Adaptive Interventions

Module 1

Experimental Design and Analysis Methods for Developing Adaptive Interventions: Getting SMART

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50 minutes

Introduction to Adaptive Interventions

What are adaptive interventions (AI)?

What are the pieces that make up an AI?

Examples of AIs: Compare simple versus deeply-tailored AIs.

Discuss why AIs are needed

Utilizing theory to design an AI

How AIs can be used to inform clinical practice

Module 1 Learning Goals

- To understand the components that make up an Adaptive Intervention (AI).
- To understand settings in which AIs are needed
- To understand the difference between a well-operationalized vs a poorly operationalized AI
- To begin to identify critical scientific questions (gaps in your area of study) related to developing a high-quality AI

We will have practice exercises (leading to interesting discussions) at the end of this module aimed at helping to ensure you achieve these learning goals.

Outline

- What are Adaptive Interventions?
- Why use Adaptive Interventions?
- Adaptive Intervention Design Goals
- Summary & Discussion

Definition of AI

- An intervention design, not an experimental design
- …in which intervention options are individualized to accommodate the specific and changing needs of individuals.
- Sounds much like actual clinical, policy or public health practice? Yes!
- Go by many different names: adaptive health interventions, adaptive treatment strategies, dynamic treatment regimes, treatment algorithms, stepped care models, treatment protocols, individualized interventions...

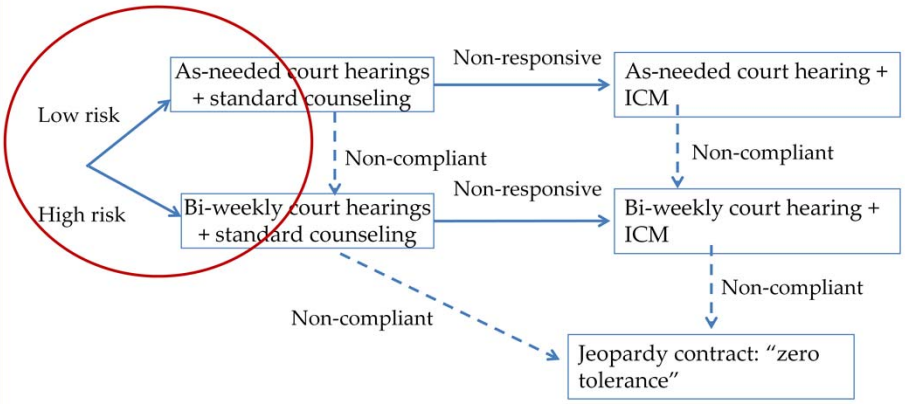
AIs are individualized sequences of treatments

AIs operationalize clinical practice, and in fact it mimics how we make decisions in real-life.

Example

- Adaptive drug court program for drug abusing offenders
  - The goal: Minimize recidivism and drug use
  - Operationalized by graduating from the drug court program
  - Marlowe et al., 2008; 2009; 2012)

Adaptive Drug Court Program



First Stage Decision Rule

4. Decision rule

3. Intervention options:
Type/Dose

At point of entry into the program

If risk = low

Then, stage 1 intervention= {As-needed + SC}

Else if risk=high

Then, stage 1 intervention = {Bi-weekly + SC}

5. Outcomes:
Distal →Long-term goal of intervention:
Program graduation (14 consecutive weekly negative drug urine specimens)
Proximal→ Short-term goal of decision rules:
Compliance and *response* in the course of intervention (mediator)

2. Tailoring Variable:
Patient information used to make treatment decisions

1. Decision Point:
A time in which treatment options should be considered based on patient information (Yoshino et al., 2009)

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AI: 5 Elements

1. Decision Points → **Trigger**
2. Tailoring Variable → • Monitoring
3. Decision rule → • Individualizing
4. Intervention Options → • Delivering

Adaptation process

5. Proximal + Distal Outcomes → **Guide**

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Various Types of AI

- Two dimensions:
  1. Adaptation Singular/Sequential
     - ***Singular:*** for each participant, treatment is individualized at most once
     - ***Sequential***: for some (or all) of the participants, treatment may be individualized multiple times
  2. Adaptation Static/Dynamic
     - ***Static***: adaptation based on information that is unlikely to change over time as a result of treatment (e.g., personality, baseline)
     - ***Dynamic***: adaptation based on information that can change over time as a result of treatment (e.g., response status, engagement in treatment).

