

Desirable features in a decision aid for prenatal screening – what do pregnant women and their partners think? A mixed methods pilot study

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Abstract

Background

To help pregnant women and their partners make informed value-congruent decisions about Down syndrome prenatal screening, our team developed two successive versions of a decision aid (DAv2017 and DAv2014). We aimed to assess pregnant women and their partners' perceptions of the usefulness of the two DAs for preparing for decision making, their relative acceptability and their most desirable features.

Methods

This is a mixed methods pilot study. We recruited participants of study (women and their partners) when consulting for prenatal care in three clinical sites in Quebec City. To be eligible, women had to: (a) be at least 18 years old; (b) be more than 16 weeks pregnant; or having given birth in the previous year and (c) be able to speak and write in French or English. Both women and partners were invited to give their informed consent. We collected quantitative data on the usefulness of the DAs for preparing for decision making and their relative acceptability. We developed an interview grid based on the Technology Acceptance Model and Acceptability questionnaire to explore their perceptions of the most desirable features. We performed descriptive statistics and deductive analysis.

Results

Overall, 23 couples and 16 individual women participated in the study. The majority of participants were between 25 and 34 years old (79% of women and 59% of partners) and highly educated (66.7% of women and 54% of partners had a university-level education). DAv2017 scored higher for usefulness for preparing for decision making (86.2 ± 13 out of 100 for DAv2017 and 77.7 ± 14 for DAv2014). For most dimensions, DAv2017 was more acceptable than DAv2014 (e.g. the amount of information was found "just right" by 80% of participants for DAv2017 against 56% for DAv2014). However, participants preferred the presentation and the values clarification exercise of DAv2014. In their opinion, neither DA presented information in a completely balanced manner. They suggested adding more information about raising Down syndrome children, replacing frequencies with percentages, different values clarification methods, and a section for the partner.

Conclusions

A new user-centered version of the prenatal screening DA will integrate participants' suggestions to reflect end users' priorities.

Introduction

Screening tests for fetal genetic disorders are now a routine part of prenatal care, and pregnant women and their partners need unbiased, non-directive information about these tests (1). Women should be given the option to take the tests or not (2) and also be supported to choose between the various tests available (2, 3). These decisions can be difficult (4). First, the decision making often involves uncertainty (5–7). Second, women need to understand probabilistic data and the characteristics of the various screening tests and detection rates, but this information is complex (8). Third, prenatal testing for Down syndrome (DS) involves the woman's personal values and those of her partner, and they may find it difficult to articulate them (4, 6). Fourth, waiting for the test results can be stressful (9–11). Fifth, if the initial results indicate a higher risk of genetic disorder, the woman will have to decide whether to undergo more invasive diagnostic testing, with the risk of miscarriage it entails. If these results indicate that the fetus is affected, she will have to choose between terminating the pregnancy or preparing for a child who will have special needs throughout his/her life (2, 12). With shared decision making (SDM), women can be supported to face these difficulties and make informed value-congruent decisions in keeping with their values and preferences (4, 13).

SDM is an interpersonal and interdependent process whereby health professionals and patients work together to make informed value-congruent decisions about the patient's health (14, 15). Decision aids (DAs) are SDM tools that support decision making by providing factual information about health status, treatment options, associated benefits, disadvantages, probabilities, and scientific uncertainties, as well as helping users clarify their personal values concerning the decision (16, 17). A Cochrane systematic review of more than 100 randomized trials of patient DAs found that DAs performed better than usual care at increasing knowledge, improving the accuracy of risk perceptions, and promoting decisions that were informed and consistent with patients' values (18, 19). A systematic review on DAs in pregnancy care showed their positive effects on informed decision making (1). For prenatal testing decisions in particular, studies show they reduce decisional conflict and indecision, and help women and their partners to make choices that are informed by evidence and by what matters most to them (16–18, 20). Despite the efficacy of DAs, however, they are rarely used for prenatal screening (21) or indeed in any context (22, 23).

In earlier studies, embedded in a larger research initiative called the PEGASUS project (Personalized Genomics for Prenatal Aneuploidy Screening Using Maternal Blood) (24), we developed two successive versions of a paper-based DA to assist pregnant women and their partners to reach an informed, values-congruent decision about prenatal screening. Both versions were based on literature reviews and consultation with experts, including a medical biochemist subspecialized in molecular genetics, a family physician, a decision science specialist, a policy maker, behavioral scientists and pregnant women. Both versions were guided by basic educational and linguistic theory and risk communication research to maximize comprehension (25, 26). Both DAs met the International Patient Decision Aids Standards (IPDAS) (27). We aimed to assess pregnant women and their partners' perceptions of the usefulness of the two DAs for preparing for decision making, their relative acceptability and their most desirable features.

Materials And Methods

We used the Guidelines for Conducting and Reporting Mixed Research in the Field of Counseling and Beyond to report this study (28).

Study design

This is a convergent parallel mixed methods pilot study (29). We collected and analyzed quantitative and qualitative data separately before merging them. This study was approved by the Ethics Committee of Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (Project 2017-2018-15 MP).

Settings

We conducted the study in three clinical prenatal care sites in Quebec City: (i) the Maison de naissances de la Capitale Nationale (a birthing centre); (ii) the Maizerets Family Medicine Group (FMG); (iii) the Obstetrics and Gynecology Department of Saint François d'Assise Hospital. The objective was to recruit pregnant women in different socio-demographic milieus and who were being followed by different kinds of healthcare professionals: midwives (birthing centre), family physicians (family medicine group) and obstetricians (hospital).

Participants and recruitment

Study participants were pregnant women with or without their partners and women who had recently given birth. To be eligible, women had to: (a) be at least 18 years old; (b) be more than 16 weeks pregnant (we did not want to influence the outcome of their decision, and in Quebec, at 16 weeks women will have already taken the public screening test or refused it); or having given birth in the previous year; (c) be able to speak and write in French or English; (d) be able to give informed consent. We excluded women who: (i) participated in certain phases of our earlier studies on DAs (30, 31) and/or (ii) presented a high-risk pregnancy (e.g. preeclampsia, gestational diabetes, multiple pregnancy).

We approached managers of the three clinical prenatal care sites in Quebec City and obtained their consent for recruitment. We conducted the recruitment from May 2018 to February 2019. We approached participants in the waiting rooms of clinical sites where a research assistant informed them about the project and evaluated their interest in participating in the study. The research assistant gave consent forms to participants who volunteered to participate in the study and noted their contact details on the recruitment form in order to follow up with them and to find a date for the meeting. Participants were invited by phone or email to a meeting of about 60 to 90 minutes either at our research center, in a room at the clinical site, or in a place of their choice (e.g. home) depending on their preference.

