Title: Addressing health literacy in patient decision aids: an update from the International Patient Decision Aid Standards

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ABSTRACT (275 words)

Background: There is increasing recognition of the importance of addressing low health literacy in patient decision aid (PtDA) development.

Purpose: An updated review as part of IPDAS 2.0 examined the extent to which PtDAs are designed to meet the needs of low health literacy/disadvantaged populations and their impact on decision-making and health outcomes.

Data Sources: Reference list of Cochrane review of randomised controlled trials (RCTs) of PtDAs (2014, 2017 and upcoming 2020 versions).

Study Selection: RCTs that assessed the impact of PtDAs on low health literacy or other disadvantaged groups (i.e. ≥50% participants from disadvantaged groups and/or subgroup analysis in disadvantaged group/s).

Data Extraction: Two researchers independently extracted data into a standardized form including PtDA development details, decision-making and health outcomes. We searched online repositories and emailed authors to access PtDAs to verify reading level.

Data Synthesis: Twenty-five out of 213 RCTs met inclusion criteria illustrating only 12% of studies addressed the needs of low literacy/disadvantaged populations. Only seven (28%) calculated a reading age (recommended in previous IPDAS guidelines) and none met guidance for low literacy populations. We pooled outcomes in the meta-analysis using random effects models and assessed heterogeneity using I^2. PtDAs improved knowledge (mean difference(MD)=14.65, 95% confidence interval (CI):9.48,19.83, I^2=96%) and patient-clinician communication (risk ratio (RR)=1.62, 95%CI:1.42,1.84, I^2=0%), and reduced decisional conflict (MD=-4.15, 95%CI:-7.38,-0.93, I^2=81%) and proportion undecided (RR=0.23, 95%CI:0.11,0.50, I^2=66%).

Limitations: The source of heterogeneity was not assessed due to expected variable contexts and outcomes. Results should be interpreted considering this limitation.

Conclusions: Only 12% of PtDA studies addressed disadvantaged groups. Greater attention to health literacy and disadvantaged populations is needed in the field of PtDAs to ensure equity in decision support.

INTRODUCTION

Health literacy is defined as people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and decisions, and act upon their decision in everyday life concerning healthcare, disease prevention and health promotion.[1] Low health literacy is prevalent in many countries including those with high incomes, for example, estimates range between 1/3 and ½ population have basic or inadequate literacy depending on the measure used in countries such as US, UK and Australia). Despite this, few patient decision aids (PtDAs) address the needs of adults with lower health literacy. In a 2013 review of 97 trials, only three PtDAs overtly addressed the needs of lower health literacy users.[2] In 90% of trials, user health literacy and readability of the PtDAs were not reported.[2]

There has been increasing international recognition of the importance of addressing the needs of patients and consumers with low health literacy when developing shared decision-making tools.[3] The original International Patient Decision Aid Standards (IPDAS) quality criteria checklist, for example, included three criteria pertaining to the use of 'plain language' (see Box 1).[1] Although this was reduced to one item in the 2009 (IPDASi v3.0) and 2013 (IPDASi v4.0) revisions of the standards ("The decision support technology (or associated documentation) reports readability levels (using one or more of the available scales)) several shared decision-making tools designed since then have been guided by this criterion.

[1] a) Is written at a level that can be understood by the majority of patients in the target group; b) Is written at a Grade 8 equivalent level or less according to readability score [SMOG or FRY]; c) Provides ways to help patients understand information other than reading [audio, video, in-person discussion].

IPDAS quality criteria checklist (2005)

- ☐ Is written at a level that can be understood by the majority of patients in the target group 10.3
- ☐ Is written at a grade 8 equivalent or less according to readability score (SMOG or FRY) 10.4
- ☐ Provides ways to help patients understand information other than reading [audio, video, in-person discussion] 10.5

IPDAS instrument (IPDASi v3.0) (2009) and IPDAS minimal criteria (IPDASi v4.0) (2013)

- ☐ The decision support technology reports readability levels (using one or more of the available scales). 3.06

Box 1. IPDAS criteria pertaining to the use of 'plain language'

Evidence reviews show that the comprehension of health information among individuals with low health literacy can be improved through modifications to communication and other mixed-strategy interventions [4,5] . For example, two systematic reviews (and the individual projects that they draw upon) highlight benefits of reducing medical jargon and presenting essential information only (or first) in materials for adults with lower health literacy, as well as the potential utility of different communication formats (e.g., illustrated text; spoken animations; pictorial information).[4,5] There has also been growing movement towards, and evidence-base for, consumer involvement in the development and review of patient information materials.[6] However, it is unclear the extent to which new evidence and recommendations related to health literacy have been implemented in the development and evaluation of PtDAs since 2013, and its impact on decision making and health outcomes.

Aims

This systematic review is an update of our previous 2013 review of the evidence relating to health literacy and PtDAs for IPDAS 2.0. We aimed to examine the extent to which PtDAs had been designed and tested on lower health literacy and disadvantaged populations and if so, to understand their impact on decision making and health outcomes.

Review questions

We reviewed literature on PtDAs to understand the extent to which they have been tailored to low health literacy and other disadvantaged groups. Our research questions are summarized below:

1. In the randomized trials studying PtDAs' effectiveness, to what extent are low health literacy and other disadvantaged groups considered in the development and evaluation of PtDAs?
    a. What proportion of PtDAs have considered low health literacy and other disadvantaged groups in their development and/or evaluation?
    b. How have these PtDAs been tailored for adults with low health literacy and other disadvantaged groups?
    c. What are the readability and cognitive demand scores of the PtDAs tailored for adults with low health literacy and other disadvantaged groups?
2. What is the impact of tailored PtDAs for adults with low health literacy and other disadvantaged groups on decision making and health outcomes?

METHODS

Protocol and registration

The aims and methods for this systematic review were registered on Prospero (Registration number CRD42019159042). Reporting is guided by the Preferred Reporting Items for Systematic Reviews (PRISMA) checklist [7].

Information sources and search strategy

We searched for published trials of PtDAs in the 2014, 2017 and 2020 versions of the Cochrane systematic review of randomized controlled trials (RCTs) of PtDAs.[2] This series of Cochrane reviews aim to examine the effects of PtDAs for individuals who are making treatment or screening decisions (aged 18+, making decisions for themselves, a child, or an incapacitated significant other). Their scope covers all published RCTs that compare the effects of PtDAs on decision-making outcomes (e.g., knowledge, risk perceptions and involvement in decision

[2] We include studies from 2014 onwards because 28 studies were excluded from the 2017 review. We also include studies from the unpublished 2020 review to ensure more recent RCTs were included.

making) relative to some alternative 'usual care' (e.g., general information, clinical practice guideline, placebo, no intervention).[8,9] PtDAs are defined as "evidence-based tools designed to help patients make specific and deliberated choices among healthcare options" (p. 7) [9].

Eligibility criteria

To be included in the current systematic review, studies had to include at least 50% of participants from disadvantaged groups and/or conduct a separate analysis exploring the impact of the PtDA on disadvantaged groups. Disadvantaged groups were defined using the following eight criteria, based on previous work by Durand et al [10]:

1. People who have lower literacy and/or lower health literacy
2. People who have lower educational attainment
3. People who are socially disadvantaged with respect to poverty or lower socioeconomic status
4. People who are socially disadvantaged as a result of their ethnicity or race
5. People who are socially disadvantaged with respect to geographical location (areas described as disadvantaged/or medically underserved)
6. People who are uninsured or on public health insurance
7. People who have lower numeracy
8. People who are socially disadvantaged as a result of speaking a primary language that differs from the official language(s) of their country of residence.

All conditions and clinical settings (e.g., lay care, primary care, secondary/tertiary care) were included.

Screening and study selection

Articles were independently screened in two stages by JS and OM as follows: screening of titles and abstracts followed by the retrieval and screening of relevant full-text articles using the inclusion criteria described above. Disagreements were resolved through discussion, or with the help of a third reviewer (DM).

Data extraction and risk of bias assessment

We used a standardized form to extract relevant data, which was pilot tested and iteratively revised. Of nine researchers (DM, JS, OM, KM, TC, AG, AL, AH, SS), two were assigned to each study to independently extract data including the methodology of each study, the development and/or evaluation of the PtDAs and the outcomes of the RCT. Data items extracted relating to each research question are presented in Table 1.

Risk of bias assessments were not conducted for studies that had already been assessed as part of the Cochrane Review (2014 and 2017 versions). Recent studies that had not yet been assessed for the 2020 version of the Cochrane Review were assessed for risk of bias by two independent reviewers from the study team using the revised Cochrane tool.[11]

Independent PtDA readability and cognitive demand assessment

To access PtDAs not published with their corresponding articles, we searched the Decision Aid Inventory Library maintained by the Ottawa Hospital Research Institute.[12] If the PtDA was not publicly available, we made two email attempts via the corresponding authors' emails specified on the manuscript.

Data synthesis and analysis

We pooled data for outcomes in a meta-analysis if they were reported at least three times across the included studies and used similar and comparable measures to assess the same construct (Revman 5.3). For continuous outcomes assessed on different scales, we standardized scores to range from 0 to 100 points to facilitate the pooling of data. We used a random-effects model because of the diversity of the included studies and the anticipated variability in populations and PtDAs. Where studies included more than two groups, we analyzed those that aligned more closely with a control and PtDA. We pooled continuous outcomes based on the mean, standard deviation (SD) and number of people assessed for the PtDA and control groups to calculate mean difference (MD) and 95% confidence interval (CI). When measures were repeated, we selected the time point that reported the most conservative estimate. We calculated a relative risk for outcomes reported as proportions using percentage and number of people assessed in each group.

Outcomes that could not be pooled in a meta-analysis were synthesized using narrative synthesis. We reported means or percentages for each outcome for each group in trials including ≥50% low health literacy or other disadvantaged population, and indicators of statistical significance (e.g., p-values). For studies that conducted subgroup analyses of disadvantaged groups, we similarly reported means or % for each outcome and performed narrative synthesis.

Assessment of heterogeneity

We anticipated there would be substantial heterogeneity in our pooled effect estimates due to the grouping of studies across different populations and contexts. As a result, we decided to consider the variability in direction of effects (rather than size of effects) to interpret heterogeneity. Therefore, we did not downgrade for inconsistency where the direction of effect was consistent across studies.

Assessment of reporting biases

We produced funnel plots for each outcome included in the meta-analysis to visually assess potential for publication bias.

Subgroup and sensitivity analysis

No subgroup or sensitivity analyses were pre-specified; however, one arose after extracting data. Decisional conflict was measured using two different versions of the Decisional Conflict Scale: the low-literacy 10-item version and the full 16-item version. Therefore, we conducted a subgroup analyses to compare the results based on the type of scale used.

Table 1. *Data items for each research question.*

Research question	Data items, summary measures and synthesis approach
***1a**. How many PtDAs considered low health literacy and other disadvantaged groups?*	Proportion of PtDAs included in the 2014, 2017 and 2020 versions of the Cochrane systematic review that consider low literacy and other disadvantaged groups in their development or evaluation as stated in the manuscript or determined by study participants or analyses.
***1b**. How have these PtDAs been tailored for adults with low health literacy and other disadvantaged groups?*	Narrative description of how PtDAs meeting our inclusion criteria were developed or tailored for low literacy and other disadvantaged groups, including an inventory of the strategies used.
***1c.** What are the readability and cognitive demand scores of the PtDAs tailored for adults with low health literacy and other disadvantaged groups?*	We reported the proportion of PtDAs that were written at a $\leq 8^{th}$ grade level and < 6^{th} grade. Grade reading level was calculated using the Online-Utility.org readability calculator.[13] We average the SMOG and Gunning-Fog scores to provide an overall grade reading level for PtDAs we accessed. Video format PtDAs were transcribed verbatim to assess the readability of the transcript. Full text of the PtDAs were prepared in line with guidelines by removing text that is not in full sentences (i.e. titles, headings, subheadings, short captions), embedded punctuation, and document design elements (e.g., gaps, white spaces, pictures and images, and text boxes). Bulleted text was included if it was in a full sentence or could be adapted to form a full sentence (e.g., moving words from the stem into the list) and punctuated by adding a full stop. Footnotes were removed unless they were essential to understanding the main PtDA content. We reported the proportion of PtDAs that met the PEMAT criteria for ≥70% actionability and understandability. Understandability and actionability were calculated for each PtDA that we are able to access using the Patient Education Materials Assessment Tool (PEMAT; see Box 2) [14,15]. [14,15]. PEMAT scores were independently scored by two team members (JS and OM) and disagreements were resolved via discussion with a third.
***2.** What is the impact of tailored PtDAs for adults with low health literacy and other disadvantaged groups on psychosocial and clinical outcomes?*	Psychosocial and clinical outcomes were extracted for each study: attributes of the choice made (knowledge, accurate risk perception, values-choice congruence), attributes of the decision-making process (decisional conflict, patient-clinician communication, participation in decision making, satisfaction), behavior (intentions and preferences, behavioral outcomes), health outcomes (anxiety, regret, confidence) and attitudes towards the intervention.

Domain: Understandability (17 items P; 13 items AV)
Assesses 6 topics/ domains: content, word choice and style, use of numbers, organisation, layout and design, use of visual aids. (see appendix for full list)

Domain: Actionability (7 items P; 4 items AV)
Item 20: The material clearly identifies at least one action the user can take (P and A/V)
Item 21: The material addresses the user directly when describing actions (P and A/V)
Item 22: The material breaks down any action into manageable, explicit steps (P and A/V)
Item 23: The material provides a tangible tool whenever it could help the user take action (P)
Item 24: The material provides simple instructions of how to perform calculations (P)
Item 25: The material explains how to use charts, graphs, tables or diagrams to take actions (P and A/V)
Item 26: The material uses visual aids whenever they could make it easier to act on instructions (P)

Box 2. Overview of Patient Education Materials Assessment Tool (PEMAT - Print and AV versions)

RESULTS

Study characteristics

We analyzed 25 articles that met the inclusion criteria as they included at least 50% of participants from a disadvantaged population (n=10 studies), conducted a separate analysis including participants from a disadvantaged population (n=5), or did both (n=10; Table 2). (Figure 2). The total number of participants in all included trials was 9865.