Various Types of AI: Examples

Adaptation	Dynamic	Static
Singular	***At program entry*** Stage 1 = As-needed + SC ***Then, at week 4*** *If* program **response** = no *Then*, stage 2 = {more SC} *Else if* program **response** = yes *Then*, stage 2 = {continue}	***At point of entry into the program*** *If* **baseline risk** = low *Then*, stage 1 = {As-needed + SC} *Else if* **baseline risk**=high *Then*, stage 1 = {Bi-weekly + SC}
Sequential	***At point of entry into the program*** *If* **baseline risk** = low *Then*, stage 1 = {As-needed + SC} *Else if* **baseline risk** = high *Then*, stage 1 = {Bi-weekly + SC} ***Then, at week 4*** *If* program **response** = no *Then*, stage 2 = {more SC} *Else if* program **response** = yes *Then*, stage 2 = {continue}	***At point of entry into the program*** *If* **baseline risk** = low *Then*, stage 1 = {As-needed + SC} *Else if* **baseline risk** =high *Then*, stage 1 = {Bi-weekly + SC} ***Then, at week 4*** *If* **age** < 18 *Then*, stage 2 = {maintenance prog. A} *Else if* **age** ≥ 18 *Then*, stage 2 = {maintenance prog. B}

.

About JITAIs…

Any Time

1. Decision Points → **Trigger**

2. Tailoring Variable → •Monitoring
3. Decision rule → •Individualizing
4. Intervention Options → •Delivering

Adaptation Process

5. Proximal + Distal Outcomes → **Guide**

Momentary

Summary

- The objective of an AI is to guide clinical practice or public health policy.
  - Which are adaptive in nature.
- From the **individual/patient/client's** point of view:
  - AI is a sequence of (individualized) treatments
- From the **clinician's** point of view:
  - AI is a sequence of decision rules that recommend one or more treatments/intervention options at each critical decision point.

AIs provide a paradigm by which to improve clinical, policy, and public health practice which by its nature is often adaptive.

Individualization/personalization/tailoring is achieved by use of a decision rules at each decision point. Each decision rule takes accumulated, ongoing information about the unit (e.g., individual) including past response, adherence, burden, etc., and outputs a recommended, individualized treatment tailored to the circumstances of that unit.

A scientist first develops an AI. Later, they are used by clinicians to guide their thinking in actual clinical practice.

We use the term AI but others might use the terms: dynamic treatment regimes, treatment algorithms, stepped care models, expert systems, adaptive interventions, treatment protocols.

More Examples of Decisions

- About treatment **timing**:
  - How long should we use the first treatment
    - before transitioning to a maintenance/relapse prevention treatment? And which treatment should this be?
    - before declaring non-response and moving to another treatment? And which treatment should this be?
    - About treatment **engagement**:
  - How do we re-engage patients who are non-adherent?

Some More Examples …

- About intervention **delivery**
  - Who should make health-related goals (patient vs. provider)?
  - The location of the treatment (home vs. clinic; home vs. school)?
  - Mode of delivery (internet vs. in-person)

Other critical decisions: The individual's participation in treatment (e.g., who should set health-related goals, the participant or the care provider?), the location of the intervention offered (e.g., is it

Even More Examples …

- About intervention **tactics**
  - For people who do **not respond** well to treatment A
    - Should we enhance the intensity of A or add B
    - Should we enhance the intensity of A or switch to B
    - Should we continue with A or step-up to C
  - For people who **respond** well to treatment A
    - Should we continue or step-down
    - Should we stop immediately or gradually
    - Do we need a booster or not

More Examples of Tailoring Variables

- Static: 

  age, gender, personality, SES, baseline severity of illness, comorbid conditions, past failed treatment, family background, baseline social support