Data collection

We collected data focusing on two prenatal screening decision aids whose features we detail below. Table 1 presents the differences between the DAs.

Table 1
Differences between DAv2017 and DAv2014

Version of DA	Decision point	Options				Types of trisomy	Values Clarification method	Length	Font size	Colors
		IBT	NT	NIPT	No test					
v2014	1	1	x	x	1	21	Information + List for summarizing	4 pages	10–12	Gray Tone
v2017	1	1	1	1	1	21, 18 & 13	Information + Star circling exercise	6 pages	12	Blue Tone Red Green
IBT: Integrated Biochemical Test; NT: Nuchal Translucency; NIPT: Non-Invasive Prenatal Testing.										

Prenatal screening decision aid, version 2014 (DAv2014)

The DAv2014 is a four-page DA that presents two options: to do the test or not to do it. Specifically, it includes (i) evidence-based **information** on Down syndrome (DS) and the risk of having a baby with DS given the mother's age; (ii) evidence-based information on the **advantages and disadvantages** of doing the test or not; (iii) evidence-based representations of the **probabilities of false positive/negatives** for the tests offered in the Quebec public healthcare system; (iv) a work chart to help women reflect on and write down the advantages and disadvantages of doing the test or not in terms of what is most important to them; (v) a box to note the **decision taken** and (vi) the SURE test (Sure of myself - Understand information - Risk-benefit ratio - Encouragement/support) for **evaluating the person's certainty** about the decision made (32) (Table 1, Appendix 1).

Prenatal screening decision aid, version 2017 (DAv2017)

The DAv2017 is a six-page DA that presents the yes/no choice, but also the additional choices between four screening options (not doing the test and the three test options). Specifically, it differs from DAv2014 in that it includes (i) **updated** evidence-based information on **more than one anomaly** (T21 or DS, plus T18, and T13) as well as the risk of having a baby with these anomalies given the mother's age; (ii) **more** and **updated** testing options available in the Quebec healthcare system integrated biochemical test (IBT) with or without nuchal translucency (NT), and non-invasive prenatal testing (NIPT); (iii) two work charts. The first section is on advantages and disadvantages of doing the test (e.g. being reassured, vs. unnecessary worry) and of not doing it (e.g. avoiding a later decision to terminate the pregnancy or not, vs. not knowing the risk of having a baby with DS). The second is on factors affecting the choice between the three tests (e.g. detection rates, costs). The work charts, instead of leaving space for users to write down their thoughts, are organized using a multiple criteria decision-making structure (25) whereby users circle 1–5 stars to indicate how important the pros and cons of the different options are to them. This DA also contains a box to note

the **decision taken** and the SURE test for **evaluating the person's certainty** about the decision made (Table 1, Appendix 2).

*INSERT Table 1 HERE

Procedure

We administered questionnaires to individual women and couples, to be self-completed, and conducted individual interviews with women or dyadic interviews with women and their partners. We pre-tested the questionnaires and the interview guide with two participants (pregnant women) and improved them following their feedback. At the beginning of the meeting, the research assistant welcomed participants and presented the context and purpose of the study. Then she collected signed consent forms and ensured that participants had no questions about the study. After making sure that the participants were ready to start the study, the research assistant began data collection. In step 1, she distributed questionnaire 1 (items on socio-demographic information). Only one questionnaire was given to couples, who were invited to complete it together. In step 2, participants watched the beginning of a video demonstrating the use of a DA by a clinician and a couple (about 2 minutes). In step 3, they received and read DAv2017. The women and couples were asked to imagine making a prenatal testing decision with the help of the DA. In step 4, participants received questionnaire 2 (items on acceptability and usefulness of the DA to prepare for decision-making, in relation to DAv2017) and completed it alone or with their partner. In step 5, they received and read DAv2014. In step 6, participants filled in questionnaire 3 (items on usefulness to prepare for decision-making, acceptability, and relative acceptability of the two DAs). The last step consisted of interviews, using an interview guide, on users' opinions on the various features of the DAs. The encounters lasted about 60 to 90 minutes.

Questionnaire material

We quantitatively assessed pregnant women's and their partners' perceptions of the usefulness of the two DAs for preparing for decision making and the relative acceptability of the features of the two DAs (e.g. graphic presentation, amount of information).

Usefulness was assessed using the Preparation for Decision Making scale (PrepDM) (33). This is a 10-item scale evaluating how useful the DA was for preparing participants to communicate about the decision with their practitioner in a consultation, for example, "Did this educational material help you recognize that a decision needs to be made?" and "Did this educational material help you think about which pros and cons are most important?" This scale has good psychometric properties with Cronbach's α ranging from 0.92 to 0.96 (33).

Acceptability was assessed using the 10-item Acceptability questionnaire (34). This questionnaire includes both structured and semi-structured questions evaluating the comprehensibility of components, length, amount of information, sufficiency of information, balance in presentation of information about options, and overall suitability of the DA for decision making. It can be used for both patients and practitioners (34).

After participants had read both DAs, we asked them which version of the DAs they found more acceptable, and how much they preferred one version to the other as measured on a 5-point Likert scale with the answer choices: Very little, Little, Moderately, Enough and A lot.

Interview material

We qualitatively explored (in more depth) the features of each DA that participants found most desirable and to solicit their suggestions. The development of the interview guide was inspired by the Technology Acceptance Model (TAM) (35) and the Acceptability questionnaire (34). According to the TAM, perceived utility and perceived ease of use are determinants of current usage (35). Perceived utility is influenced by a number of factors such as the perceived complexity of the information. Perceived ease of use is influenced by factors such as ease of navigation. Both constructs are also influenced by factors such as the characteristics of the technology (e.g. perceived attractiveness) and personal characteristics of the user (e.g. perceived pleasure) (35, 36). Thus, participants were invited to comment on visuals, colors, ease of navigation, aspects they liked or did not like, most helpful page, and suggestions for improvement of the DA.

Interviews were conducted by TTA, assisted by SAR, MC, MPD, APH or AAT who took notes during each interview. All interviews were audio recorded with the consent of the participants. At the end of the interview, participants received financial compensation of CAN\$25 for their participation in the study.