Most included studies evaluated unique PtDAs. Exceptions include two studies by Kuppermann et al.[16,17] that evaluated the same PtDA titled 'Prenatal testing: exploring your options'. Three studies evaluated variations of a previously validated PtDA which included two videos[18,19] and a computerized program titled 'CHOICE' (Communicating Health Options through Interactive Computer Education).[20]

Studies were conducted in the United States (n=22), Australia (n=2) and England (n=1; see Table 2). Participants included people considering prostate-specific antigen testing for prostate cancer screening (n=6), colorectal cancer screening (n=8), people with osteoarthritis considering knee replacement (n=2), women with early stage breast cancer considering surgery options (n=2), men with prostate cancer deciding about treatment (n=1), and people with chest pain deciding to be admitted for further testing or followed-up (n=1). Participants also included those considering living donor kidney transplantation (n=1), prenatal genetic testing (n=2), diabetes screening (n=1), or early intervention for children

with developmental concerns (n=1). Characteristics of disadvantaged populations relative to the reasons for inclusion are shown in Table 2.

Studies included participants from disadvantaged groups including at least 50% of the sample with lower literacy (n=3) or lower education (n=7), or who were socially disadvantaged with respect to poverty or socioeconomic status (n=6), ethnicity or race (n=16), geographical location (n=2), or insurance status (n=5). Two studies recruited socioeconomically disadvantaged participants by targeting particular postcodes.[21,22] Three studies also implied that the majority of their sample included participants from disadvantaged groups as they recruited from disadvantaged geographical locations or sites that primarily serve disadvantaged groups.[19,20,23] Studies that conducted separate analyses explored the moderating effects of literacy or health literacy (n=5), education (n=8), numeracy (n=1), poverty or socioeconomic status (e.g. income, n=2), ethnicity or race (n=5), geographical location (n=2), insurance status (n=3) or language preference (n=1) by including interactions. One study that conducted a separate analysis only restricted their analysis within the low-literacy group, but did not compare to a high literacy group [24] and another conducted a separate analysis to test the effect of their intervention among Latino participants only [18].

Risk of bias

Of the nine studies we assessed for risk of bias, four had unclear risk of bias overall (Appendix; Table 2). This was mainly due to concerns regarding deviations from the intended interventions (n=8), outcome measurement (n=4) and reporting results (n=5). These concerns typically arose because there was no blinding of participants or researchers delivering interventions, lack of information about blinding of outcome assessors or no evidence of planned analyses. Of the sixteen studies that were already assessed as part of the 2014 and 2017 versions of the Cochrane review (Appendix; Table 3), three had low risk of bias for all domains, but many had unclear risk of bias for allocation concealment (n=11), blinding of participants (n=9) and selective reporting (n=10).

Assessment of reporting biases

Lack of symmetry was observed when examining the funnel plot for decisional conflict indicating potential publication bias. Funnel plots are shown in the Appendix (Figure 1).

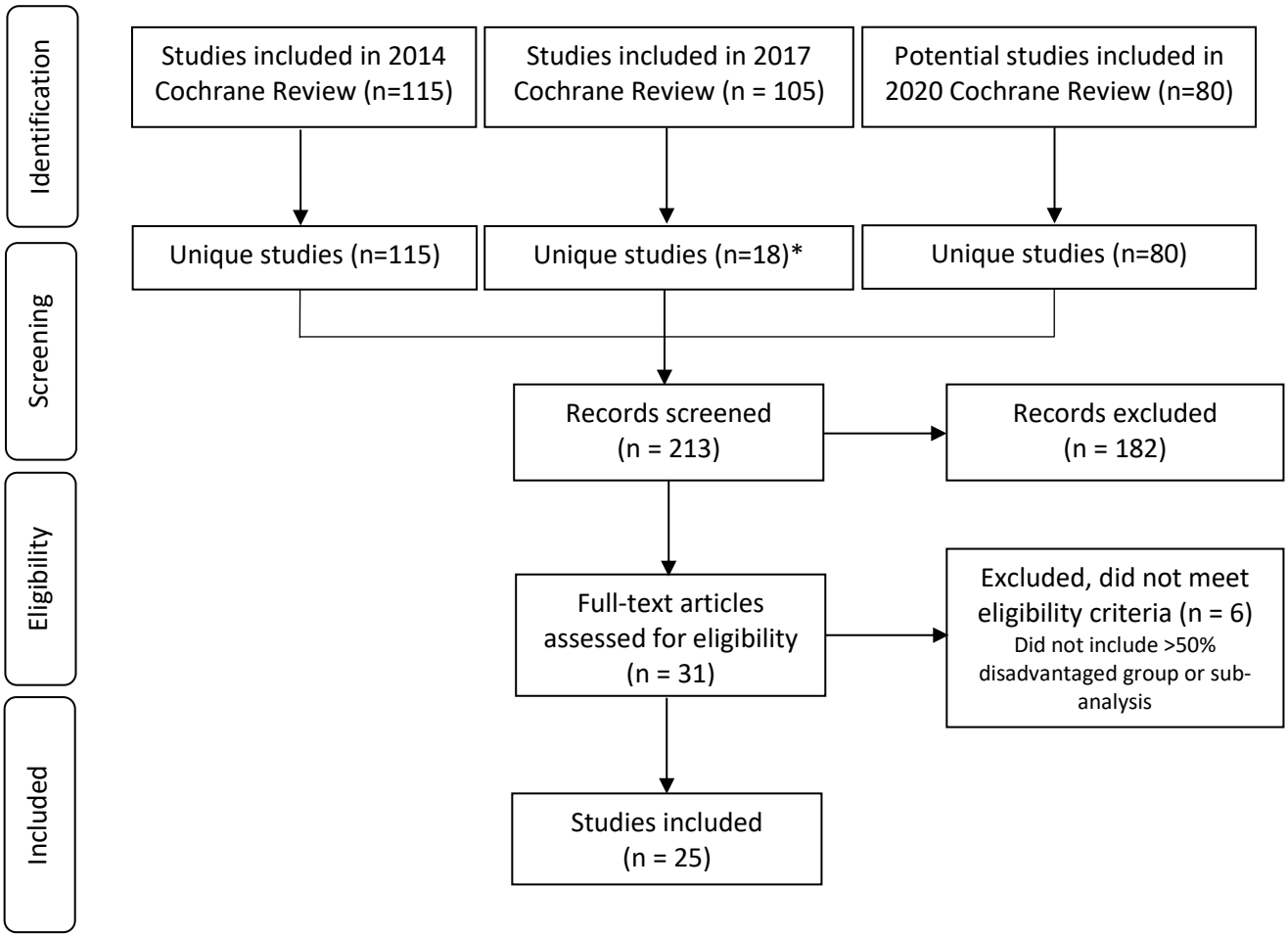


Figure 2. Inclusion and exclusion of studies in 2014-2020 versions of the Cochrane review

* There is substantial overlap between the 2014 and 2017 reviews (n=87). The 2017 version included 18 new studies, but also excluded 28 previously included studies because they compared detailed and simple PtDAs.

Table 2. *Characteristics of included studies (total participants in all trials = 9,865)*

			Inclusion criteria										
Authors and year	**Area and Country**	**Sample size for baseline charact-eristics**	Poverty or SES	Ethnicity or race	Education	Low literacy/health literacy	Geographical location	Uninsured or public health insured	Lower numeracy	Different language	Separate analysis	**Target population** *Participants targeted for recruitment, as described by authors*	**Basis on which population was classified to be within a disadvantaged group**	**Context of decision**
Boulware et al 2018	Baltimore MD, USA	92	✓	✓	✓			✓				Patients who initiated hemodialysis within 2 years of screening, AA, English speaking, 18+ years	59% ≤$20k income, 100% AA, 73% ≤high school, 74% no private insurance	Living donor kidney transplantation
Brenner et al 2016	Nth Carolina, New Mexico USA	262		✓				✓			✓	50-75 years, English or Spanish speaking, average risk, not up to date with recommended screening, had upcoming appointment	61% Lat., 88% no private insurance. Separate analysis to test moderating effects of race, insurance, education, literacy, language and site	CRC screening
Diefenbach et al 2018	USA	349									✓	Patients with PCa (localized), not yet made a treatment decision, English-speaking, access to computer	Separate analysis to test moderating effects of race and education	PCa treatment
Hoffman et al 2017	Houston USA	88		✓							✓	49-75 years, AA, due for screening, English speaking	100% AA. Separate analysis to test moderating effects of health literacy	CRC screening
Ibrahim et al 2017	Philadelphia USA	336	✓	✓								50+ years, AA, chronic and frequent knee pain, evidence of knee osteoarthritis	50% annual household income <$15k, 100% AA	Total knee replacement
Jimenez et al 2017 (pilot)	Philadelphia USA	64 (parent-child dyads)		✓							✓	English-speaking parents of children <36 months referred to early intervention for developmental concerns	88% AA parents. Separate analysis of low health literacy group	Early intervention for developmental concerns in children
Jibaja-Weiss et al 2011	Urban-Sth USA	138		✓				✓				Women diagnosed with early stage BCa (I-IIIA), candidates for breast-conserving surgery	38% AA, 45% Hisp., 100% uninsured	BCT vs. mastectomy
Kuppermann et al 2009	California USA	496		✓							✓	Pregnant women, ≤20 weeks gestation who have not undergone prenatal testing	15.5% AA, 17.7% Lat., 13.3% Asian, 5.6% Other. Separate analysis to test moderating effects of educ. and site	Prenatal genetic testing
Kuppermann et al 2014	California USA	710	✓	✓			✓					Pregnant women, ≤20 weeks gestation who have not undergone prenatal testing	45% Lat., 16% AA, 59% from sites serving women of low-SES	Prenatal genetic testing
Lepore et al 2012	Urban NE USA	490		✓	✓							Men aged 45-70, of AA descent, without PCa diagnosis, or testing <12 months prior	100% AA, 63% ≤ high school	PSA testing for PCa

Marteau et al 2010	England	1272							✓	Men and women aged 40-69 at risk of type 2 diabetes	Separate analysis to test moderating effects of SES	Diabetes screening
Miller et al 2011	Urban-Sth USA	264	✓	✓	✓	✓	✓		✓	Age 50-74, due for screening, SES disadvantaged	70% income <$20k, 73% AA, 67% ≤high school, 56% limited health literacy. Separate analysis to test moderating effects of health literacy	CRC screening
Miller et al 2018	Nth Carolina USA	450	✓				✓		✓	Age 50-74, English-speaking, scheduled to see primary care physician, due for screening	Separate analysis to test moderating effects of income, health literacy and race	CRC screening
Myers et al 2005	Urban-NE USA	242		✓	✓					Men, AA, 40-69, eligible for screening	100% AA, 61% ≤high school	PSA testing
Rising et al 2017	USA	898				✓			✓	Age 18+, presented to emergency with chest pain, negative cardiac workup, no ischemic ECG changes, cardiac troponin < upper limit of normal	> 61% low health literacy. Separate analysis to test moderating effects of race, income, insurance, education, health literacy and numeracy	Chest pain testing vs. observation and follow-up
Ruffin et al 2007	Midwest USA	174					✓		✓	Age 50-70, due for screening, no previous screening	Separate analysis to test moderating effects of geographical location, insurance, education and race	CRC screening
Schroy et al 2011	Urban NE USA	666		✓				✓		Age 50-75, due for CRC screening	63% AA, 6% Hisp., 66% Medicaid, Medicare, free care, or none	CRC screening
Smith et al 2010	NSW Australia	572	✓		✓					Age 55-64, English-speaking, average or slightly above average risk of bowel cancer, low education	59% 0-10 years in education	Bowel cancer screening
Street et al 1995	Urban-Sth USA	60							✓	Females with stage I or II BCa	Separate analysis to test moderating effects of education	BCT vs. mastectomy
Taylor et al 2006	USA	238		✓						Men aged 40-70, no history of prostate cancer	100% AA. Separate analysis to test moderating effects of education	PCa screening
Trevena et al 2008	Australia	314			✓				✓	Age 50-74, good English, no personal history of CRC	78% <high school. Separate analysis to test moderating effects of education	CRC screening
Vina et al 2016	USA	493	✓	✓						Age 50+ years, AA, chronic knee pain, evidence of knee osteoarthritis	100% AA, 47% <$15k income	Knee replacement
Volk et al 2008	Urban-Sth USA	450							✓	Male primary care patients, age 50-70 if not AA, 40-70 if AA, no history of PCa	Separate analysis to test moderating effects of low literacy	PSA testing
Williams et al 2013	Urban-Sth USA	543		✓					✓	Men aged 40-70, no PCa history, pre-registered for screening >5 days in advance, English-speakers	61% AA. Separate analysis to test moderating effects of race	PSA testing
Wolf et al 1996	Urban/Rural NE/Sth USA	205	✓		✓			✓		Men ≥50 years, no PSA testing or PCa history	65% income <$15k, 68% <high school, 59% public insurance	PSA testing

AA=African American, Lat.=Latina, Hisp.=Hispanic CRC=colorectal cancer, PSA=prostate-specific antigen, PCa=prostate cancer, BCa=breast cancer, BCT=breast conserving therapy, SES=socioeconomic status

PtDA format and implementation

Formats of PtDAs varied but were most commonly computerized or web-based multimedia programs that included audio, video and interactive learning modules (n=10 studies; Table 3).[16,17,19,20,23,25-29] Other formats included print (n=4),[21,30-32] video (n=3)[18,33,34] and audio (n=1).[35] Often interventions included a combination of formats such as print/video (n=3).[22,36,37] Four studies used print/video with another element such as text messages,[24] telephone[38,39] or face-to-face counselling.[40] It was generally not specified whether a modality was chosen specifically to accommodate users with low literacy, with the exception of two studies that reported using a touch screen PtDA format to this end.[19,29]

Tailoring for adults with low health literacy and other disadvantaged groups

Table 3 lists strategies for tailoring PtDAs to disadvantaged groups. In total, eight studies (33%) reported assessing readability to improve their PtDas, which represents the minimum requirement to meet IPDAS quality criteria. Seven studies (28%) reported designing their PtDA at a reading level of grade ≤8, four of which reported involvement of experts in either plain language, literacy, adult education or health communication.[22,25,31,37] Readability analysis software was used in one study to refine the PtDA text,[21] one study reported the text was written at reduced readability,[38] and one study simply reported that the reading grade level was calculated, however it is not clear whether it was specifically designed to be below grade 8.[19] Four studies stated that IPDAS criteria were followed; three attended to the original IPDAS quality criteria checklist,[24,32,37] while one attended to the IPDAS instrument (IPDASi v3.0) checklist.[22] An additional study reported that the IPDAS guidelines contributed to the conceptual framework that guided PtDA development,[33] and another updated their PtDA after the study was conducted to satisfy the original IPDAS quality criteria checklist.[26] Eight studies reported using strategies to reduce cognitive burden including plain language, the use of a glossary of key terms, bullet points, visual cues and illustrations, narration, and simple navigation.[22,24,26,27,32,33,36,39] Three studies used the Edutainment Decision Aid Model (EDAM) to guide development of PtDAs.[26,27,33] This approach was initially developed in 2007 by Jibaja-Weiss and Volk with the aim to make a PtDA both entertaining and educational for users with low-literacy by incorporating tailored soap opera scenes and linking them to interactive

learning modules.[41] In the PtDAs that utilized EDAM, the characters in the soap opera episodes were tailored to the ethnicity/race and age of the user.

