Adaptive Interventions

Module 1

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

Institute for Social Research
Survey Research Center
SRC

MICHIGAN
STATISTICS

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.
- A sequence of individualized treatments.
- Mimics how we make decisions in real-life

AIs are individualized sequences of treatments

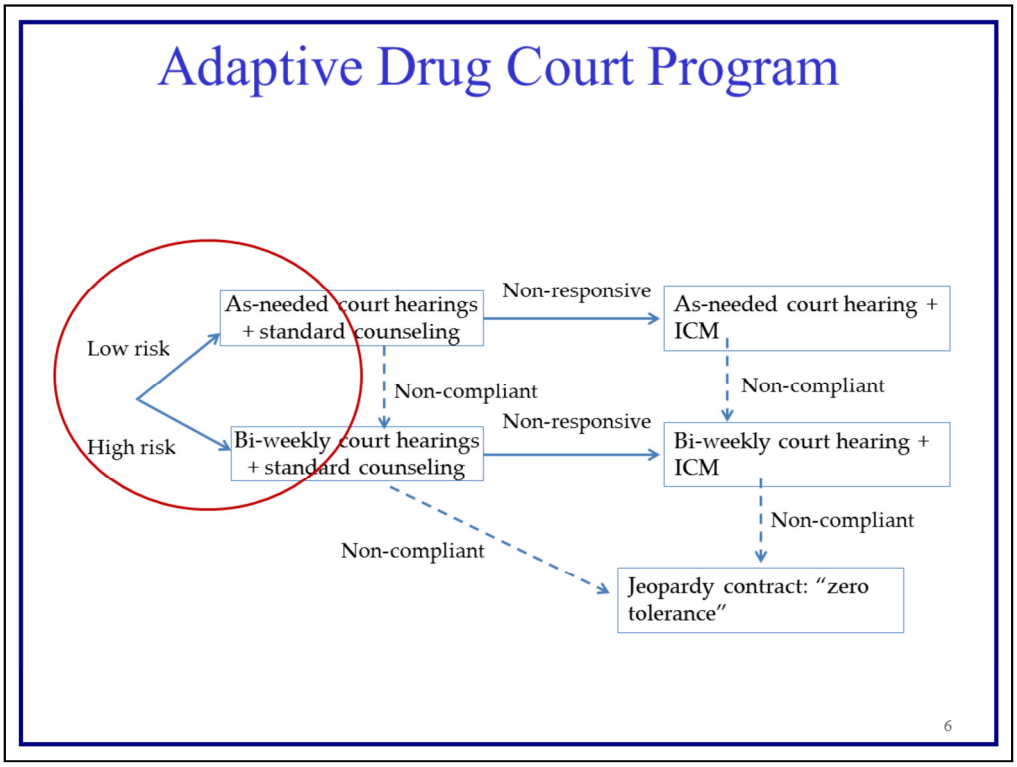
AIs operationalize clinical practice, and in fact it mimics how we make decisions in real-life.

Definition of AI

- Go by many different names:
  - Adaptive health interventions,
  - Adaptive treatment strategies,
  - Dynamic treatment regimes,
  - Treatment algorithms,
  - Stepped care models,
  - Treatment protocols,
  - Individualized interventions
  - ...

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)



Following their initial court hearing, risk was assessed.

High risk: ASPD (Antisocial Personality Disorder, based on Diagnostic Interview: APD-DI) or history of formal drug abuse treatment otherwise low risk.

These are assessed monthly: Noncompliance= (1) falls below threshold for attendance in counseling sessions or
(2) fails to provide 2 or more scheduled urine specimens; Nonresponsive = (1) is attending sessions and completing program requirements,
and (2) is not committing new infractions, but (3) provides 2 or more drug-positive urine specimens.

If non compliance, contact with the judge is increased.

ICM– intensive clinical case management: Participants are required to meet twice weekly with an intensive clinical case manager who provides
individual substance abuse counseling with an emphasis on motivational enhancement, relapse prevention, and cognitive restructuring ("criminal thinking") techniques.

Jeopardy contract: involves "zero tolerance" for further violations of the rules of the program.
Any further violation leads to a termination hearing.