Sample size

The variable of interest was perceived usefulness of the DAs. This was assessed using the Preparation for Decision Making scale, a five-point Likert-type scale. Considering that this is a pilot study, to limit selection bias we needed 37 pregnant women with or without their partners for evaluating the usefulness of the DAs. This number was based on the 10% sample size planned for a future province-wide study that aims to produce a DA that will be routinely used in the general population (37). This calculation is based on the determination of power and sample size for linear models (38). We estimated that a sample size of 343 pregnant women with or without their partners would be sufficient to detect a partial correlation of 0.15 between the usefulness of the DA in preparing for decision making and the potentially confounding variables to be included in the model. We used a power of 80% and a statistical significance level of 5%. To account for missing data and to ensure that the sample was large enough to perform subgroup analyses (e.g., by age), we added 10% of its value to the estimated size. Therefore, the total sample for the larger study will be 377 pregnant women and their partners.

Data analysis

For the quantitative data, we used basic descriptive statistics (means, standard deviations, percentages, and 95% confidence intervals) to describe the sample in terms of socio-demographic characteristics and for all quantitative variables. For Usefulness (Preparation for Decision Making scale), items were summed and scored (divided by the number of items and multiplied by 25). Thus, scores were converted to a 0–100 scale with higher scores indicating higher perceived usefulness for preparing for decision making (33). To assess which DA was more useful overall for preparing for SDM, we performed a Student's t-test. We calculated

descriptive statistics of the six closed-ended Acceptability scale questions, while the open-ended Acceptability questions were analyzed together with the qualitative data. The comparison questions about the DAs were analyzed descriptively as well. All quantitative analyses were performed using SAS 9.4. No processing of the missing data was done.

For the qualitative part, all the audio recordings were transcribed verbatim. Two team members performed a deductive thematic analysis based on questions inspired by the TAM and the Acceptability questionnaire (34, 35). For dyadic interviews (women and partners), the point of view of each member of the couple interviewed was included in the analysis. We proceeded to a within-dyad and across-dyad analysis by identifying points of agreement and disagreement within dyads. We combined patterns and ideas across dyads (39). We used the software Nvivo 12 to analyze the qualitative data. Data analysts separately familiarized themselves with the content of the transcripts by reading about half of them. We chose two interviews at random and separately coded them. We created a theory-driven codebook based on our preliminary coding exercise (40). We separately coded all the transcripts while reviewing and revising the codebook in light of the data (40). We created a detailed summary of all themes from the data, specifying the number of statements and the overall trend of opinions on each theme. In two working sessions of three hours each, we cross-checked findings, analyzed the interrelation between themes (40) and reached consensus on discrepancies while going back to the verbatim or Nvivo nodes as needed. We reported on the most important findings. Based on Chang et al. (2009) (33), we reported qualitative data using the graded quantifier words *few*, *some*, *many* and *most*. (41). Based on Chang et al. (2009) (42), we used “few” when three to nine participants commented on a theme, “some” when 10 to 17 commented, “many” when 18 to 25 commented, and “most” when 26 to 39 participants commented.

Results

Participants’ characteristics

Figure 1 shows the flow of participants. Briefly, 214 participants were approached in the three clinical sites, of whom 62 participants entered the study (Fig. 1). Those who declined to participate cited the following reasons: lack of interest among women, their partners or both, and lack of time. Participants who cancelled their participation mostly mentioned lack of time or the unavailability of the partner. We met 18 women at their homes, 16 women at our research centre, six women at the clinical sites and one woman at Laval University.

*INSERT FIGURE 1 HERE

Table 2 shows socio-demographic characteristics of participants and characteristics related to their decision-making. Briefly, the majority of participants were between 25 and 34 years of age (79% of women and 59% of partners), Caucasian (90%), Canadian (90%), married or in a common-law relationship (85%), highly educated (66.7% of women and 54% of partners had a university-level education) and with a relatively high socioeconomic status (46% had an annual family income of CAN\$60,000 to \$99,999).

Table 2
Participant characteristics (n = 39)

Sociodemographic characteristics		
Characteristics n (%)^a	Women	Partners
	(n = 39)	(n = 39)
Age^b (years)		
Mean (SD)	30.2 (3.7)	-
18–24	2 (5.1)	-
25–34	31 (79.5)	23 (59.0)
35–44	6 (15.4)	14 (35.9)
Ethnicity		
Caucasian	35 (89.7)	35 (89.7)
African or African American	3 (7.7)	3 (7.7)
Indigenous	1 (2.6)	1 (2.6)
Residency status		
Canadian	35 (89.7)	35 (89.7)
Permanent Resident	4 (10.3)	4 (10.3)
Civil status		
Married or in common-law relationship	33 (84.6)	33 (84.6)
Single	5 (12.8)	5 (12.8)
Separated	1 (2.6)	-
Divorced	-	1 (2.6)
Education		
Elementary school	-	1 (2.6)
High school or professional diploma	-	6 (15.4)
College diploma	13 (33.3)	11 (28.2)
University, bachelor's degree or equivalent	19 (48.7)	8 (20.5)
University, master's degree or equivalent	4 (10.3)	12 (30.8)
University, PhD	2 (5.1)	1 (2.6)
Other	1 (2.6)	-

Sociodemographic characteristics	
Maternal status (women)	
Pregnant	31 (79.5)
Postpartum	8 (20.5)
Characteristics (couples) and decision made about prenatal screening	
Household size	
Mean (SD)	3 (1.2)
Range	2–7
Annual Family income^c	
< 29 999\$	1 (2.6)
30 000\$ – 59 999\$	3 (7.7)
60 000\$ – 99 999\$	18 (46.1)
100 000\$ et plus	12 (30.8)
Decision made	
To do the test	31 (79.5)
To not do the test	6 (15.4)
No decision made	2 (5.1)
Decision support	
Midwife	11 (28.2)
Family physician	9 (23.1)
Obstetrician-gynecologist	6 (15.4)
I made the decision alone	7 (17.9)
Doctor who monitored pregnancy	2 (5.1)
Partner	2 (5.1)
Didn't have to make this decision	2 (5.1)
Prenatal screening test	
IBT	1 (2.6)
IBT + NT	22 (56.4)
NIPT	5 (12.8)

Sociodemographic characteristics	
NIPT + NT	2 (5.1)
IBT + NT + NIPT	1 (2.6)
No test	8 (15.4)
PhD: Postgraduate doctoral degree; IBT: Integrated Biochemical Test; NT: Nuchal Translucency; NIPT: Non-Invasive Prenatal Testing. SD: Standard deviation. ^a n: number, %: percentage (unless otherwise specified) ^b Partner missing data = 2 ^c Missing data = 5	

In total, 79% of the women participating in the study were pregnant and 21% were postpartum. Approximately 80% of the women had decided to take the prenatal screening test before their participation in this study. Most of the decisions were made with a healthcare professional (28% with a midwife, 23% with a family doctor and 15% with an obstetrician-gynecologist). However, some participants made the decision alone (18%) or were not aware that they had any choice (5%). Approximately 56% of the women and their partners had chosen the Integrated Biochemical Test with nuchal translucency (IBT + NT).