Studies that used other methods of tailoring for disadvantaged groups are specified in Table 3. Of note, sixteen studies reported involvement of consumers, whereby two reported having a patient partner on the research team[36,37] and fourteen involved patients/consumers in the development of the PtDA. Six reported conducting focus groups with patients,[16-18,29,36,37] three reported conducting interviews with patients,[20,22,39] and two reported conducting both focus groups and interviews.[23,24] Thirteen studies reported conducting pilot, user or usability testing with target disadvantaged groups (Table 3). Five additional studies conducted a form of user testing but did not specify whether it was in disadvantaged groups.[16,17,25,29,33] Communication or literacy expert involvement was reported in nine studies, indicated in Table 3.

Table 3. *Methods used to tailor PtDAs for disadvantaged groups*

	Methods of tailoring for disadvantaged groups								
Author and year	Reading age calculated	Strategies to reduce cognitive demand	Use of media other than text	Consumer involvement in development	User testing with disadvantaged groups	Language adaptation	Communication/literacy experts	**Decision-aid format and strategy used to tailor it for low health literacy/disadvantaged group**	**Brief description of comparator/control group**
Boulware et al 2018^	✓		✓	✓	✓		✓	1) PREPARED: 50-min DVD describing *living donor kidney transplant* and a 162-page book written at 4th grade reading level summarizing the evidence about treatment effects on aspects of patients' lives. Focus groups of patients, families, experts (clinicians, health education specialist, patient advocacy specialist, video scriptwriter, medical illustrator). Cognitive interviews with patients. Two pilot phases with 48 diverse patients. 2) PREPARED PLUS: offered donors reimbursement along with PtDA video and book.	Routine care in hemodialysis facilities. Participants in any 3 groups could have received educational materials or financial assistance through usual care
Brenner et al 2016^#			✓	✓	✓	✓		Video: *Communicating Health Options through Interactive Computer Education (CHOICE*): 15 mins, *CRC screening* overview, comparison of test options and selection of a colored brochure to correspond to readiness. Spanish translation using original PtDA appraisal (Miller et al 2011), literature review, assessment of demographic trends, solicitation of information from target population. Trained navigators provided tailored support immediately after clinician encounter.	Attention control: food safety video before encounter and usual care after encounter
Diefenbach et al 2018^	✓		✓				✓	*Healing Choices*: multimedia software on CD-ROM including information about *PCa treatment,* ethnically diverse patient videos, physician's view of treatment and recovery, opportunity to determine values/preferences. Theoretical frameworks and literature review guided content selection. Development included conceptual, literacy and cultural appropriateness review, user and usability testing, 7th grade reading level, guided by literacy and patient education experts.	Usual care: spoke to specialist who answered questions, received standard CIS and NCI print materials
Hoffman et al 2017		✓	✓					Video: 30mins, *colorectal cancer screening* educational and decision support, encouraging patients to talk to their PCP, ask questions and share concerns and preferences using AA family story. Content review by experts, prototyping, video production, pilot testing using cognitive interviews. Incorporated IPDAS, Ottawa Decision Support Framework, and Integrated Model of Behavior. EDAM used to improve saliency for AAs and ensure PtDA was accessible across literacy levels.	Attention control: hypertension video providing similar educational content but lacking decisional support and tailored components
Ibrahim et al 2017			✓					Video: 40mins, discusses *knee osteoarthritis treatment options* (lifestyle changes, medications, injections, complementary therapy and surgery, risks, benefits and known efficacy of each option, clinical indications, rehabilitative care, recovery time, effort and cost). Developed by Foundation for Informed Medical Decision Making. Same PtDA tested by Vina 2016.	Educational booklet developed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases

Jibaja-Weiss et al 2011^		✓	✓		✓	✓		Interactive computerized web soap opera episodes walk women through *BCa* journey, episodes adapted to linguistically, race/ethnically and age targeted to user. EDAM utilized. Special design considerations for low literate computer users: voice-over navigational instructions, limited on-screen text. Developed with expert panel, usability interviews with target population, user testing in subgroups. Adapted episodes to Spanish. Updated version followed IPDAS guidelines.	BCa treatment educational materials generally provided to patients in these hospitals
Jimenez et al 2017		✓	✓	✓				Video (3mins) + text message explaining child development and Early Intervention (EI). Focus groups and interviews with parents & primary care professionals. Followed IPDAS criteria and accommodated low health literacy users using strategies such as plain language, visual reinforcement of key ideas, summaries of key information, and provided specific action steps. Feedback from parents, leaders from EI agency and other experts in child development. SMS reminder based on parent interviews to augment DA intervention.	Standard care: additional age-appropriate handout, publicly available from the CDC "Learn the Signs. Act Early" campaign
Kuppermann et al 2009*			✓	✓		✓	✓	Interactive computerized web-program emphasizing decision is personal and depends on values, explains screening vs. diagnostic tests, risks/benefits, describes Down Syndrome, gives tailored estimates. Focus groups and pilot testing among women and genetic counsellors. Spanish translation using forward and backward translation process with three bilingual team members. Kuppermann 2014 evaluated same PtDA.	Computerized version of booklet provided to pregnant women by California Expanded AFP Screening Program obstetricians
Kuppermann et al 2014			✓	✓		✓	✓	'*Prenatal Testing: Exploring Your Options*': interactive computer program (audio, video and text elements) narrated by bilingual actress. Educational module (general information + role of values and preferences), features of screening and tests. Input from clinicians, decision scientists, communication/literacy experts, focus groups of women, pilot testing with women and genetic counsellors, Spanish translation process. Participants told study would pay for any tests discussed for which they did not have insurance coverage. Kuppermann 2009 evaluated same PtDA.	No intervention or financial support provided
Lepore et al 2012^	✓		✓	✓	✓			Information booklet "*Prostate Cancer: Your Life – You Decide*" and telephone counselling session (education about risk, benefits and harms of screening, values clarification and shared decision-making). Feedback from expert consultants and men in target subgroups, cognitive interviews to ensure comprehension. Pilot testing conducted with low income undeserved men. Written at reduced readability level. SMOG grade level of 7 and Flesch grade level of 2.7	Telephone education about fruit and vegetable intake guidelines + education pamphlet
Marteau et al 2010^	✓		✓	✓				Letter informing participants they are at risk of developing *Type 2 diabetes* and inviting them to screen. Provides diabetes information: risk factors and complications, screening process, possible benefits and harms and their likelihood of occurring. Words, numbers and pie charts used to convey risks and benefits. Developed iteratively using think-aloud approaches. Flesch-Kincaid Grade level = 5.76, reading age 11 or above. Text refined using readability tools.	Standard letter stating participant is at increased risk of diabetes
Miller et al 2011^			✓	✓	✓			Interactive web-based program (*CHOICE*): includes video clips, graphics and animations. Presents prevalence information, *CRC screening* rationale, description of tests. Content based on previously validated video guided by subgroup interviews; navigation designed for 'low-literacy' subgroup. User testing with participants with wide range of computer experience and education level.	Computer presented program about prescription drug refills and safety
Miller et al 2018^	✓		✓		✓		✓	Video (8mins) reviewing *fecal testing and colonoscopy* (based on *CHOICE* PtDA). Delivered via mobile app on iPad 'mPATH-CRC.' Participants can self-order test on app, PCP notified if participant self-ordered. Participant received follow-up messages with information about test ordered. Content and navigation designed for people with low health and computer literacy (simple interface, audio	Video: 4.3 mins about diet and exercise produced by Centers for Disease Control

							narration). Team included experts in app development, health literacy and CRC screening. Usability study conducted in disadvantaged population. All material written at 6th grade level or lower.	
Myers et al 2005*^		✓		✓	✓	✓	*PCa* information booklet, risk factors, symptoms, pros/cons of screening, follow-up tests and treatment options. Telephone decision counselling session where major decision factors elicited and participant identifies top three factors, entered into pre-programmed calculator and preference score shared with participant. Content field-tested by literacy expert in face-to-face interviews with sub-group. Feedback resulted in simplification of text. Decision counselling protocol pilot tested in primary care practices in target community.	Information booklet addressing PCa, risk factors, symptoms, pros and cons of screening, follow-up tests and treatment options
Rising et al 2017		✓		✓	✓		Patients provided with 100-person risk pictograph to depict personalized risk for acute coronary syndrome within 45 days. Provides explicit management options. Each patients' PtDA color coded to correspond to level of risk to reduce cognitive demand. Iterative development process whereby research team and designers field tested with clinicians and patients in emergency (25% ≤high school). Participatory action research design included revisions based on feedback from patients and caregivers and ensured IPDAS criteria was met.	Usual care: clinicians instructed to have discussions regarding test results and treatment as per usual practice
Ruffin et al 2007^			✓	✓	✓		Interactive web-based education tool: 'Colorectal Web'. Used graphics, text, and videos to encourage patients to weigh preferences to make an informed choice. Content and usability testing guided by focus groups and interviews conducted with participants from geographical areas with high rates of advanced CRC and a low incidence of CRC screening.	Non-interactive CRC website sponsored by Cancer Research and Prevention Foundation
Schroy et al 2011			✓	✓			Two intervention groups: 1) received interactive computer program using audio-visual and touch-screen format including descriptions of CRC screening methods, audio and visual comparisons, summary of test features, decision-making module. 2) received program and personal risk assessment. Subgroup focus groups of racially/ethnically diverse screened and unscreened men and women, assess out-of-pocket cost concerns, cultural sensitivity issues, usability tests.	9 Ways to Stay Healthy and Prevent Disease discussing generic lifestyle changes other than screening for minimizing risk of preventable diseases
Smith et al 2010^	✓	✓		✓	✓	✓	Information booklet + video presenting tailored risk information about the outcomes of screening for CRC with FOBT. Informed by interviews with adults of varying education/literacy level, experts in adult literacy and linguists. Plain language, basic design, illustrations and simple techniques to reduce cognitive effort (reduce amount of text, lay language, glossary, simplified diagrams, active voice, contextual information before factual). Existing PtDA adapted to reduce the Flesch-Kincaid Grade level from 10 to 7. Pilot testing using same recruitment strategy.	Standard consumer information booklet Flesch-Kincaid readability score grade 9
Street et al 1995*			✓				Interactive multimedia program: *Options for Treating Breast Cancer*, including understanding the problem, treatment options (mastectomy and lumpectomy with radiation), and experiences of other women who had undergone either mastectomy or lumpectomy.	Care of Patients with Early Breast Cancer brochure (8 pages).
Taylor et al 2006^		✓	✓	✓		✓	Two intervention groups: 1) Booklet: 16-page, information about PCa screening, questions to ask doctor, glossary, celebrity spokesperson. 2) Video: 25-mins, depicts middle-aged AA man, discussing screening with friends, family, doctor; decision process (attempts to understand, fears, doubts, questions). Eight focus groups conducted with AA men and two with clinicians and researchers. Participants provided feedback. Research team included urologists, nurse, Public Health educators, AA men, and behavioral science staff.	Wait-list: single pre-intervention interview occurred 1 month following randomization but before receipt of intervention
Trevena et al 2008	✓						Information booklet (20pages): CRC screening definition, baseline risk information over next 10 years, mortality reduction from screening, outcomes from biennial FOBT, information about how to	Consumer version of Aus guidelines mailed consisting of 3

						collect FOBT. Flesch-Kincaid readability score was grade 10. Incorporated expert and lay beliefs about core issues for informed choice about FOBT obtained from previous research, including studies conducted by the authors.	pages of text with information about biennial FOBT. FK readability grade 9
Vina et al 2016^			✓			Two components: 1) Video (40mins) - see Ibrahim 2017. 2) Motivational interviewing: ~30mins session, face-to-face, motivational interviewing by trained, certified interventionists. Participants asked thoughts about total knee arthroplasty, goals/preferences regarding arthritis, and provided information and support for discussing with PCP. Same PtDA evaluated by Ibrahim 2017.	Educational booklet developed by NIH National Institute of Arthritis and Musculoskeletal and Skin diseases.
Volk et al 2008*		✓	✓		✓		Interactive DVD/CD-based soap opera episodes: 53-68mins, EDAM design, didactic soap-opera episodes integrated with interactive learning modules to complement content, navigational instructions provided, ethnicity of main character tailored to viewer, story took character through process of PCa screening decision. Content tailored using racial/ethnic concordance and social matching, acceptability tests conducted in subgroups.	Audio-booklet: same content, accompanied by narration. Lacked interactivity of intervention, testimonials and values clarification exercise
Williams et al 2013	✓				✓	✓	Booklet (24 pages): *Prostate Cancer Screening*: Making an Informed Decision. Includes information on leading causes of death among men, accuracy of PSA test, PCS guidelines and diagnostic procedures and treatments. Adapted to 8th grade readability by plain language experts, usability tests in subgroups.	Usual care educational materials – National Cancer Institute's 3-page fact sheet.
Wolf et al 1996					✓		Script about PSA screening read aloud by research assistant: overview of PSA screening, stated lifetime probability of developing and dying from PCa, known risk factors, ability of PSA test to detect early asymptomatic cancer, description of management options and major complications. Content developed by physician experts, piloted with primary care patients via subgroup interviews, assessed for comprehensibility.	Brief statement: blood test known as the PSA is available that can sometimes detect early prostate cancer before it is otherwise apparent