At the termination hearing, the individual is terminated from the program and sentenced on the original charge/s
unless he/she can provide a good reason to be given another chance.
The decision of whether or not to grant another chance is within the discretion of the judge.

To graduate offender must attend 12 counseling sessions; provide 14 consecutive weekly negative drug urine specimens; remain arrest-free; obey program rules and procedures; pay 200 dollar court fee.

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)

AI: 5 Elements

1. Decision Points ← Triggered

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

} Adaptation process

5. Proximal + Distal Outcomes ← Guided

AI: 5 Elements

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4. Intervention Options ← • Delivering

Adaptation process

5. Proximal + Distal Outcomes ← Guided

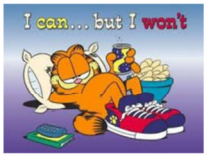
Not all individualization is adaptive…

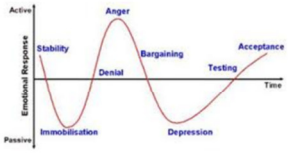
Various Types of Individualization

Individualization can take various forms

Singular **vs.** **Sequential**

Static **vs.** **Dynamic**





Various Types of Individualization

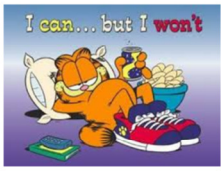
Singular/Sequential

Singular: for each participant, treatment is individualized at most once.

Sequential: for some (or all) of the participants, treatment may be individualized multiple times

Various Types of Individualization

Static/Dynamic



Static: individualization based on information that is unlikely to change over time as a result of treatment.

Dynamic: individualization based on information that can change over time as a result of treatment.

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Static examples: baseline symptoms, personality traits, gender, age...

Dynamic examples: response status, adherence, engagement in treatment.

Various Types of Individualization:

Individualization	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}

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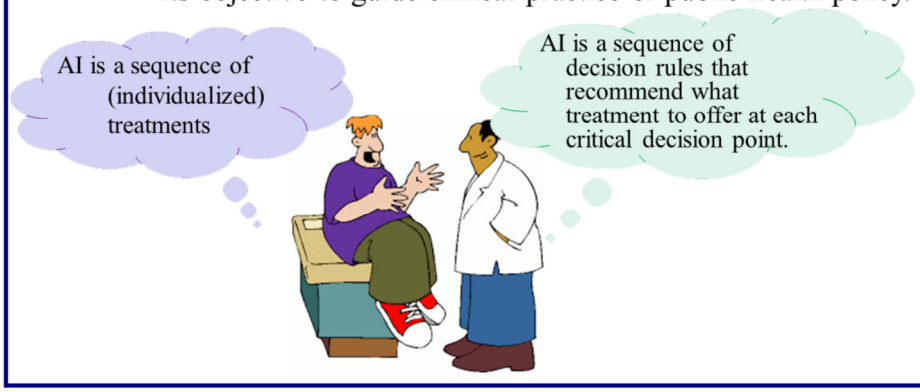
Various Types of Individualization:

Adaptive=Dynamic individualization

Individualization	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}

Summary

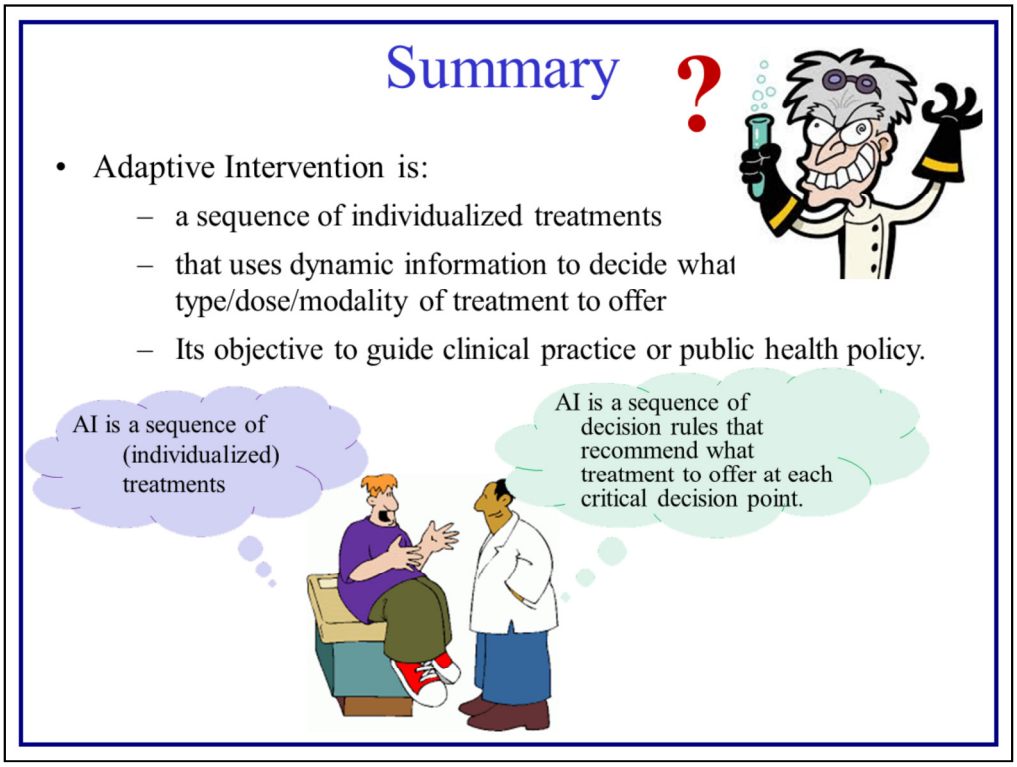
- Adaptive Intervention is:
  - a sequence of individualized treatments
  - that uses dynamic information to decide what type/dose/modality of treatment to offer
  - Its objective to guide clinical practice or public health policy.



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.

Summary

The role of the researcher?

Develop good decision rules to guide clinical practice and health policy

Answer **open scientific questions** concerning the development of good decision rules

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: patients with major depression, schizophrenia, bipolar disorders

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

Here, decision rules are well specified.

Outline

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

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

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

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

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

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.

Outline

- What are Adaptive Interventions?
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Overview of Design Goals

- Concrete example to guide our discussion
- General design goals: strength and replicability
- Design goals for
  - Distal outcome
  - Proximal outcomes
  - Intervention options
  - Decision points
  - Tailoring variables
  - Decision rules

Design Goals: Concrete example

- 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

Why tech-based (mobile + web)?

- Effective approach in reducing at-risk drinking
- Require substantially lower delivery costs.

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".

Weekly limits: Men, > 14; Women, > 7 drinks per week
Daily limits: Men, ≥ 5; Women, ≥ 4 drinks per day

Design Goals: Strength

Maximize the ***strength*** of the AI ***(not the trial)***

- This can be achieved by:
  - Define your proximal and distal outcomes,
  - Select effective intervention options
    - That will affect your proximal outcome
  - Well chosen tailoring variables,
    - Theory, clinical experience, expert opinion, consult your clinical staff
  - Well measured tailoring variables,
  - Well formulated decision rules,
  - Well implemented decision rules.

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.

Design Goals: Replicability

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.

Non standard scenario: for example when you use self report to measure a tailoring variable (e.g., response/non-response) and the person does not provide the self-report;

what would you do, how would you classify this person?

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**

AI Design Goals: 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

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I select this outcome because it is clinically meaningful;

I actually want at-risk drinkers to transition from at –risk to non-at-risk drinking patterns; but I selected a more reasonable proximal outcome given that I want to focus on brief interventions.

AI Design Goals: Proximal Outcome

- Clearly define proximal outcomes
  - Pathways through which you want the intervention to achieve its ultimate goal

Performance-based

Stress, over-estimating social norms for drinking

Engagement/adherence–based

Use of intervention content

Response-based

Monthly reduction in at-risk drinking days

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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.

Response-based pathways: short-term information that is (for obvious reasons) 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-based: these are indicators of engagement and adherence that predict the distal outcome.

Often there are various ways to achieve the distal outcome; the distal outcome can be a combination of all pathways.