*INSERT Table 2 HERE

Quantitative results

Usefulness for preparing for decision-making

Participants agreed or strongly agreed that DAv2017 was more useful for decision-making than DAv2014 in every category except “recognition that a decision needs to be made”, for which they considered DAv2014 more useful. The mean score of usefulness for preparing for decision-making was 86.2 ± 13 and 77.7 ± 14 out of 100 for DAv2017 and DAv2014, respectively. The mean of difference of the usefulness for preparing for decision-making scores was $-8.48 \pm$ and this difference was statistically significant at $p = 0.0052$.

Acceptability

Overall, participants rated DAv2017 as more acceptable than DAv2014 in every acceptability category (e.g. amount of information, balance of information). Briefly, 80% of participants rated the presentation of DAv2017 as “excellent/good” against 67% for DAv2014. The amount of information was found “just right” by 80% of participants for DAv2017 against 56% for DAv2014. The worksheet was rated “excellent /good” by 62% of participants for DAv2017 against 51% for DAv2014. Regarding balance, 90% of participants rated DAv2017 “balanced” against 82% for DAv2014. Also, 10% of participants thought DAv2017 was unfairly slanted towards choosing to do the test, and another 10% thought that DAv2014 was unfairly

slanted towards choosing *not* to do the test. For Usefulness, DAv2017 was rated “very useful/useful” by 92% of participants against 74% for DAv2014. Sufficient information, 87% of participants said “yes” for DAv2017 against 67% for DAv2014 (Table 3).

Table 3
Acceptability of DAv2017 and DAv2014 (n = 39)

	Answer choice	DAv2017 N (%)	DAv2014 N (%)
Presentation	Excellent	9 (23.1)	14 (36.0)
	Good	22 (56.4)	12 (30.8)
	Fair	7 (18.0)	12 (30.8)
	Poor	1 (2.6)	1 (2.6)
Amount of information	Too little information	3 (7.7)	17 (43.6)
	Just right	31 (79.5)	22 (56.4)
	Too much information	5 (12.8)	0
Worksheet	Excellent	7 (18.0)	6 (15.4)
	Good	17 (43.6)	14 (35.9)
	Fair	14 (35.9)	16 (41.0)
	Poor	1 (2.6)	3 (7.7)
Balance	Slanted towards choice to be tested	4 (10.3)	3 (6.7)
	Slanted towards choice to not be tested	0	4 (10.3)
	Balanced	35 (89.7)	32 (82.1)
Usefulness	Very useful	24 (61.5)	6 (15.4)
	Useful	12 (30.8)	23 (59.0)
	Somewhat useful	3 (7.7)	10 (25.6)
	Useless	0	0
Sufficient information	Yes	34 (87.2)	26 (66.7)
	No	5 (12.8)	13 (33.3)

*INSERT Table 3 HERE

Preferred version

For the choice of answer “a lot” i.e. the strongest perceptions, 46% of participants preferred DAv2017 overall while 28% of the same participants preferred DAv2014.

Qualitative results

Below we summarize participants' comments along with stated or implied suggestions. We organized them into categories based on combined aspects of the TAM (35, 36) and the Acceptability questionnaire (34), namely presentation (graphics, colours, fonts and format), information (amount, content and comprehensibility), values clarification, balance, and navigation. In Table 4, we present quotations illustrating these themes.

Table 4

Participant preferences and suggestions according to dimensions of the Acceptability questionnaire

Dimensions of Acceptability questionnaire	Participants' preferences and suggestions	N=	Illustrative quotes
Presentation	Clearer graphics of DAv2014	24/34	"The esthetics of DAv2014 is more interesting, more modern... And the graphics, with those little symbols... when you go through it quickly, you know, that pair of scales shows that it's talking about the pros and cons, and then there are the numbers. So you don't have to read it to know what kind of information to expect and you can go directly to what interests you." (MN-26-25/Partner)
	Simpler color scheme of DAv2014	19/23	"I much prefer the simplicity of the Dav2014 [colour scheme]. In DAv2017, the choice of colors varies... pastel colors here, different colors here and there, it makes the whole thing a bit more confusing." (MN-31-20/Woman)
	Larger font size of DAv2014	21/35	"There's too much text [DAv2017], so the fonts are too small." (MN-31-20/Woman)
	Format of both could be more convenient	15/39	"I think of myself, when I go to appointments, I like everything to fit in my handbag. So ... it could be the same format as the Pregnancy Kit, that would be good. If not you end up with all these huge bits of paper." (GYN-31-18-Woman)
	<i>Suggestion for presentation</i> Present the decisions to be made in logical order		"The first question to ask is ... do you want to do the test? And then which prenatal test should I choose. Because the way it is [choice of tests, then whether to do test or not], basically you've already made the decision to do the test. After [deciding to do the test], then you can think about [which one]." (MN-28-17-Partner)
Information : content	Different types of trisomy	9/39	"This is the kind of information [about T13 and T18] I like to read. Because no-one's talked to me about this before, and I'm in my third pregnancy. Plenty of doctors could have mentioned T18 and T13, but it's never happened. So having that information here is really interesting." (MN-25-32/Woman)
	That Down syndrome children can have a rewarding life	3/39	"The implications [of having a Down syndrome child], that they can be independent but will need some, uh, some accompaniment. We knew it already but for someone who was less familiar [with Down syndrome], it's interesting to have that information." (GMF-27-05/Woman)
	Information missing in both DAs	27/37	"What's missing in terms of information on Down syndrome is more statistics on how families cope, is there government support, are families with a Down syndrome child happy, or is it miserable for them ... is it like having a child with cancer, with suffering every day, or are they happy like they'd be with a healthy child, but it's just that there's social discrimination. That can be serious, but it's... There must be studies on this, on how

people feel, do they feel helpless about it or not. Do they regret their decision, so that 20 years down the road, even if they love the child, they think perhaps they would have done differently." (MN-30-18/Woman).

