

Developing (and getting funded) Shared decision making interventions

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Agenda

- Who funds SDM research?
- What are the funders looking for?
- Challenges
 - Specifying the outcome
 - Measuring the outcome
 - Evaluating the outcome
- Grant development and review tips
- Selected key methods to include in grants

Poll

- What funding groups have you applied to for research related to SDM? (click all that apply)
 - VA
 - NIH
 - PCORI
 - Others (list _____)
 - None—yet!

Who funds SDM?

- VA HSR&D
- NIH (specific institutes)
- PCORI
- Foundations (for example)
 - American Cancer Society
 - BCBS
- Sometimes others: DoD, CMS – keep your eye open for announcements and calls

What Funders are Looking For

- Know the sponsor; each will have priorities or focus areas. Do your homework!
- “Shared decision making” may not be named as a priority area, but might fall under one
- Is your study interventional or observational? Find out what the funder is willing to fund

VA HSR&D Priority Areas

- Access & Rural Health
- Equity and Disparities
- Informatics
- Longterm care & caregiving
- Mental & behavioral health
- Women's health
- Collaboration with operational partners is stressed

NIH

- Check institute priorities: not all fund SDM
- NCI, NHLBI, NIDCD, NIDDK, NIA have current DM projects
- Different mechanisms fund different things
 - K - career/training (do you need SDM skills?)
 - R21 – high risk/high payoff, focus on innovation (do you need to develop a decision aid?)
 - R01 – large observational, secondary data, RCT
- TIP: NIH Reporter is a good place to search key words to find out what has been funded
(<http://projectreporter.nih.gov/reporter.cfm>)

PCORI Focus Areas

- **Communication & Dissemination Research:** Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision making between patients & their providers.
- **Assessment of Prevention, Diagnosis & Treatment Options**
- **Addressing Disparities**
- **Accelerating Patient-Centered Outcomes Research and Methodological Research**

Types of SDM Grants

Examples of Types of SDM Studies

- Types of SDM grants
 - Observational/survey study
 - Developing a decision aid / decision support intervention with small pilot study
 - Secondary data analysis (depending on outcomes)
 - Intervention: e.g., large RCT of a decision aid / decision support intervention
 - Implementation/dissemination (to be discussed in next Webinar by Dr. Politi!)
- The mechanism/institute you apply will depend in part on the type of grant you are doing/plan to do

Poll

- What is the next SDM grant you are thinking about doing/planning to do (if any)? (check all that apply)
 - Observational/cross-sectional
 - Decision aid development
 - Secondary data analysis
 - RCT of an SDM intervention or decision aid
 - Other

Challenges

Poll

- What have been some problems in developing your SDM grant (check all that apply)?
 - Making the case for impact
 - Measuring the decision making outcome
 - Coming up with the right study design
 - Not having the intervention developed
 - Not having enough preliminary work in the area

Grant Development

- What is your idea? What is the process to study it? What is your conceptual framework?
- Fatal flaws:
 - Overly ambitious
 - Not having sufficient preliminary work
 - Inappropriate measures / measurement timing
- Know what you need:
 - Additional training (ie, K/CDA)
 - Pilot data
 - Developmental funding (pilot grant, R21) to develop a DA
 - Larger funding (R01, IIR) to evaluate the DA

Specifying the Outcome

- A “good” or shared decision?
 - So what? Why do Reviewers care if you study a decision or a decision process?
 - Often not sufficient for larger funding unless linked to a clinical outcome
 - Can you make this link and if so, how?
 - May have a primary and secondary outcome
 - Are you linking your outcome to an intervention? If so, when do you need to measure it?
 - Needs to be crystal clear in the proposal: conceptual framework very important!