PCP=Primary Care Physician, IPDAS=International Patient Decision Aid Standards, ODSF=Ottawa Decision Support Framework, EDAM=Edutainment Decision Aid Model, AA=African American, PCa=prostate cancer, CRC=colorectal cancer, BCa=breast cancer, PSA=prostate-specific antigen, AA=African American, FK= Flesch-Kincaid

* Included in 2014 Cochrane Review of PtDAs but excluded from 2017 update due to comparing simple versus detailed PtDAs

^ Development reported in separate paper

Decision-making outcomes reported in Brenner et al., 2016, implementation outcomes reported in Reuland et al., 2017

Cognitive demand: readability, comprehension and actionability scores of PtDAs

We were able to access 11 PtDAs out of the total 24 unique PtDAs from journal articles or supplementary material (n=2), decision-aid repositories (n=2) or via direct contact with the PtDA author (n=7). For two of these, we were only able to access a component of the intervention; an information booklet evaluated by Myers et al. (accompanied by motivational interviewing),[39] and the video component of an iPad program evaluated by Miller et al.[19] Of those obtained, the readability, understandability and actionability is shown in Table 4. Using our measure of readability, none of the PtDAs were written at or below 8th grade reading level. Notably, none of the PtDAs were written at 6th grade level or below.

Using the PEMAT measure, understandability scores were high with 92% (n=11) achieving the recommended threshold (Table 4). However, only 42% (n=5) of PtDAs achieved the recommended threshold for actionability. The mean understandability score was 83.3% (SD=9.3%) and the mean actionability score was 68.6% (SD=20.2%).

Table 4. *Readability and Patient Education Materials Assessment Tools (PEMAT) scores for PtDAs which could be accessed*

Authors and year	Readability score*	PEMAT score# *Score >70% = suitable for lower literacy popln*	
		Understandability (%)	Actionability (%)
Print			
Boulware et al 2018	9.07	94.1	60.0
Marteau et al 2010	8.98	81.3	66.7
Myers et al 2005	9.99	87.5	66.7
Rising et al 2017	12.66	75.0	75.0
Smith et al 2010‡	8.47	93.8	83.3
Taylor et al 2006	11.49	75.0	50.0
Trevena et al 2008	11.54	87.5	60.0
Audio-visual (computerized program or video)			
Boulware et al 2018	12.82	83.3	100.0
Jibaja Weiss et al 2011+	10.60	92.3	100.0
Miller et al 2018	11.49	84.6	50.0
Reuland et al 2017	11.23	84.6	75.0
Taylor et al 2006	8.25	60.0	33.3

*readability scores are the average of the SMOG index and the Gunning Fog index. High scores indicate the PtDA is harder to read.
print PtDAs assessed using the PEMAT-P (printable materials), video and computerized PtDAs assessed using the PEMAT-A/V (audiovisual materials)
‡ We did not assess the video component of the PtDA evaluated by Smith et al., as we were informed by authors that the content was identical
+PtDA updated after the study to meet IPDAS quality criteria checklist, version used for readability and PEMAT analysis may differ from the version evaluated in the study
^ Wolf et al 1996 excluded from readability and PEMAT analysis due to format of PtDA

Impact of the PtDAs

In total, 19 of the 20 reviewed studies that included at least 50% of participants from a disadvantaged population assessed the overall effectiveness of their PtDA on decision making and health outcomes. The remaining study did not report overall effectiveness of the PtDA as it focused on effectiveness of PtDA across subgroups.[27] Fourteen studies conducted separate analyses exploring either the moderating effect of disadvantage on the effectiveness of PtDAs, or the impact on disadvantaged groups only (either instead of, or in addition to, the overall analysis) (Table 6). One study met our inclusion criteria for conducting a separate analysis as they conducted a bivariate analysis across disadvantaged groups, however, the interaction between disadvantage and intervention was not analyzed.[36]

Impact on attributes of the choice

A common reported measure of effectiveness of PtDAs relating to attributes of the choice was *knowledge* (n=12). Of these 12 studies, 10 reported knowledge as a continuous outcome and were included in the meta-analysis (Figure 3). After standardizing means to a scale of 1 to 100, the pooled mean difference was 14.65 (95% CI 9.48, 19.83) with substantial heterogeneity (I^2=96%, p<0.001). Two studies could not be pooled into a meta-analysis (Table 5): one reported knowledge dichotomously (knowledge increased in the PtDA group),[30] and one was a pilot study that reported 14 items relating to knowledge/attitudes without merging into one score.[24]

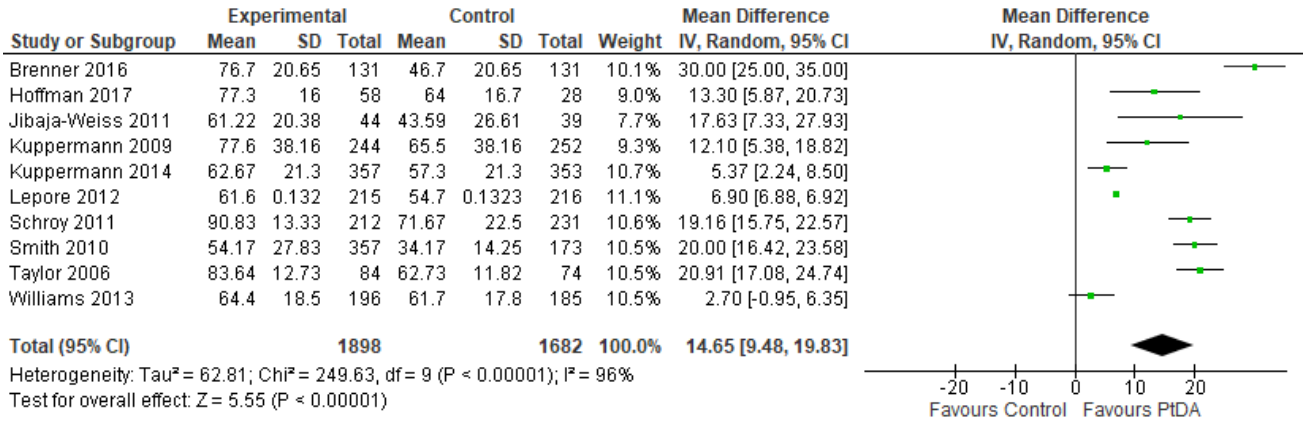


Figure 3. Forest plot for knowledge

Seven studies analyzed moderating effects of disadvantage on knowledge (Table 6). Knowledge increases resulting from a PtDA were evident in most studies across both disadvantaged and non-disadvantaged groups. However, one study found moderating effects of race, such that knowledge increases were significantly greater for white participants who received their PtDA compared to non-white participants.[32]

Two studies assessed *accurate risk perception* so were not pooled in a meta-analysis (Table 5). PtDAs increased accuracy of risk perception for prenatal genetic testing compared to control,[16,17] but this difference was not maintained at follow up.[16]

Two studies assessed *values-choice congruence* so were not pooled in a meta-analysis (Table 5). They found participants who received the PtDA made more informed choices (adequate

knowledge and attitudes-behavior congruence),[22] and integrated decisions (clear values and adequate knowledge)[30] than those who did not receive the PtDA.

Impact on attributes of the decision-making process

Nine studies assessed *decisional conflict.* Six were included in the meta-analysis (Figure 4). On a scale of 1 to 100, the pooled mean difference was -4.16 (95% CI -7.38, -0.93) with substantial heterogeneity (I^2=81%, p<001). We conducted a subgroup analysis according to scale (original decisional conflict scale versus low-literacy version) and found that the pooled mean difference for studies using the original scale was -1.58 (95% CI -2.66, -0.49) with no heterogeneity (I^2=0%, p=0.48) (Figure 5). The pooled mean difference for studies using the low literacy scale was -8.93 (95% CI -17.14, -0.73) with substantial heterogeneity (I^2=86%, p<001) (Figure 6).

Of the remaining three studies that were not included in the meta-analysis (Table 3), one reported decisional conflict dichotomously and found that the PtDA reduced decisional conflict compared to control.[36] One only reported the values clarity subscale and found no differences between PtDA and control groups.[30] One did not provide sufficient detail for inclusion.[31]

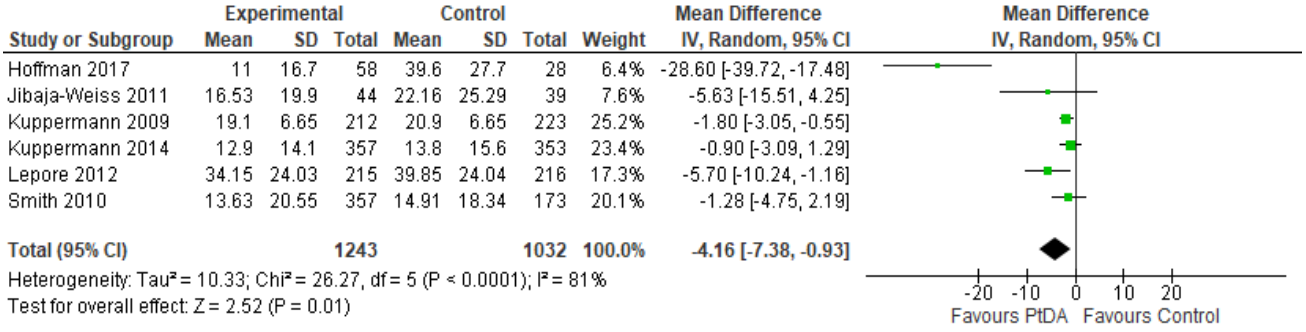


Figure 4. Forest plot for decisional conflict.

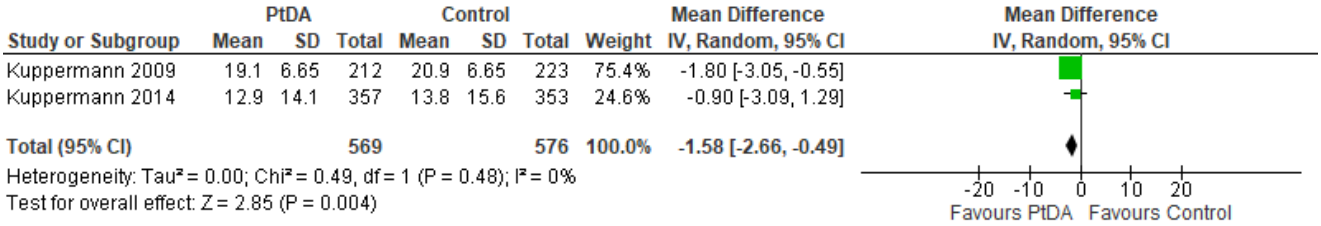


Figure 5. Subgroup forest plot for decisional conflict (studies using the original Decisional Conflict Scale only).

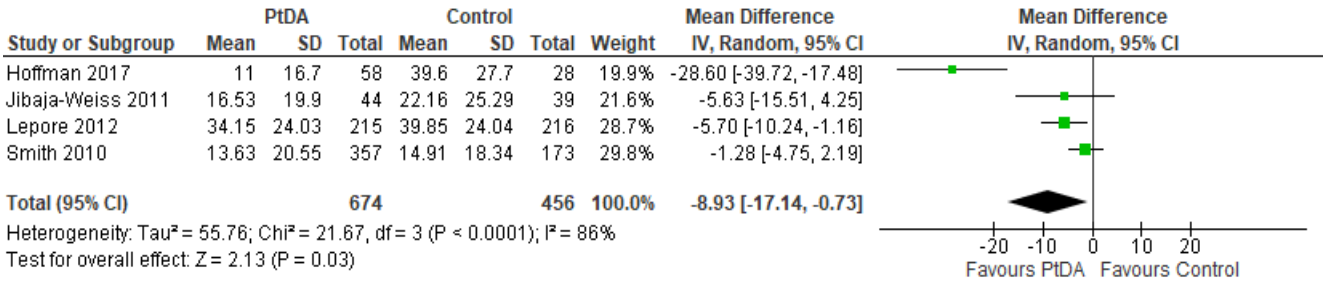


Figure 6. Subgroup forest plot for decisional conflict (studies using the low-literacy version of the Decisional Conflict Scale only).

Other outcomes relating to decision-making were reported but not pooled in a meta-analysis (Table 5). For *satisfaction with decision,* this was because four studies used different scales/items or provided insufficient information, but all reported no differences between PtDA and control groups.[22,26,31,36] Only two studies measured s*atisfaction with the decision-making process,* so were not included in a meta-analysis: one reported a difference between groups[29] and the other did not.[26] Three studies assessed *participation in decision*,[16,22,33] but only one reported a statistically significant increase in the PtDA group.[33]

Four studies measured *patient-clinician communication*.[18,19,37,38] Three were pooled in a meta-analyses (Figure 7). The relative risk was 1.62 (95% CI 1.42, 1.84) with no heterogeneity (I^2=0%, p=0.78). The remaining study was not included in the meta-analysis because it combined reporting of discussions with doctor and/or family (Table 5). No differences between PtDA and control groups were evident.