- Dynamic: 

  Adherence to present treatment, side effects while on present treatment, symptoms while on present treatment, social support during treatment

Other tailoring variables are genetics, family background, proteomics

Other Examples of Adaptive Interventions

- McKay (2005; 2009): AIs for alcohol and drug-use disorders
- Booner et al., (2004): Adaptive behavioral contingencies to enhance adherence to methadone treatment in opioid-dependent patients
- Rush et al. (2003) medication algorithms for treating depression, schizophrenia, and bipolar disorders
- Connell et al., (2007): An adaptive approach to family intervention targeting problem behaviors

Connell, A. M., Dishion, T. J., Yasui, M., & Kavanagh, K. (2007). An adaptive approach to family intervention: linking engagement in family-centered intervention to reductions in adolescent problem behavior. *Journal of consulting and clinical psychology*, *75*(4), 568.

Adapt the intensity of family-based interventions to the needs and motivation of the family.
Aim: reduce substance use and antisocial behavior among students ages 11–17.

McKay, J. R. (2005). Is there a case for extended interventions for alcohol and drug use disorders?. *Addiction*, *100*(11), 1594-1610.
Adapt the types of engagement strategy to the engagement status of the patient in treatment
How to extend behavioral and pharmacotherapy interventions for alcohol and drug-use disorders

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Brooner, Robert K., Michael S. Kidorf, Van L. King, Kenneth B. Stoller, Jessica M. Peirce, George E. Bigelow, and Ken Kolodner. "Behavioral contingencies improve counseling attendance in an adaptive treatment model." *Journal of Substance Abuse Treatment* 27, no. 3 (2004): 223-232.

Population: opioid-dependent patients (n = 127) newly admitted to an ambulatory treatment program that provides methadone.

Two types of adaptation:

During the program, they adapted the type of behavioral contingencies to promote counseling attendance and drug negative urine specimens (e.g., latter medication time if you missed a session, discharge from the program if you missed too many sessions).

They also provided a rescue intervention if the participant was classified as a non-responder (defined as a 50% or higher rate of missed counseling sessions or a 50% or higher rate of drug-positive urine specimens (or both) over the first 90 days of randomized care).

Rush, A. J., Crismon, L., Kashner, T. M., Toprac, M. G., Carmody, T. J., Trivedi, M. H., ... & Altshuler, K. Z. (2003). Texas Medication Algorithm Project, phase 3 (TMAP-3): rationale and study design. *Journal of Clinical Psychiatry*.

Population: patienst with major depression, schizophrenia, bipolar disorders

Type of adaptation: mediation algorithms to guide clinical care. Clinicians could deviate from the algorithms.

Decision rules are wellspecified

Outline

- What are Adaptive Interventions?
- Why use Adaptive Interventions?
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Why Adaptive Interventions?

1) High **heterogeneity** in need for or response to any one treatment
   - What works for one person may not work for another,
   - Thus, need to
     - Detect early signs of treatment failure
     - and modify the treatment
     - to prevent ultimate treatment failure

This is really "why do we need to consider a sequence of treatments?"

Why Adaptive Interventions?

2) Chronic or **waxing and waning** course of disorders
   - Improvement is not linear
   - Need to identify:
     - Intervals during which more intense treatment is required
     - Intervals in which less treatment is sufficient
     - Adapt treatment intensity accordingly

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This is really "why do we need to consider a sequence of treatments?"

Why Adaptive Interventions?

3) When treatment is **burdensome**
   - Side effects
   - Patient required to invest Time/Effort
   - Burden leads to non-adherence
   - Non-adherence reduces positive intervention effect

   - Need to:
     - Identify signs of burden
     - Modify intensity based on signs of burden

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Burden==exceeds personal resources

Why Adaptive Interventions?

4) Many treatments are **costly**
   - Certain treatments can be very expensive
   - Resources are often limited
   - Difficulties in scalability
   - Need to:
     - Try less expensive treatment first
     - Offer more costly treatments to people who need it

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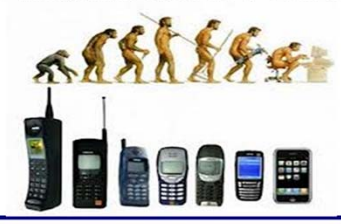
Why Adaptive Interventions?

