



Designing Clinical Addiction Research

Richard Saitz MD, MPH, FACP, DFASAM
Chair, Department of Community Health Sciences
Professor of Community Health Sciences and Medicine
Boston University Schools of Medicine & Public Health
Boston Medical Center





Boston Medical Center is the primary teaching affiliate of the Boston University School of Medicine.

We encourage you to use these slides when teaching. If you do, please cite this source and note any changes made.

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

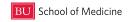




Top Ten Considerations for Designing Clinical Research as a Fellow

- 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
 - --Biostats, data collection and management, coordination, expertise
- 8. Consider innovation (has the question been answered?)
- 7. Consider limitations. Avoid fatal flaws but don't get paralyzed
- Consider a line of research
- 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



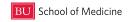


Incorporating addiction questions

- 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.





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







SITE SEARCE

of the NATIONAL INSTITUTES OF HEALTH

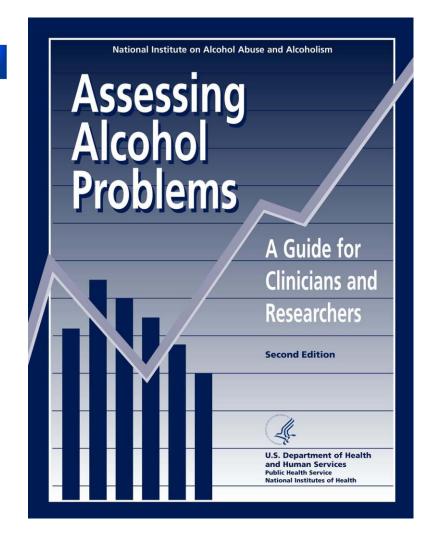
▶ Advanced Search Pace

Publications

Back to: NIAAA Home > Publications

Quick-Reference Instrument Guide

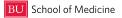
Instrument	Target population	Screening	Diagnosis	Assessment of drinking behavior	Treatment planning	Treatment/ treatment process assessment	Outcome evaluation
Adapted Short Michigan for Fathers (F– SMAST) and Mothers (M– SMAST) Alcoholism Screening Test	Adults and adolescents	P			S		
Addiction Admission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



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







Section Instrument	<u>Page</u>
Section A Demographics	1
Section B Form 90D Use Pattern Chart	4
Section C Alcohol Use-AUDIT-C, Past Month Use, CAGE, CAGE-I	D7
Section D CIDI-SF Drug 12 Month	12
Section E Short Inventory of Problems (SIP-2R)	15
Section F Short Inventory of Problems - Drugs (SIP-D - 2R)	17
Section G Injury	
Section H ACASI	20
Section I PHQ-9	21
Section J OASIS	22
Section K EuroQoL	24
Section L Pain History	25
Section M Form 90-AIR/ED Modified	26



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





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

