Refining the Shared Decision Making Process Survey in ADHD Medication Decisions

Protocol and analysis plan

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Background: Shared decision making (SDM) is recommended for common pediatric conditions; however, there is limited data on measures of SDM in pediatrics. This study adapted the SDM Process scale and examined validity and reliability of the scale for ADHD treatment decisions.

Purpose: The primary purpose is to examine the performance of the SDM Process scale for pediatric medical decisions. A secondary purpose is to evaluate the impact of a Decision Aid on participant knowledge of ADHD treatment options.

Design: Retrospective observation study of parents who had recently made a decision about medication for their child's ADHD. We worked with a national sampling firm to obtain a target of 500 responses. The sampling firm sent an email invitation to potentially eligible panel members informing them that a survey is available for which they are eligible. Respondents choose to participate or not. The sampling firm's database does not hold sensitive or confidential panelist information. The firm stopped emailing web panel members once they received 500 completed surveys. The study investigators received de-identified participant information from the firm and did not have access to participants' emails or any of their personal information.

After completing the main decision making surveys, participants in the sample will be randomized 1:1 to one of two arms. Participants in the intervention arm will review a Decision Aid (patient educational tool) partway through the survey and those in the control arm will not receive any educational materials.

Sample: Participants were caregivers (n=498) of children (aged 5-13) diagnosed with ADHD, who had made a decision about ADHD medication in the last 2 years. The sample was not a national probability sample; however, the recruitment efforts were managed to be geographically diverse and to have at least 25% non-White respondents.

Intervention: Intervention arm received the Behavioral Attention Deficit Hyperactivity Disorder Treatment Decision Aid presenting benefits and harms of different treatments for ADHD. The decision aid was created at Cincinnati Children's Hospital.

The control arm did not receive any materials.

Survey protocol: The online survey was fielded between February 2021 and March 2021. Participants completed screener questions to determine eligibility. Then, they reviewed an information sheet that described the study and had to acknowledge that they read it and were willing to continue to the survey. Then, they continued to the survey. They were asked to identify the main decision they made about ADHD medicine over the past two years ("In the last 2 years, what was the main decision you made about using medicine to treat your child's ADHD?"; see Table 1) and were instructed to respond to the rest of the items thinking about that main decision.

All participants completed surveys before viewing the decision aid including the SDM Process scale Pediatric version (scores range 0-4, higher scores indicate more SDM), decisional conflict, decision regret, and decision involvement. Participants in the intervention arm completed the knowledge survey after reviewing the decision aid.

Starting 7 days after they completed the survey, respondents were invited to complete a brief follow-up survey to examine short term test-retest reliability. The goal of the retest was to obtain 200 completed surveys. Consent was implied by completion of the survey.

Risks and Adverse Events: No diagnosis or treatments were offered or administered as part of this study. The standard of care is that physicians discuss appropriate treatment options, including their benefits and risks with the caregiver and child. There are minimal risks associated with participating in the online field. The respondents to the online panel have already given permission to be contacted by signing up for the panel. The participants in the online panel may stop their participation at any time. No confidential or PHI was collected as part of this study.

There are no adverse events expected for this minimal risk survey study. Study staff will review the completed data set and will notify the site PI about any serious or moderate potential adverse events (AEs) immediately and any minor or potential ones at weekly meetings. The PI will review AEs individually real-time and in aggregate on a weekly, basis at team meetings. The PI and clinician co-investigators will review potentially serious adverse events (SAEs), as soon as

they are discovered. The PI ensures all protocol deviations, AEs, and SAEs are reported to the IRB according to the standard requirements.

There are no formal stopping rules for this minimal risk study.

Outcomes: The survey collected the following information:

- *SDM Process scale pediatric version (administered before the decision aid)*: Four items cover discussion of options, pros, cons, and preferences.[14] The items measures whether or not a specific behavior had occurred during an interaction with a healthcare provider about the treatment decision (see Table 2 for all items). Items were scored and summed in accordance with previously published work and a total score between 0 and 4 was calculated.[14] Higher scores indicate more SDM occurred. Participants with missing answers were not given a Pediatric SDM Process score.