5) Motivations for adapting mHealth

– **Boredom**
  - Need to change delivery modalities

– **Cognitive overload**
  - Sequence and adapt content to people's attention capacity

– **Habituation:** repetition→ lower arousal
  - Stop intervention from time to time, introduce new content, change presentation.



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Outline

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Design Goals

- Help me build a tech-based AI for at-risk drinkers:
  - Why at-risk drinking?
    - Exceeding gender-specific weekly/daily limits at least once in past 3 months
    - Associated with serious adverse consequences:
      - Subsequent alcohol use disorders, injuries, accidents etc.
  - Why tech-based (mobile + web)
    - Approach was found to be effective in reducing at-risk drinking
    - Require substantially lower delivery costs relative to in person alternatives.

CLARIFICATION NOTE: Here we are discussing the design of the adaptive intervention (hence "treatment design"). We are not discussing the design of a trial to inform the development of an AI—that's the next module on "trial design".

Use behavioral/social/biological theory, clinical experience, expert opinion, consultation with clinical staff, review of extant literature to help select the tailoring variables and form the decision rules.

Weekly limits: Men, > 14; Women, > 7 drinks per week

Daily limits: Men, ≥ 5; Women, ≥ 4 drinks per day

Design Goals

1. Maximize the ***strength*** of the AI ***(not the trial)***
   - This can be achieved by:
     - Well defined proximal and distal outcomes,
     - Select effective intervention options
     - Well chosen tailoring variables,
     - Well measured tailoring variables,
     - Well formulated decision rules,
     - Well implemented decision rules

CLARIFICATION NOTE: Here we are discussing the design of the adaptive intervention (hence "treatment design"). We are not discussing the design of a trial to inform the development of an AI—that's the next module on "trial design".

Select intervention options that will affect my proximal outcome.

Use behavioral/social/biological theory, clinical experience, expert opinion, consultation with clinical staff, review of extant literature to help select the tailoring variables and form the decision rules.

Design Goals

2. Maximize ***replicability***
   - in future ***experimental*** conditions, and
   - and real-world ***implementation*** conditions
   - We have confidence in an AI when its effects are replicable with different samples, clinical staff, locations, etc.
   - This can be achieved by
     - Clear articulation of the AI (make AI explicit)
     - Fidelity of implementation
     - Think carefully about and plan for non-standard scenarios that may arise

Fidelity of implementation -- intervention is delivered in the way it was designed to be delivered.

Recall: 5 Elements of AI

1. Decision Points → **Trigger**
2. Tailoring Variable → •Monitoring
3. Decision rule → •Individualizing
4. Intervention Options → •Delivering

Adaptation process

5. Proximal + Distal Outcomes → **Guide**

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Design Considerations:
Distal Outcome

- Define the ultimate goal of the intervention
  - What you want the AI to achieve at the end
    - Reduce # of at-risk drinking days in young adults at-risk drinkers in the course of a 12 week intervention
  - **Other examples:**
    - Enhance treatment engagement (session participation)
    - Prevent relapse
    - Improve school performance

I select this outcome because it is clinically meaningful

Often there are various ways to achieve the distal outcome. For, both stress reduction and reducing social norms for drinking are known as useful mechanisms to reduce heavy drinking.

I can choose to target both, or I can choose to target just one (given practical considerations).

Selecting a proximal outcome is important because it will guide the type of intervention you will offer, and/or the tailoring variable that you will select

If my proximal outcome is stress reduction, my intervention options might be designed to reduce stress (e.g., stress-management intervention), and/or I will adapt the intervention based on the participant's level of stress.

Design Considerations:
Proximal Outcome

- Select and clearly define proximal outcomes
  - Pathways through which you want the intervention to achieve its ultimate goal
  - Three types of pathways:
    - Response-based pathways
      - Example: at-risk drinking days by week 4
    - Performance-based pathways
      - Example: Stress, over-estimating social norms for drinking
    - Engagement/adherence–based pathways
      - Example: Weekly use of tech-based intervention

Response-based pathways are obvious short-term information that is part of the distal outcome: these are proximal measures that are part of the distal outcome, they form the distal outcome.

