those studies” Moyer A. Addiction 2002;97:279
- “‘Few answers, many questions’ and the probable hypothesis that BAI sometimes does and sometimes does not reduce alcohol use and problems suggest that future studies should explore systematically the influence of factors related to the patient, counsellor, intervention, setting and research methodology.” Daeppen JB et al. Addiction 2008;103:377

Thoughts

- "When implemented prematurely [before it is clear that benefits outweigh harms], wishful thinking can replace careful evaluation, and an unproved innovation can become an enduring but possibly harmful standard of care."
  Landefeld CS et al. BMJ 2008;336:1277

Thoughts

- “Humans are notoriously bad at, and often even averse to, the straightforward use of data and probability in making daily judgments…not restricted to certain educational levels…or professions….Despite its image of being scientifically based, the actual application of evidence in medicine is, like a drunkard's walk, quite haphazard and inconsistent.”
  Mlodinow L *The Drunkard's Walk: How Randomness Rules our Lives*



WHAT DO YOU THINK OF THE EVIDENCE AND WHAT IT SUPPORTS?

Patient requesting help

Patient with obvious symptoms

Patient with possible symptoms

Asymptomatic patient with risk factor

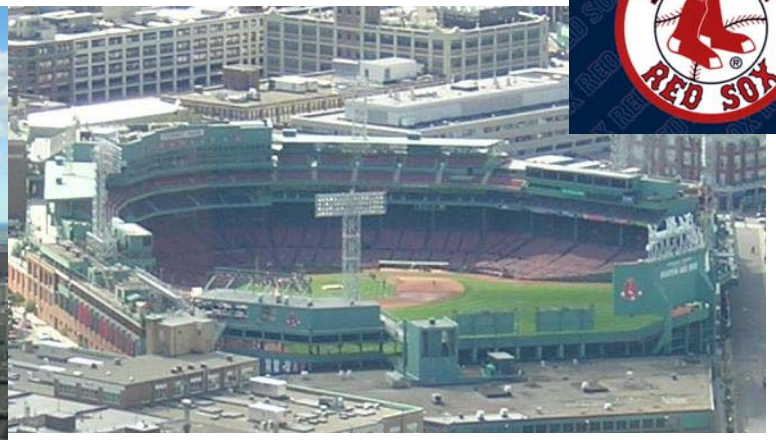
Asymptomatic patient without increased risk

Population (in a setting or anywhere)

Policy/Performance measure

www.inebriaboston.org

INEBRIA 2011 in Boston 9/21



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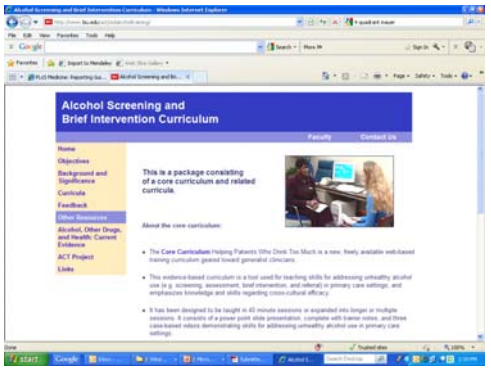
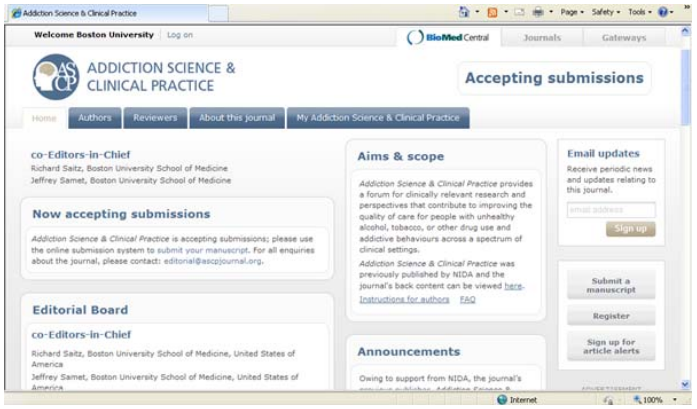
FREE RESOURCES

Alcohol, Other Drugs and Health: Current Evidence www.aodhealth.org

www.mdalcoholtraining.org



Addiction Science & Clinical Practice
(formerly published by NIDA, now BMC)
www.ascpjournal.org



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