Designing Clinical Addiction Research

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Boston Medical Center is the primary teaching affiliate
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Goals and Objectives

Goal: Cover general principles of designing feasible clinical addiction research

- **Learning objectives**
  - Review the top ten considerations for designing and implementing clinical research as a fellow
  - Be able to specify and refine each component of a research question
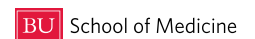 - Share ways to incorporate addictions questions into other studies

Top Ten Considerations for Designing Clinical Research as a Fellow

10. Make a long list of possible research questions

9. Consider your resources (usually limited-money, time, expertise) and feasibility. You can't do it alone
    --Mentor (expertise+), biostats, data collection/management, coordination

8. Consider innovation (has the question been answered?)

7. Consider limitations. Avoid fatal flaws but don't get paralyzed

6. Consider a line of research

5. Get feedback

4. Don't forget the IRB

3. Consider need for Certificate of Confidentiality

2. Implement at least two studies, gain different skills

1. Make sure you love it

Clinical research question: PICO

- **P = Patient or problem**
- **I = Intervention, prognostic factor, or exposure**
- **C = Comparison**
- **O = Outcomes**

Measure/assessment: Use something validated
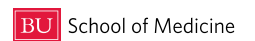Analysis: Specify variable

Incorporating addiction questions

- Add measures to other studies

- Link data to other studies

- Stratify or subset on people with addictions

- Address addiction and the other medical condition simultaneously

- Address addiction to impact other medical condition outcomes

- Study addiction in people with other medical conditions

NOTE: MANY studies of people with HIV or HCV do not include measures of alcohol and drug use. Causes problems in interpretation, and creates opportunity for study!

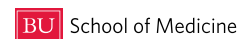# Questionnaire measures

How much do you drink?

AUDIT-C

Question #1: How often did you have a drink containing alcohol in the past year?

• Never	(0 points)
• Monthly or less	(1 point)
• Two to four times a month	(2 points)
• Two to three times per week	(3 points)
• Four or more times a week	(4 points)

Question #2: How many drinks did you have on a typical day when you were drinking in the past year?

• 1 or 2	(0 points)
• 3 or 4	(1 point)
• 5 or 6	(2 points)
• 7 to 9	(3 points)
• 10 or more	(4 points)

Question #3: How often did you have six or more drinks on one occasion in the past year?

• Never	(0 points)
• Less than monthly	(1 point)
• Monthly	(2 points)
• Weekly	(3 points)
• Daily or almost daily	(4 points)

The AUDIT-C is scored on a scale of 0-12 (scores of 0 reflect no alcohol use). In men, a score of 4 or more is considered positive; in women, a score of 3 or more is considered positive.

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How many times in the past year have you had five (four for women) or more drinks in a day?

Smith PC, Schmidt SM, Allensworth-Davies D, Saitz R.
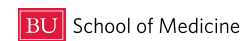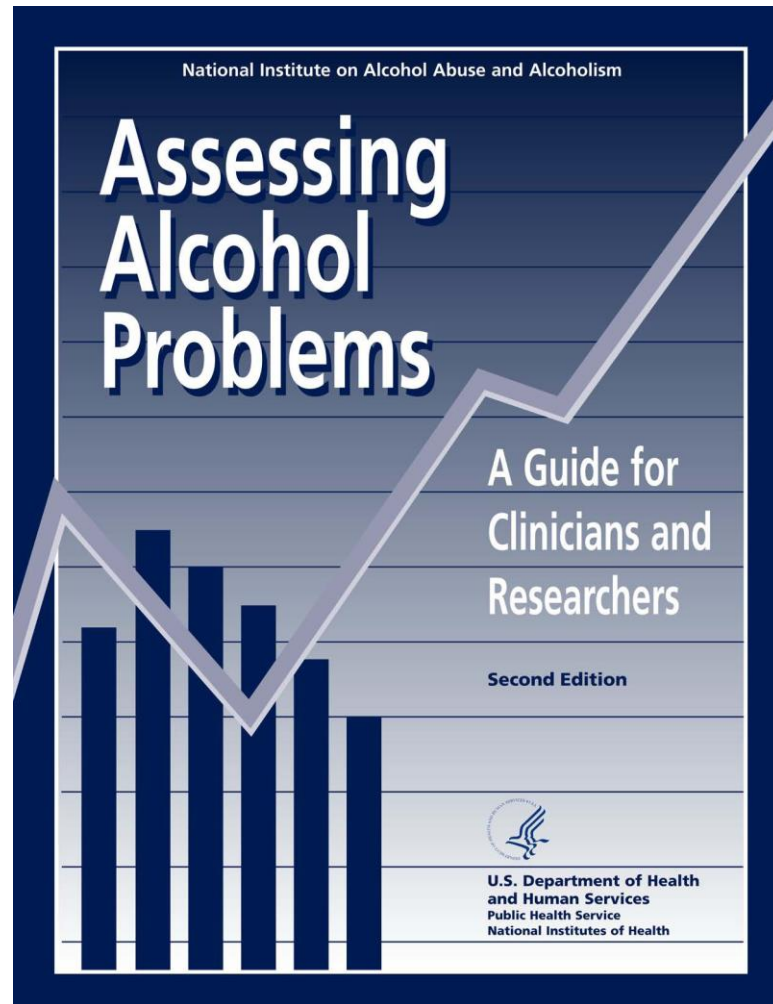J Gen Intern Med 2009 24:783-8

NIAAA NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
of the NATIONAL INSTITUTES OF HEALTH

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Quick–Reference Instrument Guide

Instrument	Target population	Screening	Diagnosis	Assessment of drinking behavior	Treatment planning	Treatment/ treatment process assessment	Outcome evaluation
Adapted Short Michigan for Fathers (F–SMAST) and Mothers (M–SMAST) Alcoholism Screening Test	Adults and adolescents	P			S		
Addiction Admission Scale (AAS)*	Adults	P					
Addiction Potential Scale (APS)*	Adults	P					
Addiction Severity Index (ASI)	Adults				P		S
Adolescent Alcohol Involvement Scale (AAIS)	Adolescents	P					
Adolescent Diagnostic Interview (ADI)	Adolescents		P		S		S
Adolescent Obsessive–Compulsive Drinking Scale (A–OCDS)	Adolescents	P					
Alcohol Abstinence Self–Efficacy Scale (AASE)	Adults				P		

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/quickref.htm (1 of 8) [3/22/2012 4:15:35 PM]

National Institute on Alcohol Abuse and Alcoholism

Assessing Alcohol Problems

A Guide for Clinicians and Researchers

Second Edition

U.S. Department of Health and Human Services
Public Health Service
National Institutes of Health

http://pubs.niaaa.nih.gov/publications/Assesing%20Alcohol/index.pdf

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Demographics
Substance use
Substance diagnosis
Substance use severity and consequences
Medical diagnosis, mental health diagnosis
Health related quality of life/function (mental and physical)
Risk behaviors
Mental health symptoms
Healthcare utilization

Domains

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Specifics of your research questions?
What questions could you add to ongoing studies?