- *Decisional Conflict (administered before the decision aid)*: The SURE scale is the 4-item short form of the Decisional Conflict Scale that measures the level of uncertainty about which treatment to choose. Each item is scored as "Yes" (1 point) or "No" (0 points) with total scores ranging from 0-4. A total score of 4 indicates no decisional conflict.[15,16] SURE has been shown to correlate positively with the SDM Process score in a range of surgical decisions,[14] as well as for decisions surrounding medication to manage depression.[17] The longer Decisional Conflict scale has been used to measure decisional conflict both in surrogate decision makers,[18] as well as in pediatric populations.[19]

- *Decision Regret (administered before the decision aid)*: 1 item assessed whether or not respondents would make the same decision again. Response options were on a scale from 1 (definitely make same decision again) to 4 (definitely NOT make same decision again). This item has not been used in pediatric studies, but has been used in previous studies by the authors and has been shown to be inversely related to the SDM Process scores for surgical decisions.[14]

- *Modified Control Preferences Scale (administered before the decision aid)*: 1-item, modified by the researchers and used in prior work,[20] asking who made the decision, with response options: "Mainly you", "Mainly your child's healthcare provider", "You and the healthcare provider made the decision together", and "Mainly someone else".[21] This version has not yet been used in a pediatric context, however the original Control Preference Scale been used in pediatric contexts.[22,23]

- *Knowledge (administered <u>after</u> the decision aid):* 7 multiple choice knowledge items that covered options, benefits and harms of medication and other treatments for ADHD. A total score (0-7) was created and converted to a 0-100% scale. Higher scores indicated higher knowledge.

- *ADHD severity :* Parent Informant Performance subscale of the National Institute for Children's Health Quality (NICHQ) Vanderbilt Assessment Scales.[24] Score range from 8 to 40 with higher scores indicating more problematic behavior.

- *Demographic and other information*: Participants were also asked to report on demographic information, current ADHD treatment(s), prior AHDH treatment(s), and years with ADHD.

Sample Size: The sample size was determined to ensure sufficient power to detect differences in knowledge by DA exposure of about 0.25SD at 0.05 significance with 80% power would require 250 per group.

Statistical methods: First, we examined descriptive results for the main decision item, the SDM Process scale, knowledge and other outcomes.

For the SDM Process scale, we also looked to see whether the scores spanned the range of total possible scores, were normally distributed, and whether there was evidence of floor or ceiling effects. Using a one-way ANOVA we tested for differences in Pediatric SDM Process scores by main decisions.

Then we examined the convergent validity and reliability of the SDM Process scale. As there is no gold-standard for measuring SDM, we tested the following hypotheses to examine validity of the scales by looking at relationships between known constructs such as decision conflict and decision regret.

Validity Hypotheses

1. Patients with higher Pediatric SDM Process scores (≥.33SD) were more likely to receive a top-score SURE score.
2. Patients with higher Pediatric SDM Process scores had less regret (r≥-.50).
3. Respondents who reported that their decision making process was mainly driven by the physician had lower Pediatric SDM Process scores (≥.33SD) than respondents who reported that they were involved and engaged in selecting treatment.

For hypothesis 1, we compared mean Pediatric SDM Process scores for those who were SURE (score=4) and those who were not (score <4) with a Welch's 2-sample t-test since Pediatric SDM Process scores showed significant heterogeneity when examined for SURE groups. For hypothesis 2, we used a Pearson's correlation to determine the relationship between Pediatric SDM Process and regret. ANOVA determined if there were differences in Pediatric SDM Process scores by who made the decision.

We assessed retest reliability using Intraclass correlation coefficient (ICC; ICC>0.7 indicating sufficient reliability).[25]

We examined individual knowledge items for % correct and % missing data. We calculated a total knowledge score and looked to see whether the scores spanned the range of total possible scores, were normally distributed, and whether there was evidence of floor or ceiling effects. We ran r point-biserial correlations of individual items with the total knowledge score. We then compared knowledge scores between arms using two sample t-test.

Data Sharing: We are committed to making resources and data from the proposed research available to other investigators in the research community. The data collected in the online field test will be made available to others for analysis and research. The study team will create a complete, cleaned, de-identified copy of the final data set. Information for investigators interested in using this data will be made available on the Health Decision Sciences Center website and in publications of the data. Dr. Sepucha will share a de-identified data set with outside investigators at no cost, according to approved Mass General Brigham policies for data sharing. Investigators from other sites will be able to request the data and will be required to complete a data use agreement that ensures that all local IRB requirements are met before using the data, that they will not attempt to identify any data in the dataset, and that they will not share the data set with anyone outside their project team.

We will also make information necessary to interpret the data, such as study protocols, data dictionaries, and survey tools available to interested investigators.

After the primary manuscripts are published, the MGH investigators will post the data and supporting materials in an open access service such as, ICPSR (https://www.icpsr.umich.edu/icpsrweb/). On ICPSR, individuals must register and agree to ICPSR's Responsible Use statement prior to accessing datasets. Additionally, before a dataset is made available for access, ICPSR completes a detailed review of all datasets to assess disclosure risk. If necessary, ICPSR modifies data to reduce disclosure risk or limits access to datasets for which modifying the data would substantially limit their utility or the risk of disclosure remains

high. No information that contains identifiers or that could be used to link an individual to the data will be included in the de-identified data set.