User involvement in the development of patient decision aids:

A systematic review

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Abstract (350/350 words)

Background: Multiple guidelines recommend involving patients and stakeholders in developing patient decision aids; however, best practices have yet to be identified. User-centered design is a well-established approach for engaging users in developing tools. We aimed to compile reports of patient decision aid development, using a user-centered design framework to synthesize evidence of existing practices and identify potential opportunities for improvement.

Methods: We conducted searches in MEDLINE, EMBASE, PubMed, Web of Science, the Cochrane Library, the ACM library, IEEE Xplore and Google Scholar. We included articles describing (1) at least one development step of a patient decision aid, (2) at least one development step of user- or human-centered design of another patient-centered tool, and/or (3) evaluation of included decision aids and other patient-centered tools. Two analysts independently screened for inclusion, assessed study quality, and extracted data.

Results: We included 623 articles describing 390 projects: 325 patient decision aid projects and 65 user-centered design projects. Fifty percent of patient decision aid projects reported involving users in at least one development step for understanding users, 35% in at least one development step for developing/refining the prototype and 84% in at least one development step for directly or indirectly observing prospective users' interaction with the prototype. User-centered design projects reported 91%, 49% and 92%, respectively. Seventy-four percent of patient decision aid projects reported iterative development processes with median 3 development cycles (interquartile range 2-4); 92% of user-centered design projects reported iterativity, with median 3 development cycles (interquartile range 2-3). Sixty-six percent of patient decision aid projects and 89% of user-centered design projects reported preliminary evaluations such as usability testing or feasibility testing.

Conclusions: We identified 3 key opportunities for improving the user-centeredness of patient decision aid development: involving users earlier to understand their needs, goals, strengths, limitations, context and intuitive processes; asking about and observing users' interactions with developing versions of the decision aid; and reporting changes between iterative cycles. Additionally, developers of patient decision aids and other patient-centered tools may wish to more often involve patients, clinicians and other users in co-design of prototypes and in formal advisory or partnership roles.

Main Text

Introduction

Patient decision aids are key tools for supporting shared decision making, a practice described as “the pinnacle of patient-centered care” [1] and advocated as a solution to the “silent misdiagnosis” of patient preferences [2]. These tools make health decisions explicit, provide balanced information on benefits and harms of options, and help people clarify what matters to them in their own context and circumstances.

Patient decision aids are intended to complement counselling from a healthcare professional in order to help people make evidence-informed, values-congruent health decisions. Their growing number [3] and legislative power [4] are precursors of their probable ever-increasing development. Yet little is known about how to best engage users of patient decision aids in their development. There is interest in and enthusiasm for participatory approaches such as user-centered design, but little evidence to guide practice.

User-centered design is a well-established approach that has been used to develop products, services, systems [5–9], including patient-centered tools [10–13]. Examples of tools developed using this approach range from programs inciting good health habits like smoking and alcohol cessation [14,15] to Internet-based support systems for self-management of chronic diseases [16–18] and computer interfaces adapted for people with severe motor paralysis [19,20].

User-centered design involves an iterative method of involving prospective users in repeated cycles of development. Our framework, as shown in Figure 1, synthesizes seminal literature [5,7,9,21–23] and defines three elements in each iterative cycle: (1) understanding users, their needs and their environment, (2) developing/refining the prototype, and (3) observing the users interacting with the prototype. Each of these elements can include multiple methodological steps and the process as a whole may be reported across multiple papers.

Figure 1. User-centered design framework and associated development steps.

In this systematic review, we aimed to synthesize the published development processes of patient decision aids and to situate these in the context of a framework of user-centered design [24]. Herein, we describe the development processes of patient decision aids and, for context, also describe the development processes of other patient-centered tools that explicitly named user-centered or human-centered design as their guiding model.

Methods

The overall study design included synthesizing published articles describing the development process of a patient decision aid and articles describing the user-centered development of a patient-centered tool. We report this review according to PRISMA guidelines. (See PRISMA checklist in Appendix 4.)

Protocol and registration

We previously registered this review in PROSPERO (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014013241) and published the protocol describing our systematic review methodology [24].

Eligibility criteria

We identified articles that describe at least one development step and/or any type of evaluation of a patient decision aid intended to support a personal health decision, or that explicitly used

one of the four terms ‘user-centered design’, ‘user-centred design’, ‘human-centered design’ or ‘human-centred design’ to develop a patient-centered health-related tool (e.g., tools for education, social support, or self-management). We excluded articles that applied user-centered design to tools solely intended for clinicians. We also screened additional articles suggested by authors of included articles when we contacted them to validate the data we extracted from their article(s). No language or date restrictions were applied for any searches.

Information sources and search

Our search strategy expanded slightly from our initial plans. Between April 30, 2014 and May 11, 2014, we conducted initial database searches for articles describing patient decision aid development and evaluation. On September 29, 2014, we searched for articles describing user-centered design projects. We had assumed that any randomized controlled trials of patient decision aids would not need to be identified again, as they would already have been captured in the Cochrane review of patient decision aids available at the time [25]. However, because the Cochrane review included patient decision aids that addressed screening or treatment decisions but not other decisions, we re-screened articles excluded from the 2014 Cochrane review. We then replicated Stacey and colleagues’ search strategy for randomized controlled trials on July 9, 2015, using nearly the same inclusion and exclusion criteria except that we sought articles describing other types of decisions. Our originally-planned search strategy did not include evaluation of user-centered design projects. This created an imbalance in which we captured more publications describing the evaluation of patient decision aids. To rectify this, on June 20, 2017, we used Google Scholar to search for articles describing the evaluation of the tools developed in user-centered design projects by searching for articles that cited the included papers for user-centered design projects. All search strategies were developed by an information specialist (WW) and peer-reviewed by an independent information specialist (ME, MF, see Acknowledgments). Appendix 1 provides full details of all search strategies.

Study selection

We conducted the screening process in accordance with standard methods for systematic reviews [26]. After a training period where all screeners practiced on randomly-selected subsets of search results, pairs of independent screeners reviewed each title and abstract for inclusion or exclusion. Once all of the articles had been screened by title and abstract, we obtained the full text of retained articles for screening by two independent reviewers, who divided them into three categories: include and retain for data extraction, retain for a screen of the references but do not include for data extraction, and exclude. At all stages of screening, if the two independent screeners disagreed and were unable to come to agreement in discussion, a third person adjudicated to determine if the article should be included for further screening.

Data extraction

Based on our conceptual framework of user-centered design and with reviews among authors of this paper and 15 additional experts in the field, we created and iteratively revised our extraction form with 4 cycles of testing (See Appendix 2: Data extraction form). Throughout the data

extraction process, when a field allowed the option to indicate 'Other', we created new categories from this open text whenever there were at least 10 occurrences of a response.

Trained pairs of data analysts extracted data from each included article using this standardized form [24]. Lack of agreement was resolved through discussion with the team until consensus was reached.

We extracted key factors grounded in our conceptual framework of user-centered design. Data presented in this paper include: (1) what steps were conducted as part of development, (2) whether patients and other stakeholders were involved in the development and, if yes, (3) who they were (e.g., people who had previously faced the issue, people who might potentially face this issue, patients who were actually facing this issue, caregivers, clinicians who were not part of the research team), (4) how they were identified and recruited, and (5) how many were recruited; (6) whether there were iterative cycles of consultation, and, if yes, (7) how many cycles, (8) at what point(s) in the process were they involved, and (9) what their involvement consisted of (i.e., were they observed interacting with the decision aid in a naturalistic fashion or were they asked to speculate on how they might use it); and (10) types of feedback sought (i.e., comprehensiveness or appropriateness of content, format, other), and (11) how their feedback was incorporated into the design. We also extracted secondary data about whether or not each article cited a relevant guideline, theory or framework. In addition, from articles describing the evaluation of a tool, we extracted information about the type of evaluation, including whether or not outcomes such as feasibility, acceptability, and usability were reported.

For each article, two trained reviewers extracted and reconciled all data. If consensus could not be reached, a third trained reviewer adjudicated the disagreement, bringing concerns or questions to group meetings. Major questions were referred for discussion with the project's steering committee.

We were unable to capture data for two planned elements in our protocol due to low reporting of these elements. Specifically, we were unable to extract information about users' needs and personal contexts (item numbered iv in our protocol) and about measures of feasibility, acceptability, and usability.

Data quality assessment

The quality of each article was appraised by two independent reviewers guided by a scoring system developed to score and appraise studies in a mixed method review [27]. We adapted and modified this tool by adding specific criteria for intervention development studies, a study type not previously represented in the original system. Because of the exploratory, descriptive nature of our study and because there were no established thresholds in this area, we did not set thresholds for quality.

Data validation

Because of the heterogeneity of reporting of development processes, we contacted all authors to verify our extraction of key variables, including the merging of articles into projects; and to collect any data that we were unable to extract from publications. We also invited authors to provide additional articles that might further inform our understanding of their development process. We began by sending each corresponding author an email, following as needed with up to three reminder emails spaced one to two weeks apart. For nonresponding corresponding authors of randomized controlled trials, we also followed up with phone calls. When authors provided additional information or corrected extracted data, we inserted the authors' statements into our data matrix. When authors submitted new articles, we extracted new data from those articles into our data matrix. In such cases, once again, two independent analysts extracted data, reconciled their extractions through discussion until consensus was reached, and discussed points and questions at regular team meetings.

After updates were made based on authors' feedback, an independent analyst who had not been involved in data extraction screened all changes and classified them into one of four categories: (1) addition of previously missing data, (2) precision of data we had extracted more vaguely (e.g., we extracted "at least 3 iterative cycles" and the author informed us that they conducted 5 cycles), (3) correction of incorrect data, or (4) differences that did not materially affect the extracted data (e.g., we had extracted a development step as "not reported", which would be analyzed as lack of information that the step was done, and the authors confirmed that it was not done, changing our data entry to "not done").

If, after data extraction and validation, we did not have any indication that a development step had been conducted, we analyzed the step as not done. We applied this same approach to all data extracted. For example, if a step had been reported as being done but we had no data that users had been involved in it, we recorded that users had not been involved in the step, even if the combination was unusual; for example, if authors reported conducting a pilot test but did not report any participants being involved in the pilot test.

Combining papers into projects

For some projects, data was distributed across multiple papers. Prior to data analysis, we linked all articles describing different aspects of the same projects to develop and/or evaluate a given patient decision aid or other patient-centered tool. We conducted linkage by first grouping papers by clinical context, authors, and, when available, name of the tool. We then manually linked papers and verified our linkages when we contacted authors. Our unit of analysis is therefore each project of developing one patient decision aid or other patient-centered tool. Projects may have multiple papers.

Synthesis of results

To understand our data sets describing the development of patient decision aids (hereafter referred to as "patient decision aid projects") and the application of user-centered design to

develop other patient-centered tools (hereafter referred to as “user-centered design projects”) we first assessed the frequencies of their basic characteristics such as clinical context and timing of each tool’s intended use.

We then conducted descriptive analyses, overall and by user-centered design element, with which patient decision aid projects and user-centered design projects reported conducting development steps, involving users in those steps, and the number of users involved and other aspects of development processes such as iteration. We elected not to conduct formal hypothesis testing between patient decision aid projects and user-centered design projects for three reasons. First, even with adjustment for multiple comparisons, the large number of variables would likely result in spurious findings. Second, the purpose of presenting both groups of results was to offer context from actual practices in user-centered design when situating patient decision aid projects within this framework, not to formally compare approaches. Third, and importantly, user-centered design projects designed and developed different kinds of tools than patient decision aids. Namely, such projects frequently had to do with physical assistive devices or tools designed for daily use, not tools intended to be used as a complement to a clinical consultation. Therefore, any differences we observed could simply reflect different types of tools.

We conducted these analyses on projects that explicitly reported at least one step of their development process. We performed descriptive analyses in R, version 3.2.3 [28] and SAS, version 9.4.

Results

Tabular details of all results are presented in Tables 3 and 4 below, and in Appendix 3.

Study selection

In total, our searches identified 83,441 unique potentially eligible articles. Of these, we retained 1032 articles for full-text screening to which we added 53 articles identified through author suggestions and 109 articles from our hand search. After full text screening, we retained and extracted data from 623 articles. The search results and reasons for exclusion are presented in the PRISMA Flow Diagram, Figure 2.

Figure 2. PRISMA Flow Diagram

The 623 included articles described 390 distinct projects. Each project represented one unique patient decision aid or other patient-centered tool (tables 1 and 2). Three hundred and twenty-five (83%) projects developed patient decision aids; 65 (17%) projects developed patient-centered tools using user-centered design. Within the patient decision aid group of projects (n=325), 283 of projects associated articles described at least one development step while 42 exclusively described the tool's evaluation. Of the 283 patient decision aid development projects, 2 descriptions explicitly stated the development process was user-centered design. We had predetermined in our protocol that we would group these with patient decision aid projects.