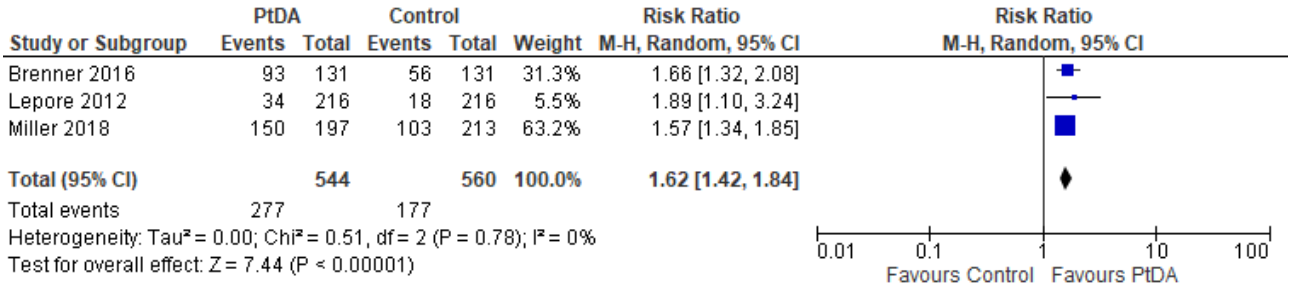


Figure 7. Forest plot for patient-clinician communication.

Five studies analyzed moderating effects of disadvantage on attributes of the decision-making process (Table 6). Three analyzed *decisional conflict*: two found no moderating effects,[31,32] but one reported that the PtDA was more effective in reducing decisional conflict in low literacy

participants than high literacy participants.[27] One study also found increased *decisional support* (DCS subscale) after receiving the PtDA was more pronounced for African American and lower educated participants.[25] Regarding *participation in decision*, two studies found that there were no differences across subgroups,[28,32] but another found their PtDA increased low literacy participants' willingness to be involved compared to control more than for high literacy participants.[27] One study found no moderating effects of race on *decisional satisfaction.*[31]

Two studies analyzed moderating effects of disadvantage on *patient-clinician communication* and both found no moderating effects of race or education.[18,28]

One study analyzed moderating effects of disadvantage on *trust in physician* and found greater increases among those with lower health literacy receiving the PtDA than those with higher health literacy.[32]

Impact on attitudes

Four studies assessed attitudes towards a procedure or test. These were not pooled in a meta-analysis because of the varied attitudes that were measured. Details are shown in Table 5. Of these four studies, only one reported a significant difference: attitudes towards bowel cancer screening were slightly more negative for those who received the PtDA compared to control.[22]

Impact on behavior (preferences, intentions, behavioral outcomes, adherence to chosen option)

Preferences for different screening tests were measured in six studies. Four reported the *proportion undecided* so were included in the meta-analysis.[18-20,26] The pooled relative risk was 0.23 (95% CI 0.11, 0.50) with high heterogeneity (I^2=66%, p=0.03) (Figure 8). Two were not included in the meta-analysis because they reported preference as increased willingness for the procedure or provided insufficient information: both reported no differences between groups (Table 5).[29,40] Additionally, one study found their PtDA was more likely to affect participants' pre-natal testing plans compared to control, but this difference was not maintained at follow-

up (Table 5).[16]

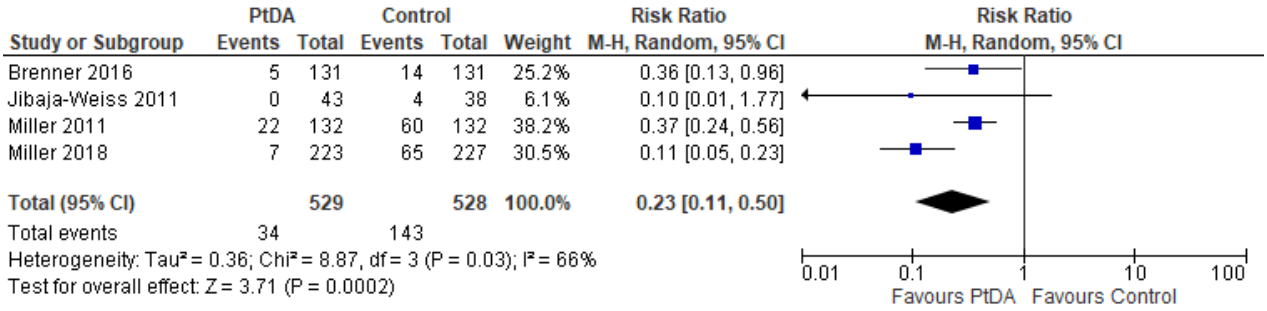


Figure 8. Forest plot for proportion undecided.

Intentions, readiness and interest were measured in eight studies. Five reported cancer screening intentions using proportions and were included in the meta-analysis (Figure 9).[18,19,30,33,38] The pooled relative risk was 1.06 (95% CI 0.96, 1.16) with moderate heterogeneity (I^2=65%, p=0.02). Three studies were not included in the meta-analysis due to continuous measurement or assessing slightly different constructs (i.e. readiness/interest). All three found the PtDA increased screening intention, interest or readiness (Table 5).[20,29,35]

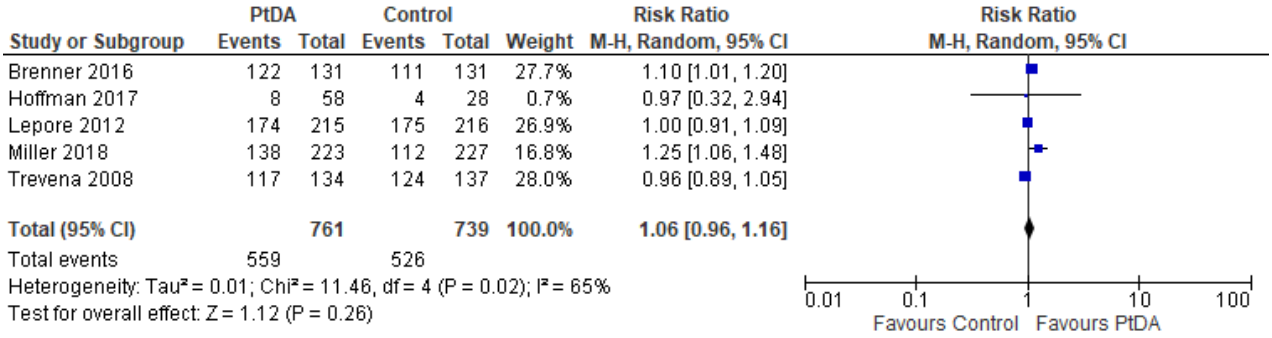
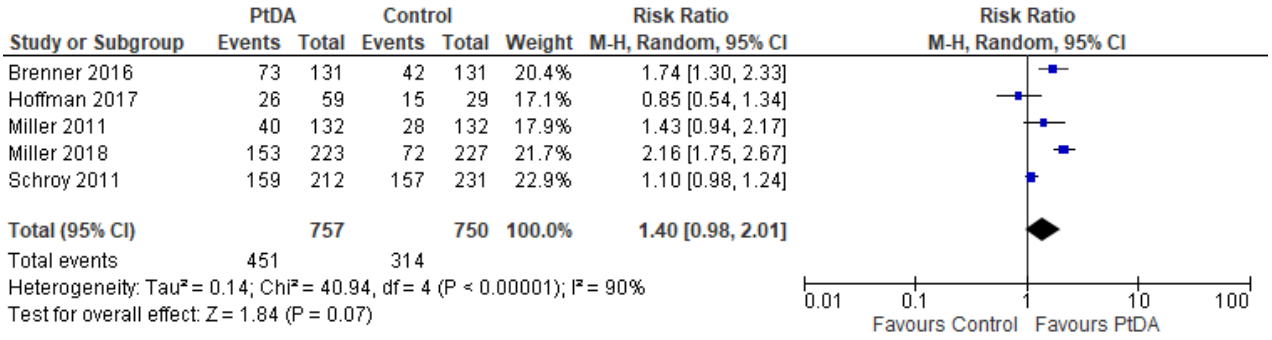


Figure 9. Forest plot for screening intention

Two studies analyzed moderating effects of disadvantage on *ability to state a screening preference* and *screening readiness.* Improvements in these outcomes as a result of receiving the PtDA relative to control were evident in both low and high health literacy groups,[20] as well as both Latino and non-Latino participants.[18]

Behavioral outcomes were measured in 15 studies. Of these 15 studies, five assessed *test ordering* in the cancer context and were included in the meta-analysis (Figure 10).[18-20,29,33] The pooled relative risk was 1.40 (95% CI 0.98, 2.01) with substantial heterogeneity (I^2=90%,

p<0.001). Nine assessed *test completion* for cancer screening and were pooled in the meta-analysis (Figure 11). The pooled relative risk was 1.35 (95% CI 0.93, 1.94) with substantial heterogeneity (I^2=91%, p<0.001). Five studies reported behavioral outcomes that were not pooled due to their heterogeneity (Table 5). Three found no behavioral differences between PtDA and control groups.[24,37,40] However, some behavior change was evident in two studies: one reported increased receipt of total knee replacement surgery as a result of viewing the PtDA[34] and another found decreased use of invasive prenatal diagnostic testing after receiving a PtDA.[17] One study did not report enough details but reported no statistically significant differences in behavior.[31]



F*igure 10.* Forest plot for screening test ordered.

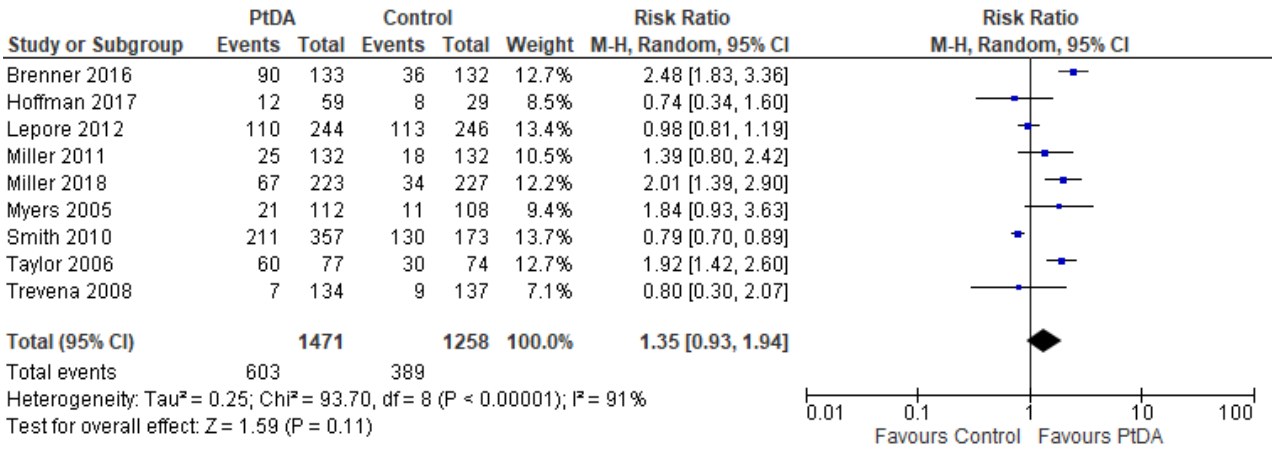


Figure 11. Forest plot for screening test completed.

Eight studies analyzed moderating effects of disadvantage on behavioral outcomes. Five reported no moderating effects of poverty,[21] health literacy,[19,20] income[19] or race.[19,23,31] One found their PtDA increased intake and evaluation for early intervention for developmental

delay compared to control within a low health literacy group, but did not report statistical tests.[24] Brenner et al. found no moderating effects of ethnicity on colorectal cancer screening test ordering,[18] but their follow-up paper reporting implementation outcomes showed greater screening completion among Latinos and those without private insurance.[42]

Two studies assessed *adherence to a chosen option* and were not included in a meta-analysis.[29,38] One measured intention-behavior congruence for prostate cancer screening and found no differences between PtDA and control groups at 1 or 2 year follow up.[38] The other study did not report enough detail.[29]

Impact on health outcomes

Anxiety was measured in three studies with no differences between groups reported (Table 5).[22,30,38] These were not pooled in a meta-analysis because they used quite different scales. Two studies also measured *decisional regret*[16,17] and one measured *confidence in decision-making*;[22] both reporting no differences between groups (Table 5).

Attitudes towards and acceptability of PtDAs

Attitudes and acceptability of the PtDAs were measured in different ways and studies report varied results. These are described in more detail in the Appendix.