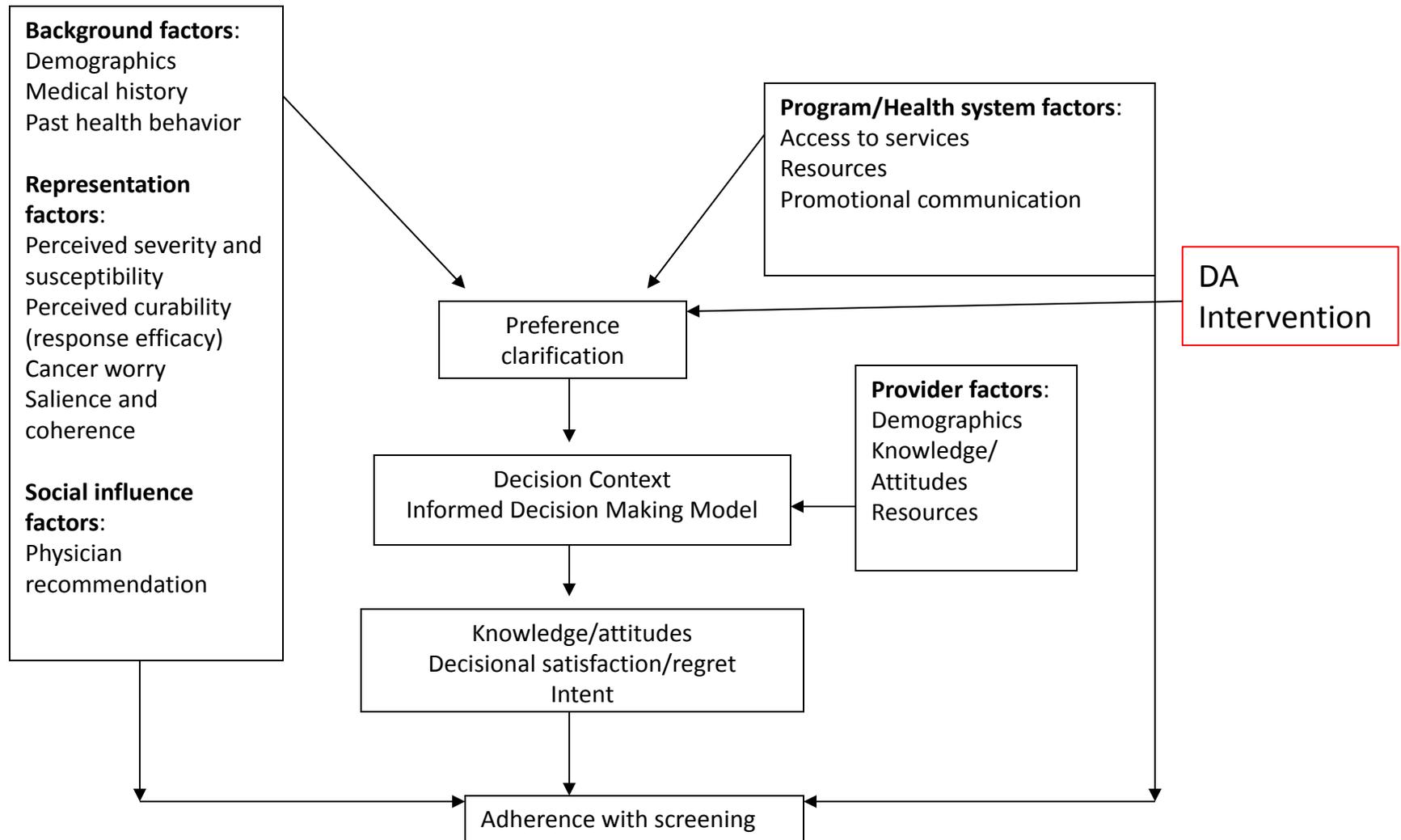
Measuring the Outcome

- ❑ Note that “shared” decision assumes you are studying a decision between patient & provider
- ❑ The measure(s) of DM used is critical, and few good ones exist
 - High quality decision: Sepucha et al., 2011, 2012
 - Decision satisfaction: Holmes-Rover et al., 1994
 - Decision conflict: O’Connor et al., 1995
 - Decision regret: Brehaut et al., 2003
 - COMRADE: Edwards et al, 2003
- Timing of measurement is key for what you are studying: impact of intervention, patient appraisal

Evaluating the Outcome

- Observational/cross sectional survey
 - Surveys most common
- Developmental
 - Outcome = a product (e.g., DA)
 - Qualitative methods
- Secondary data analysis
 - Most large datasets do not include SDM measures
 - Are there other patient reported outcomes?
- Interventional
 - Testing the impact of a decision aid; is this an RCT or other design?
- Important to link conceptual model to study hypotheses and measures