Performance-based: these are mechanisms (behaviors, experiences and feelings) that predict the distal outcome.

Engagement: these are indicators of engagement and adherence that predict the distal outcome.

Often– the distal outcome is a combination of all pathways.

Selecting a proximal outcome is important because it will guide the type of intervention you will offer, and/or the tailoring variable that you will select

If my proximal outcome is stress reduction, my intervention options might be designed to reduce stress (e.g., stress-management intervention), and/or I will adapt the intervention based on the participant's level of stress.

Design Considerations:
Intervention Options

- Engagement/adherence–based pathways
  - Weekly use of tech-based intervention → 2 types of delivery modes: 1) Mobile-based 2) Web-based
- Performance-based pathways
  - Stress, over-estimating social norms for drinking → 2 types of content: 1) Stress Management 2) PNF
- Response-based pathways
  - Monthly at-risk drinking days → 2 augmentation tactics: 1) with In-person sessions 2) Continue

Select intervention options in light of the proximal outcomes

Here, we select intervention options based on the proximal outcomes we selected earlier.

Design Considerations:
Decision Points

1. When do you need to make decisions/What kind

Program entry → What type of delivery modes
1) Mobile-based
2) Web-based

Program entry → What type of content:
1) Stress Management
2) PNF

End of week 4 → What type of augmentation tactics:
1) With In-person sessions
2) Continue

Design Considerations:
Decision Points

2. Which decisions are *critical* and need to be guided (e.g. manualized, structured)?

- Not all decisions need to be guided.
  - But knowing which are and which are not is helpful.
- Need to guide decisions that likely influence the outcome
- My example:
  - **Guide:** delivery modality, content, augmentation tactic
  - **No need to guide:** timing of initial interview

variance: different staff would provide the same individual with different treatments

Non-systematic variance: this variance is due to issues unrelated to the individual (staff member is in a hurry, staff member is tired, last patient of the day, etc.)

Systematic variance: this variance is due to (unconscious) bias on the part of the staff member. One staff member connects to the individual whereas the other staff member does not. R

Design Considerations:
Tailoring Variables

How to select a tailoring variable?

- Select variables that are useful for making intervention decisions.

Useful how???

Design Considerations:
Tailoring Variables

Type 1: **The Obvious**

Useful in identifying a sub-group for whom specific options should not be considered for obvious practical/ ethical /clinical reasons

Type 2: **The Predictor**

Useful in identifying a sub-group who need an intervention.

Type 3: **The Moderator**

Useful in identifying a sub-group of people who would benefit more from one type of intervention option over another

Design Considerations:
Tailoring Variables

Type 1: **The Obvious**

Useful in identifying sub-groups of people for whom different intervention options should not be considered for obvious practical, ethical, and/or clinical reasons.

Examples:

- Practically, its not reasonable to offer a mobile-based intervention to people who do not have a mobile device.
  - Owning a mobile device is a tailoring variable
- Practically, I will not consider an intervention that requires family support to a participant with poor family functioning
  - Family functioning is a tailoring variable

Design Considerations:
Tailoring Variables

Type 2: **The Predictor**

Useful in identifying a sub-group of people who need an intervention (not clear what type) and a sub-group who do not need an intervention.

Example:

- Consider my tech-based intervention for at-risk drinkers.
- Empirical evidence and theories suggests that
  - People who remain at risk at week 4 (i.e., non-responders) are likely to fail in long-term (remain at-risk drinkers at week 12)
  - Hence, non-responders require an intervention.

Design Considerations:
Tailoring Variables

Type 3: **The Moderator**

Useful in identifying a sub-group of people who would benefit from one intervention option over another, and another sub-group

(a) for whom there is insufficient evidence to decide; or

(b) who would benefit from a different intervention option.