Table 5. *Outcomes of trials including >50% disadvantaged population*

Authors and year	Scale used	Timing	Decision aid		Comparison		P-value	Notes
			N	Mean/ %	N	Mean/ %		
Attributes of the choice – *Knowledge*								
Jimenez et al 2017	14-item scale developed in consultation with pediatric experts, informed by qualitative interviews with parents and providers	Post-intervention						See footnote[#]
Trevena et al 2008	4 free-text questions; mark given for correct piece of information (max score=3), mark deducted for piece of incorrect information, % adequate knowledge	Post-intervention	134	20.9%	137	5.8%	0.0001	Adequate knowledge if positive score for understanding potential benefits and harms of screening
Attributes of the choice – *Accurate risk perception*								
Kuppermann et al 2009	Procedure-related miscarriage estimate % correctly estimated risk	Post-intervention	244	64.9%	252	48.1	0.002	
		1-2 weeks later	212	55.7%	223	51.0%	0.39	
	Down Syndrome affected fetus estimate	Post-intervention	244	63.5%	252	15.1%	<0.001	
		1-2 weeks later	212	42.8%	223	15.7%	<0.001	
Kuppermann et al 2014	Miscarriage risk	Post-intervention	357	73.8%	353	59.0%	<0.001	
	Down Syndrome risks	Post-intervention	357	58.7%	353	46.1%	0.001	
Lepore et al 2012	Benefits:risks % agree benefits outweigh risks	Post-test	215	33.5%	216	28.2%	>0.05	Measured perceived importance, not accuracy
Attributes of the choice – *Values-choice congruence*								
Smith et al 2010	*Informed choice* if adequate knowledge + attitudes congruent with behavior	Post-intervention	357	34%	172	12%	< 0.001	
	Partly uninformed choice – completing test with positive attitudes but inadequate knowledge	Post-intervention	357	15%	172	41%	NA	
Trevena et al 2008	*Integrated decision*	Post-intervention	134	10.4%	137	1.5%	0.002	Values clear + adequate knowledge
Attributes of the decision-making process – *Decisional conflict*								
Taylor et al 2006^	DCS low-literacy version, 10-item; 2 excluded, dichotomized; *Waitlist randomized to print/video arms before 1-month assessment.*	Baseline	84	33.3	74	41.9	> 0.05	Print DA (column), video DA (n=80): 31.3
		1-month	84	8.3	-	-	<0.05	Print DA (column), video DA (n=80): 24.1
Trevena et al 2008	DCS: values (% <25 on values subscale of DCS)	Post-intervention	134	61.9%	137	59.1%	0.63	Values clarity only reported
Williams et al 2013	10-item low-literacy version. (See paper for more details regarding intention-to-treat and per-protocol analysis and delivery modes).	Baseline	NA	NA	NA	NA	NA	No significant main effects for booklet type
		2-months	185	NA	175	NA	NA	
		13-months	NA	NA	NA	NA	NA	
Attributes of the decision-making process – *Satisfaction with decision*								
Jibaja-Weiss et al 2011	SWD scale (6-item, range 1-5)	Pre-surgery	40	2.87	36	2.85	0.65	
Smith et al 2010	Decision attitude scale (10-item)	Post-intervention	357	NA	173	NA	0.49	
Taylor et al 2006	Single item 4-point scale; dichotomized (% high)	Baseline	84	76%	74	78%	>0.05	Print DA (column), video DA n=80): 78%
		1-month	84	85%	-	-	>0.05	Print DA (column), video DA (n=80): 80%
Williams et al 2013	SWD scale 6-item measure; range1-5 Reported as % highly satisfied (scored 4 or 5)	2-months	226	NA	223	NA	NA	Multivariate analyses revealed no significant main effects or interactions
		13-months	226	NA	223	NA	NA	
Attributes of the decision-making process – *Satisfaction with decision-making process*								

Jibaja-Weiss et al 2011	Modified SWDMP scale (7-item; range 1-3)	Pre-surgery	44	1.12	39	1.15	0.70	
Schroy et al 2011^	SWDMP scale (12-item; range 12-60)	Post-test	205	50.7	217	46.7	<0.001	PtDA+risk calculator YDR (n=214): 50.5
		6 months	22	27%	26	19%	> 0.05	PREPARED PLUS (n=26): 19%
Attributes of the decision-making process - *Participation in decision*								
Hoffman et al 2017	Patient self-advocacy scale - 12 items; range 1-3	Post-intervention	59	1.6	28	1.8	0.01	3-point scale, low=more self-advocacy
Kuppermann et al 2009	Information given by provider	26-30 wks gestation	202	44.8%	218	49.2%	0.40	Satisfaction with decision-making involvement - 3 items % responding 'very satisfied' or 'satisfied'
	The way your provider involved you	26-30 wks gestation	202	44.3%	218	48.1%	0.45	
	The degree of involvement you and provider had	26-30 wks gestation	202	72.6%	218	79.9%	0.10	
Smith et al 2010	Involvement preference (making decision on own)	Pre-intervention	384	37%	188	41%	NA	Difference across timepoints for both groups < 0.001.
		Post-intervention	355	90%	171	96%	NA	
Patient-clinician communication								
Boulware et al 2018^	Discussion about LDKT with doctor or family	Baseline	30	17%	31	13%	> 0.05	PREPARED PLUS (n=31): 36%
		6 months	22	23%	26	23%	> 0.05	PREPARED PLUS (n=26): 23%
	Discussion about LDKT with doctor and family	Baseline	30	27%	31	33%	> 0.05	PREPARED PLUS (n=31): 10%
		6 months	22	27%	26	19%	> 0.05	PREPARED PLUS (n=26): 19%
Attitudes								
Boulware et al 2018	*Beliefs about kidney transplant* – 4 items	Four timepoints	30	Graphs	31	Graphs	NA	PREPARED PLUS (n=31) Did not change among study groups – see text on page 31
	Concerns about LDKT – 10 items	Four timepoints	30	Graphs	31	Graphs	NA	
Hoffman et al 2017	*Attitudes toward CRC screening*: 3 items; 1-5 scoring, max score 15	Baseline	58	9.7	28	8.9	-	*Change scores not significant High = positive attitudes
		Post-intervention	58	9.4	28	8.6	0.49*	
	Perceived social normative pressures about CRC screening: 3 items; 1-5 scoring, max score 15;	Baseline	58	10.5	28	11.6	-	*Change scores not significant Higher = positive perceived social norms
		Post-intervention	58	9.4	28	8.6	0.49*	
Jimenez et al 2017	Knowledge and attitudes (14 items)							See footnote[#]
Smith et al 2010	6 item scale, range 6-30, higher = positive	Post-intervention	357	26.4	173	27.3	0.003	
Behavior – *Intentions and preferences*								
Kuppermann et al 2009	Intervention affected prenatal testing plans	1-2 weeks	212	47.8%	223	27.5%	< 0.001	% of women responding 'strongly agree' or 'agree'
		26-30 wks gestation	202	38.2%	218	36.0%	0.85	
Miller et al 2011	Screening readiness	Immediately after	132	52%	132	20%	0.001	
Schroy et al 2011^	Preferences (captured in module)	Post-intervention	212	NA	223	NA	>0.05	
	Screening intentions (5-point); *scheduling appt.*	Post-intervention	212	3.9	231	3.9	< 0.001	PtDA + risk calculator YDR (n=223): 4.3
	Screening intentions (5-point); *completing test*	Post-intervention	212	4.3	231	3.9	< 0.001	PtDA + risk calculator YDR (n=223): 4.3
Vina et al 2016	TKA preference (% increased willingness)	2-weeks	238	34%	252	33%	0.779	
		3 months	238	33%	252	26%	0.106	
		12 months	238	29%	252	27%	0.678	
Wolf et al 1996	Interest in PSA screening – 5-point response	Post-intervention	103	3.8	102	3.0	<0.001	
Behavior – *Behavioral outcomes*								
Boulware et al 2018^ *No statistically significant difference in LDKT*	Initiation of recipient medical evaluation for live donor kidney transplant – no donor identified	Baseline	30	0%	31	3%	NA	PREPARED PLUS (n=31): 7%
		6 months	22	0%	26	4%	NA	PREPARED PLUS (n=26): 8%
	Completion of recipient medical evaluation for live donor kidney transplant – no donor identified	Baseline	30	3%	31	0%	NA	PREPARED PLUS (n=31): 7%
		6 months	22	0%	26	4%	NA	PREPARED PLUS (n=26): 0%
	Initiation of recipient medical evaluation for live donor kidney transplant – donor identified	Baseline	30	13%	31	19%	NA	PREPARED PLUS (n=31): 13%
		6 months	22	9%	26	19%	NA	PREPARED PLUS (n=26): 12%

behaviors across study groups (p=0.66) or timepoints.	Completion of recipient medical evaluation for live donor kidney transplant – donor identified	Baseline	30	10%	31	7%	NA	PREPARED PLUS (n=31): 3%
		6 months	22	18%	26	15%	NA	PREPARED PLUS (n=26): 15%
Ibrahim et al 2017	Received recommendation for surgery	6-months	168	20.2	168	15.5	0.25	Intention-to-treat analysis. Per-protocol: PtDA n=150 and control n=154
	Receipt of surgery	12-months	168	14.9%	168	7.7%	0.04	
Jimenez et al 2017	Completed intake for early intervention	6-months	31	65%	33	64%	0.80	
	Completed evaluation for early intervention	6-months	31	55%	33	52%	0.68	
Kuppermann et al 2014	Invasive diagnostic test use: amniocentesis	Post-intervention	357	3.9%	353	8.2%	0.02	
	Invasive diag. test use: chorionic villus sampling	Post-intervention	357	2.4%	353	4.1%	0.22	
	Invasive diag. test use: any	Post-intervention	357	5.9%	353	12.3%	0.005	
	Testing strategy: none	Post-intervention	357	25.6%	353	20.4%	0.005	
	Testing strategy: screening test only	Post-intervention	357	68.5%	353	67.3%	0.02	
	Testing strategy: invasive without screening	Post-intervention	357	3.0%	353	4.6%	0.37	
	Testing strategy: screening followed by invasive	Post-intervention	357	2.9%	353	7.7%	Ref	
Vina et al 2016	Receipt of referral to orthopedic surgery	12-months	238	32%	252	36%	0.277	
Williams et al 2013	Screening behavior outcomes	2 months	185	NA	175	NA	NA	Overall increase in % screened from 2-months to 13-months (all p < 0.001)
	No intervention effect (p > 0.30)	13 months	NA	NA	NA	NA	NA	
Behavior – *Adherence to chosen option*								
Lepore et al 2012	Congruence between intention and actual behavior	1-year follow up	244	55.3%	246	58.1%	> 0.05	Medical claims scanned so full sample size accessed
		2-year follow up	244	59.0%	246	59.3%	> 0.05	
Schroy et al 2011	Test concordance - % who ordered preferred test	Post-test	212	NA	223	NA	NA	Control is YDR intervention group
Health outcomes – *Anxiety*								
Lepore et al 2012	7-item subscale of Hospital Anxiety and Depression Scale (range 0-21); higher = more anxiety	Pre-test	244	2.05	246	1.95	> 0.05	
		Post-test	215	2.02	216	2.16	> 0.05	
Smith et al 2010^	State Trait Anxiety Inventory (6-item; range 20-80)	Post-intervention	357	28.2	173	28.4	0.80	Short form; higher = more anxiety
	Worry about developing bowel cancer: (4-item; dichotomized: 'none' or 'a bit' vs 'quite' or 'very')	Baseline	196	91.0~	188	92%	>0.05	DA+questions; DA+ DVD (n=188): 94.0
		Post-intervention	357	94.0	173	92.0	0.78	% responding 'none' or 'a bit'
Trevena et al 2008	State Trait Anxiety Inventory (6-item; range 20-80)	Post-intervention	134	9.33	137	9.58	0.59	Short form; higher = more anxiety
Health outcomes – *Regret*								
Kuppermann et al 2009	3 questions, % responded definitely-mostly true	26-30 wks gestation	202	9.6%	218	12.8%	0.28	5-point scale; dichotomize
Kuppermann et al 2014	Decision Regret Scale (5-item)	Post-intervention	357	8.29	353	6.83	0.12	
Health outcomes – *Confidence*								
Smith et al 2010	Decision self-efficacy scale (3-item; adapted)	Post-intervention	357	4.7	173	4.6	0.91	

Table only includes studies which included >50% disadvantaged group. NA=data not available in published studies; requested data from authors. P-values refer to between-group differences at each time point unless otherwise specified.

^Study had a second intervention group; results reported in 'notes' column.

[#]Knowledge/attitudes measured with 14 items (6-point scale). PtDA: greater understanding of child developmental delay, p=0.02; more positive attitudes towards early intervention, p=0.03

Table 6. *Outcomes of the subgroup analyses to test moderating effects of disadvantage*

Authors and year	Overall finding and subgroup analysis details	Results
Attributes of the choice – *Knowledge*		
Brenner et al 2016	PtDA increased knowledge relative to control. Restricted analysis to **Latino participants only** and assessed the interaction between intervention group and **site** (North Carolina vs. New Mexico)[#]	Similar effects when analysis restricted to Latino participants only *Intervention*: baseline 2.7, follow-up 4.5 *Control*: baseline 2.5, follow-up 2.8, adjusted difference 1.6 (1.2, 1.9), (p<0.001) North Carolina: 2.3 increase vs. New Mexico: 1.5 increase* (p<0.001)
Hoffman et al 2017	PtDA increased knowledge relative to control. Assessed the interaction between intervention group and **health literacy**	No interaction effect
Rising et al 2017	PtDA increased knowledge compared to control. Numbers within PtDA group only reported. Examined the moderating effect of different types of disadvantage within the PtDA group only.	**Race** – white: 11.0% *knowledge* increase vs. non-white: 4.8% increase, (p=0.018). No difference in *knowledge of risk* (p=0.177)
		Income - No difference in *knowledge* (p=0.317) or *knowledge of risk* (p=0.519)
		Insurance - No difference in *knowledge* (p=0.236) or *knowledge of risk* (p=0.834)
		Education - No difference in *knowledge* (p=0.059) or *knowledge of risk* (p=0.2)
		Health literacy - No difference in *knowledge* (p=0.095) or *knowledge of risk* (p=0.626)
		Numeracy - PtDA: typical group 10.6% increase vs. low group 4.7% increase (p=0.025). No significant difference in knowledge of risk (p=0.282)
Trevena et al 2008	PtDA increased knowledge relative to control. Assessed the interaction between intervention group and **education** (categorized as left school <16 years/high school >16 years/tertiary)	*PtDA vs. control*: Left school<16 years: 50% vs. 17.8% High school>16 years: 31.3% vs. 19.4% Tertiary education: 79.4% vs. 32.1%
Volk et al 2008	Compared the effect of intervention across **low and high-literacy sites**	Low-literacy subjects had lower scores than high-literacy, but both groups had significant improvements regardless of PtDA they received. Means not available.
Williams et al 2013	No significant differences between PtDA and control groups. Assessed the interaction between intervention and race (dichotomized African American/whites)	No differences in effect of PtDA between African American (n=330) and whites (n=162)
Attributes of the decision-making process		
Diefenbach et al 2018	PtDA increased decisional support relative to control. Assessed the interactions between intervention and **race (African American/White)**, and intervention and **education (lower/higher)**	**Race -** greater increase in *decisional support* after receiving PtDA for African Americans, B=-0.18, b=-9.65 (p=0.04)
		Education - greater increase in *decisional support* after receiving PtDA for lower educated participants, B=0.21, b-3.87 (p=0.05)
Rising et al 2017	PtDA decreased decisional conflict and increased patient involvement relative to control. Examined the moderating effect of different types of disadvantage within the PtDA group only.	**Race** - No difference in *decisional conflict* (p=0.863) or *involvement in decision* (p=0.316)
		Income - No difference in *decisional conflict* (p=0.366) or *involvement in decision* (p=0.832)
		Insurance - No difference in *decisional conflict* (p=0.167) or *involvement in decision* (p=0.727)
		Education - No difference in *decisional conflict* (p=0.962) or *involvement in decision* (p=0.552)
		Health literacy - No difference in *decisional conflict* (p=0.829) or *involvement in decision* (p=0.812)
		Numeracy - No difference in *decisional conflict* (p=0.454) or *involvement in decision* (p=0.885)
Street et al 1995	No significant differences between PtDA and control groups. Assessed the interactions between intervention and age/education[+] as well as overall comparison between younger, more educated participants and older, less educated participants.	No interaction between intervention and age/education for *patients' perception of involvement*
		No interaction between intervention and age/education for *patients' perceived control over decision*