Figure 1. Conceptual Framework: Mechanism for Preference Clarification to Motivate CRC Screening Behavior



* Adapted from Myers et al. Preventive Health Model (PHM), 1994 and Braddock et al., Informed Decision Making Model, 1999

Review Process

Review Process

- Each sponsor has different review process and criteria: know what these are
- In general, the grant will be reviewed by an external review panel that may or may not include stakeholders (e.g., at PCORI)
- Know your audience!!
- TIP: Often you are writing for someone who will read your grant on the plane on the way to the study section. May not have expertise in DM.

VA & NIH: Making the Case

- Impact/significance: what is the long term impact of what you are studying?
 - You may be studying a specific decision process but it has implications that go beyond, and this needs to be very clear in the proposal
- Innovation: what is new or different about what you are studying or doing?
- Approach: What is the design and analysis?
- VA: Collaboration with operational partners
- All are important for funding!

PCORI: Making the Case

- How is what you are doing patient-centered?
- Is your project consistent with PCORI priorities?
- Importance of stakeholder involvement
 - Patients, systems, insurance payers
 - Patient and clinician involvement important throughout process; development of question, writing, participation (paid) in project, analysis of results
- Do you have a solid, scientific, patient-centered approach to your study?

Examples: Funded DM Grants

Colon Cancer Screening

- Problem: multiple test options available, screening rates are too low
- A preference tailored colon cancer screening decision aid in the VA (IIR)
 - Hypothesis: matching VA patients with the CRC screening test they prefer will increase adherence
 - Primary outcome: Adherence with screening 6 months after enrollment
 - Secondary outcomes: Patient reported decision process
 - Design: RCT comparing preference-tailored to static CA

Early-Stage Breast Cancer Treatment

- **Problem: Knowledge about treatment is low, and patients want help with decision making**
- **Breast cancer treatment decision tool (R01-type) :**
 - Hypothesis: the rate of high quality decisions will be higher in patients who view a tailored, interactive decision aid than those who view a static decision aid
 - Primary outcome: a high quality decision 4 weeks following enrollment
 - Secondary outcome: decision process measures
 - Design: RCT of tailored, interactive tool vs. static tool

Decision Support Networks

- Problem: Patients do not make decisions alone, but little is known about the impact of their supporters
- Decision support network Study (ACS RSG):
 - Research objectives: to document the decision support network of breast cancer patients, and to evaluate the engagement of supporters in breast cancer treatment decision making
 - Primary outcome: the engagement of a decision support person in breast cancer treatment (developed by us)
 - Design: cross sectional survey of patients and their decision supporters

Design Methodology

Types of SDM Measurement

- Survey
- Audio/video recording
- Medical records

VA Study Example

- Tested 2 different decision aids among localized prostate cancer.
- Recruited at biopsy and followed them through treatment.
- Measures
 - Surveys: Baseline, minutes before received diagnosis, 1 week post diagnosis.
 - Audio recorded diagnosis visit between patient and urologist.
 - Used CPRS to determine PSA, Gleason Score, Stage, treatment received.

Measurement Details to Include in Grant

□ Surveys

□ Timing of surveys

- Which measures, which time periods?
- WHY those time periods?

□ Description of measures

- Using existing instruments: Provide reliability and validity.
 - What construct are you measuring
- Tables of measures at each time periods can be really helpful.
- Include appendix of measures

Measurement Details to Include in Grant

- Audio recordings
 - Describe and defend the “Hawthorne Effect”
 - Emphasize people can decline
 - Discuss how you are going to analyze the data
 - Software
 - Key elements of analysis
 - People who have track record of analysis
 - Hypotheses
 - May be helpful to use a previously designed measures (e.g., OPTION measure which measures SDM)
 - Reliability of raters, how many will you double rate (all, 5%, 25% etc.)
 - Security issues

Composing the Survey

- What was the scale designed to measure, and in what population?
 - Is this what YOU want to measure?
 - Have others been using it as intended?
- Adapting questions

