PILOT TESTING A NEW PREGNANCY DECISION MAKING TOOL FOR WOMEN WITH PHYSICAL DISABILITIES

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INTRODUCTION

Due to advances in maternal and fetal healthcare and the expansion of civil rights, between 100,000 and 200,000 American women with physical disabilities (WWPD) are pregnant each year.[1] Birth rates among WWPD have tripled since 2000,[2] with comparable rates of live births as their peers without disability.[3] Physical disability resulting from injury or illness is characterized by a loss of physical function and mobility. A decision to pursue pregnancy should involve well-informed deliberation between a woman and her clinicians given potential risks and tradeoffs in health (e.g., pre-term birth, miscarriage, infection) and function (e.g., further loss of mobility and independence). Unfortunately, enduring stigma continues to influence the experience of many WWPD seeking counsel about pregnancy.[4] Receipt of family planning services are highly variable, with WWPD with low education, low income and who are unemployed are particularly disadvantaged.[5] Clinicians' limited competence in disability[6,7] and lack of clinical guidelines[8] result in a substandard decision-making process for many. The development of a decision-making tool specifically for WWPD considering pregnancy can significantly improve the decision-making process by driving high quality decisions – that is, decisions that are informed by the evidence and align with the woman's values and preferences. Ultimately, a better decision-making process can improve healthcare quality and outcomes for this population of women. However, many pregnancy-related decision-making tools focus on pre-natal testing or delivery options[9] and few, if any, focus on the decision to become pregnant. None are designed to comprehensively address the complexities, challenges, and biases that WWPD often face in the decision to pursue pregnancy.

Despite a long history of stigma and discrimination, tens of thousands of WWPD in the U.S. are having children every year; a substantial number do so despite having a severe disability.[1,10] Women with disabilities are no different than their non-disabled peers in their desire or intention to have children, but they are almost twice as likely to be uncertain whether they will be able to realize their intention.[11] For many WWPD, pregnancy is not without elevated risk and significant tradeoffs in health, function and independence. The decision to pursue pregnancy is too often made in a vacuum of knowledge and guidance by clinicians, and in many cases, in the face of bias and discrimination. Clinicians face their own ambivalence and limited knowledge of disability in providing necessary care.[6] Their ambivalence reflects broader societal expectations that women with disabilities are asexual and that pregnancy is highly improbable.[12,13] Such longstanding myths and barriers have resulted in ill-informed and inadequate healthcare dramatically out of step with the hopes of WWPD.

METHODS

Sample Characteristics – In this study, physical disability is defined by loss or impairment of physical function limiting one or more important life activities. It can occur as a result of but not limited to: 1) traumatic injury, such as spinal cord injury; 2) neuro-developmental conditions, such as cerebral palsy; 3) chronic medical conditions, such as multiple sclerosis; or 4) a combination of these. Three items from the Behavioral Risk Factors Surveillance System[14] will determine disability severity based on the need for assistance with daily life activities and/or personal care; women with mild, moderate or severe severity will be eligible. Women who are eligible will be actively planning or in the process of making a decision about whether or not to get pregnant in the near future. The language is deliberately open based on feedback from women during development. The decision-making process or many women with physical disabilities can be protracted given many uncertainties and a general lack of information and health care provider expertise.

Description of the Decision Making Tool – The decision making tool is a 23-page tool and set of 9 downloadable worksheets (uploaded in Section 12, Exemption 3, #8 of the application). We developed the tool through iterative brainstorming sessions with stakeholders and used a survey, focus group, and interview data from women with physical disabilities who have been pregnant, decided not to get pregnant, or are considering a future pregnancy. The tool covers topics relevant to women with disabilities in considering or planning a

pregnancy and reflects core elements of decision making tools based on the Ottawa Framework for Decision Support.[15] This framework targets determinants of decisions that may be potentially modifiable by a decision-making tool, but are currently suboptimal for patients and health care providers due to factors such as inadequate knowledge, high uncertainty, or biased perceptions of others.