Table 1. Included Patient Decision Aid Projects

Articles in this project	Patient decision aid name (if name exists)	Clinical context
Agre et al., 1994[44]		Colorectal Cancer
Akl et al., 2007[45]		Chronic Obstructive Pulmonary Disorder
AlFaleh et al., 2011[46]		Low Birth Weight Infants (Patent Ductus Arteriosus)
Allen et al., 2009[47]		Prostate Cancer
Allen et al., 2010[48]		Prostate Cancer
Ameling et al., 2012[49]	"Preparing for Kidney Treatment: You Have a Choice"	Advanced Chronic Kidney Disease
Anderson et al., 2011[50]		Ovarian Cancer
Aneja et al., 2012[51]	Skinsafe	Melanoma
Aoki et al., 2007[52]	u-SHARE (ubiquitously-Support and Heal patients with intracranial Aneurysms with Risk communication and Empowerment)	Unruptured Intracranial Aneurysms
Arimori, 2006[53]	Ottawa Personal Decision Guide (<i>translated into Japanese</i>)	Reproductive Health
Arterburn et al., 2011[54]	Weight Loss Surgery: Is It right For You?	Obesity
Au et al., 2011[55]; Lam et al., 2013[56]		Breast Cancer
Auvinen et al., 2004[57]		Prostate Cancer
Baena Canada et al., 2010[58]	Adjuvant! Online	Breast Cancer
Bailey Jr. et al., 2013a[59]; Bailey Jr. et al., 2013b[60]		Fragile X Syndrome
Barnieh et al., 2011[61]		End-Stage Renal Disease
Barry et al., 1995[62]; Barry et al., 1997[63]; Piercy et al.,	The Shared Decision Making Program (SDP)	Benign Prostatic Hyperplasia

1999[64]; Rovner et al., 2004[65]; Holmes-Rovner et al., 2006[66]; Wills et al., 2006[67]; Pylar et al., 2007[68]		
Bass et al., 2013[69]		Colorectal Cancer
Bastian et al., 2002[70]; McBride et al., 2002[71]		Reproductive Health; Breast Cancer
Beach et al., 1976[72]		Reproductive Health
Beamond et al., 2009[73]		Interphalangeal Joint Arthritis
Becker et al., 2009[74]		Reproductive Health
Bekker et al., 1999[75]; Bekker et al., 2004[76]		Reproductive Health; Down Syndrome
Berman et al., 2011[77]		Abdominal Aortic Aneurysms
Bernstein et al., 1998[78]	Treatment Choices for Ischaemic Heart Disease: A Shared-Decision Making Program Videotape	Cardiovascular Health
Berry et al., 2010[79]; Berry et al., 2013[80]	The Personal Patient-Profile Prostate (P3P)	Prostate Cancer
Bieber et al., 2004[81]		Fibromyalgia
Björklund et al., 2012[82]; Öhman et al., 2012[83]		Reproductive Health
Breslin et al., 2008[84]; Mullan et al., 2009[85]	Diabetes Medication Choice	Diabetes
Brink et al., 2000[86]; Fagerlin et al., 2004[87]; Taylor et al., 2010[88]	Prostate Cancer: Your Decision Notebook	Prostate Cancer
Brohan et al., 2014a[89]; Brohan et al., 2014b[90]	CORAL or COnceal or ReveAL	Mental Illness
Brundage et al., 2000[91]; Brundage et al., 2001[92]		Lung Cancer
Brunette et al., 2011[93]		Smoking
Caldon et al., 2011[94]; Jones, 2012[95]; Sivell et al.,	BresDex	Breast Cancer

2012a[96]; Sivell et al., 2012b[97]		
Carrère et al., 2000[98]		Breast Cancer
Chewning et al., 1999[99]	Aid For Contraceptive Decision-making (ACD) Program	Reproductive Health
Chiew et al., 2008[100]		Breast Cancer
Chiou & Chung, 2011[101]		End-Stage Renal Disease
Clancy et al., 1988[102]		Vaccine-Preventable Disease
Consoli et al., 1995[103]	ISIS	Cardiovascular Health
Costanza et al., 2011[104]		Prostate Cancer
Cox et al., 2012[105]		Prolonged Mechanical Ventilation
Coylewright et al., 2012[106]	PCI Choice	Cardiovascular Health
Cranney et al., 2002[107]		Osteoporosis
Culver et al., 2011[108]		Breast Cancer; Ovarian Cancer
Cupertino et al., 2010[109]	You Can Choose	Smoking
Dales et al., 1999[110]; Wilson et al., 2005[111]		Advanced Care Planning; Chronic Obstructive Pulmonary Disorder
D'Alimonte et al., 2012[112]		Breast Cancer
Davis et al., 1998[113]		Vaccine-Preventable Disease
Deschamps et al., 2004[114]	Making Choices: Hormones After Menopause	Reproductive Health
Dillard et al., 2010[115]		Colorectal Cancer
Dobs et al., 1994[116]		Cardiovascular Health
Dodin et al., 2001[117]		Reproductive Health
Dolan & Frisina, 2002[118]		Colorectal Cancer
Dolan et al., 2013[119]		Knee Osteoarthritis
Dowding et al., 2004[120];		Benign Prostatic Hyperplasia;

Thomson et al., 2006[121]		Cardiovascular Health
Drake et al., 1999[122]; Hunter et al., 2005[123]		Reproductive Health
Drake et al., 2010[124]	Road Map	Prostate Cancer
Du et al., 2008[125]	Cancer Clinical Trials: An Introduction for Patients and their Families	Lung Cancer
Dunn et al., 1998[126]		Vaccine-Preventable Disease
Durand, 2009[127]; Durand et al., 2010[128]; Durand et al., 2012[129]	amnioDex	Reproductive Health
Eden et al., 2009[130]; Eden et al., 2014[131]		Reproductive Health
Elit et al., 1996[132]	The Decision Board (DB)	Ovarian Cancer
El-Jawahri et al., 2010[133]; Volandes et al., 2012[134]; Volandes et al., 2013[135]		Advance Care Planning; Cancer
Emmett et al., 2007[136]; Montgomery et al., 2007[137]; Frost et al., 2009[138]; Hollinghurst et al., 2010[139]		Reproductive Health
Evans et al., 2007[140]; Evans et al., 2010[141]; Joseph-Williams et al., 2010[142]	Prosdex	Prostate Cancer
Fagerlin et al., 2010[143]; Fagerlin et al., 2011[144]; Banegas et al., 2013[145]; Korfage et al., 2013[146]	Guide to Decide	Breast Cancer
Farnworth et al., 2008[147]		Reproductive Health
Feldman-Stewart et al., 2000[148]; Feldman-Stewart et al., 2001a[149]; Feldman- Stewart et al., 2001b[150]; Feldman-Stewart et al., 2003[151]; Feldman-Stewart et al., 2004[152]; Feldman-		Prostate Cancer

Stewart et al., 2006a[153]; Feldman-Stewart et al., 2006b[154]; Feldman-Stewart et al., 2012[155]		
Fetters et al., 2004[152]; Ruffin et al., 2007[156]	Colorectal Web	Colorectal Cancer
Fiks et al., 2013[157]		Vaccine-Preventable Disease
Fiset et al., 2000[158]	"Making Choices: Treatment of Stage IV Non-Small Cell Lung Cancer"	Lung Cancer
Fleisher et al., 2008[159]; Meropol et al., 2013[160]	CONNECT ^a	Cancer
Flood et al., 1996[161]; Partin et al., 2004[162]; Partin et al., 2006[163]	The PSA Decision: What YOU Need to Know	Prostate Cancer
Flood et al., 1996[161]; Partin et al., 2004[162]; Partin et al., 2006[163]	The PSA Decision: Is it Right for ME?	Prostate Cancer
Fortin et al., 2001[164]; Bond et al., 2002[165]; Col et al., 2007[166]		Reproductive Health
Fraenkel et al., 2007[167]; de Achaval et al., 2012[168]		Knee Osteoarthritis
Fraenkel et al., 2011[169]; Fraenkel et al., 2012[170]		Cardiovascular Health
Fraenkel et al., 2012[171]; Fraenkel et al., 2015[172]		Rheumatoid Arthritis
Frank et al., 2010[173]		Hospitalized Patients (50% risk of death)
French et al., 2014[174]	My Contraception Tool (MCT)	Reproductive Health
Frosch et al., 2001[175]; Frosch et al., 2003[176]	The PSA Decision: What You Need To Know	Prostate Cancer
Frosch et al., 2008[177]		Prostate Cancer; Colorectal Cancer
Frosch et al., 2008[178]; Bhatnagar et al., 2009[179]		Prostate Cancer

Furber et al., 2014[180]		Cancer
Gallo et al., 2010[181]; Wilkie et al., 2013[182]; Gallo et al., 2014[183]	CHOICES	Reproductive Health; Sickle Cell Disease and Sickle Cell Trait
Garvelink et al., 2013[184]		Reproductive Health; Breast Cancer
Gattellari & Ward, 2003[185]; Gattellari & Ward, 2005[186]	LEAFLET ("Testing for prostate cancer"); VIDEO ("The choice is yours: testing for prostate cancer"); BOOKLET ("Should I have a PSA test for prostate cancer: information for men who want to know more about screening tests for prostate cancer")	Prostate Cancer
Gilbert et al., 2008[187]	Positive Choice	Reproductive Health; Human Immunodeficiency Virus
Graham et al., 2000[188]		Reproductive Health
Grant et al., 2001[189]; Laupacis et al., 2006[190]		Cardiovascular Health
Green & Fost, 1997[191]; Lerman et al., 1997[192]; Green et al., 2001[193]; Schwartz et al., 2001[194]; Green et al., 2004[195]; Green et al., 2005[196];	Breast Cancer Risk and Genetic Testing	Breast Cancer
Green et al., 2009[197]; Hossler et al., 2011[198]; Markham et al., 2015[199]	Making Your Wishes Known: Planning Your Medical Future	Advance Care Planning; Amyotrophic Lateral Sclerosis
Griffith et al., 2005[200]		Reproductive Health
Guillén et al., 2012[201]		Reproductive Health
Gustafson et al., 1994[202]; Gustafson et al., 2001[203]; Wise et al., 2008[204]	Comprehensive Health Enhancement Support System (CHESS)	Breast Cancer
Gustafson et al., 1994[205]; Gustafson et al., 1999[206]	Comprehensive Health Enhancement Support System (CHESS)	Human Immunodeficiency Virus Infection and Acquired Immune Deficiency Syndrome

Hacking et al., 2013[207]; Hacking et al., 2014[208]	Decision Navigation	Prostate Cancer
Hamann et al., 2006[209]; Hamann et al., 2007[210]		Schizophrenia
Hartling et al., 2013[211]		Croup
Harwood et al., 2011[212]		Breast Cancer
Hawkins Virani et al., 2013[213]		Huntington Disease
Heinrich et al., 2012[214]	Diabetes Interactive Education Programme (DIEP)	Diabetes
Heller et al., 2008[215]		Breast Cancer
Henderson et al., 2013[216]	iDecide/Decido	Diabetes
Hewison et al., 2001[217]		Reproductive Health; Down Syndrome
Hightow-Weidman et al., 2011[218]; Muessig et al., 2013[219]; Muessig et al., 2014[220]; Hightow-Weidman et al., 2015[221]	HealthMpowerment.org	Human Immunodeficiency Virus; Sexually Transmitted Infections
Hill-Briggs et al., 2008[222]; Schumann et al., 2011[223]; Majid et al., 2012[224]	DECIDE program	Diabetes
Hochlehnert et al., 2006[225]		Chronic Pain (Fibromyalgia)
Hoffner et al., 2012[226]	Entering a Clinical Trial: Is it Right for You? (<i>The Clinical Trials Video</i>)	Cancer
Holbrook et al., 2007[227]		Overall Health; Cardiovascular Health
Hollen et al., 2013a[228]	DecisionKEYS for Balancing Choices	Prostate Cancer; Breast Cancer; Lung Cancer
Hollen et al., 2013b[229]	DecisionKEYS for Balancing Choices: Adolescent Substance Use	Substance Use
Holmes-Rovner et al., 2005[230]		Prostate Cancer

Hong et al., 2013[231]	PtDA-WD	Cardiovascular Health
Hooker et al., 2011[232]		Breast Cancer
Hope & Rombauts, 2010[233]		Reproductive Health
Hutchison et al., 2002[234]	Phase I Clinical Trials: What Are They All About?	Cancer
Huyghe et al., 2009[235]	Banking on Fatherhood (BOF)	Reproductive Health
Irwin et al., 1999[236]		Breast Cancer
Isebaert et al., 2008[237]		Prostate Cancer
Izquierdo et al., 2011[238]		Breast Cancer
Jackson et al., 2010[239]; Shourie et al., 2013[240]; Tubeuf et al., 2014[241]	MMR decision aid	Vaccine Preventable Disease
Jefford et al., 2005[242]		Colorectal Cancer
Jenkins et al., 2007[243]		Chronic Kidney Disease
Jenkinson et al., 1998[244]	The Prostate Centre	Prostate Cancer
Jensen et al., 1995[245]		Breast Cancer
Jibaja-Weiss et al., 2006a[246]; Jibaja-Weiss et al., 2006b[247]; Jibaja-Weiss et al., 2011[248]	A Patchwork of Life: A Woman: One Woman's Story for Women Making Breast Cancer Treatment Decisions	Breast Cancer
Johnson et al., 2006[249]		Endotontics
Johnson et al., 2010[250]; Langston et al., 2010[251]	Decision-Making Tool for Family Planning Clients and Providers	Reproductive Health
Juan et al., 2008[252]		Breast Cancer; Ovarian Cancer
Juraskova et al., 2008[253]; Juraskova et al., 2014[254];	Ductal carcinoma in situ decision aid (DCISDA)	Breast Cancer
Kasper et al., 2008[255]; Köpke et al., 2014[256]		Multiple Sclerosis
Kaufman et al., 2003[257]		Breast Cancer; Ovarian Cancer