Suggestions for missing information

"Perhaps add suggestions on readings, not complicated philosophical treatises, but on ethics and on the education of a [Down syndrome] child and on programs offered." (MN-30-18/Woman+Partner)

**Information :
amount**

It doesn't matter how much information

17/30

"For me, making a decision involving a future child, I'd automatically go online and read as much information as I could because it's a super important decision. So I don't think people would complain about the quantity of information. I think the more you have, the more reassured you feel.... The more information I have, the more details, the more arguments for the options, the advantages, the more I'll be comfortable with my choice." (GMF-27-11/Partner)

Too much information in DAv2017

11/29

"It's not that the words are hard to understand, it's the amount of information. You should look at it first with someone... I don't mean to criticize, but someone who doesn't have much education could be a bit overwhelmed." (MN-38-05/Woman+Partner)

"Still, a mother who doesn't like reading much... she's going to just read the titles and the graphics ... and perhaps she'll be scared to see a huge page full of text." (GYN-31-18-Woman)

**Information :
comprehensibility**

Too many acronyms in DAv2017

7/39

"There are lots of abbreviations in DAv2017 so sometimes I was a bit mixed up. So I was like, trying to remember what the different tests are. So it's confusing because we're not familiar with those expressions [acronyms], so after it was harder to remember which was which." (MN-26-25/Woman)

Suggestion

Replace frequencies with percentages

"Instead of putting the number of women, perhaps put the percentage so you understand the proportion, sometimes that helps to better ... the 22 women, the 22 of the 521 women, ok, but we don't necessarily know what that proportion is... Someone who looks at it quickly won't understand the importance ..." (GYN-31-18-Woman)

Values clarification exercise

Listing pros and cons (DAv2014) better than circling stars (DAv2017)

12/23

"The [list] is better, because it's all on the same page, so when you're making the decision it puts things in perspective because you can see [the pros and cons] right there ... and when you're making a list of the pros and cons, you can see which is the longest and shortest... I think it's better than the stars because visually when you [circle] the stars it doesn't necessarily mean much to you." (GYN-30-22/Woman)

Neither the list nor the star circling is necessary

3/23

"I didn't see the point of the stars ... Perhaps I didn't need to write out [the pros and cons] or circle [the stars] to make my decision, but that's a personal choice ... I don't really mind either the list or the stars being there."

	Suggestion Remove the star circling exercise		"Personally, if you'd given me that I'm not sure I would have circled those stars. I know it's there to show that it's really the patient's own decision. But even so, I don't think I would have circled them." (GYN-31-18/Woman)
Balance	Slanted one way (re. taking the test or not)	4/34	"Just a comment ... In DAv2014 there's the same amount of space for advantages and disadvantages of doing the test or not, so you have the impression that [the balance] is 50-50. But in DAv2017 you have a choice of the three tests and the choice "not to do the test" – So you have 3/4 of the page on doing the test and 1/4 on not doing it – so there's bias towards doing the test in DAv2017..." (MN-36-28/Partner)
Usefulness	Useful for making a decision	16/38	"I find [the information on the options] super interesting and it's something you don't often hear about, it shows exactly what all those options are and it's not just about I do it or I don't do it, it's basically <i>what</i> am I doing, or what am I not doing." (GYN-30-22/Woman)
Navigation	Easier navigation in DAv2014	11/34	"That's really the big problem. It's really too dense. So it's not easy to read. I have ADHD, you see, but I know I'm not the only mother has ADHD. So when we're tired, our brains don't work properly. So to figure all this out, it's a bit confusing; so like in this one [DAv2014], there's only T21 in the table, whereas here [DAv2017] there are all the others too. At some point it becomes too long to read, too dense. You could solve the problem by dividing up the sections better, because the information is good." (MN-25-32/Woman)
Other	Partners not given a place in the DA	3/39	"What I found disappointing in both [DAs] was that they were talking just to the woman, but the man should also have an important role in making that decision. It's as if it's just the woman who decides whether to do the test or not and her husband has nothing to do with it." (GYN-34-19/Woman)
	Suggestion Add partner's opinion / decision / consent to live with a Down syndrome child		"Perhaps in the other factors [to consider] you could have the partner's agreement to living with a Down syndrome child... because you're not gonna raise the child alone and it's a decision that should be made together, after all." (GYN-34-29/Woman)
n: number of people giving their opinion / total number of people who gave an interpretive response			
Participant code: Clinical site - mother's age - recruitment number/person who gave the answer			

Desirable features to include in a DA for prenatal decisions

Presentation

Participants found the presentation of DAv2014 more acceptable (e.g. its visuals, colors and font sizes) than that of DAv2014. For instance, they preferred the use of symbols over verbal instructions (e.g. a scale to indicate the pros and cons to weigh up, rather than a verbal explanation). Many of them preferred the

more sober colors used in DAv2014. Many also liked fewer colors and a paler background, which made the printed information clearer. Many participants preferred the font size of DAv2014 because DAv2017 had more pages of relatively small and non-uniform font (Table 4, Fig. 2).

Participants suggested the use of more graphics and symbols because they are helpful for understanding the message. They suggested not using pale print colours, or deep colours as background (difficult to read) and glossy paper. They suggested larger fonts i.e. at least 12-point. Even though some participants liked the booklet format presented, they suggested that to be more convenient, the DA could be in 1) a pamphlet format, 2) a smaller format that matches an existing pregnancy kit distributed to all pregnant women, or 3) a digital version (Table 4, Fig. 2).

Information

Content

Participants reported that DAs addressed a pressing need for consistent accessible information in a simple way and in a single document. Participants liked DAv2014 for its conciseness but DAv2017 for its completeness. Indeed, the favorite page (most important in terms of content and most helpful for making a decision) of some participants was the page in DAv2017 that presented the four different test options (not doing the test, IBT, IBT + NT and NIPT). The majority of participants thought DAv2014 lacked important information, i.e. the different test options. Some participants (mostly those who preferred DAv2014) found that there was too much detail in DAv2017 and that it was easy to get lost. A few participants liked having information on the other types of trisomy screened for (trisomies 13 and 18) in DAv2017; and appreciated the fact that both DAs make it clear that people with Down syndrome can lead rewarding lives. However, a few participants felt that both DAs lacked information on management of a child with DS. A few participants also felt that the role of the partner was not taken into account in either DA (Table 4, Fig. 2).