Section Title	Content
Overview of Pregnancy	Reviews changes in a woman's body during pregnancy. This is not meant to be exhaustive but a general overview.
Knowing what is important to you	Reflects ODSF' *values* component. It has several options to answer questions about values to explore what is important to guide decision-making. The associated worksheet (#1) focuses on what is important as a foundation for decision-making.
Partners, family and important relationships	Reflects ODFS' *support* component. Guides talking about the decision and engaging those most important in discussions. The two associated worksheets support conversations about pregnancy and decision making that can be challenging to have (#2 and #3).
Physical function and independence	Reviews major domains of physical function and the possible effects of pregnancy on independence. The associated worksheet (#4) highlights topic areas to discuss with different health care providers.
Health and wellbeing	An overview of the different medical specialties that might be involved in care during planning and during a pregnancy and reviews major areas of mental and physical health that could be affected during pregnancy. The associated worksheet (#5) presents a series of questions to review with family and health care providers.
Caring for an infant	Encourages consideration of various aspects of caring for an infant that may be relevant. The associated worksheet (#6) provides a list of considerations to support further dialog with family and health care providers.
Financial resources & insurance	Addresses the need for financial planning in anticipation of a pregnancy and childcare. The associated worksheet (#7) reviews various aspects of planning to consider as part of decision-making.
How to find reliable information and resources	Provides guidance for how to find information and judge its quality. The associated worksheet (#8) provides a step-by-step guide for evaluating online resources.
Connecting with other women with physical disabilities	General guidance for connecting to peers.
Dealing with reactions of others, stigma and bias, pressure	Addresses the pressures women with disabilities can face during decision-making about pregnancy.
Reaching a decision	A closing section that highlights acceptance of wherever the user is in the decision-making process, the different ways they may feel, and encourages taking breaks if needed.

Intervention Delivery, Feasibility and Efficacy Testing – We will provide the tool for a 3-month trial to 40 WWPD, allowing each woman to use the tool at her own pace. A pre-post design was selected following the recommendations of O'Connor and Jacobsen[16] for pilot testing new decision-making tools; this will help us prepare the tool for the next phase of testing that will utilize a parallel groups design. Similarly, the sample size was based on feasibility at this stage of the tool's development. We will assess outcomes at baseline, 6 weeks and the end of the trial period. For pilot testing at this stage of the tool's development, we are interested in several dimensions of feasibility and preliminary support for its efficacy. Using Bowen et al.'s phases of

intervention development,[17] we are primarily concerned with assessing "can it work". Participants will be compensated $40 for their time.

Outcome Assessment – In pilot testing the new tool, we are interested in feasibility and preliminary effectiveness. Specifically, we are interested in the tool's acceptability, demand for it, and its implementation (or use of the tool). For preliminary efficacy, the goal for pilot testing is *not* for a woman to make a decision about pregnancy during the intervention period. Rather, assessment will focus on three domains of interest we expect to be influenced positively by the use of the tool.

We will also ask a sub-set of women if they would be interested in an opened ended interview to learn more about their experience using the tool and any other feedback they wish to share. This is not required and is not highly structured; it will be an informal conversation for those wishing to share more in depth feedback.

- Decisional conflict is characterized by uncertainty about a decision. The Decisional Conflict Scale (DCS)[18] is a widely used outcome measure of decision-making with strong support for its validity.[18-20] We will use the *uncertainty sub-scale* for decisional conflict, the *support subscale* for having the support of others, and the *values subscale* for clarity of values.
- Decision or choice predisposition will be assessed using the single-item Stage of Decision-Making Scale.[21] The scale ranges from "haven't begun to think about choices" to "have already made a decision and unlikely to change my mind" but are modified to fit pregnancy and excludes the option of not having begun to think about choices since we are only including women actively planning or considering a future pregnancy.

Outcomes, measures, and time when collected are summarized in the table. All measures will be completed via online survey, or by telephone if requested by the participant.