Kellar et al., 2008[258]; Mann et al., 2010[259]; Marteau et al., 2010[260]; Kellar et al., 2011[261]		Diabetes
Kennedy et al., 2002[262]; Kennedy et al., 2003[263]		Reproductive Health
Kiatpongsan et al., 2013[264]	Managing Menopause: Choosing Treatments for Menopause Symptoms	Reproductive Health
Knapp et al., 2010[265]		Cardiovascular Health
Köpke et al., 2012[266]	EBSIMS-program	Multiple Sclerosis
Krist et al., 2007[267]		Prostate Cancer
Krones et al., 2010[268]	ARRIBA-Herz	Cardiovascular Health
Kupke et al., 2013[269]		Class-II Defect (<i>defect in a posterior tooth</i>)
Kuppermann et al., 2009[270]	Prenatal Testing Decision-Assisting Tool (PT Tool)	Reproductive Health
Kuppermann et al., 2014[271]; Norton et al., 2014[272]	Prenatal Testing: Exploring Your Options	Reproductive Health
Labrecque et al., 2010[273]		Reproductive Health
Lalonde et al., 2004[274]; Lalonde et al., 2006[275]	Making Choices: Life Changes to Lower Your Risk of Heart Disease and Stroke	Cardiovascular Health
LaVista et al., 2009[276]	Hydroxyurea : Is it Your Hope for Better Days?	Sickle Cell Disease
Lawrence et al., 2000[277]		Breast Cancer
Lee et al., 2010[278]		Breast Cancer
Légaré et al., 2003[279]		Reproductive Health
Légaré et al., 2007[280]; Légaré et al., 2008[281]; Menard et al., 2010[282]		Reproductive Health
Légaré et al., 2010[283]	DECISION +	Acute Respiratory Infections
Leighl et al., 2008[284]		Lung Cancer

Leighl et al., 2011[285]		Colorectal Cancer
Lenert & Cher, 1999[286]		Benign Prostatic Hyperplasia
Lerman et al., 1995[287]		Breast Cancer
Leung et al., 2004[288]		Reproductive Health
Lewis et al., 2008[289]	Colon Cancer Screening: Deciding What's Right for You	Colorectal Cancer
Lewis et al., 2010[290]		Colorectal Cancer
Lewis et al., 2010[291]; Miller et al., 2011[292]; Pignone et al., 2011[293]	CHOICE (Communicating Health Options through Interactive Computer Education; version 6.0W)	Colorectal Cancer
Li et al., 2013[294]; Li et al., 2014[295]	ANimated; Self-serve WEb-based Research (ANSWER)	Rheumatoid Arthritis
Liao et al., 1996[296]; Morgan et al., 2000[297]	Ischemic Heart Disease Shared Decision-Making Program (IHD SDP)	Cardiovascular Health
Loh et al., 2007[298]		Depression
Lurie et al., 2011[299]		Herniated Disc
Makoul et al., 2009[300]	Patient Education Program/Programa Educativo para Pacientes (PEP)	Colorectal Cancer
Mancini et al., 2006[301]		Breast Cancer; Ovarian Cancer
Manne et al., 2009[302]	"The Good News: Colorectal Cancer is Preventable!"	Colorectal Cancer
Manne et al., 2010[303]		Colorectal Cancer
Man-Son-Hing et al., 1999[304]; Man-Son-Hing et al., 2000[305]; McAlister et al., 2005[306]		Cardiovascular Health
Masaracchia et al., 1999[307]		Intestinal Problems
Maslin et al., 1998[308]		Breast Cancer
Mathers et al., 2012[309]; Ng	PANDAs	Diabetes

et al., 2014[310]		
Mathieu et al., 2007[311]		Breast Cancer
Mathieu et al., 2010[312]		Breast Cancer
Matlock et al., 2011[313]	Looking Ahead: choices for medical care when you're seriously ill	Advance Care Planning
Mayberry, H. & Mayberry, J.F., 2007[314]		Gastroscopy
Mayer et al., 2010[315]	HSCT-CHESS	Hematopoietic Stem Cell Transplant
McCaffery & Irwig, 2005[316]; McCaffery et al., 2006[317]; McCaffery et al., 2008[318]; McCaffery et al., 2010[319]		Reproductive Health; Cervical Cancer
McKay et al., 2005[320]		Breast Cancer
Metcalfe et al., 2007[321]		Breast Cancer
Michie et al., 1997[322]		Reproductive Health; Down Syndrome
Miller et al., 2005[323]		Breast Cancer; Ovarian Cancer
Milne et al., 2009[324]		Reproductive Health
Mitchell et al., 2001[325]; Hanson et al., 2011[326]; Snyder et al., 2013[327]		Advanced Dementia
Molenaar et al., 2001a[328]; Molenaar et al., 2001b[329]; Molenaar et al., 2004[330]; Molenaar et al., 2007[331];		Breast Cancer
Montgomery et al., 2003[332]; Emmett et al., 2005[333]		Cardiovascular Health
Montori et al., 2007[334]; Weymiller et al., 2007[335]; Jones et al., 2009[336]; Nannenga et al., 2009[337]; Mann et al., 2010[338]	Statin Choice	Diabetes; Cardiovascular Health

Müller et al., 2012[339]	Change of life	Reproductive Health
Murray et al., 2001a[340]		Benign Prostatic Hypertrophy
Murray et al., 2001b[341]		Reproductive Health
Myers et al., 2005[342]; Myers et al., 2011[343]		Prostate Cancer
Nagle et al., 2006[344]; Nagle et al., 2008[345]		Reproductive Health
Nassar et al., 2007a[346]; Nassar et al., 2007b[347]	Making choices: options for a pregnant woman with a breech baby	Reproductive Health
Nozaki et al., 2007[348]	Diagnosis and Treatment for Unruptured Cerebral Aneurysm (<i>Ver. 1 produced in 2004</i>)	Unruptured Cerebral Aneurysms
O'Connor et al., 1998a[349]; O'Connor et al., 1998b[350]; Rostom et al., 2002[351]	Ottawa HRT decision aid	Reproductive Health
Oakley & Walley, 2006[352]		Reproductive Health; Osteoporosis
O'Cathain et al., 2002[353]		Reproductive Health
O'Connor et al., 1999[354]		Reproductive Health
Ogle et al., 2003[355]	Completing a Life	Advance Care Planning
Onel et al., 1998[356]		Prostate Cancer
Ossebaard et al., 2010[357]		Attention Deficit Hyperactivity Disorder
Owens & Robbins, 1996[358]	CHESS	Breast Cancer
Ozanne et al., 2007[359]		Breast Cancer
Peate et al., 2011a[360]; Peate et al., 2011b[361]; Peate et al., 2012[362]		Reproductive Health; Breast Cancer
Peele et al., 2005[363]; Siminoff et al., 2006[364]; Vickers et al., 2009[365]	Adjuvant!	Breast Cancer
Pell et al., 2002[366]		Ovarian Cancer

Pencille et al., 2009[367]; Montori et al., 2011[368]	The Osteoporosis Choice decision aid	Osteoporosis
Perestelo-Perez et al., 2010[369]		Benign Prostatic Hyperplasia
Perestelo-Perez et al., 2010[369]		Depression
Perestelo-Perez et al., 2010[369]		Hip or Knee Osteoarthritis
Permuth-Wey et al., 2010[370]	Genetics and Breast Cancer Risks in Black Women: A Woman's Guide for Genetic Counseling	Breast Cancer; Ovarian Cancer
Peshkin et al., 2010[371]		Breast Cancer; Ovarian Cancer
Peterson et al., 2006[372]		Li-Fraumeni Syndrome
Pierce et al., 2010[373]; Hess et al., 2012[374]		Cardiovascular Health
Pignone et al., 2000[375]; Kim et al., 2005[376]; Griffith et al., 2008a[377]; Griffith et al., 2008b[378]	CHOICE	Colorectal Cancer
Pignone et al., 2004[379]; Sheridan et al., 2006[380]; Sheridan et al., 2009[381]; Sheridan et al., 2010[382]; Sheridan et al., 2011[383]	Heart to Heart	Cardiovascular Health
Protheroe et al., 2007a[384]; Protheroe et al., 2007b[385]	The Clinical Guidance Tree	Reproductive Health; Menorrhagia
Prunty et al., 2008[386]		Reproductive Health; Multiple Sclerosis
Raats et al., 2008[387]		Prostate Cancer; Reproductive Health; Depression; Breast Cancer; Cardiovascular Health; Down Syndrome
Rapport et al., 2006[388]	1-GREEN; 2-PREDICT; and 3-Deciding About Mammography for Women	Breast Cancer

	Age 40-49	
Raynes-Greenow et al., 2009[389]; Raynes-Greenow et al., 2010[390]		Reproductive Health
Redfern et al., 2006[391]		Cardiovascular Health
Renzi et al., 2006[392]		Psoriasis
Reuland et al., 2012[393]; Ko et al., 2014[394]		Colorectal Cancer
Rhee et al., 2008[395]		Asthma
Ronda et al., 2014[396]; Ickenroth et al., 2015[397]		Diabetes; Cardiovascular Health
Ross et al., 2010[398]	The PSA Test for Prostate Cancer: Is it Right for Me?	Prostate Cancer
Rothert et al., 1997[399]; Holmes-Rovner et al., 1999[400]		Reproductive Health
Rubel et al., 2010[401]		Prostate Cancer
Ruland, 1999[402]		Self Care
Ruthman & Ferrans, 2004[403]	Video - The PSA Decision: What You Need to Know	Prostate Cancer
Saver et al., 2007[404]	CHESS-MAB	Reproductive Health
Sawka et al., 1998[405]; Goel et al., 2001[406]		Breast Cancer
Sawka et al., 2011a[407]; Sawka et al., 2011b[408]; Sawka et al., 2012[409]		Papillary Thyroid Cancer
Schackmann et al., 2013[410]		Breast Cancer; Ovarian Cancer
Schapira & VanRuiswyk, 2000[411]		Prostate Cancer
Schapira et al., 1997[412]		Prostate Cancer
Schapira et al., 2007[413]		Reproductive Health
Schonberg et al., 2014[414]		Breast Cancer

Schoorel et al., 2014[415]		Reproductive Health
Schroy et al., 2011[416]; Schroy et al., 2012[417]; Schroy et al., 2014[418]		Colorectal Cancer
Schwalm et al., 2012[419]		Cardiovascular Health
Schwartz, L.M. et al., 2009[420]	Drug facts box	Cardiovascular Health
Schwartz, M.D. et al., 2009[421]		Breast Cancer
Sepucha et al., 2009[422]	Living with Metastatic Breast Cancer: Making the Journey Your Own	Breast Cancer
Shaffer et al., 2013[423]		Breast Cancer
Shaw et al., 2001[424]		Colorectal Cancer
Sheppard et al., 2010[425]		Breast Cancer
Sheridan et al., 2004[426]		Prostate Cancer
Sherman et al., 2014[427]	Breast reconstruction decision aid (BRECONDA)	Breast Cancer; Ductal Carcinoma In Situ
Shorten et al., 2004[428]; Shorten et al., 2005[429]		Reproductive Health
Simon et al., 2012[430]	Patient Dialogue	Depression; Acute Low Back Pain
Smith et al., 2008[431]; Trevena et al., 2008[432]; Smith et al., 2009[433]; Smith et al., 2010[434]		Colorectal Cancer
Smith et al., 2011[435]		Prostate Cancer; Breast Cancer; Colorectal Cancer; Lung Cancer
Solberg et al., 2010[436]		Reproductive Health
Sorenson et al., 2004[437]		Hemophilia
Spunt et al., 1996[438]; Deyo et al., 2000[439]; Phelan et al., 2001[440]		Low Back Problems (<i>herniated disks; spinal stenosis; and other diagnoses</i>)

Sridhar et al., 2015[441]	Plan A Birth Control	Reproductive Health
Stacey et al., 2003[442]		Breast Cancer
Stacey et al., 2014[443]	Treatment Choices for Knee Osteoarthritis	Knee Osteoarthritis
Stalmeier & Roosmalen, 2009[444]		Breast Cancer; Ovarian Cancer
Stalmeier & Roosmalen, 2009[444]		Breast Cancer; Ovarian Cancer
Stalmeier et al., 1999[445]		Breast Cancer
Steckelberg et al., 2004[446]; Steckelberg et al., 2011[447]		Colorectal Cancer
Stein et al., 2013[448]	Living with Advanced Cancer	Advance Care Planning; Cancer
Stephens et al., 2008[449]		Prostate Cancer
Stiggelbout et al., 2008[450]		Abdominal Aortic Aneurysm
Stirling et al., 2012[451]	GOLD Book (Guiding Options for Living with Dementia)	Dementia
Street et al., 1995[452]	Options for Treating Breast Cancer	Breast Cancer
Sudore et al., 2014[453]	PREPARE	Advance Care Planning
Sullivan et al., 2007[454]; McCarthy et al., 2010[455]; Chambers et al., 2012[456]	Ottawa Influenza Decision Aid (OIDA)	Vaccine-Preventable Disease
Sundaresan et al., 2011[457]		Prostate Cancer
Tan & Wolfe, 2012[458]; Tan & Wolfe, 2014[459]		Psoriasis
Taylor et al., 2006[460]; Dorfman et al., 2010[461]; Kassan et al., 2012[462]	Prostate Cancer Screening: Making an Informed Decision (<i>one of three patient decision aids</i>)	Prostate Cancer
Taylor et al., 2006[460]; Dorfman et al., 2010[461]; Kassan et al., 2012[462]; Williams et al., 2013[463]	Prostate Cancer Screening: Making an Informed Decision (<i>one of three patient decision aids</i>)	Prostate Cancer