Volk et al 2008	No overall effects of PtDA and control groups reported. Compared the effects of intervention across **low and high-literacy sites**	**Low-literacy -** *Decisional conflict* (PtDA vs. control): 12.0 v. 21.7 (p=0.04). *Values* 17.4 v. 34.9 (p=0.03), *uncertainty* 5.8 v. 6.8 (p=0.8), *informed* 9.1 v. 18.8 (p=0.9), *social support* 17.8 v. 27.6 (p=0.12). **High-literacy** - no differences
		Low-literacy - a) *illness & treatment education*: PtDA 1.45 v. control 1.69 (p=0.03), b) *assertiveness*: no difference, c) *mindful nonadherence*: no difference **High-literacy -** no differences in *patient involvement in decision-making.*
Williams et al 2013	No significant differences between PtDA and control groups. Assessed the interaction between intervention and race (dichotomized African American/whites)	No differences between African American (n=330) and whites (n=162) in *decisional conflict or satisfaction with decision*
Patient-clinician communication		
Brenner et al 2016	PtDA increased discussion relative to control. Restricted analysis to **Latino participants,** assessed interaction between PtDA group & **site (Nth Carolina vs. New Mexico)**[#]	Similar screening discussion effects when analysis restricted to Latino participants only (no test statistic)
		North Carolina 41.6% screening discussion increase vs. New Mexico 17.3% p=0.015
Street et al 1995	Assessed the interactions between intervention and age/education[+·] as well as overall comparison between younger, more educated participants and older, less educated participants.	No interaction for asking questions.
		No interaction for offering opinions.
		No interaction for producing expressions of concern.
		No interaction for active communication.
		No interaction for use of patient-centered responses.
Trust in physician		
Rising et al 2017	No significant differences between PtDA and control groups. Examined the moderating effect of different types of disadvantage within the PtDA group only.	**Race** - no difference (p=0.062)
		Income - no difference (p=0.371)
		Insurance - no difference (p=0.991)
		Education - no difference (p=0.348)
		Health literacy - low: PtDA = 3.7 trust increase, typical: DA = 1.4 decrease (p=0.011)
		Numeracy - no difference in trust in physician (p=0.090)
Behavior - ***Intentions and preferences***		
Brenner et al 2016	PtDA increased screening intent relative to control. Restricted analysis to **Latino participants only** and assessed the interaction between intervention group and **site** (North Carolina vs. New Mexico)[#]	Similar screening intent effects when analysis restricted to Latino participants PtDA: baseline 71%, follow-up 94%; control: baseline 70%, follow-up 85%, adjusted difference 9.3%; p<0.05
		Similar screening intent effects, North Carolina vs. New Mexico (p=0.642)
Miller et al 2011	PtDA increased ability to form test preference and intent to receive screening relative to control. Assessed the interaction between intervention group and **health literacy** (REALM tool)	*Limited*: PtDA 76% stated screening preference vs. control 51% (p<0.001) *Adequate*: PtDA 93% states screening preference vs. control 60% (p<0.001)
		Limited: PtDA 60% ready to receive screening vs. control 24% (p<0.001) *Adequate*: PtDA 42% ready to receive screening vs. control 15% (p<0.05)
Behavior – ***Actual behavior***		
Brenner et al 2016*	PtDA increased test ordering and screening completion relative to control. Restricted analysis to **Latino participants only** and assessed the interaction between intervention group and disadvantaged groups.	Similar test ordering effects when analysis restricted to Latino participants PtDA 93% vs. control 71%, adjusted difference 23.4% (p<0.001) Observed larger effect of screening completion among Latinos (49%) vs. non-Latinos (black 25%, white 40%), (p=0.17, not significant)
		Observed larger effect of screening completion by insurance status; none=34%, public 54%, private 12% (p=0.29, not significant)
		Similar effects across North Carolina & New Mexico[#] on test ordering (p=0.185). Observed larger effects of PtDA on screening completion at New Mexico 48% vs. North Carolina 29%, (p=0.10, not significant)

		Education - No difference in screening completion (p=0.74)
		Literacy - No difference in screening completion (p=0.82)
		Language - No difference in screening completion (p=0.29)
		Income - No difference in screening completion (p=0.13)
		Employment - No difference in screening completion (p=0.72)
Jimenez et al 2017	No significant differences between PtDA and control groups. Compared effect of intervention across **low and high-health literacy** groups	Completed intervention intake for low health literacy group: PtDA 67% vs. control 40%
		Completed intervention evaluation for low health literacy group: PtDA 58% vs. control 30%
Marteau et al 2010	No significant differences in screening attendance between PtDA and control groups. Assessed the interaction between intervention group and **social deprivation**‡	No interaction. However, attendance decreased with deprivation (p<0.01) Lowest deprivation tertile: 64.3% attended Highest deprivation tertile: 47.5% attended
Miller et al 2011	PtDA increased test ordering and test completion relative to control. Assessed the interaction between intervention group and **health literacy** (REALM tool).	*Limited*: PtDA 34% ordered screening test vs. control 26% (p>0.05) *Adequate*: PtDA 25% ordered screening test vs. control 16% (p>0.05)
		Limited: PtDA 21% completed screening vs. control 16% (p>0.05) *Adequate*: PtDA 17% completed screening vs. control 10% (p>0.05)
Miller et al 2018	PtDA increased test ordering relative to control. Assessed the interaction between intervention group and **income, health literacy and race** (no statistically significant interaction between intervention and subgroups).	*>20k:* PtDA 38% vs. control 15%; *<20k:* PtDA 25% vs. control 15%
		Adequate: PtDA 34% vs. control 15%; *Limited:* PtDA 24% vs. control 16%
		Non-Hispanic white: PtDA 34% vs. control 19% *Not non-Hispanic white:* PtDA 27% vs. control 12%
Rising et al 2017	Overall effect of PtDA on cardiac stress testing not reported. Examined the moderating effect of different types of disadvantage within the PtDA group only.	**Race** - White patients had lower odds of having cardiac stress test; 0.48 (p=0.004)
		Income - Income > $40k group had lower odds of having cardiac stress test; 0.54 (p=0.028)
		Insurance - No difference in testing rates (p=0.249)
		Education - No difference in testing rates (p=0.613)
		Health literacy - No difference in testing rates (p=0.054)
		Numeracy - No difference in testing rates (p=0.927)
Ruffin et al 2007	PtDA increased screening rates relative to control. Assessed interaction between intervention group and **race**	No difference in impact of intervention on CRC screening rates, OR=1.1, 95% CI: 0.90-1.10
Williams et al 2013	No significant difference between PtDA and control groups. Assessed interaction between intervention group and **race**	No differences between African American (n=330) and whites (n=162) in prostate cancer screening

*Implementation outcomes reported in separate paper (screening completion; Reuland et al, 2017)

North Carolina represents new and rapid Latino immigration, whereas New Mexico represents regions with established, multi-generational Latino populations.

‡ Measured using index of multiple deprivation

+ Inversely correlated; Composite variable: <65 years attended college (n=28) vs. >65 years ≤ high school education (n=32)

DISCUSSION

As part of the IPDAS 2.0 process, we sought to update a review of health literacy and PtDAs published in 2013.[2] Specifically we examined the extent to which PtDAs are designed to meet the needs of low health literacy and disadvantaged populations and their impact on decision-making and health outcomes. The included studies comprised almost 10,000 patients/community members and indicated that of the 213 PtDAs developed and included as part of the Cochrane review and updates since 2006, only 11% of PtDAs (n=24) were developed for, or evaluated with patients and populations who are disadvantaged with respect to health literacy, education, income, race/ethnicity, neighborhood or health insurance. This represents an increase from 5% reported in 2013 (although note that slightly different criteria were used for this search),[2] yet is still remarkably low given the number of patients in the health system who are disadvantaged and likely to require health decision support. Of the PtDAs that were developed and evaluated only one third (n=8) adhered to the IPDAS instrument and IPDAS minimum standards by reporting *any* readability statistic. Only 7 PtDAs reported that they met the Grade 8 reading level criteria (the reading level recommended for an average population sample), a requirement of the original IPDAS quality criteria checklist. However, among the subset that were available to be assessed independently, none when independently reviewed met the criteria. This is partly due to the methods we used in our independent review process for preparing and analyzing the PtDA text. In particular, the readability calculator we used is considered superior to other readability calculators (as recommended by health literacy experts) but has not been widely used by PtDA developers. In our assessment of understandability and actionability using the PEMAT which requires the rater to make a more subjective assessment of materials and coded by multiple coders, we found that the PtDAs scored well on the understandability domain but poorly on the actionability dimension of the scale. The poor rating on actionability of health materials is a common finding as they often fail to pay attention to the clarity of instructions and actions for people/patients to follow,[6,43] it may also reflect the fact that some PtDAs may not require clear actions or next steps. The discrepancy between more simple but objective measures of readability versus more sophisticated but subjective ratings of comprehension are not unexpected. However, efforts to

overcome subjectivity in PEMAT are addressed by the use of two or more raters. This measure also correlates with readability scores and patient reported comprehension and actionability rating and has the advantage of including an audiovisual dimension.[14] In total our results suggest there is room for significant improvement in the design and reporting of decision aids for lower literacy populations.

In addition to the assessment of readability, developers of PtDAs included in our review used a range of strategies to tailor their PtDAs to disadvantaged patients and populations. The main strategies included working with patients or consumers in various ways (e.g., pilot or user testing and focus groups or interviews), the involvement of adult education, communication, or literacy experts, and the use of PtDA formats other than text (e.g., video or multimedia programs). Note few studies reported including patients as partners. It is important as research goes forward that patients are included as equal partners in research and that pilot testing (and other forms of tailoring / gathering feedback) is conducted and clearly reported with patients / consumers from the target disadvantaged groups. This was often not made clear in the included studies.

Our review of the impact of the PtDAs showed reasons to be cautiously optimistic. Outcomes pooled in our meta-analysis suggested many improvements as a result of viewing a PtDA. These improvements included increased knowledge and patient-clinician communication, as well as reductions in decisional conflict and proportion undecided. Notably, studies that used the low-literacy version of the Decisional Conflict Scale reported greater decreases in decisional conflict. However, this result should be interpreted with caution given the high heterogeneity comparative to the summary estimate of studies using the original scale. Despite high heterogeneity for many pooled outcomes, the direction of effects was consistent across included studies. In the narrative synthesis, we found three of three studies reported increased accuracy in risk perceptions and two reported greater congruence between attitudes and choice and more informed choices (adequate knowledge and congruent attitudes and choice). There were no effects of PtDAs evident on decision satisfaction, adherence to chosen option or health outcomes including anxiety, regret and confidence. Mixed effects were evident for

decision-making process satisfaction, participation in decision, attitudes, preferences/intentions and behavioral outcomes. Outcomes relating to health, wellbeing and the healthcare system were seldom measured in the included studies (i.e., health status and quality of life, depression, emotional distress, costs, cost-effectiveness, consultation length, litigation rates). Overall, our narrative synthesis of outcomes in studies that conducted separate analyses suggested some PtDAs were more beneficial among disadvantaged groups (e.g., by race, ethnicity, education, health literacy, lack of insurance). However, effects for outcomes across types of disadvantage were inconsistent across the different contexts of included studies. Encouragingly, many studies included in the narrative synthesis had similar effects for outcomes analyzed across disadvantaged and non-disadvantaged groups.

Strengths and limitations of this review

To assess readability of the PtDAs, we followed guidelines from Health Literacy Connections.[44] This included preparing the text as detailed in the methods and calculating the estimated reading grade level using the average of the Gunning Fog index and the SMOG index. Several included studies reported designing the PtDA at reduced reading grade level and calculating readability statistics of PtDAs in the development process. For many of these PtDAs, there are notable discrepancies between the readability statistics reported in the studies and those we calculated in table 6. This could be explained by factors including variations in the preparation of the text (e.g., removing headings, periods that do not indicate end of sentences, sentence fragments, bullet points not in full text), readability formula used (e.g., Flesch Kinkaid Grade Level has been reported to produce reading grade levels 2-3 lower),[45] method of conducting the analysis (e.g., using an online tool, Microsoft word function or calculating manually using the formula). Due to the subjective nature of the PEMAT, the PtDAs were dual coded by JS and OM, with any discrepancies resolved with discussion with KM. The actionability domain of the PEMAT is limited in this context, as there may not always be an explicit action to take. Furthermore, for two studies we were only able to access a component of the intervention, which may limit the accuracy of the actionability scores.