Dimension of feasibility	Evaluates	Study-Specific Outcomes	Measures	When Collected (Baseline, 6 weeks, 12 weeks)
Acceptability	How participants react to the intervention	Satisfaction with tool; usefulness of the tool; intent to keep using the tool	Likert scales of overall satisfaction, usefulness; ratings of the presentation and balance of information.	12 weeks
Demand	How much the intervention is likely to be used	Frequency of actual use of the tool, interest in using the tool	Logbook of actual use (dates, duration) and interest in continuing to use the tool	Demand item: 6 and 12 weeks. Logbook: throughout
Implementation	How can the tool be delivered successfully	Factors affecting the use of the tool, ease or difficulty of using the tool	Likert scales of barriers and facilitators of tool use	12 weeks
Preliminary efficacy	Does the tool show promise of being successful with the intended population	Less decisional conflict; support of others; more clarity of values; greater readiness to make a decision (stage of decision making)	Decisional Conflict Scale sub-scales; Stage of Decision-Making Scale.	Baseline, 6 and 12 weeks

Analysis – General linear models (GLM) repeated measures will be used to model decisional conflict sub-scales and readiness to make a decision as a function of time, with the expectation that scores would increase over the course of the pilot testing. Mean imputation will be used for missing data.

REFERENCES

1. Iezzoni LI, Yu J, Wint AJ, Smeltzer SC, Ecker JL. Prevalence of current pregnancy among US women with and without chronic physical disabilities. *Med Care.* 2013;51(6):555-562.
2. Horner-Johnson W, Biel FM, Darney BG, Caughey AB. Time trends in births and cesarean deliveries among women with disabilities. *Disabil Health J.* 2017;10(3):376-381.
3. Horner-Johnson W, Kulkarni-Rajasekhara S, Darney BG, Dissanayake M, Caughey AB. Live birth, miscarriage, and abortion among U.S. women with and without disabilities. *Disabil Health J.* 2017;10(3):382-386.
4. Mitra M, Clements KM, Zhang J, Iezzoni LI, Smeltzer SC, Long-Bellil LM. Maternal Characteristics, Pregnancy Complications, and Adverse Birth Outcomes Among Women With Disabilities. *Medical care.* 2015;53(12):1027-1032.
5. Mosher W, Bloom T, Hughes R, Horton L, Mojtabai R, Alhusen JL. Disparities in receipt of family planning services by disability status: New estimates from the National Survey of Family Growth. *Disabil Health J.* 2017;10(3):394-399.
6. Walsh-Gallagher D, Mc Conkey R, Sinclair M, Clarke R. Normalising birth for women with a disability: The challenges facing practitioners. *Midwifery.* 2013;29(4):294-299.
7. Long-Bellil L, Mitra M, Iezzoni LI, Smeltzer SC, Smith LD. Experiences and unmet needs of women with physical disabilities for pain relief during labor and delivery. *Disabil Health J.* 2017;10(3):440-444.
8. Mitra M, Smith LD, Smeltzer SC, Long-Bellil LM, Sammet Moring N, Iezzoni LI. Barriers to providing maternity care to women with physical disabilities: Perspectives from health care practitioners. *Disabil Health J.* 2017.
9. Dugas M, Shorten A, Dube E, Wassef M, Bujold E, Chaillet N. Decision aid tools to support women's decision making in pregnancy and birth: a systematic review and meta-analysis. *Social science & medicine (1982).* 2012;74(12):1968-1978.
10. Horner-Johnson W, Darney BG, Kulkarni-Rajasekhara S, Quigley B, Caughey AB. Pregnancy among US women: differences by presence, type, and complexity of disability. *Am J Obstet Gynecol.* 2016;214(4):e1-9.
11. Shandra CL, Hogan DP, Short SE. Planning for motherhood: fertility attitudes, desires and intentions among women with disabilities. *Perspect Sex Reprod Health.* 2014;46(4):203-210.
12. Iezzoni LI, Wint AJ, Smeltzer SC, Ecker JL. "How did that happen?" Public responses to women with mobility disability during pregnancy. *Disabil Health J.* 2015;8(3):380-387.
13. Iezzoni LI, Mitra M. Transcending the counter-normative: Sexual and reproductive health and persons with disability. *Disabil Health J.* 2017;10(3):369-370.
14. Diab ME, Johnston MV. Relationships between level of disability and receipt of preventive health services. *Arch Phys Med Rehabil.* 2004;85(5):749-757.
15. O'Connor AM, Tugwell P, Wells GA, et al. A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Educ Couns.* 1998;33:267-279.
16. O'Connor A, Jacobsen MJ. Workbook on Developing and Evaluating Patient Decision Aids. The Ottawa Hospital Research Institute; 2003.
17. Bowen DJ, Kreuter M, Spring B, et al. How we design feasibility studies. *American journal of preventive medicine.* 2009;36(5):452-457.
18. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making.* 1995;15(1):25-30.
19. Katapodi MC, Munro ML, Pierce PF, Williams RA. Psychometric testing of the decisional conflict scale: genetic testing hereditary breast and ovarian cancer. *Nursing research.* 2011;60(6):368-377.
20. Song MK, Sereika SM. An evaluation of the Decisional Conflict Scale for measuring the quality of end-of-life decision making. *Patient Educ Couns.* 2006;61(3):397-404.
21. O'Connor A. *User Manual - Stage of Decision Making.* Ottawa Research Institute;2000.