Amount of information

Some participants wanted as much information as possible and so found the amount of information in DAv2017 was “just right”, while others thought that too much information was intimidating “for women who don’t like to read” and that less information would be better. Paradoxically, it was sometimes the same people who wanted more information and yet a simpler DA (Table 4, Fig. 2).

Comprehensibility of information

A few participants found that there were too many acronyms in DAv2017 and that it was easier to navigate in DAv2014. A few participants found the presentation of statistics as frequencies was confusing in both DAs (Table 4, Fig. 2).

To improve the DAs in terms of the information provided, participants suggested adding information about resources for women who decide to go ahead with a Down syndrome pregnancy: how to prepare, resources for children with Down syndrome and their parents, other parents’ experiences (e.g. cost, management of

children with Down syndrome). They also suggested replacing frequencies with percentages to communicate probabilities, and using fewer acronyms. They suggested inviting the partner to be more involved to make sure both of them are comfortable with the decision taken.

Worksheet - Values Clarification Exercise

Many participants did not feel that the values clarification exercise in DAv2017, designed using the multiple criteria decision-making structure (circling the stars) to evaluate the advantages and disadvantages of each test and the decision-making factors, was useful. Some of them preferred the pros and cons list in DAv2014 and being able to simply write down the factors they felt were most important. They specified that the list should be close to the values clarification information (on the same page). A few participants felt that no values clarification exercise at all was necessary. The information alone was enough to help them make up their mind (Table 4, Fig. 2).

Several alternative solutions to the star-circling exercise were suggested by the participants: 1) using a scale from 0 to 5 with a legend at the bottom, 2) adding lines for taking notes, 3) choice of YES/NO, 4) inviting readers to rank the factors in order of importance before circling the stars, 5) using checkboxes.

Balance

A few participants felt that DAv2017 was weighted towards the decision to take the test because there was little space given to the “not to do the test” option, while the decision to “do the test” included three options, with information about each taking up much more space. One participant felt DAv2014 was oriented towards the decision not to take the test because of the choice of words used. One participant pointed out that using a green background for some options and red for others could be interpreted as “go” and “stop”, i.e. subliminally urging the user to choose one over the other (Table 4, Fig. 2).

*INSERT Table 4 HERE

*INSERT FIGURE 2 HERE

Agreement/disagreement within couples

In general, couples agreed about the DAs. However, in one couple, the woman and her partner preferred different versions of the DAs: the woman preferred DAv2017 because of its detail (like most of the participants in this study), but her spouse preferred DAv2014 because it was shorter. Two other couples disagreed about the format and the importance of the T13 and T18 information. Other numerous minor differences were reconciled during the interviews.

Data triangulation

The interviews gave us a better understanding of the participants’ quantitative assessment of the DAs and showed some interesting inconsistencies with the quantitative data, namely regarding presentation of information and values clarification.

From a quantitative point of view, the choice of participants seemed to be in favor of DAv2017 for all acceptability dimensions, while during the interviews, participants clearly stated that they preferred the presentation of DAv2014. In fact, a detailed analysis of the dimensions of acceptability showed that this inconsistency was also present in the quantitative data: although globally 80% of participants rated the presentation of DAv2017 as “excellent/good” against 67% for DAv2014, more participants (36%) rated the presentation of DAv2014 as “excellent” than DAv2017 (23%) (Table 3).

In addition, participants judged the worksheet of the DAv2017 to be more acceptable than that of the DAv2014 for weighing up pros and cons, and yet in the interviews clearly indicated that the star circling in DAv2017 was not a helpful values clarification exercise. These discrepancies show the importance of mixed methods in user evaluations of decision making tools. The addition of qualitative data provided nuances and correctives to qualitative data and deeper insights into users’ perceptions.

Discussion

In this mixed-methods pilot study, we assessed pregnant women and their partners’ perceptions of the usefulness of the two DAs for prenatal screening for preparing for decision making, their relative acceptability and their most desirable features. Globally DAv2017 had better scores of usefulness for preparing for decision making and of acceptability than DAv2014. The preferred version of most participants was DAv2017, while they preferred the presentation and the values clarification exercise in DAv2014. Neither DA presented information in a completely balanced manner. These results lead us to make the following observations on the most desirable features in a prenatal screening DA.

First, participants preferred the presentation of DAv2014, suggesting that appealing visuals (esthetics, colors, fonts) favoured acceptability and usability of a DA. This is consistent with other literature relating to evaluation of DAs, where authors report suggested changes to be made to their DAs in terms of font size (43), background colours (43) and colors in general (43–46). According to these studies, participants dislike colors that are “flat”, “uninteresting” or “somber”. We learned from our study that a font size of at least 12 would be ideal. However, choice of colors remains difficult, because “there’s no accounting for taste” and there are no visual standards or guidelines for designing DAs. This highlights the importance of involving potential users in designing the DAs. Researchers could also consult outside the field, such as in the advertising industry, which has extensive experience in presenting material in a visually attractive way.

Second, most participants found that the additional information (on the different tests) in DAv2017 was important. This suggests that the more complete a DA is, the more useful it is for preparing people to make a decision. A previous study has shown that the amount of information can be both a positive and a negative factor (30) depending on user preferences and levels of literacy and numeracy. Indeed, though participants in our study were highly educated, a few participants still felt that DAv2017 was confusing because of the amount of information. To reach the whole population of pregnant women and their partners in Quebec, where over a quarter of the population have literacy problems that affect the management of their health (47), the DA will need to take this critique seriously. In a 2013 review of 97 DA trials, only three DAs overtly addressed the needs of lower health literacy users (48). This is perennial

challenge for DA developers, as participants want as much information as possible in as simple a format as possible. Hence the importance of presenting as much information as possible using graphics, as suggested by study participants, and developing digital versions, in order to add links and hyperlinks toward additional resources (49) or using the guiding principles of the edutainment model for developing low-literacy patient decision aids (50).