Survey Modes

- In-person interview
 - Good for difficult topics or to explore an issue
 - Interviewer can explain/follow-up questions
 - Can be useful if your participants are low literacy
 - BUT, social desirability may influence answers
 - Very time consuming and high effort
- Phone interview (CATI)
 - Structured script (can be tailored to react to responses)
 - Easy to randomize (random digit dialing)
 - Can be good for follow up surveys
 - Costly

Survey Modes

- Paper & pencil
 - Good for targeted populations (e.g. patients)
 - Respondents complete at their own pace
 - Cheaper: postage and printing costs
 - Can do large surveys, but response rate issues
- Internet surveys
 - Easiest to experimentally vary
 - FAST data collection of LARGE samples
 - Data is pre-entered and coded
 - Lower response rates, lack of representativeness

Questions to Ask When Choosing Between Survey Modes

- How many subjects do you need? (Power analyses)
- How many subjects will it take to get your sample size?
 - Response rates vary widely across modes
 - Factor in attrition for longitudinal studies

Things to Consider When Choosing Response Scales

- Use equal number of positive and negative response options.
- Use terms of the response scale in the question.
 - To what extent to you *agree* or *disagree* with the following statements?
 - How *likely* are you to do each of the following
- Make sure responses are mutually exclusive.
 - Example: age responses -> 20-24, 25-29, 30-34
 - Not 20-25, 25-30, 30-35

Things to Consider When Choosing Response Scales

- Likert scales:
 - Middle/neutral point?
 - Do you want a neutral category or to force them “to take a stand”
 - Length of scale: 4,5,6,7,10,11 point scales
 - How much variability do you expect there will be?
 - One directional or two?
 - One direction: Not at all likely => Extremely likely
 - Two directions: Strongly Disagree <=> Strongly Agree
 - Scales typically range from negative to positive

Things to Consider When Choosing Response Scales

- Inclusion/exclusion of don't know/refuse to answer options?
- Avoid “check all that apply”
 - Higher respondent burden
 - Won't know for sure whether they skipped them or didn't endorse them.
 - Can make them into a series of yes/no response options
- Include “none apply”
 - If appropriate
- Option set biases
 - Is the option set a useful way to divide *your* population?
 - E.g., income at the VA vs. at the airport
 - Can people infer “right” answers from your choices?

Other Things to Think About

- Avoid double barrel questions: If you fixed dinner at home last night, did you eat meat?
- Define all relevant time periods:
 - In the past X months, how often have you....
- Accuracy of recall (and methods to increase accuracy of recall)
 - Remembering last week vs. 6 months ago
- Literacy/numeracy levels

User Centered Design

- Individual interviews, feedback
- Especially relevant when designing interventions
- Often done in batches of 2-3 participants, make adaptations, repeat until saturation reached.

Pilot Testing

- What is it?
 - Conducting the survey with a small, representative sample of individuals for trying out the survey.
 - A chance to see what works well and what doesn't prior to wide-spread distribution of the survey.
 - Important step in the survey process.

Pilot Testing

- Just do it!
 - Obtain feedback from respondents about the questionnaire and their experience in completing it
 - Cognitive interviews – have respondents tell you what is going through their mind *as they are completing the survey*
 - Interview respondents or have discussion groups with respondents after completing survey to obtain feedback

Pilot Testing

- **Just Do It!**
 - Measure how much time survey actually takes to complete
 - Collect initial data to see what survey responses look like

Final Advice

- Survey development is a team sport
- Don't develop surveys in isolation
 - Brainstorm with collaborators.
 - Have people read through your surveys.
 - Work with your mentors: You learn best by doing and getting feedback.

Common measures used in decision aids (<http://decisionaid.ohri.ca/eval.html>)

- Knowledge
- Risk perceptions
- Decisional conflict scale (O'Connor et al)
- Decisional regret scale (Brehaut et al)
- COMRADE (Edwards et al)
- Satisfaction with decision (Holmes-Rovner et al)
- Preparation for decision making (Graham & O'Connor)
- Anxiety
- Satisfaction with decision making
- Values/values concordance

GEM: NIH's SDM Measures

- <https://www.gem-measures.org/public/Home.aspx?cat=0>
 - Content area: Risk and Decision Making

Questions?

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