

Clinical Addiction Research and Education

Designing Clinical Addiction Research

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Boston Medical Center is the primary teaching affiliate
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Learning Objectives

Convey general advice on developing and implementing clinical addiction research that is realistic

- Understand implications of design decisions
- Describe assembly of research team
- Share ways to incorporate addictions questions
- Raise awareness of addiction research tools and data sources

Top Ten Considerations for Designing Clinical Research as a Fellow

1. Make a long list of possible research questions
2. Consider your resources (usually limited-money, time, expertise) and feasibility. You can't do it alone
3. Consider innovation (has the question been answered?)
4. Consider limitations. Avoid fatal flaws but don't get paralyzed
5. Consider a line of research
6. Get feedback
7. Don't forget the IRB
8. Consider need for Certificate of Confidentiality
9. Implement at least two studies, gain different skills
10. Make sure you love it

Research teams or roles

- Biostatistics
- Data management (entry, cleaning, analysis)
- Project management
- Data collection
- Principal investigator
- Co-investigators/consultants including content experts
 - e.g. addiction
 - e.g. ID, GI

Ethical issues

- Vulnerable subjects
- Compensation
- Confidentiality
- Administration of drug
- Withholding treatment

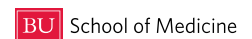
Clinical research question: PICO

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

Design

- Question type
 - Therapy/prevention
 - Randomized trial
 - Follow-up
 - Diagnosis
 - Cohort or cross-sectional
 - Reference standard
 - Prognosis
 - Inception cohort
 - Cohort studies (or case-control studies)
 - Harm
 - Adjustment for confounders
 - Cohort or case-control studies (or randomized trials)
 - What people think
 - Survey, qualitative
 - Decision
 - Cost-effectiveness
 - Relevant questions
 - Simulations

Highest level of evidence: systematic review and meta-analysis
-clear relevant question



Design

- Subjects: eligibility, exclusions, sample selection
- Power and sample size
- Direct measurements
 - Questionnaires
 - Examination
 - Biological measures
- Secondary/existing data
- Analysis

Addiction questions

- Does topiramate decrease relapse to heavy drinking in people with alcohol dependence and HIV infection who are seeking treatment?
- What is the probability that a person with alcohol dependence and hepatitis C will drink lower risk amounts without consequences? What is the chance they will stop drinking without treatment?
- How accurate is carbohydrate deficient transferrin for detecting heavy alcohol use among people with hepatitis C? How accurate is urine opioid screening for opioid dependence among patients with HIV infection?
- Does marijuana use cause oral cavity cancer?
- Is screening and brief intervention for drug use cost-effective? Is oral naltrexone more or less cost effective than injectable naltrexone?

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. For example, studies of bone loss in HIV...Causes problems in interpretation, and creates opportunity for study!

Assessments: use something validated

(or validate something)

- Content, construct
- Reliability
- Validity
 - Face
 - Accuracy [reference standard]
 - Precision
 - Change over time

Questionnaire measures

- Are you on HAART?
- How much do you drink?
- Do you have unprotected sex?
- Do you use drugs?

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?

Have you ever felt you should **Cut down** on your drinking?

Have people **Annoyed** you by criticizing your drinking?

Have you ever felt bad or **Guilty** about your drinking?

Have you ever taken a drink first thing in the morning (**Eye-opener**) to steady your nerves or get rid of a hangover?

How many *times* in the last 90 days did you have vaginal sex with any sexual partner (meaning a penis was inserted into her/your vagina)?

Response: ____ ____ ____ times

Refused

Of these (*AUTO-POPULATE ANSWER TO Q6*) times, how many times was a condom used?

Response: ____ ____ ____ times

Refused

Section A Demographics..... 1

Section B Form 90D Use Pattern Chart..... 4

Section C Alcohol Use-AUDIT-C, Past Month Use, CAGE, CAGE-D...7

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.....19

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 Modified26

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

Fellow project: Peter Smith

- Single item screening question recommended by NIAAA
- No validation studies
- Existing research team
- Grant supplement
- Interview 300 people in medical clinic with single item and reference standards
- Calculate sensitivity and specificity
- Published in Arch Intern Med and J Gen Intern Med
- Recommended for adoption in electronic health records nationwide

Fellow project: Meredith D'Amore (Manze)

- Objective: to assess disparities in receipt of safe sex counseling
- Existing data from randomized trial of people with substance dependence; RCT was test of a disease management intervention on substance use outcomes
- Existing team; add disparities expert
- Blacks and people reporting manic episodes significantly more likely to report safe sex counseling; no difference in safe sex practices because of advice received
- Paper under review