Third, of the two values clarification exercise, participants preferred that of DAV2014 consisting in writing their personal pros and cons of doing the test or not in a summary table. They found that the star circling values clarification system, based loosely on the multiple criteria decision-making model, in DAV2017 was useless or too complicated. As we did not provide a legend for interpreting the star circling (51), its purpose was not clear. Perhaps if we had adopted the whole MCDA model, especially if the DA was in the form of an application, it would have helped them more. A MCDA model incorporates not only alternatives (actions which can possibly solve the problem), criteria (aspects on which the alternatives are assessed), evaluations (assessment of the performance of alternatives on the criteria), weights (assessment of the relative importance of the criteria), but also an aggregation method (algorithm for synthesis of the above information) (52). Study participants preferred to have other types of values clarification methods or none at all. Indeed, values clarification methods tend to give mixed results: some studies show they improve the decision-making processes (53, 54) and others that they have no effect on them (55). However, some authors argue that many people need help in clarifying their values (55, 56) even while using their intuition parallel to this analytical process (57). Hence, it would be important to further explore the appropriate values clarification method for a complex decision such as DS prenatal decisions.

Fourth, participants suggested merging the two versions to present the complete decision process, and wanted more information on management of children with Down syndrome, i.e. information to prepare them for making a future decision about their pregnancy. They made us realize the importance of clearly defining and presenting all decision points related to prenatal screening. Initially we wanted the DA to address decision making about the prenatal screening test alone. However, each positive test result require a further decision. The decision about a screening test ultimately involves many decision points, even if not all couples will have to proceed through all of them (e.g. couples who choose not to take the screening test). The decisions points are 1) to do the screening test or not, 2) which test to do, 3) to do the diagnostic test or not, 4) which diagnosis test to do, of those available and 5) to prepare for a child who will have special needs throughout his/her life or terminate the pregnancy. It is thus inadequate to approach the notion of screening without addressing the further decisions about diagnosis and pregnancy termination or continuation.

Fifth, participants suggested making room for the pregnant woman's partner in the DAs. This shows the importance of partners in this decision and is one of the reasons for its complexity, as both partners need to come to a common decision. The difficulty or ease of making a common decision stems from the couple's decision-making process, which may be open and communicative (straightforward and rational), closed and personal (immediate and non-communicative), or searching and communicative (common but complex and arduous) (58). However, several recent studies confirm our findings that women prefer to share the responsibility of making decisions and their consequences with their partner (59–61). Partners too perceive

themselves to be just as important in the decision making as the women (62). For couples who cannot agree on a decision, the DA could facilitate their arriving at a shared decision. Indeed, in our study some couples disagreed over which elements of the DA were most important. The idea of providing gender-specific information (58) should also be explored to promote better understanding and help each partner consider his or her specific role in the decision and its consequences.

Limitations

The strengths of this study should be considered in the context of its limitations. First, participants were highly educated, which does not represent the overall population of pregnant women in Quebec City. In a future investigation we will seek a more heterogeneous group of participants to identify usability issues from a diverse range of perspectives. Second, all participants received DAv2017 before DAv2014. This order may have influenced their opinions. Third, we had a considerable refusal (44%) and abandonment rate (60%) related to encounters being estimated at 60 to 90 minutes long. However, we mitigated this limitation by being flexible about the place and time of the meeting. Finally, we met the participants after they had already made a decision to do the screening test or not. Participants had to imagine they were still in the situation of making the decision to answer the questions. This may have biased their answers. However, the time between their decisions and the study was relatively short.

Conclusion

We assessed pregnant women and their partners' perceptions of the usefulness two DAs for prenatal screening for preparing for decision making, its relative acceptability and its most desirable features. Our results reflect the paradox inherent in the design of all DAs, i.e. the challenge of designing DAs that achieve the correct balance between simplicity and enough information. A new, user-centered version of the prenatal screening DA will integrate participants' suggestions to reflect end users' priorities. The new version will include all decision points, information presented in a more balanced and accessible manner, a simpler values clarification exercise, and will include partners as decision-makers.

Abbreviations

DA: Decision aid; DAv2014: Decision aid version 2014; DAv2017: Decision aid version 2017; SDM: Shared decision making; PEGASUS: Personalized Genomics for Prenatal Aneuploidy Screening Using Maternal Blood; IPDAS: International Patient Decision Aids Standards; SURE: Sure of myself - Understand information - Risk-benefit ratio – Encouragement; PrepDM: Preparation for Decision Making.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Centre intégré universitaire de santé et de services sociaux de la Capitale-Nationale (Project 2017-2018-15 MP). The project was described to eligible

participants and they were told that the data was anonymous and confidential. Those who wished to participate gave written consent.

Data Availability Statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest Statement

The authors declare that they have no conflict of interest.

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Authors' contributions

The study was led by FL, Chairholder of the Tier 1 Canada Research Chair in Shared Decision Making and Knowledge Translation. All authors contributed to the conception and writing of this study. ATT, SAR, MPD, AAT and APH participated in recruitment of pregnant women and their partners on clinical sites. ATT, SAR, MC, MPD, APH or AAT contributed to data collection. TTA, MPD, APH, AAT performed verbatim transcription of the audio files. CDD, MC, ATT and HE performed quantitative analysis. ATT, AAT, MC drafted the preliminary manuscript. SAR and FL conceived of the study, participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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Figures