In the next slide you will see why I call this the moderation: because I is guided by empirical evidence concerning how this variable moderates intervention effects.

Design Considerations:
Tailoring Variables

Type 3a: one sub-group would benefit from one intervention option over another, and another for whom there is insufficient evidence to decide

Data from a randomized trial in which:

Participants started with a tech-based intervention

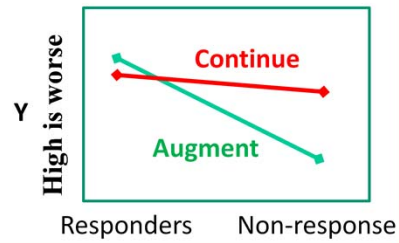
At week 4 everyone randomized to either Augment or Continue.

$$Y=\beta_0+\beta_1 R+\beta_2 T+\beta_3 R*T+e$$

Y= # at-risk drinking days at week 12

R= Response status at week 4

T= Tactic at week 4 (continue vs. augment)



I used this moderated regression to determine whether and how response status can be used to tailor the tactic (i.e., to decide what tactic to offer and for who)

Moderation is used because via moderation I can determine whether the effect of the tactic varies depending on response status (my candidate tailoring variable)

Results: Tactic interacts with the response status in the following way:

Design Considerations:
Tailoring Variables

Type 3b: one sub-group would benefit from one intervention option over another, whereas another sub-group would benefit from a different intervention option

Data from a randomized trial in which:

Participants started with a tech-based intervention

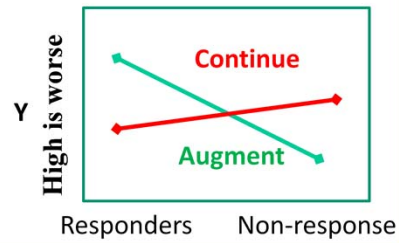
At week 4 everyone randomized to either Augment or Continue.

$$Y=\beta_0+\beta_1 R+\beta_2 T+\beta_3 R*T+e$$

Y= # at-risk drinking days at week 12

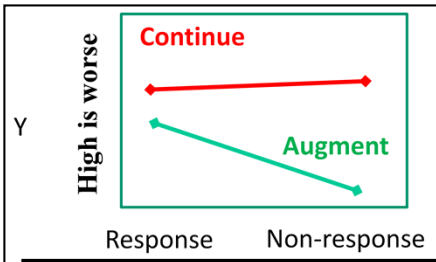
R= Response status at week 4

T= Tactic at week 4 (continue vs. augment)



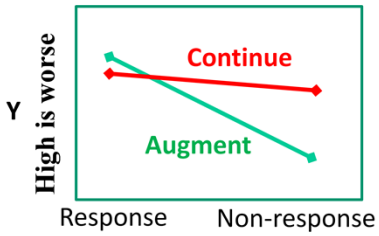
Now you know why we call this type of tailoring variable the Moderator: because it is guided by empirical evidence concerning whether and how this variable moderates the intervention effect.

But its not a simple moderation that we are looking for in empirical evidence, it's a special type of moderation that is informative for decision making

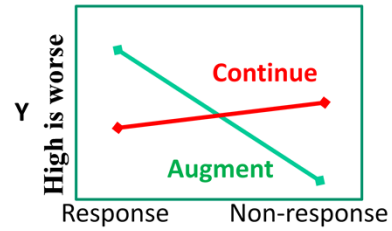


Response status is a moderator variable because the magnitude of the effect of tactic differs by response status.

Response status is not a tailoring variable: Continue is better for all subjects.
However, what if for responders, the diff is zero?



Response status is a Type 3a tailoring variable because it is useful for making an intervention decision for non-responders.



Response Status is a Type 3b tailoring variable because the direction of the effect of tactic differs for responders vs. non-responders

Response status is useful for making different intervention decisions for different sub-groups

Design Considerations:
Tailoring Variables

Tailoring variables can be

- Baseline variables: gender, age, symptom severity
- Proximal outcomes
  - Short term representations of the distal outcome
    - Example: Monthly at-risk drinking days
  - Performance-based mechanisms
    - Example: Stress, social norms for drinking
  - Engagement/adherence–based mechanisms
    - Example: Weekly engagement in a web-based intervention

Design Considerations:
Tailoring Variables

How to measure a tailoring variable?