Taylor et al., 2006[460]; Dorfman et al., 2010[461]; Kassan et al., 2012[462]; Williams et al., 2013[463]; Taylor et al., 2013[464]	Prostate Cancer Screening: Making an Informed Decision (<i>one of three patient decision aids</i>)	Prostate Cancer
Thomas et al., 2013[465]		Cardiovascular Health
Thomson et al., 2002[466]; Kaner et al., 2007[467]; Thomson et al., 2007[468]		Cardiovascular Health
Tiller et al., 2003[469]; Tiller et al., 2006[470]		Ovarian Cancer
Tracy et al., 2004[471]	Health Care Information Directive (HCID)	Disclosure of Personal Health Information
van der Krieke et al., 2012[472]	WEGWEIS	Schizophrenia
van Peperstraten et al., 2010a[473]; van Peperstraten et al., 2010b[474]		Reproductive Health
van Roosmalen et al., 2004a[475]; van Roosmalen et al., 2004b[476]		Breast Cancer
van Steenkiste et al., 2008[477]		Cardiovascular Health
van Til et al., 2010[478]		Ankle-Foot Impairment in Stroke; Arm-Hand Function in Cervical Spinal Cord Injury
van Tol-Geerdink et al., 2006[479]; van Tol-Geerdink et al., 2008[480]		Prostate Cancer
van Tol-Geerdink et al., 2013[481]		Prostate Cancer
van Vugt et al., 2010[482]		Prostate Cancer
Vandemheen et al., 2009[483]; Vandemheen et al., 2010[484]		Cystic Fibrosis
Vernon et al., 2011[485]	Screen for Life	Colorectal Cancer
Veroff et al., 2012[486]	Living with Heart Failure:	Cardiovascular Health

	Helping your Heart Day-to-Day	
Vodermaier et al., 2009[487]		Breast Cancer
Vodermaier et al., 2011[488]		Breast Cancer
Vogel et al., 2013[489]		Advance Care Planning; Ovarian Cancer
Volandes et al., 2009a[490]; Volandes et al., 2009b[491]; Volandes et al., 2010[492]		Advance Care Planning; Dementia
Volk et al., 1999[493]; Volk et al., 2003[494]	The PSA Decision: What YOU Need to Know	Prostate Cancer
Volk et al., 2008[495]		Prostate Cancer
Volk et al., 2014[496]	Lung Cancer Screening: Is It Right for Me?	Lung Cancer
Vuorma et al., 2003[497]; Vuorma et al., 2004[498]		Menorrhagia
Wakefield et al., 2007[499]; Wakefield et al., 2008a[500]; Wakefield et al., 2008b[501]		Breast Cancer; Ovarian Cancer; Colorectal Cancer
Wakefield et al., 2008[502]		Colorectal Cancer
Wakefield et al., 2011[503]; Watts et al., 2014[504]		Prostate Cancer
Wall, 1985[505]		Reproductive Health
Wang et al., 2005[506]		Breast Cancer; Ovarian Cancer
Watson et al., 2006[507]	PSA Testing for Prostate Cancer- an information sheet for men considering a PSA test	Prostate Cancer
Weinrich et al., 2008[508]	Your life-You decide	Prostate Cancer
Weng et al., 2007[509]		Knee Osteoarthritis
Westreich et al., 1995[510]		Mental Health
Weyand et al., 2011[511]		Neonatal Intensive Care

Whelan et al., 1995[512]; Whelan et al., 1999[513]; Whelan et al., 2003[514]; Whelan et al., 2004[515]	Decision Board	Breast Cancer
Whiskey & Taylor, 2005[516]		Mental Health
Wilkins et al., 2006[517]	Early Stage Breast Cancer: Choosing Your Surgery	Breast Cancer
Willemsen et al., 2006[518]		Smoking
Wilson et al., 2015[519]		Intensive Care Unit; Cardiovascular Health
Wilt et al., 2000[520]	Early prostate cancer	Prostate Cancer
Wolf & Schorling, 2000[521]		Colorectal Cancer
Wolf et al., 1996[522]; Wolf & Schorling, 1998[523]		Prostate Cancer
Woltmann et al., 2011[524]		Mental Health
Wong et al., 2006[525]		Reproductive Health
Wong et al., 2012[526]		Breast Cancer
Wright et al., 2002[527]; Wright et al., 2004[528]	Interactive Decision Explorer (IDEX)	Cardiovascular Health
Wroe et al., 2005[529]	Deciding about Immunizations: The benefits and the risks.	Vaccine-Preventable Disease
Yun et al., 2011[530]	Patients Want to Know the Truth	Advance Care Planning; Cancer
Zapka et al., 2004[531]	Say Yes to the Test	Colorectal Cancer
Zeliadt et al., 2013[532]	Making the Choice: Deciding What to Do About Early Stage Prostate Cancer	Prostate Cancer

Table 2. Included User-Centered Design Projects

Articles in this project	Patient-centered tool name (if exists)	Clinical context
Adamo-Villani, 2007[533]		Deafness

Ahlers-Schmidt et al., 2011[534]; Hart et al., 2011[535]; Ahlers-Schmidt et al., 2012a[536]; Ahlers-Schmidt et al., 2012b[537]; Ahlers-Schmidt et al., 2012c[538]; Ahlers-Schmidt et al., 2013[539]		Vaccine-Preventable Disease
Al-Abdullatif et al., 2013[540]	Arabic Brain Communicator (ABC)	Disability
Amiri et al., 2012[541]		Physical Injury
Atkinson et al., 2007[542]; Atkinson et al., 2009[543]; Atkinson et al., 2010[544]		Obesity; Physical Activity; Nutrition
Bae et al., 2009[545]		Depression
Cafazzo et al., 2012[546]	bant	Diabetes
Carey-Smith et al., 2013[547]		Elderly
Cavallo et al., 2013[548]	ASTROMOBILE	Elderly
Civan & Pratt, 2007[549]; Civan-Hartzler et al., 2010[550]		Breast Cancer; Cancer
Cofré et al., 2012[38]		Disability
Dabbs et al., 2009[551]	Pocket Personal Assistant for Tracking Health (Pocket PATH)	Lung Transplant
Das & Svanoes, 2013[552]		Obesity
Faraji & Farahmand, 2014[553]		Work-Related Musculoskeletal Disorders
Felice et al., 2007[554]	The e-LIS dictionary	Deafness
Fico et al., 2010[555]; Fico et al., 2011[18]	METABO system	Diabetes
Fonda et al., 2010[17]		Diabetes
Gilliam et al., 2014[556]		Reproductive Health
Harada et al., 2007[557]	VoiceDraw	Disability

Hawley et al., 2013[39]	Voice-input voice-output communication aid (VIVOCA)	Dysarthria (speech impairment)
Herschman et al., 2014[558]		Lupus
Izard et al., 2014[559]; Hartzler et al., 2016[560]		Prostate Cancer
Jia et al., 2013[561]		Cardiovascular Health
Johnston et al., 2009[562]		Chronic Obstructive Pulmonary Disorder
Lalji & Good, 2008[563]		Illiteracy
Lepicard et al., 2007a[564]; Lepicard et al., 2007b[565]	Virtual Paddle	Disability
Lewis et al., 2000[566]; Shopland et al., 2005[567]	Virtual City	Learning Disability
Limbach, 2012[568]	The MeMoTray	Dementia
Ma et al., 2007[569]		Hemiplegia
MacCallum et al., 2013[570]	Know Your Colours	Cardiovascular Health
Marcu et al., 2012[571]	MONARCA system	Bipolar Disorder
Markopoulos et al., 2011[572]	Us'em	Cardiovascular Health; Impaired Limbs (post-stroke)
Marti & Giusti, 2010[573]	Iromec	Autism Spectrum Disorder; Intellectual Disability; Physical Impairment
Massoudi et al., 2010[574]; Olmsted et al., 2015[575]		Physical Activity
Mawson et al., 2014[576]; Parker et al., 2014[577]	Personalised Self-Managed Rehabilitation System (PSMrS)	Cardiovascular Health
McDaniel et al., 2005[15]		Smoking
McGaffey et al., 2010[578]	The Fitwits School program	Obesity
Munoz et al., 2012[579]		Autism Spectrum Disorder
Nasir et al., 2008[580]		Cardiovascular Health
Neale et al., 2002[581]		Autism Spectrum Disorder

Nordfeldt et al., 2007[16]	DiabIT simulator	Diabetes
Osborn & Mulvaney, 2013[582]	MEssaging for Diabetes (MED) intervention	Diabetes
Peters et al., 2004[583]; Mancas-Thillou et al., 2007[584]	SYPOLE	Blindness
Petrie et al., 1997[585]	the MoBIC Travel Aid (MoTA)	Blindness
Pigini et al., 2012[586]		Elderly
Rizzo et al., 2009[587]; Rizzo et al., 2010[588]	Virtual Iraq/Afghanistan	Post-Traumatic Stress Disorder
Robinson et al., 2009[589]	Keep in Touch Everyday (KITE)	Dementia
Sanchez & Flores, 2008[590]	AudiodMC	Blindness
Sanchez-Morillo et al., 2015a[591]; Sanchez-Morillo et al., 2015b[592]	AMICA (Autonomy Motivation & Individual Self-Management for COPD patients)	Chronic Obstructive Pulmonary Disorder
Siek et al., 2006[593]; Connelly et al., 2012[594]	Dietary Intake Monitoring Application (DIMA)	Patients Receiving Hemodialysis
Slagle et al., 2010[595]	MyMediHealth	Medication
Stinson et al., 2014[596]	iCanCope with Pain	Chronic Pain
Taylor et al., 2003[597]		Amblyopia
van der Weegen et al., 2013[598]; Verwey et al., 2014[599]	It's Life!	Diabetes; Chronic Obstructive Pulmonary Disorder; Chronic Disease(s)
Verdezoto & Grönvall, 2012[600]; Verdezoto & Wolff Olsen, 2012[601]; Dalgaard et al., 2013[602]	MediFrame	Older Adults Medication Intake
Verhoeven et al., 2010[603]		Vaccine-Preventable Disease
Vermeulen et al., 2013[604]		Elderly People's Physical Functioning
Walji & Zhang, 2008[605]		Not reported
Weightman et al., 2010[20]		Cerebral Palsy

Wentz et al., 2012[606]	SalutChat	Autism Spectrum Disorder; Attention Deficit Hyperactivity Disorder
Wolpin et al., 2015[607]	Electronic Self-Report Assessment for Cancer (ESRAC)	Cancer
Wu et al., 2009[608]		Disability
Yu et al., 2014a[609]; Yu et al., 2014b[610]	Diabetes Online Companion	Diabetes
Zhang et al., 2008[611]	CogKnow navigator	Dementia
Zickler et al., 2013[19]; Höhne et al., 2014[612]; Botrel et al., 2015[613]	Brain Painting	Disability; Hemiplegia; Tetraplegia; Amyotrophic Lateral Sclerosis

Data quality assessment

The quality of studies is summarized in Appendix 3. Overall, quality was acceptable, though with some weaknesses in evaluation studies, such as low rates of controlling of potentially confounding variables in non-experimental studies.

Data validation

Two hundred thirty four project authors (60%) responded to validate or correct data. Within those projects, authors' comments changed 4.3% of all extracted data. This 4.3% consisted of 2.7% for addition of previously missing data, 0.05% for precision of data, 0.2% for correction of incorrect data, and 1.3% for differences that did not materially affect the extracted data.

Project and tool characteristics

Overall, projects were reported in articles published from 1976 to 2016. Patient decision aid publications dated from 1976 and user-centered design publications from 1997. Half of patient decision aid projects (51%) cited no theory, model, framework, or standards. The two most commonly cited such foundations were the International Patient Decision Aid Standards (19%) and the Ottawa Decision Support Framework (17%).

Among the 325 patient decision aids, 61% were paper based. The most common clinical contexts addressed were breast cancer (20%) and reproductive health (19%) and the most common purposes were to support a treatment (57%) or screening (21%) decision. Regarding intended context of use, almost half of the patient decision aids (46%) were designed for use at home or in a private setting. Regarding timing of use, many were designed to be used before (38%), during (31%) or between (23%) clinical encounters.

Among the 65 other health tools developed via user-centered design, 42% used an online application format. The most common clinical contexts addressed were disabilities (25%) and the most common purposes were to support everyday activities (45%) or other activities such as monitoring, self-management or self-monitoring (40%). The majority of tools (68%) were designed to be used in an everyday context, wherever the person happened to be. Regarding timing of tool usage, many tools (34%) were not associated with clinical encounters.

Development steps, overall and by user-centered design element

In the following sections, we present (1) the frequency with which a development step was reported out of all projects, with or without user involvement, (2) the frequency with which a development step was reported with users involved in some way, and (3) the number of reported users involved in development steps. For this latter reporting element, because many projects did not report the numbers of users involved in any development step, we present data only from projects in which a specific number of users was reported. In other words, when we report the median number of users involved in particular development steps, this is the median only among projects that reported how many users were involved.

Overall

Among projects that described at least one development step (n=348), 89% reported at least one step to do with understanding users, 91% with developing/refining prototype, and 93% with observing users interacting with the prototype.

Patient decision aid projects with at least one step of development (n=283) reported a median of 5 steps (interquartile range 4-7, full range 1-11) of the 12 predefined development steps within our user-centered design framework. User-centered design projects (n=65) reported a median of 6 steps (interquartile range 4-8, full range 2-12). Out of 12 possible development steps in total, patient decision aid projects reported involving users in a median of 2 steps (interquartile range 1-3, full range 0-7) while user-centered design projects reported involving users in a median of 3 steps (interquartile range 2-5, full range 0-8). Out of all 348 projects that described development, 261 reported a specific number of users involved in one or more of the 12 predefined steps and up to 4 other steps. Within these 261 projects, 201 patient decision aid projects involved a median of 39 users (interquartile range 23-82, full range 1-1210) and 60 user-centered design projects involved a median of 35 users (interquartile range 16-65, full range 2-3770). Tables 3 and 4 provide further details of the percent of projects that reported each step, involved users in each step, and the numbers of users involved.