OUTCOME MEASURES

Acceptability – How participants react to the intervention

Items drawn from O'Connor and Cranney, *User Manual - Acceptability*, 1996, 2002. www.ohri.ca/decisionaid.)

- Collected at the end of the trial.

Items	Response set
Please rate each section about how the information was presented in section X. (Each section header given.)	poor, fair, good, excellent
The length of the tool was …	too long, too short, just right
The amount of information in the tool was …	too much information, too little information, just right
The way information was presented in the tool was …	slanted toward getting pregnant, slanted towards not getting pregnant, balanced
How was this tool useful or not in supporting your decision making about pregnancy?	Open ended comments
How useful was the worksheet for X (each one in separate item)?	Very useful, somewhat useful, uncertain, not very useful, not at all useful
Do you think the tool will help women with a disability make a decision about whether or not to get pregnant?	Yes, No, Uncertain; Comments
What did you like or not like about the tool and worksheets?	Open ended comments
What suggestions do you have to improve the tool and worksheets?	Open ended comments

Demand – How much the intervention is likely to be used

- Collected during trial (log book) and 6 weeks and end of trial (likelihood of using)

Item	Response set
Log book of use	Simple paper or digital log of dates and duration the woman used the tool during the pilot testing period.
How likely are you to keep using the tool after the study is over?	Very likely, somewhat likely, not sure, not likely, definitely not likely

Implementation – How can the tool be delivered successfully

- Collected at the end of the trial.

Item	Response set
In general, how easy was it to use the tool? This would be things like going through the chapters, using the worksheets.	Very easy, somewhat easy, neither easy nor hard, somewhat hard, very hard
What made the tool easy or hard to use?	Open comments
Were there things that made the tool hard to use, if any?	Open comments
Were there things that made the tool easy to use?	Open comments

Preliminary Efficacy

Decisional Conflict Scale: Values clarity, Support, and Uncertainty subscales (*O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995;15(1):25-30.)*

- Response scale: strongly agree, agree, neither agree nor disagree, disagree, strongly disagree
- Collected at baseline, 6 weeks and end of pilot testing

Sub-scale	Items
Values Clarity	I am clear about which values matter most to me.
	I am clear about which risks matter most.
	I am clear about what is important to me.
Support	I have enough support from others to make a choice.
	I am choosing without pressure from others.
	I have enough advice to make a choice.
Uncertainty	I am clear about the best choice for me.
	I feel sure about what to choose.
	This decision is easy for me to make.

Stage of Decision-Making Scale (O'Connor A. *User Manual - Stage of Decision Making.* Ottawa Research Institute;2000).

- Collected at baseline, 6 weeks and end of pilot testing

Item	Response set
Making a decision about whether or not to get pregnant can be complicated. At this time, would you say you:	haven't begun to think about it (1)* haven't begun to think about it, but am interested in doing so (2)* are considering the decision now (3) are close to making a decision (4)

	have already made a decision, but am willing to reconsider (5) have already made a decision and am unlikely to change my mind (6)

* These options are not relevant given our inclusion criteria