I. Daily Drinking Questionnaire (DDQ)/Frequency of Heavy Drinking (*B, NW, W*)

This section asks you to report on your drinking and to estimate others' drinking over the **past month**.
For all questions, one *standard* drink equals:

- 4oz. wine
- 10oz. wine cooler
- 12oz. beer (8 oz. Of Canadian, Malt Liquor, or Ice Beers, or 10oz. of Microbrew)
- 1 Cocktail with 1 oz. of 100 proof liquor or 1 ¼ oz. of 80 proof liquor.

1. How frequently in the **past month** did you drink more than 4 (women) or 5 (men) *standard* drinks in a single day?

- ❑ I do not drink at all → Skip to question ##
- ❑ About once in the month.
- ☒ Two to three times in the month.
- ❑ Once or twice a week.
- ❑ Three to four times a week.
- ❑ Nearly every day.
- ❑ Once a day or more

Assume that I want to use this instrument to define response and non-responders so that non-responders will receive augment and responders will receive continue.

I need to make sure is instrument is reliable and valid

Design Considerations:
Tailoring Variables

- **Reliability:** the degree to which an assessment tool produces stable and consistent results with repeated trials.
- Unreliability: Assume no black box
  - participants with the same level of drinking mark an answer depending on whatever they think a standard drink is
  - I'm capturing random variability (noise) in the testing method rather than actual differences in at-risk drinking (signal).
  - I might be making unsystematic assignment of people to subsequent interventions.

Design Considerations:
Tailoring Variables

- **Validity:** how well the test truly assesses the characteristic it is intended to study as judged by external criteria
- **Invalid (biased):** assume I didn't frame the question well, so
  - People consistently report that they had fewer at-risk drinking days than they actually did.
  - Instrument is reliable, but it is not valid because self-report is always lower than true drinking.
  - This will weaken intervention effect (assuming my theory is correct) as I will be systematically assigning people to the wrong subsequent intervention option

Assume that because of the way I framed the question, people consistently report that they had fewer at-risk drinking days than they actually did

Design Considerations:
Tailoring Variables

How to Time Assessments of Tailoring variable?

- Tailoring variable should be assessed at sufficiently frequent intervals so that non-response is detected in a timely manner.
  - Too infrequent → condition may deteriorate so much that you might not be able to rescue with available options.
  - Too frequent → disengagement or non-adherence
  - Example: should I measure at-risk drinking monthly, or weekly

Empirical evidence suggests that in my population, change from at-risk to more heavy drinking patterns is unlikely to occur within a week, and I don't want to burden my participants.

Design Considerations:
Decision Rules

How to derive decision rules?

- Articulate a theoretical model
  - For how treatment effect on key outcomes should differ across values of the tailoring variable.
  - For every value of the tailoring variable, state expected outcome associated with each intervention option.
- How?
  - Use prior clinical experience
  - Use prior experimental and observational studies
  - Discuss with research team / clinical staff, "What intervention option would be best for people with this value on the tailoring variable?"

Design Considerations:
Decision Rules

- Good decision rules are objective, are operationalized.
- Strive for comprehensive rules, yet clear and specific
- Cover situations that can occur in real-life and practice
  - Including when tailoring variable is missing or unavailable.

Design Considerations:
Decision Rules

How to operationalize decision rules?

Bad: Individuals who drinking too much are non-responders and receive augment.

Better: Individuals who experience 2 + heavy drinking days (HDDs) in the past month are declared non-responders and receive in-person in addition to initial treatment

Awesome: Individuals who experience 2+ HDDs in the past month are declared non-responders and receive in-person in addition to initial treatment; Whereas those with HDDs<2 in the past month continue with initial treatement.

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Questions?

More information:

•L.M Collins, S.A. Murphy and K.A. Bierman (2004), A Conceptual Framework for Adaptive Preventive Interventions, *Prevention Science* 5:185-196.

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