Table 3. Development steps: steps and users' involvement

	Development steps reported		Users reported as being involvement in step(s)	
	Patient decision aid	User-centered design	Patient decision aid	User-centered design

	projects (n=283) n (%)	projects (n=65) n (%)	projects (n=283) n (%)	projects (n=65) n (%)
Understanding user				
Literature review	230 (81%)	41 (63%)	5 (2%)	0 (0%)
Observation of existing processes (e.g., ethnography)	35 (12%)	30 (46%)	18 (6%)	27 (42%)
Formal needs assessment	43 (15%)	23 (35%)	38 (13%)	22 (34%)
Informal needs assessment	133 (47%)	47 (72%)	110 (39%)	42 (65%)
Developing/refining prototype				
Develop and/or validate underlying model	47 (17%)	3 (5%)	0 (0%)	0 (0%)
Storyboarding/wireframing	69 (24%)	39 (60%)	11 (4%)	13 (20%)
Adapt/translate tool	95 (34%)	12 (18%)	4 (1%)	0 (0%)
Content/format review prior to prototyping	157 (55%)	33 (51%)	48 (17%)	21 (32%)
Prototype development	248 (88%)	62 (95%)	53 (19%)	9 (14%)
Observing prospective user's interaction with prototype				
Content/format review after	189 (67%)	33 (51%)	101 (36%)	24 (37%)
Pilot/usability testing	231 (82%)	58 (89%)	208 (73%)	58 (89%)
Second pilot/usability testing	32 (11%)	12 (18%)	29 (10%)	9 (14%)

Table 4. Development steps: numbers of users involved

	Number of users involved in the step(s), when numbers of users were reported	
	Patient decision aid projects: Median (IQR) (Range) (n/283)	User-centered design projects: Median (IQR) (Range) (n/65)
Understanding user		
Literature review	-	-

Observation of existing processes (e.g., ethnography)	36 (12-56) (4-605) (n=9)	13 (9-18) (1-100) (n=10)
Formal needs assessment	24 (16-44) (8-400) (n=24)	20 (15-23) (8-3710) (n=13)
Informal needs assessment	30 (15-43) (3-1119) (n=38)	18 (9-33) (1-325) (n=22)
Developing/refining prototype		
Develop and/or validate underlying model	-	-
Storyboarding/wireframing	-	10 (5-13) (2-18) (n=7)
Adapt/translate tool	35 (33-38) (30-40) (n=2)	-
Content/format review prior to prototyping	14 (8-25) (2-153) (n=16)	16 (15-18) (5-20) (n=8)
Prototype development	10 (6-26) (1-44) (n=14)	10 (2-11) (1-44) (n=5)
Observing prospective user's interaction with prototype		
Content/format review after	20 (9-30) (1-90) (n=61)	8 (7-10) (4-23) (n=14)
Pilot/usability testing	28 (15-45) (1-605) (n=161)	12 (6-20) (1-202) (n=49)
Second pilot/usability testing	17 (12-40) (7-188) (n=26)	6 (4-13) (1-18) (n=7)

IQR: InterQuartile Range

Iteration

Most projects reported iterative development processes (74% of patient decision aid projects, 92% of user-centered design projects). The median numbers of iterative cycles was 3 (interquartile range: 2-4) for patient decision aids and 3 (interquartile range: 2-3) for user-centered design of other patient-centered tools. Changes between versions of prototypes were described in 23% of reports of patient decision aid projects and 52% of reports of user-centered design projects.

Users involved

Primary users: patients, family members, caregivers, surrogates

Most patient decision aid projects (95%) and user-centered design projects (98%) reported involving individuals who previously, currently, or potentially will face the health issue. The majority of these users were reported as currently facing the health issue (85% for patient decision aid projects and 94% for user-centered design projects). Surrogate decision-makers were involved in 2% of patient decision aid projects and 0% of user-centered design projects. Caregivers and family members or friends were involved in 5% and 11% of patient decision aid projects, respectively, and 22% and 20% of user-centered design projects. As we reported elsewhere, 16% of patient decision aid projects specifically involved members of vulnerable populations in the development process [29].

Clinician users

Many patient decision aid projects (63%) and user-centered design projects (55%) reported involving clinician users, meaning health care professionals who might interact with the tools in different ways than primary users. The median numbers of clinician users involved in total were 10 (interquartile range: 5-22) and 9 (interquartile range: 4-20), respectively. Clinician user involvement was typically not reported with the same level of detail as primary user involvement. Teams consulted clinician users mainly before developing a first prototype (64% patient decision aid projects, 64% user-centered design projects) and/or between prototype versions (69% patient decision aid projects, 53% user-centered design projects). The majority of projects reported changing the tool based on clinicians' feedback (73% patient decision aid projects, 72% user-centered design projects).

Advisory panels, organizations, and expert panels

Nine percent of patient decision aid projects and 6% of user-centered design projects reported working with a formal patient, family, caregiver or surrogate user advisory panel. In addition, in patient decision aid and user-centered design projects, 12% and 14%, respectively, reported working with at least one formal, named patient organization, and 2% in each group reported with at least one formal, named health professional organization. Other types of experts were more involved, namely, 47% of patient decision aid projects and 38% of user-centered design projects reported engaging an expert panel that might include academic researchers, health

professionals, and experts in other areas (e.g., plain language experts, web developers, designers).

Recruitment and compensation

The majority (82%) of patient decision aid projects recruited convenience samples of primary users. About half (55%) of user-centered design projects recruited primary users with this method. Five percent of patient decision aid projects did not report how they recruited primary users; 32% of user-centered design projects did not report recruitment methods.

Primary users were compensated in around one quarter of each kind of projects, with 27% of patient decision aid projects and 26% of user-centered design projects. Cash was the most common form of compensation. Cash was used in 19% of patient decision aid and 12% of user-centered design projects.

Individual or group involvement

For content and format reviews before and after the prototype development, projects reported involving primary users in groups; for example, in focus groups (20% for patient decision aid projects, 25% for user-centered design projects). Otherwise, users were typically involved individually; for example, in interviews.

Degree of involvement

Primary users were reported as being involved as participants in studies in nearly every project (over 99% of patient decision aid projects; 97% of user-centered design projects). They were sometimes reported as being involved in an advisory capacity (27% patient decision aid projects versus 22% user-centered design projects). Fewer projects reported involving users on an advisory panel (9% versus 6%) or as partners on the research or development team (8% versus 14%).

Methods of eliciting users' responses to the tool

User-centered design methods often include direct observation of users (e.g., ethnographic observation prior to developing a tool, conducting usability testing with methods such as think aloud) whereas more traditional health services research tend towards asking users their opinions (e.g., focus groups, interviews, surveys) and assessing the effects of a tool on users (e.g., testing knowledge and decisional conflict in pre-post studies or randomized controlled trials). Therefore, in addition to the mode of involvement, we also observed the nature of involvement.

A large majority of patient decision aid projects (75%) and user-centered design projects (94%) reported asking users their thoughts and opinions of a tool. Forty-one percent of patient decision aid projects and 72% of user-centered design projects reported observing users interacting with the tool. Eighty-eight percent of patient decision aid projects and 45% of user-centered design projects reported assessing the impact of the tool on users.

Evaluation

In capturing data about what tools had been evaluated, we first determined whether projects assessed any preliminary metrics such as feasibility, acceptability, satisfaction with the tool, usability, or other metrics typically measured before launching a trial or product. Sixty-six percent of patient decision aid projects reported conducting this type of evaluation of preliminary metrics as did 89% of user-centered design projects. We then determined whether the project had conducted any evaluation of the efficacy of the tool (for example, via an explanatory randomized controlled trial) or the effectiveness of the tool (for example, via a pragmatic trial). Eighty-nine percent of patient decision aid projects reported conducting this type of efficacy or effectiveness evaluation, as did 45% of user-centered design projects. Finally, we determined whether projects assessed the implementation of tools in any way, including their integration into routine care, barriers and facilitators to usage, uptake, and usage statistics. Nine percent of patient decision aid projects and 12% of user-centered design projects reported having evaluated the implementation of tools.

Discussion

Principal results

Overall, these results suggest that many patient decision aid projects use elements of user-centered design, such as involving users in developing and pilot-testing prototypes. However, additional opportunities remain to better adapt tools to users rather than requiring that users adapt to tools. We suggest four key opportunities for learning and improvement of development processes.

First, developers could involve users in more steps to understand their needs, goals, strengths, limitations, contexts, and intuitive processes prior to developing their tool. This may help address the known gap in the implementation of decision aids by more fully adapting the tools to the people who will use them. Specifically, projects may benefit from engaging in formal or informal needs assessments, and by directly observing existing processes; for example, using ethnographic methods, prior to developing any content or specifying format.

Second, it is important to recognize the different data that one gets from asking users to comment on a prototype, observing users' interactions with the prototype, and assessing the impact of a tool among users. Patient decision aid projects may benefit from using methods of asking and observing that help to optimize user experience. User-centered design projects may also benefit from more formal assessment of impact.

Third, both patient decision aid projects and user-centered design projects demonstrated iterativity, but user-centered design projects more commonly explicitly reported changes between iterative cycles. Patient decision aid developers may wish to consider doing the same. Reporting on changes between versions serves multiple purposes. It provides a record of concepts and ideas that have been attempted and how users responded to them, helps explain

the design rationale for the final version, and incentivizes rigorous iterative practices in which teams make efficient use of users' time and expertise.

Finally, there may be room for all projects to involve users and clinician users more. Relatively few projects reported involving users in advisory or partnership roles. Patient participation and engagement in research teams has been recently encouraged and required by national funding bodies in the US and elsewhere [30–32]. As partnerships take time to build, our systematic review of the existing literature might simply be too early to observe the effects of these initiatives. More user-centered design projects reported users being members of the team, suggesting that such collaboration and sharing of power is more common in that tradition and may be worth considering in patient decision aid projects as well.

Comparison to previous literature

To the best of our knowledge, there are no previous systematic reviews of development methods of patient decision aids, nor of the application of user-centered design to patient decision aid development. Our work was responding to a call for more information on user-centered design for patient decision aid development in the most recent update of the International Patient Decision Aid Standards [33–35]. However, situating our work in the broader literature, we offer two main observations.

Our finding that patient decision aids were predominantly intended to be used in or around a clinical encounter aligns with previous literature that already characterized patient decision aids as tools to help patients make specific choices about their health [3] and to encourage them to participate in the shared decision making process with health professionals [36,37]. As methods of delivering patient decision aids increase; for example, via patient portals to electronic health records, it may be worth considering whether tools that are explicitly designed to be used outside the clinical encounter ought to be considered separately from those explicitly designed to be used within the encounter. Similarly, our finding that other patient-centered tools developed using user-centered design included many tools intended to be used everyday reflects authors' characterizations of such tools as “real” tools for everyday lives [38–40].

Our findings about variations in development methods, particularly the way in which user-centered design projects may involve users more often and earlier, aligns with definitions and standards of user-centered design specifying that such a process must incorporate users' needs early and throughout an iterative development process [5,9]. In contrast, standards for patient decision aid development have thus far been less prescriptive regarding the way and frequency with which users must be involved [33,34].

Finally, our study adds to literature from fields such as human factors, human-computer interaction, ergonomics, design, and others that aim to adapt tools to the people who will use them [5,7,9,21–23] by explicitly structuring such processes for patient decision aid development. Some evidence suggests that involving users in the development of health care or health-related tools may lead to more usable, accepted, or effective tools [41,42]. Improving our understanding of users' needs, goals, strengths, limitations, contexts, and intuitive processes to

inform the development of patient decision aids may offer additional gains toward supporting evidence-informed health decisions aligned with what matters to those most affected by the decision.

Limitations

Our review has three main limitations. First, like all systematic reviews of the literature, our original data were limited to what was reported in publications. This limitation may be especially important in our review given we were seeking data about development processes, which are reported in different ways and sometimes with unclear or minimal details. It is possible that in some cases, project teams undertook a development step or involved users without reporting it. We chose to require explicit reporting of steps and user involvement because we posit that when authors take methodological steps seriously, they are more likely to ensure that such steps are reflected in publications about their project. We deliberately used an expansive search strategy and made concerted efforts to contact all authors to maximize opportunities to capture all relevant data. Analyses of authors' responses for 60% of projects suggested very low rates of data omission or error in our data extraction process. However, we cannot be certain that the low rates of omission or error observed in these projects also apply to the other 40%.

Second, our results may reflect differences between the purposes of tools. User-centered design has been applied more in cases such as a person using a wheelchair or navigating a website. In such cases, the user's interaction with the tool is likely easier for the user to report through methods such as think aloud and also easier for a designer or researcher to observe directly. Patient decision aids, on the other hand, are designed to facilitate interactions such as learning and decision making that are largely internal and whose processes may be difficult to articulate or to observe directly.

Lastly, although it is reasonable to suggest that user-centered design methods may help ensure that tools like patient decision aids are well-adapted to their intended users, this study was not intended to evaluate the quality of development processes of patient decision aids, only to describe them. This work is intended to help situate development processes observed within patient decision aid projects and user-centred design projects in relation to each other in order to identify potential areas of improvement. We note that even among user-centered design projects, users were not involved to the maximum extent. It may be that there is a threshold of involvement that optimizes a tool for use while respecting limited resources such as users' time, developers' time, and funds for development.

Conclusions

Patient decision aid projects and user-centered design projects show differing patterns of involving users during their development processes, especially regarding the stage, the methods of eliciting users' responses to the tool, and the timing of users' involvement. Some of these reported differences reflect differences between the types and purposes of tools and traditions in different domains. Other differences offer opportunities for learning and

improvement. Patient decision aid developers may wish to engage in formal or informal needs assessments, ask about and observe user experience, and explicitly report changes between iterations. All who develop patient-centered tools, whether relevant to a health decision or not, may wish to involve users and clinician users in co-design of prototypes, in advisory and partnership roles, and better report on such involvement. Improving our understanding of how to optimize user involvement will serve to better adapt all tools to the people who will use them.

APPENDICES

Appendix 1. Search strategy

Appendix 2. Data extraction form

Appendix 3. Full details of study quality, data and analyses

Appendix 4. PRISMA 2009 Checklist

DECLARATIONS

Abbreviations

None

Ethics Approval, Consent to Participate and Consent for Publication

Not applicable.