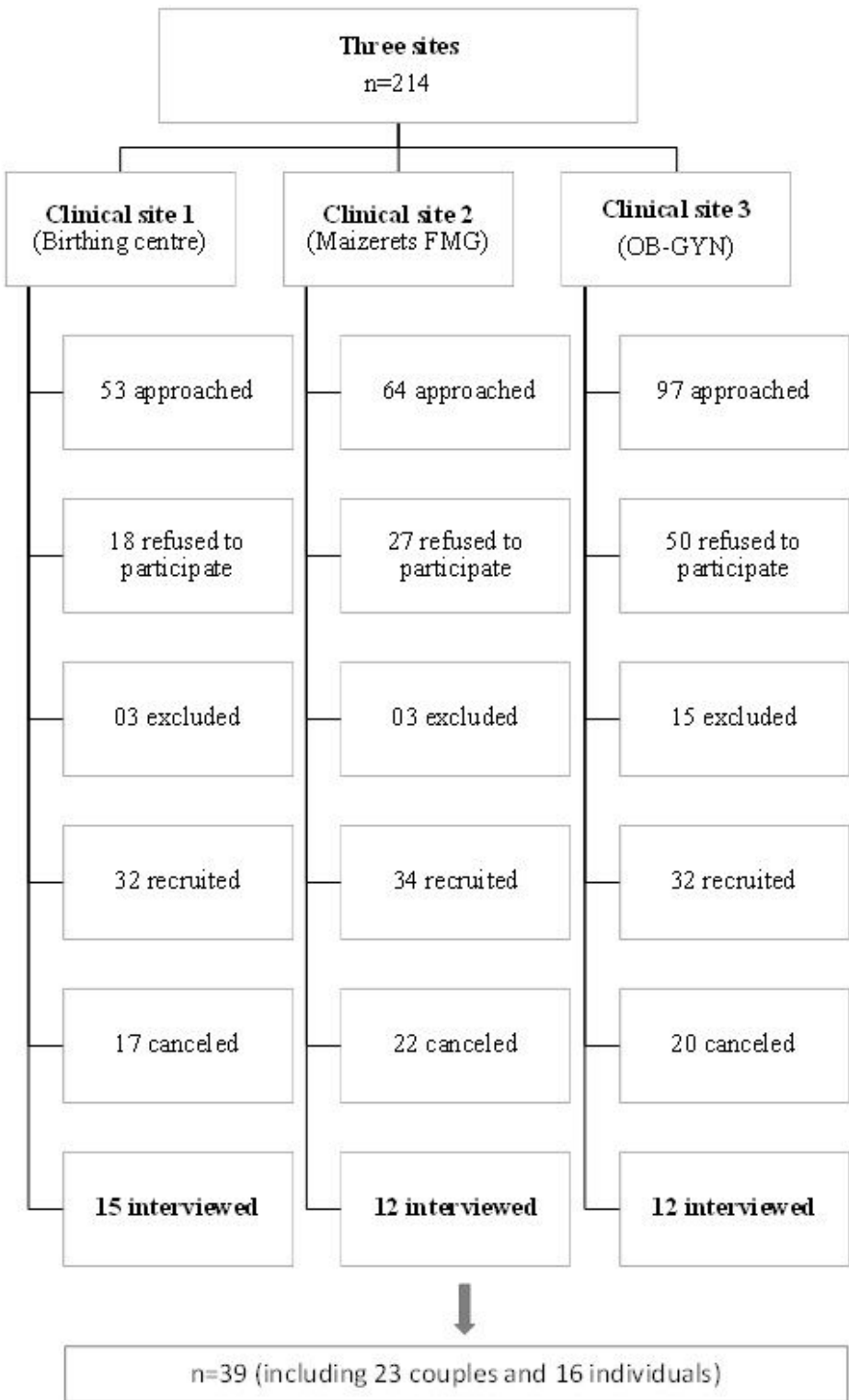


Figure 1

Study flow chart

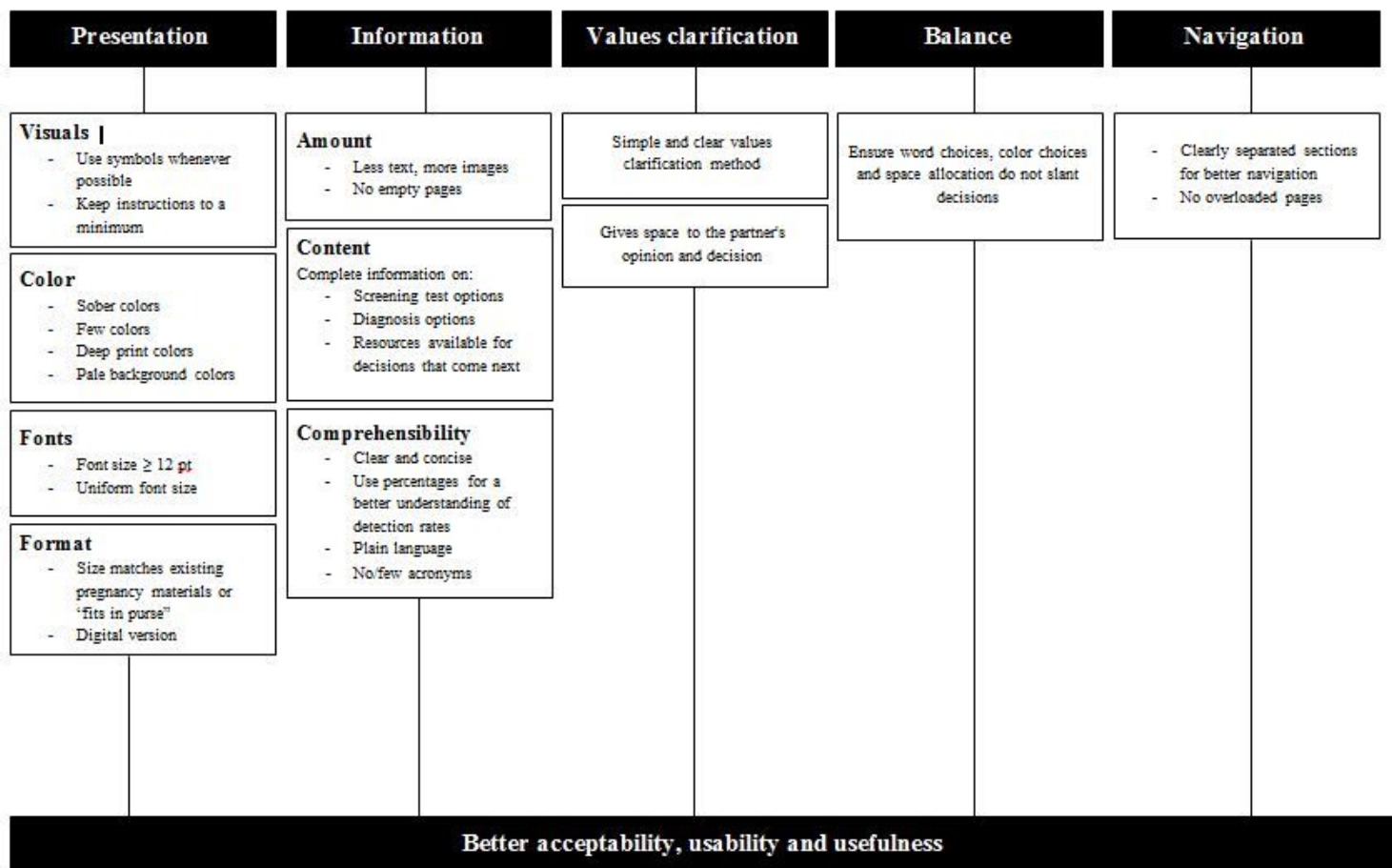


Figure 2

Desirable features v2020 04 28

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