AI Design Goals: Intervention Options

- Select intervention options in light of proximal outcomes

Stress reduction (Performance-based) → Stress Management Program including:
1 in-person session
mobile-based intervention

Monthly reduction in at-risk drinking days (Response-based) →
1) Intensify with in-person sessions (for participants who do not show sufficient monthly reduction).
2) Continue (for those who show sufficient monthly reduction)

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Remember, practically, monthly reduction in at-risk drinking will help me achieve my distal outcome.

So, practically, it makes sense to identify participants who do not show sufficient reduction on a monthly basis, and intensify the intervention;

whereas those who show enough reduction can just continue with the initial intervention.

AI Design Goals: Intervention Options

- Select intervention options in light of proximal outcomes

Stress reduction
(Performance-based) →

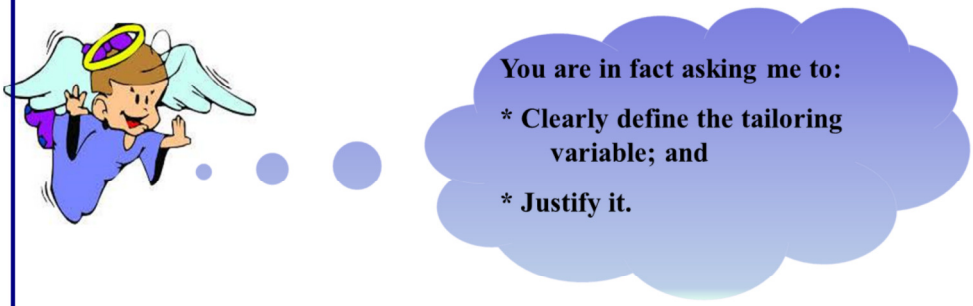
Stress Management Program
including:
1 in-person session
mobile-based intervention

Monthly reduction in
at-risk drinking days →
(Response-based)

1) Intensify with in-person sessions (for participants who do not show sufficient monthly reduction).
2) Continue (for those who show sufficient monthly reduction)

What is the justification for selecting different intervention options for different subgroups?

AI Design Goals: Tailoring Variables



- How to select a tailoring variable?
  - Select variables that are useful for making intervention decisions.

Useful how???

AI Design Goals: 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

AI Design Goals: Tailoring Variables

Type 1: The Obvious

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

Example:

- 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

Another example: Practically, I will not consider an intervention that requires family support to a participant with poor family functioning

Family functioning is a tailoring variable

AI Design Goals: 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:

- Empirical evidence 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.

AI Design Goals: 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 moderator: because it is guided by empirical evidence concerning how this variable moderates intervention effects.

AI Design Goals: 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

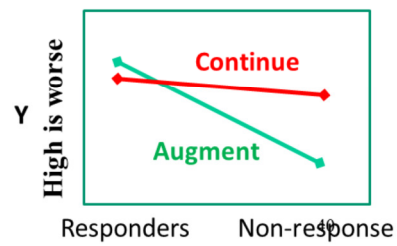
At week 4 everyone randomized to either Augment or Continue.

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

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.

AI Design Goals: 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

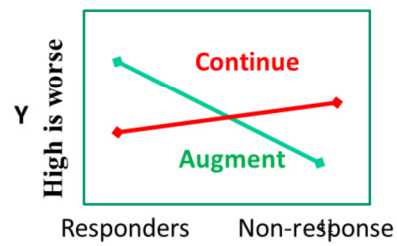
At week 4 everyone randomized to either Augment or Continue.