Availability of Data and Materials

The data files used in the analyses described in this paper may be accessed at: {link to be added to accepted version} for the primary analyses and {link to be added to accepted version} for quality assessment data. An R Markdown document accompanies the data at {link to be added to accepted version} and provides code for all descriptive analyses described here.

Competing Interests

During the course of this project, CAL (see Acknowledgements) received salary support as Research Director for the Informed Medical Decisions Foundation, the research division of Healthwise, Inc., a not-for-profit organization (<http://www.informedmedicaldecisions.org>). Healthwise produces solutions to deliver consistent health content and patient education (including patient decision aids) to various health-care organizations.

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Conceptualization and methodology: GV, TP, MD, MET, SCD, HC, AF, AMCG, LH, ASH, NMI, ASJ, FL, CAL, JSR, DS, RJV, HOW; Formal analysis: GV, ASJ, HOW; Investigation: GV, TP, MD, MET, SCD, HH, HOW; Resources: HOW; Data curation: GV, TP, HOW; Writing - Original Draft: GV, TP, HOW; Writing - Review and editing: GV, TP, MD, MET, SCD, HC, AF, AMCG, HH, LH, ASH, NMI, ASJ, FL, CAL, JSR, DS, RJV, HOW; Visualization: GV, TP, HOW; Supervision: HOW; Project administration: GV, SCD, HOW; Funding acquisition: HOW. Contributions are reported according to the CRediT taxonomy [43]. Specific systematic review roles: record screening: GV, TP, MD, MET plus research assistants/associates EB, IB (see Acknowledgements); data extraction: GV, TP, MD, MET plus research associate EB; data validation: HH; adjudication: SCD, HOW; project steering committee: AF, AMCG, SG, FL, KS, RJV, HOW.

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Appendix 1. Search strategy

Applying Methods of User-Centered Design to Achieve Patient-Centered Care

Prepared by: William Witteman, MLIS

Literature Search Methodology

The goal of this literature search is to obtain all references describing tools of any kind that aid in the making of a medical decision. These references will be assessed for indications that the users of the tools have been consulted in their creation and design. Unfortunately, while medical decision aids are not particularly new, nor are user-centered design methods novel, there is no clear, specific way to easily identify references in the scholarly literature that combine these concepts.

Due to this limitation in the indexing of the literature, a very broad, highly sensitive set of search methods was applied to ensure that no important papers or other materials describing this subject were missed.

For the medical literature, the existing Cochrane Review by Dawn Stacey et al entitled “Decision aids for people facing health treatment or screening decisions” provides a guide for finding decision aids. The search strategy in this review contains much of what is needed in the search for this project. However, because they were looking to only synthesize randomized controlled trials for screening and treatment of medical conditions, it was more restrictive than would be appropriate for this project.

With that in mind, the search strategy was slightly modified and applied to the following databases: Thompson Web of Science (all databases), PubMed (ILM), MEDLINE (Embase.com), EMBASE (Embase.com), and the Cochrane Library (Wiley). However, this search strategy along is unlikely to provide full coverage of the existing literature, especially for references published outside of the medical literature. Additionally, it was deemed essential that if a decision aid development process was described in the scholarly literature, it may not discuss in sufficient detail the medical decision, and so would be missed by this approach. To that end, additional search strategies were formulated and executed.

First, the existence of the International Patient Decision Aid Standards (IPDAS) makes it a literary keystone, very likely to be cited by any publication creating a decision aid. Therefore, we used the Thompson Web of Science (all databases) citation tools to search for all references that cite this paper.

The concept of “user centered” design was the central concept that was used to create a second broad search strategy. This approach was used to search the following databases: Thompson

Web of Science (all databases), PubMed (ILM), MEDLINE (Ovid), EMBASE (Embase.com), the Cochrane Library (Wiley) and IEEE Xplore.

In addition, the screening process in the Stacey review was more restrictive than appropriate for this investigation, and so it had to be re-run and re-screened to ensure that RCTs which were excluded from the Cochrane review were not erroneously ignored in the context of this review. This involved running the same search conducted in the Stacey review in PsycINFO (Ovid), CINAHL (EBSCOHost), MEDLINE (Ovid), EMBASE (Embase.com), and the Cochrane Library (Wiley).

We also conducted a screen of the references of the Stacey Cochrane review, as well as each other literature review that appeared in our set of results. The procedure here was that if a paper was describing the methods or synthesising the results of studies that provided a decision aid to patients, we screened the references of that paper to ensure that any studies or other relevant materials were captured in our search.

The screening process was conducted in accordance with the standard methods for systematic reviews. After a training period where all screeners practiced on a small sub-set of the results, two screeners reviewed each title and abstract for inclusion or exclusion. If those two screeners disagreed, a third screener adjudicated the reference and determined if the reference should be included for further screening.

Once all of the references had been screened by title and abstract, the full text of the papers still thought to be of value to the review were obtained, and screened by two independent reviewers. These references were then divided into three categories; include and retain for data extraction, exclude, and retain for a screen of the references, but do not include for data extraction.

Below are the search strategies for each database searched. These strategies were peer-reviewed by Marina Englesakis, MLIS or Michelle Fiander, MA MLIS.

Search Strategies

Decision Aids:

Web of Science – Search Conducted 2014/05/11

Line Number	Search String	Article Count
# 3	#2 AND #1	15,597
# 2	TOPIC: (TOPIC: ((user OR human) (centered OR centred)) OR TOPIC: ('development' NOT grow*) OR TOPIC: (evaluation) OR TOPIC: ('feasibility' (test* OR stud* OR evaluat*)) OR TOPIC: (acceptability) OR TOPIC: (pilot (test* OR stud* OR evaluat*)) OR TOPIC: (usability) OR TOPIC: (user (stud* OR test* OR evaluat*	Approximately 425,340

	OR experience)) OR TOPIC: (patient* (satisfact* OR opinion* OR knowledg* OR outcome* OR 'decisional conflict'))))	
# 1	TOPIC: (TOPIC: ((decision* OR decid*) (support* OR aid* OR tool* OR material*)) OR TOPIC: (decision (board* OR guide* OR counsel*)) OR TOPIC: ('computer decision making') OR TOPIC: ('shared decision making') OR TOPIC: (informed (choice* OR decision*)))	Approximately 33,450

Referencing IPDAS

Three hundred and twenty-two (322) articles refer to the International Patient Decision Aid Standards (IPDAS) primary publication, according to the Web of Science reference database. The citation for the IPDAS primary publication is here:

Glyn Elwyn, Annette O'Connor, Dawn Stacey, Robert Volk, Adrian Edwards, Angela Coulter, Richard Thomson, Alexandra Barratt, Michael Barry, Steven Bernstein, Phyllis Butow, Aileen Clarke, Vikki Entwistle, Deb Feldman-Stewart, Margaret Holmes-Rovner, Hilary Llewellyn-Thomas, Nora Mounjid, Al Mulley, Cornelia Ruland, Karen Sepucha, Alan Sykes, Tim Whelan, on behalf of the International Patient Decision Aids Standards (IPDAS) Collaboration. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. British Medical Journal. 2006 Aug 26;333(7565):417.

Embase.com – MEDLINE and Embase - Search conducted 2014/05/01

Line Number	Search String	Article Count
#38	#36 AND [medline]/lim	19,444
#37	#36 AND [embase]/lim	20,438
#36	#34 OR #35	27,147
#35	#7 AND #33	12,810
#34	#7 AND #17	20,865
#33	#18 OR #19 OR #20 OR #21 OR #22 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32	6,752,488
#32	cross AND sectional NEXT/2 (study OR studies)	153,915
#31	epidemiologic\$ NEXT/2 (study OR studies)	25,015
#30	observational NEXT/2 (study OR studies)	91,674
#29	'follow up' NEXT/2 (study OR studies)	51,565
#28	'case control' NEXT/2 (study OR studies)	114,434
#27	cohort NEXT/2 (study OR studies)	117,425
#26	'cohort analysis'/exp	164,730
#25	#23 NOT #24	243,865
#24	'randomized controlled trials'/exp	49,809
#23	'prospective study'/exp	245,239
#22	'retrospective study'/exp	335,655
#21	'longitudinal study'/exp	65,506

#20	'family study'/exp	10,382
#19	'case control study'	107,228
#18	'clinical study'/exp	6,550,290
#17	#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16	5,360,797
#16	patient* NEAR/3 (satisfact* OR opinion* OR knowledg* OR outcome* OR 'decisional conflict')	320,696
#15	user NEAR/5 (stud* OR test* OR evaluat* OR experience)	4,731
#14	usability	5,978
#13	pilot NEXT/1 (test* OR stud* OR evaluat*)	105,375
#12	acceptability	22,979
#11	'feasibility' NEAR/5 (test* OR stud* OR evaluat*)	82,306
#10	evaluat*	3,014,903
#9	'development'/exp OR 'development' NOT grow*	2,395,811
#8	(user OR human) NEXT/2 (centered OR centred)	887
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6	46,996
#6	informed NEAR/2 (choice* OR decision*)	8,121
#5	'shared decision making'	3,079
#4	computer* NEXT/2 'decision making'	631
#3	'decision-making computer assisted'/exp OR 'decision-making computer assisted'	12,338
#2	decision NEAR/3 (board* OR guide* OR counsel*)	5,375
#1	(decision* OR decid*) NEAR/4 (support* OR aid* OR tool* OR material*)	32,435

Cochrane Library – Searched conducted 2014/04/30

Line Number	Search String	Article Count
#19	#7 and #18	5524
#18	#8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17	188293
#17	patient* near/3 (satisfact* or opinion* or knowledg* or outcome* or 'decisional conflict')	33900
#16	user near/5 (stud* or test*)	1038
#15	usability	276
#14	pilot next/1 (test* or stud*)	15334
#13	acceptability	5694
#12	'feasibility' near/5 (test* or stud* or evaluat*)	6481
#11	evaluation	116006
#10	MeSH descriptor: [Computer Systems]	2946

	explode all trees	
#9	'development'	41021
#8	(user or human) next/2 (centered or centred)	147
#7	#1 or #2 or #3 or #4 or #5 or #6	8900
#6	informed near/2 (choice* or decision*)	1192
#5	'shared decision making'	1299
#4	computer* next/2 'decision making'	228
#3	MeSH descriptor: [Decision Making, Computer-Assisted] explode all trees	3552
#2	decision near/3 (board* or guide* or counsel*)	544
#1	(decision* or decid*) near/4 (support* or aid* or tool* or material*)	3178

User-Centered Design:

Ovid MEDLINE – Search Conducted 2014/09/26

#	Searches	Results
1	'user-centred design'.mp.	55
2	'user centered design'.mp.	185
3	'user-centered design'.mp.	185
4	'user centred design'.mp.	55
5	'human-centred design'.mp.	14
6	'human centered design'.mp.	39
7	'human-centered design'.mp.	39
8	'human centred design'.mp.	14
9	or/1-8	286

Embase.com – Search Conducted 2014/09/26

Line Number	Search String	Article Count
#9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	345
#8	'human centred design'	21
#7	'user centred design'	94

#6	'human-centred design'	21
#5	'user-centred design'	94
#4	'human-centered design'	46
#3	'user-centered design'	191
#2	'human centered design'	46
#1	'user centered design'	191

Cochrane Library – Search Conducted 2014/09/26

Line Number	Search String	Article Count
#9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	6
#8	'human centred design'	2
#7	'user centred design'	2
#6	'human-centred design'	2
#5	'user-centred design'	2
#4	'human-centered design'	0
#3	'user-centered design'	2
#2	'human centered design'	0
#1	'user centered design'	2

PubMed – Search Conducted 2014/09/26

((("user centered design" OR "user-centered design" OR "user centred design" OR "user-centred design")) OR ("human centered design" OR "human-centered design" OR "human centred design" OR "human-centred design"))

297 Results

Web of Science – Search Conducted 2014/09/26

Line Number	Search String	Article Count
#3	#2 OR #1	2187
#2	TOPIC: (("user-centred design")) OR TOPIC: (("user centred design")) OR TOPIC: (("user-centered design")) OR TOPIC: (("user centered design")) OR TOPIC: (("human-centred design")) OR TOPIC: (("human centred design")) OR TOPIC: (("human-centered design")) OR TOPIC: (("human centered design"))	2187
#1	TITLE: (("user-centred design")) OR TITLE: (("user centred design")) OR TITLE: (("user-centered design")) OR TITLE: (("user centered design")) OR TITLE: (("human-centred design")) OR TITLE: (("human centred design")) OR TITLE: (("human-centered design")) OR TITLE: (("human centered design"))	493

	design")) OR TITLE: (("human centered design"))	
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IEEE Xplore – Search Conducted 2014/09/29

("user centered design" or "user centred design" or "user-centered design" or "user-centred design") OR "human centered design" or "human centred design" or "human-centered design" or "human-centred design")

528 Results

Stacey RCT Search

CINAHL – Search Conducted 2015/07/09

#	Query	Results
S28	S17 and S27 Limiters - Exclude MEDLINE records	1,478
S27	S18 or S19 or S20 or S21 or S22 or S23 or S24 or S25 or S26	316,150
S26	TI (singl* or doubl* or tripl* or trebl*) and TI (blind* or mask*)	8,385
S25	AB (singl* or doubl* or tripl* or trebl*) and AB (blind* or mask*)	18,302
S24	AB (random* or trial or placebo*) or TI (random* or trial or placebo*)	190,656
S23	MH Quantitative Studies	13,556
S22	MH Placebos	9,296
S21	MH Random Assignment	39,367
S20	MH Clinical Trials+	189,073
S19	PT Clinical Trial	78,151
S18	PT “randomi?ed controlled trial”	50,591
S17	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16	99,603
S16	“informed choice*” or “informed decision*”	2,662
S15	“shared decision making”	1,468
S14	“adaptive conjoint analys?s”	13
S13	(interactive N2 “risk information”) or (interactive N2 “risk communication”) or	