Publications

Back to: [NIAAA Home](#) » [Publications](#)

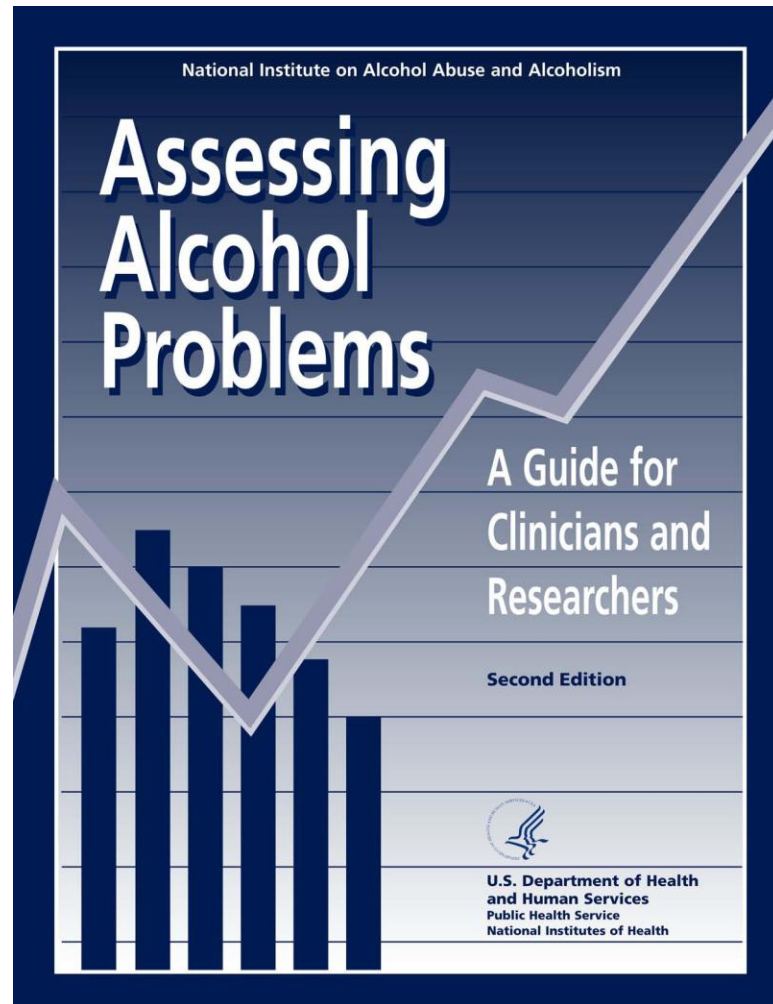
Quick-Reference Instrument Guide

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	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]

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

FIT 2012



Data Sources

- APIS: Alcohol policy information system
- COMBINE Study
- NESARC: National Epidemiologic Survey on Alcohol Related Conditions
- NAHDAP: National Addiction and HIV Data Archive Program
- BRFSS: Behavioral Risk Factor Surveillance Survey
- Others...

<http://www.icpsr.umich.edu/icpsrweb/NAHDAP/>

<http://www.niaaa.nih.gov/Resources/DatabaseResources/Pages/default.aspx>

Unanswered research questions (including yours...)

- Does alcohol intervention improve HIV outcomes?
- What level of drinking accelerates HCV disease progression?
- Does drug use interfere with treatment response to...?
-BRAINSTORM....

Concept Sheet (1 page)

- Title
- Background (1 or 2 sentences; specific)
- Aims/Objectives
- Hypotheses
- Methods
 - Population/sample/data source
 - Measures (predictors/independent variables, interventions, outcomes/dependent variables, covariates/confounders, descriptive variables)
 - Design
 - Analysis (sample size and power, statistical techniques—description, comparisons)

Analytic Plan

(see Research Design Concept Sheet, RDCS)

- Same as Concept Sheet
- BUT detailed definition of variables in databases and detailed description of analyses

EXAMPLE:

Concept: We will compare risky sex for those who have unhealthy alcohol use as defined by the AUDIT-C to those who do not.

Analytic plan: Unhealthy alcohol use is defined as an AUDIT-C score of >3 for women and >4 or more for men. We will report the frequency of past 30-day heterosexual sex without condom use and frequency of unhealthy alcohol use, then test the risk of unprotected sex by unhealthy alcohol use in a 2x2 table, providing the chi-square and p-value, as well as the odds ratio for unprotected sex for those with compared to (reference group) those without unhealthy alcohol use, and 95% confidence interval.