We built on and strengthened our previous review by including 25 RCTs and including a systematic review of decision related outcomes as well as an assessment of the attention paid to health literate design. Given the larger number of studies, we were able to conduct a meta-analysis for common and consistently measured outcomes. Despite high levels of heterogeneity, we did not assess the source given that we anticipated high levels due to the nature of included studies and variable contexts and outcomes. However, results should be interpreted in light of this limitation. We also used the new version of the Cochrane Risk of Bias tool and conducted screening and risk of bias assessments with two independent reviewers. Data was extracted independently by two reviewers. Where necessary to attain unreported data, we made efforts to contact authors, included values reported in 2014 and 2017 Cochrane reviews, or used the Cochrane calculator where appropriate.

Alternative formats for decision support, such as Option Grids,[46] have also been developed which generally have less textual information compared to typical decision aids and are designed to be used jointly with a provider within an encounter. We did not consider the studies that included older adults (that did not report any other measures of disadvantage) despite the fact that this population may comprise a greater proportion of people with low health literacy skills compared to the general population.

Recommendations to IPDAS

On the basis of our review we make the following recommendations for consideration in future IPDAS criteria related to health literacy:

- all PtDAs report readability scores and in addition use and adhere to PEMAT thresholds for comprehension and actionability of written and audiovisual documents.
- readability scores are assessed using utility.com and suggest where possible PtDA developers develop tools at reading grade level 5/6 consistent with a Universal Precautions approach and the AHRQ Health Literacy Universal Precautions Toolkit.[47]
- patient partners are included in all studies with low literacy populations
- studies that target disadvantaged populations must report how PtDAs have been piloted with their target group to ensure needs and preferences are addressed.

- In line with good principles of health communication we recommend the use of audiovisual, audio as well as written health information and the provision of translated materials.

Directions for future research

There is a need for greater consistency in the measurement of outcomes, particularly relating to attributes of the decision and decisional conflict (e.g., the low literacy DCS is not always used). Greater consistency in the use and reporting of sub-analyses is also needed to ensure PtDAs are suitable and beneficial for disadvantaged groups, and outcomes can be synthesized in future reviews. A few studies (mostly more recent) examined the impact of the PtDA on patient-clinician communication.[18,19,37,38] More research in this vein would be valuable to better understand the impact of PtDAs on the clinical encounter among disadvantaged groups. A few studies examined longer term outcomes, but this was rare – further work to understand if knowledge improvements and decisional conflict outcomes are maintained would also be valuable. Last, little research has addressed how disadvantaged populations best access PtDAs. This is vitally important if we truly wish to improve equity with respect to accessing decision support.

Conflicts of interest

Marie-Anne Durand has contributed to the development of Option Grid TM patient decision-aids, which are licensed to EBSCO Health. She receives consulting income from EBSCO Health, and may receive royalties in the future.

No other authors have conflicts of interest to report.

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APPENDIX

Attitudes towards and acceptability of PtDAs

Volk et al. tested the moderating effects of literacy level on the acceptability of two prostate cancer screening PtDAs.[27] Compared to those with high literacy, low literacy participants were more likely to rate the entertainment aid as having too much information, but also less likely to rate it as too long and were more likely to ask questions overall. Low literacy participants rated the clarity of the audio-booklet higher than the entertainment aid but were more engaged with elements of the entertainment aid. Kuppermann et al. tested the moderating effects of education on intervention satisfaction. They found that all women were more likely to say they would recommend the PtDA to a friend, but the increase was more pronounced among women with a bachelor's or graduate degree.[16]

Table 1. *PEMAT scoring*

Item #	PEMAT items	'Agree' responses n (%)
	Understandability	
	Content	
1	Makes its purpose completely evident (P and A/V)	12 (100)
2	Does not include information or content that distracts from its purpose (P)	7 (100)
	Word Choice and style	
3	Common everyday language (P and A/V)	12 (100)
4	Medical terms are defined and used only to familiarise readers (P and A/V)	12 (100)
5	Active voice (P and A/V)	12 (100)
	Use of numbers	
6	Numbers are clear and easy to understand (P)	7 (100)
7	Does not expect the user to perform calculations (P)	7 (100)
	Organization	
8	Chunks information into short sections (P and A/V)	10 (83)
9	Sections have informative headings (P and A/V)	8 (67)
10	Presents information in a logical sequence (P and A/V)	12 (100)
11	Provides a summary (P and A/V)	
	Layout and design	
12	Provides visual cues to draw attention to key points (P and A/V)	10 (83)
13	Text on the screen is easy to read (A/V)*	4 (100)
14	The material allows the user to hear the words clearly (A/V)	5 (100)
	Use of visual aids	
15	Uses visual aids whenever possible (P)	3 (43)
16	Visual aids reinforce rather than distract (P)	7 (100)
17	Visual aids have clear titles and captions (P)	6 (86)
18	The material uses illustrations and photographs that are clear and uncluttered (P and A/V)*	11 (100)
19	Tables are simple with short, clear row and column headings (P and A/V)	4 (100)^
	Actionability	
20	Clearly identifies at least one action for the user to take (P and A/V)	12 (100)
21	Addresses the user directly when describing actions (P and A/V)	11 (92)
22	Breaks down actions into manageable, explicit steps (P and A/V)	8 (67)
23	Provides a tangible tool whenever it could help the user take action (P and A/V)	7 (100)
24	Provides simple instructions or examples of how to perform calculations (P)#	-
25	Explains how to use the charts, diagrams, graphs, or tables to take actions (P and A/V)~	3 (33)
26	Uses visual aids whenever possible to help take action (P)	1 (14)

*N/A for 1 PtDA, ^N/A for 8 PtDAs, #N/A for all PtDAs, ~N/A for 3 PtDAs

Table 2. *Risk of bias summary for each included study not included in 2014/17 Cochrane review*

Author and year	Randomization	Deviations from the intended interventions	Missing outcome data	Outcome measurement	Reporting results	Overall risk of bias
Boulware et al 2018	+	?	?	+	?	?
Brenner et al 2016	+	-	+	?	+	?
Diefenbach et al 2018	+	?	?	?	?	?
Hoffman et al 2017	+	?	+	?	+	+
Ibrahim et al 2017	+	?	+	+	+	+
Jimenez et al 2017	?	?	+	?	?	?
Miller et al 2018	+	?	+	+	?	+
Rising et al 2017	+	?	+	+	+	+
Vina et al 2016	+	+	+	+	?	+

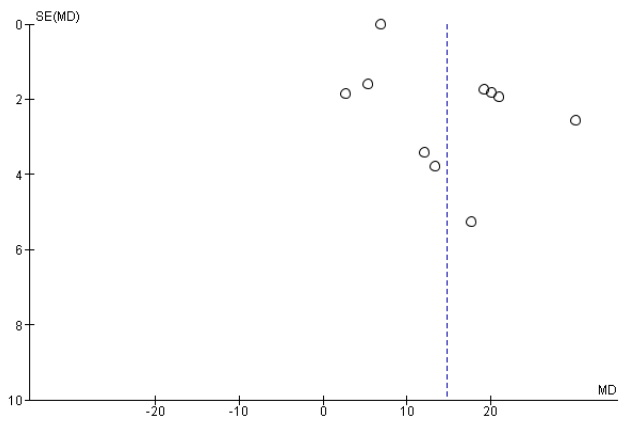
+ low risk of bias, ? some concerns, - high risk of bias

Table 3. *Risk of bias summary for each included study in 2014 and 2017 Cochrane review*

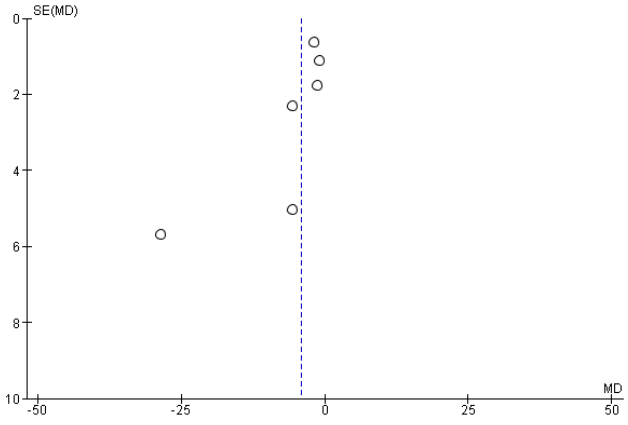
Author and year	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Jibaja-Weiss et al 2011*	+	?	?	+	?	?	+
Kuppermann et al 2009^	?	+	+	+	?	?	+
Kuppermann et al 2014*	+	+	+	+	+	+	+
Lepore et al 2012*	+	?	?	+	+	+	+
Marteau et al 2010*	+	+	+	+	+	+	+
Miller et al 2011*	+	?	+	+	+	+	?
Myers et al 2005^	?	?	+	?	?	?	+
Ruffin et al 2007*	+	?	+	+	+	?	+
Schroy et al 2011*	?	?	?	+	+	?	+
Smith et al 2010*	+	+	+	+	+	+	+
Street et al 1995^	?	?	?	?	+	?	+
Taylor et al 2006*	?	?	?	?	+	?	?
Trevena et al 2008*	+	+	?	+	?	+	+
Volk et al 2008^	+	?	?	?	?	?	+
Williams et al 2013*	?	?	?	?	+	?	+
Wolf et al 1996*	?	?	?	+	+	?	+

+ low risk of bias, ? unclear risk of bias, - high risk of bias
*Risk of bias assessed as part of 2017 version of Cochrane Review
^Risk of bias assessed as part of 2014 version of Cochrane Review

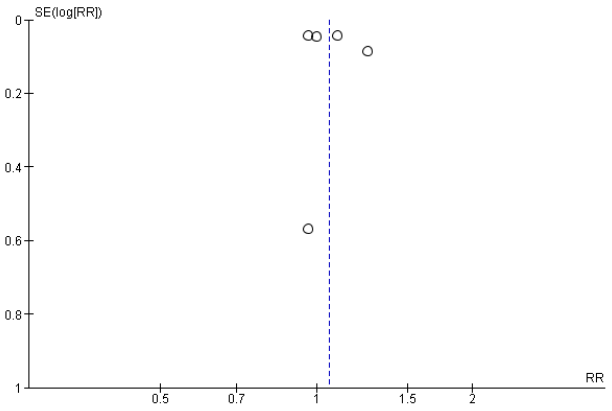
Figure 1. Funnel plots for each outcome included in meta-analysis.



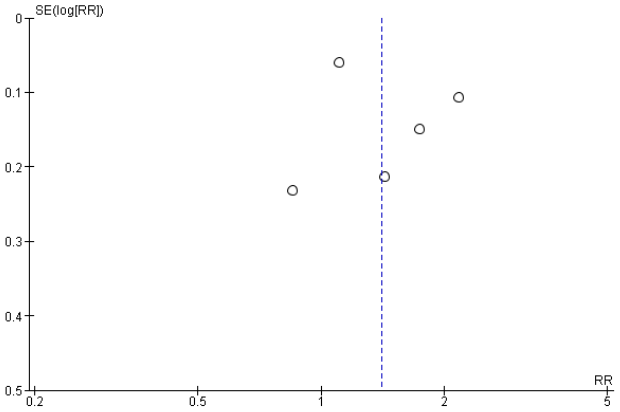
Knowledge



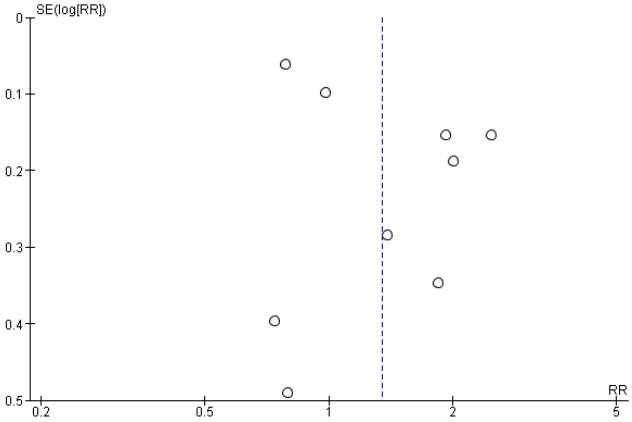
Decisional conflict



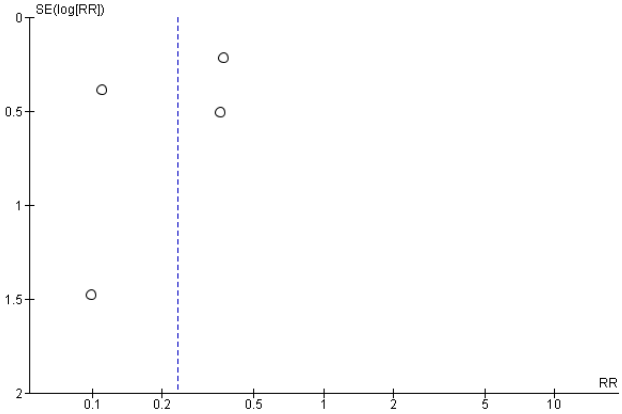
Intent to be screened



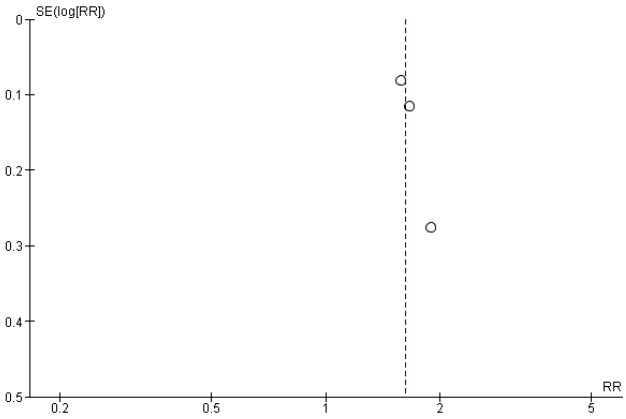
Screening test ordered



Screening test completed



Proportion undecided



Patient-clinician communication