	(interactive N2 "risk presentation") or (interactive N2 "risk graphic*")	2
S12	"interactive internet" or "interactive online" or "interactive graphic*" or "interactive booklet*" or (interacti* N3 tool*)	406
S11	"interactive health communication"	25
S10	computer* N1 "decision making"	1,072
S9	("risk communication" N3 tool*) or ("risk communication" N3 method*) or ("risk information" N3 tool*) or ("risk information" N3 method*) or ("risk assessment" N3 tool*) or ("risk assessment" N3 method*)	6,979
S8	"evidence based risk communication" or "evidence based risk information"	6
S7	"decision board*" or "decision guide*" or "decision counseling"	50
S6	(decision* N3 support*) or (decision* N3 aid*) or (decision* N3 tool*) or (decision* N3 instrument*) or (decision* N3 technolog*) or (decision* N3 technique*) or (decision* N3 system*) or (decision* N3 program*) or (decision* N3 algorithm*) or (decision* N3 process*) or (decision* N3 method*) or (decision* N3 intervention*) or (decision* N3 material*)	19,551
S5	"decision making" or "choice behavior" and MH consent	81,704
S4	MH decision making, computer assisted	1,049
S3	MH decision making, patient	11,144
S2	MH decision support systems, clinical	2,797
S1	mh decision support techniques+	4,578

Cochrane Library – Search conducted 2015/07/15

ID	Search	Hits
#1	(decision-support or decision-aid):kw in Trials	1140
#2	decision-tree:kw in Trials	42

#3	patient-decision-making:kw	117
#4	(decision-making or choice-behavior):ti,ab,kw and (informed-consent:kw,ti or (patient or parent* or carer or caregiver or care- giver):ti,ab,kw) in Trials	2397
#5	((decision or decid*) near/4 (support* or aid* or tool or instrument or technolog* or technique or system or program* or algorithm or process or method or intervention or material)):ti,ab,kw	3559
#6	(decision next (board or guide or counseling)):ti,ab,kw	15
#7	((risk-communication or risk-assessment or risk-information) near/4 (tool or method)):ti,ab,kw	197
#8	(computer* near/2 decision-making):ti,ab,kw	196
#9	(interactive-health-communication or (interacti* near/4 tool)):ti,ab,kw	46
#10	(interactive next (internet or online or graphic* or booklet)):ti,ab,kw	59
#11	((interactiv* or evidence-based) near/3 (risk-information or risk-communication or risk-presentation or risk-graphic*)):ti,ab,kw	6
#12	shared-decision-making:ti,ab,kw	267
#13	(informed next (choice or decision)):ti,ab,kw	263
#14	adaptive-conjoint-analysis:ti,ab,kw	3
#15	(#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14)	5813
#16	decision:ti,ab	7823
#17	patient:ti,ab	104242
#18	consumer:ti,ab	853
#19	#16 and (#17 or #18)	2491
#20	shared decision making:ti,ab	356
#21	decision aid\$:ti,ab	570

#22	informed choice:ti,ab	555
#23	#19 or #20 or #21 or #22	3408
#24	#15 or #23	7190
Trials - 4798		

EMBASE – Search Conducted 2015/07/09

'decision support system'/exp OR 'patient decision making'/exp OR 'decision aid' OR 'decision tree'/exp OR ('decision making':ab,ti AND 'informed consent':ab,ti) OR ((decision* OR decid*) NEAR/4 (support* OR aid* OR tool* OR instrument* OR technolog* OR technique* OR system* OR program* OR algorithm* OR process* OR method* OR intervention* OR material*)):ab,ti OR decision NEAR/1 (board* OR guide* OR counseling) OR ('risk communication' OR 'risk assessment' OR 'risk information') NEAR/4 (tool* OR method*) OR computer* NEAR/2 'decision making' OR interactive NEXT/1 health NEXT/1 communication* OR interactive NEAR/1 (internet OR online OR graphic* OR booklet*) OR interacti* NEAR/4 tool* OR (interactiv* OR 'evidence based') NEAR/3 ('risk information' OR 'risk communication' OR 'risk presentation' OR 'risk graphic' OR 'risk graphics') OR 'shared decision making' OR informed NEAR/1 (choice* OR decision*) OR adaptive NEXT/1 conjoint NEXT/1 analys?s AND ('randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR random* OR placebo* OR (singl* OR doubl*) NEAR/1 (blind* OR mask*) OR crossover OR 'cross over' OR factorial* OR 'latin square' OR assign* OR allocat* OR volunteer*) NOT ('nonhuman'/exp NOT ('human'/exp AND 'nonhuman'/exp)) NOT [medline]/lim OR ('decision making'/exp OR 'decision theory'/exp OR decision\$ OR 'educational technology'/exp AND ('health behavior'/exp OR 'patient attitude'/exp OR 'health education'/exp OR 'informed consent' OR patient OR consumer) OR (patient\$ OR consumer\$) NEAR/1 (decision\$ OR choice OR preference OR participation) OR (women OR men) NEAR/1 (decision\$ OR choice OR preference OR participation) OR parent\$ NEAR/1 (decision\$ OR choice OR preferenc\$ OR participat\$) OR (personal OR interpersonal OR individual) NEAR/1 (decision\$ OR choice OR preference\$ OR participat\$) OR 'shared decision making' OR decision NEXT/1 aid\$ OR 'informed choice' AND ('randomized controlled trial'/exp OR 'controlled clinical trial'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR random* OR placebo* OR (singl* OR doubl*) NEAR/1 (blind* OR mask*) OR crossover OR 'cross over' OR factorial* OR 'latin square' OR assign* OR allocat* OR volunteer*) NOT ('nonhuman'/exp NOT ('human'/exp AND 'nonhuman'/exp)) NOT [medline]/lim) AND [2011-2015]/py

8917 Hits

Ovid MEDLINE – Search Conducted 2015/07/09

#	Searches	Results
1	decision support techniques/	13785
2	decision support systems clinical/	5325
3	decision trees/	9233
4	(decision making or choice behavior).mp. and informed consent.sh.	4424
5	((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).tw.	50856
6	(decision adj (board* or guide* or counseling)).tw.	131
7	((risk communication or risk assessment or risk information) adj4 (tool* or method*)).tw.	3789
8	decision-making computer assisted/	2555
9	(computer* adj2 decision making).tw.	161
10	interactive health communication*.tw.	54
11	(interactive adj (internet or online or graphic* or booklet*)).tw.	529
12	(interacti* adj4 tool*).tw.	2527
13	((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).tw.	21
14	shared decision making.tw.	2829
15	(informed adj (choice* or decision*)).tw.	6095
16	adaptive conjoint analys#s.tw.	39
17	or/1-16	88294
18	randomized controlled trial.pt.	405032

19	controlled clinical trial.pt.	91212
20	randomized.ab.	327382
21	placebo.ab.	166089
22	clinical trials as topic.sh.	177247
23	randomly.ab.	236144
24	trial.ti.	144027
25	or/18-24	983099
26	exp animals/ not humans.sh.	4078149
27	25 not 26	907197
28	17 and 27	6611
29	choice behavior/	23310
30	decision making/	72450
31	exp decision support techniques/	64270
32	Educational Technology/	1154
33	decision\$.tw.	237905
34	(choic\$ or preference\$).tw.	331004
35	communication package.tw.	13
36	exp health education/	140894
37	Health Knowledge, Attitudes, Practice/	78625
38	informed consent.tw,hw.	49648
39	patient.tw,hw.	2013415
40	consumer.tw,hw.	68108

41	((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.	10200
42	((women or men) adj1 (decision\$ or choice or preference or participation)).tw.	282
43	(parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.	2497
44	((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.	3624
45	shared decision making.tw.	2829
46	decision aid\$.tw.	1621
47	informed choice.tw.	1062
48	or/29-35	634345
49	or/36-40	2200111
50	48 and 49	161265
51	or/41-47	20949
52	50 or 51	169374
53	clinical trial.pt.	502914
54	randomized controlled trial.pt.	405032
55	random\$.tw.	786219
56	(double adj blind\$).tw.	123876
57	double-blind method/	133324
58	or/53-57	1183857
59	52 and 58	20340
60	28 not 59	4032
61	28 or 59	24372

PsycINFO – Search Conducted 2015/07/09

#	Search	Results
1	decision support systems/	(2433)
2	(decision making or choice behavior).mp. and (informed consent.sh. or (patient* or parent* or carer* or caregiver* or care giver*).mp.)	(18144)
3	((decision* or decid*) adj4 (support* or aid* or tool* or instrument* or technolog* or technique* or system* or program* or algorithm* or process* or method* or intervention* or material*)).ti,ab,id.	(30851)
4	(decision adj (board* or guide* or counseling)).ti,ab,id.	(53)
5	((risk communication or risk assessment or risk information) adj4 (tool* or method*)).ti,ab,id.	(836)
6	computer assisted therapy/	(617)
7	(computer* adj2 decision making).ti,ab,id.	(176)
8	interactive health communication*.ti,ab,id.	(39)
9	(interactive adj (internet or online or graphic* or booklet*)).ti,ab,id.	(252)
10	(interacti* adj4 tool*).ti,ab,id.	(781)
11	((interactiv* or evidence based) adj3 (risk information or risk communication or risk presentation or risk graphic*)).ti,ab,id.	(12)
12	shared decision making.ti,ab,id.	(1415)
13	(informed adj (choice* or decision*)).ti,ab,id.	(2528)
14	adaptive conjoint analys#s.ti,ab,id.	(36)
15	or/1-14	(49434)
16	random*.ti,ab,hw,id.	(143994)
17	intervention.ti,ab,hw,id.	(184957)
18	trial.ti,ab,hw,id.	(76557)
19	placebo*.ti,ab,hw,id.	(33115)

20	((singl* or doubl* or trebl* or tripl*) and (blind* or mask*)).ti,ab,hw,id.	(23459)
21	(cross over or crossover).ti,ab,hw,id.	(7681)
22	latin square.ti,ab,hw,id.	(454)
23	(assign* or allocat* or volunteer*).ti,ab,hw,id.	(127327)
24	treatment effectiveness evaluation/	(18683)
25	mental health program evaluation/	(1929)
26	exp experimental design/	(49987)
27	or/16-26	(492822)
28	15 and 27	(9249)

PRISMA Flow Diagram

Database	Search Approach	Article Count	Date Searched
IEEE Xplore	User-Centred Design	528	2014/09/29
Web of Science	User-Centred Design	2187	2014/09/26
PubMed	User-Centred Design	297	2014/09/26
Cochrane Library	User-Centred Design	6	2014/09/26
Embase.com	User-Centred Design	345	2014/09/26
Ovid MEDLINE	User-Centred Design	286	2014/09/26
Cochrane Library	Decision Aids	5524	2014/04/30
Embase (Embase.com)	Decision Aids	20,438	2014/05/01
MEDLINE (Embase.com)	Decision Aids	19,444	2014/05/01
Web of Science	Decision Aids	15,597	2014/05/11
Web of Science	Referencing Elwyn	322	2014/05/01
CINAHL	RCT Search	1478	2015/07/09
Cochrane Library	RCT Search	4798	2015/07/15
Embase (Embase.com)	RCT Search	8917	2015/07/09
Ovid MEDLINE	RCT Search	24,372	2015/07/09
Ovid PsycINFO	RCT Search	9249	2015/07/09
References Not Included in Stacey Cochrane Review		10	2014/09/30

Results of Reference Searching of Screened Articles		16	
Cited in Searches in the Stacey Cochrane Review		46	
Other Screening Results			
Combined	Decision Aids	39465	2014/05/11
Combined	User Centered	3500	2014/09/26
Title and Abstract Screening	Decision Aids	662 Articles Retained	2014/06/16
Title and Abstract Screening	User Centered	153 Articles Retained	2014/06/30
Full-Text Screening	Decision Aids	366 Articles Retained	2014/06/30
Full-Text Screening	User Centered	76 Articles Retained	
RCT Search	RCT Search	40,476 Articles	2015/07/09
Title and Abstract Screening	RCT Search	163 Articles Retained	
Full Text Screening	RCT Search	23 Articles Retained	2015/09/03
Total Articles from All Searches		537 Articles	

PRISMA Flow Diagram

Decision Aid Searches

**537 Total
Articles**

User-Centered Design Searches

RCT Searches

References from
Screened Articles
16 Articles

References not
in Stacey
2014/09/30
10 Articles

References Cited
by Stacey
46 Articles

Appendix 2 : Draft Data Extraction Plan

When assigning data extraction pairs, have a step between to avoid double entry.

Global Definitions (in addition to those that appear right in the question):

- **PFCS (patient/family and friends/caregiver/surrogate) users** (actual or potential) are people who **are** (= actual) or who **might be** (= potential) either:
 - **patients** who might use this tool to address their own personal health issue,
 - **family and friends** who might support a patient through this health issue (but who are not yet caregivers or surrogate decision makers),
 - **caregivers** of people with a health issue (meaning they provide practical care and support full- or part-time), or
 - **surrogate** decision makers for someone with a health issue (meaning the person is incapacitated and the surrogate must make decisions on their behalf, also includes proxy decision makers, i.e., those who were not necessarily identified ahead of time)
- **Clinician users** (actual or potential): Health care professionals who: (1) provide care to people who face this health issue, (2) are not career researchers, and (3) have no stake in showing that the tool/decision aid works.
- **Not reported** = Authors do not mention this
- **Unclear** = may be mentioned but not clear what was done

Acronyms:

PFCS = patient/family and friends/caregiver/surrogate

UCD = user-centered design

HCD = human-centered design

Identification

Research assistant name: [automatic]

Date of extraction: [automatic]

[] Flag for exclusion (on second reading, this may not be relevant after all -> STOP extracting, go on to next article, we will discuss this at next team meeting)

1. Article ID [number from screening process]:

Number is from (check one):

- ☐ Main search
- ☐ UCD/HCD search
- ☐ Hand searches

2. First author last name (will be used to link articles):

3. Corresponding author last name (will be used for mail merge):

- ☐ Check if corresponding author is first author

4. Corresponding author email:

5. Does this article have to do with a decision aid or something else? (check one)

- ☐ Decision aid
- ☐ Other

6. Name of decision aid or tool (if available):

7. [] This article references other linked articles (e.g., an evaluation article that cites development in another article, or, occasionally, a development article citing an evaluation article)

copy and paste reference(s): _____

first author of reference 1 (will be used to link articles):

first author of reference 2 (will be used to link articles):

first author of reference 3 (will be used to link articles):

Questions about ARTICLE TYPE

REMINDER All articles in this review should fall into at least one of these circles:

Not to scale. (Elements of diagram may not be proportionally representative.)