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

Y= # at-risk drinking days at week 12

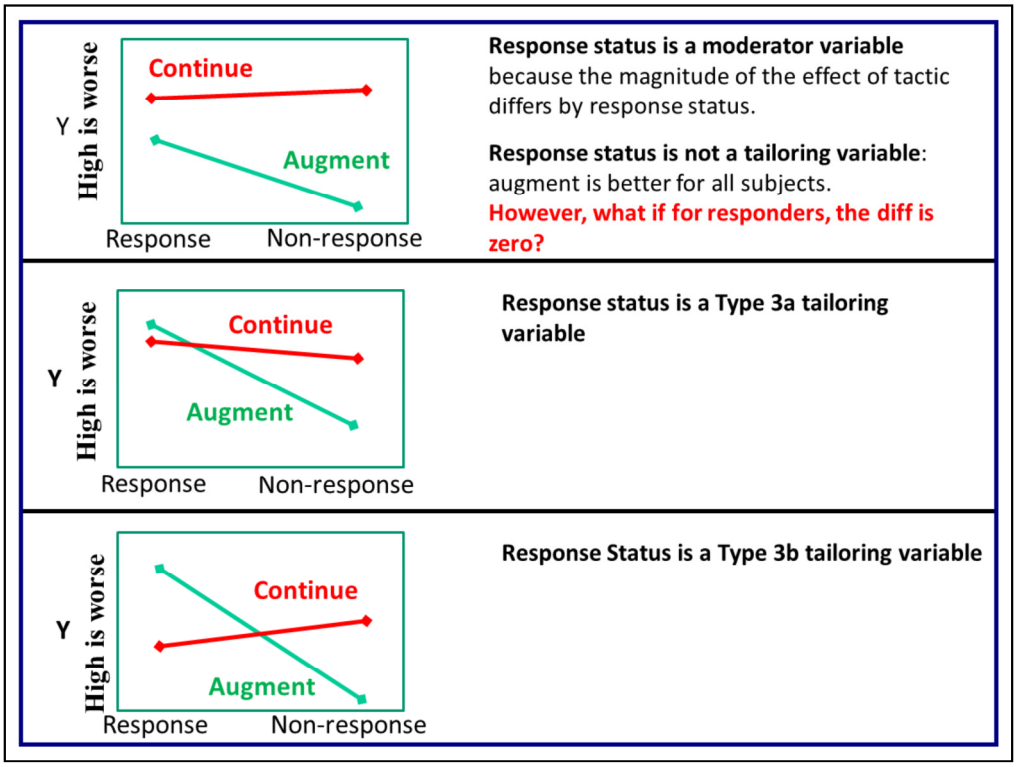
R= Response status at week 4

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



This slide demonstrates that not all moderators are tailoring variables.

AI Design Goals: Tailoring Variables

Tailoring variables can be

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

AI Design Goals: 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

Responders

Non-Responders

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.

AI Design Goals: Tailoring Variables

Reliability:

– Test produces stable/consistent results with repeated trials.

Unreliability:

– What if there is no black box?

- Participants with the same level of drinking mark an answer depending on whatever they think a standard drink is
- Captures random variability (noise) in the testing method rather than actual differences in at-risk drinking (signal).
- Unsystematic assignment of people to subsequent interventions.

AI Design Goals: Tailoring Variables

Validity:

– Test truly assesses the characteristic it is intended to assess.

Invalid (biased):

– What if I didn't frame the question well?

- People consistently report that they had fewer at-risk drinking days than they actually did.
- Test is reliable, but not valid; self-report is lower than true drinking.
- Resulting in <u>systematic</u> assignment of people to the wrong subsequent intervention option;
- Weakened intervention effect.

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.

Validity is judged by external criteria.

AI Design Goals: Decision Points

- How to select decision points?
  - Based on the ***dynamics*** of the tailoring variable.
  - ***Dynamics:***
    - Frequency at which tailoring variable is likely to change over time
    - In a meaningful manner→ changes are indicative of need for an intervention

Dynamics of tailoring variable	**Decision point**
Weekly	Every week
X weeks after baseline	At week X
Monthly	Every month
X months after baseline	At month X

AI Design Goals: Decision Rules

- Specify a decision rule for each decision point?
  - How to construct good decision rules?
    - Articulate a theoretical model that describes
      - The expected outcome associated with each intervention option, for every value of the tailoring variable.
    - Model can be based on:
      - Clinical experience
      - Experimental and observational studies
      - Discussions with research team / clinical staff,

"What intervention option would be best for people with this value on the tailoring variable?"

AI Design Goals: Decision Rules

- How to construct good 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.

AI Design Goals: 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 treatment.

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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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Backup Slides

Examples of Critical 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?

Examples of Critical Decisions

- About treatment ***engagement***:
  - How do we re-engage patients who are non-adherent?

Examples of Critical Decisions

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

Examples of Critical Decisions

- 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