*Includes all types of evaluation studies, e.g., trials, pilot, feasibility, etc.

8. Does this article describe (check all that apply):

- ☐ **Development** of a patient decision aid (PtDA) or other patient oriented tool (at least one step described)?
- ☐ **Evaluation** of a patient decision aid (PtDA) or other patient oriented tool?
- ☐ **User-centered design** for a patient decision aid (PtDA) or other patient oriented tool?

Comments _____

9. Does this report describe (check all that apply): (should always be checked for evaluation articles, may or may not be checked for development articles)

- ☐ Evaluation of any of: feasibility, acceptability, satisfaction with tool/decision aid, usability, other preliminary metric of evaluation (typically measured BEFORE implementation)
- ☐ Evaluation of efficacy (e.g., capacity to increase patient knowledge or decrease decisional conflict within the context of a formal study, e.g., RCT) or Effectiveness (e.g., effects in real-world conditions – this is effects on patients)
- ☐ Evaluation of implementation (e.g., integration into routine care, barriers and facilitators to usage, uptake, how many times decision aid used over period of time – this is things like usage statistics)
- ☐ Other _____
- ☐ None of the above reported

Comments _____

10. What clinical context is addressed by this decision aid or tool? (check all that apply):

- ☐ Cancer
 - ☐ Prostate
 - ☐ Breast
 - ☐ Ovarian
 - ☐ Colorectal
 - ☐ Lung
 - ☐ Other: _____

- ☐ Chronic Conditions
 - ☐ Diabetes
 - ☐ Chronic Obstructive Pulmonary Disorder (COPD)
 - ☐ Cardiovascular Health (Heart disease, stroke, etc.)
 - ☐ Disability
 - ☐ Other: _____
- ☐ Reproductive Health
- ☐ Advanced Care Planning
- ☐ Vaccine Preventable Diseases
- ☐ Not reported
- ☐ Other: _____

N.B. We will check the "Other" fields regularly to see if we have new categories that need to be added

11. What type of decision or health issue is addressed by this decision aid or tool? (check all that apply):

- ☐ Prevention
- ☐ Genetic Testing
- ☐ Screening
- ☐ Diagnostic Testing
- ☐ Treatment
- ☐ Everyday Life
- ☐ Not reported
- ☐ Unclear
- ☐ Other: _____

N.B. We will check the "Other" fields regularly to see if we have new categories that need to be added

[LOGIC: Before moving on to next page, validate that if any of the first three options for question 9 are checked, then Evaluation is checked in question 8.

Guidelines & Theories/Frameworks/Models

12. Does the article describe any guideline, theory, framework or model on which the tool was based/developed? (check all that apply):

- ☐ Analytic Hierarchy Process
- ☐ Differentiation and Consolidation Theory
- ☐ Edutainment Decision Aid Model (EDAM)
- ☐ Elaboration Likelihood Model
- ☐ Expected Utility Theory
- ☐ Fast and Frugal Heuristics
- ☐ International Patient Decision Aid Standards (IPDAS)
- ☐ Multiattribute Utility Theory
- ☐ Ottawa Decision Support Framework
- ☐ Precaution Adoption Model
- ☐ Preventive Health Model
- ☐ Stages of Change
- ☐ Theory of Planned Behaviour
- ☐ User-centered design
- ☐ Other theory/framework/model (IMPORTANT: We will check this regularly) _____
- ☐ No theory/framework reported (go to next question)

Questions about TOOL

13. Format of tool (check all that apply):

- ☐ Paper (booklet, leaflet, etc.)
- ☐ Paper delivered online (printable pdf file, pdf emailed, etc.)
- ☐ Recording (DVD/laser disc, audio tape, video – not Internet video)
- ☐ Conversation (discussion guided by a list, decision board, etc.)
- ☐ Electronic application – not online (look for words: CD-ROM, computer program)
- ☐ Online application (look for words: online/Internet/Web-based)
- ☐ Mobile App (look for words: native apps, mobile-enabled websites intended for use on mobile devices)
- ☐ **Offered** in multiple formats (can be used separately, e.g., a paper version and web version, choose which one you want; option to print summary at end of web-based version)
- ☐ **Requires** multiple formats (e.g., booklet with an audiotape)
- ☐ Other _____
- ☐ Not reported
- ☐ Unclear

Comments _____

14. Context in which the tool is intended be used (check all that apply, do not interpret, report what the authors say):

- ☐ At home or in a private setting
- ☐ In a health care setting but not during a clinical encounter (in waiting room, in a separate room, etc. – no clinician present)
- ☐ During an in-person clinical encounter (requires clinician presence)
- ☐ During a virtual clinical encounter (e.g., telemedicine)
- ☐ Everyday life (can be used everywhere, e.g., wheelchair)
- ☐ Other _____
- ☐ Not reported
- ☐ Unclear

Comments _____

15. Timing of tool usage (check all that apply, do not interpret, report what the authors say):

- ☐ Before clinical encounter (in preparation for discussion)
- ☐ During clinical encounter [LOGIC: Automatically check if previous is during clinical encounter]
- ☐ Between clinical encounter
- ☐ Not associated with clinical encounter
- ☐ Other (e.g., After clinical appointment with no intention for followup, e.g. to support a decision already made) _____
- ☐ Not reported
- ☐ Unclear

Comments _____

Questions about DEVELOPMENT process

REMINDER We are using this framework of user-centred design:

16. Did the development team go through the following development steps?

Literature review (reviewing articles, reading about the issue, etc.) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Observation of existing processes (sitting in the room, video-recording the process, some other way of recording/observing the process, etc.) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Formal needs assessment (formal = calls itself a needs assessment) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Informal needs assessment (informal = doesn't use the term needs assessment, but that's what they were looking for, e.g., we previously interviewed patients ...) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Develop and/or validate underlying model (e.g., decision analytic model, look for terms: Markov, decision tree, microsimulation) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Storyboarding, wireframing (may or may not be called storyboarding, involves sketching out what the tool is going to look like and the different steps involved in using it) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Adapt, translate tool (e.g., language, literacy level, clinical context, e.g., breast to prostate cancer, watch for author names: O'Connor, Stacey) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Content review PRIOR to prototype development (often, but not always, done with an "expert panel") (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Prototype development (may have >1 round of development) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear
- ☐ Not applicable (evaluation report)

Content/format review (this means **looking** at the tool but not **using** it) AFTER prototype development (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear

Pilot/usability testing (this means **using** the tool) (choose one)

- ☐ Yes
- ☐ No/Not reported
- ☐ Unclear

☐ They did something with the prototype but I'm unclear whether it's content/format review or pilot/usability testing

Other step _____
 Other step _____
 Other step _____
 Other step _____

17. In what order & how many participants?

	Order (1 = first step, 2 = second step, etc. If multiple steps were done at the same time, use the same number for each. U = order unclear NR = order not reported.)	Were PFCS users (actual or potential) involved in this step? (Y = yes, N = no, U = unclear, NR = not reported)	If yes, how many? (report number, 0 = none, U = number unclear, NR = number not reported)	If yes, how many of the number on the left were NEW users (i.e., people who had not seen the tool/decision aid before)? (report number, 0 = none, U = number unclear)	If yes, were they involved individually (i.e., via interviews) or in groups (i.e., via focus groups)? IN = interviews, FG = focus groups, B = both, U = unclear, NR = not reported, O = other (explain in comment)
Step checked off above					
Step checked off above					
Etc.					

18. Was there an iterative development process? (Looks for mention of initial version, final version, etc.)
 (choose one)

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

19. If 18 = yes, how many cycles were there? (Recall: One cycle = one prototype/version, each new cycle = showed it to someone, made a change to create new prototype) (choose one)

- ☐ Exactly this many _____

- At least this many _____, unclear on whether there were more
- At least this many _____ and probably more (subjective judgment)
- Unclear

20. If 18 = yes, do the authors describe what changes were made between versions/prototypes? (choose one)

- Yes
- No
- Not reported
- Unclear

21. In my opinion, this development process was: (OPTIONAL, check all that apply, **highly subjective**, we are flagging this for additional reading/citation)

- ☐ A very **good** development process
- ☐ A very **clearly described** process
- ☐ Other comments _____

22. After having any working prototype (initial version, final version, etc.) of their tool, does the article indicate that the developers did any of the following ... (check all that apply)

ASK words to look for as clues: semi-structured interviews, focus groups, opinions, satisfaction, etc.

- ☐ ASK **PFCS users** (actual or potential) their thoughts & opinions of the tool
- ☐ ASK **clinician users** their thoughts & opinions of the tool
- ☐ ASK **non-users** (e.g., content experts, steering committee, etc.) their thoughts & opinions of the tool

OBSERVE (often real time; words to look for as clues: « think-aloud », usability testing, pilot testing, etc.)

- ☐ OBSERVE **PFCS users** (actual or potential) interacting with the tool
- ☐ OBSERVE **clinician users** interacting with the tool
- ☐ OBSERVE **non-users** (e.g., content experts, steering committee, etc.) interacting with the tool

ASSESS the impact of the tool (often afterwards; words to look for as clues: measure, collected, questionnaire, instrument, etc.)

- ☐ ASSESS the impact of the tool on **PFCS users** (actual or potential)
- ☐ ASSESS the impact of the tool on **clinician users**
- ☐ ASSESS the impact of the tool on **non-users** (e.g., content experts, steering committee, etc.)

Questions about PEOPLE involved

23. Were **PFCS users** (potential or actual) involved: (check all that apply)

- ☐ On the research/development team (look at author list for clues)
- ☐ In a separate advisory capacity (e.g., patient advisory committee, individual patients consulted as advisors)
- ☐ As participants in studies
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____
- ☐ Not reported
- ☐ Unclear

Comments _____

24. Was there a **PFCS advisory panel** (e.g., patient steering committee) involved? (do not interpret, report what they say) (check one)

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

Comments _____

25. Was the involvement approved by an ethics board?

26. Were the following **kinds** of users involved?

(a) Patients/members of the public

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

IF YES when did/might they face the situation (health issue):

- ☐ Faced this situation **in the past** (e.g., they have made this decision before, they could have used this tool before)
- ☐ Are **currently** facing this situation (e.g., actually making this decision now, need this tool now)
- ☐ **Might** face this situation **in future** (often general public)
- ☐ Have not and will not face this situation
- ☐ Not reported
- ☐ Unclear

(b) Family members/Friends (not caregivers, not surrogates, just there to support)

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

IF YES when did/might they face the situation (health issue):

- ☐ Faced this situation **in the past** (e.g., they have made this decision before, they could have used this tool before)
- ☐ Are **currently** facing this situation (e.g., actually making this decision now, need this tool now)
- ☐ **Might** face this situation **in future**
- ☐ Have not and will not face this situation
- ☐ Not reported
- ☐ Unclear

(c) Caregivers

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

IF YES when did/might they face the situation (health issue):

- ☐ Faced this situation **in the past** (e.g., they have made this decision before, they could have used this tool before)
- ☐ Are **currently** facing this situation (e.g., actually making this decision now, need this tool now)
- ☐ **Might** face this situation **in future**
- ☐ Have not and will not face this situation
- ☐ Not reported
- ☐ Unclear

(d) Surrogate decision-makers

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

IF YES when did/might they face the situation (health issue):

- ☐ Faced this situation **in the past** (e.g., they have made this decision before, they could have used this tool before)
- ☐ Are **currently** facing this situation (e.g., actually making this decision now, need this tool now)
- ☐ **Might** face this situation **in future**
- ☐ Have not and will not face this situation
- ☐ Not reported
- ☐ Unclear

27. If any of 26 are Yes, are the following sociodemographic characteristics of PFCS users reported (look for a Table 1)?

(a) Age

- ☐ Yes
- ☐ Not reported

- Unclear

(b) Gender

- Yes
- Not reported
- Unclear

(c) Race and/or Ethnicity

- Yes
- Not reported
- Unclear

(d) Education

- Yes
- Not reported
- Unclear

(e) Income

- Yes
- Not reported
- Unclear

(f) Literacy or Health Literacy

- Yes
- Not reported
- Unclear

(g) Numeracy or Subjective Numeracy

- Yes
- Not reported
- Unclear

(h) Clinical Characteristics (e.g., stage of disease, some measure of health)

- Yes
- Not reported
- Unclear

28. What kinds of disadvantaged and/or underserved populations were represented in this development process? (check all that apply, N.B. there may be overlaps in the categories; checking these boxes will trigger a second reading of this article, these will not be left as the final word.)

- ☐ People who may be disadvantaged and/or underserved due to **physical** characteristics (e.g., race, ethnicity, age >65, age <18, sex, gender, gender identity, sexual orientation, etc.)
 - Comments _____
- ☐ People who may be disadvantaged and/or underserved due to **health** characteristics (e.g., comorbidities or multimorbidity, terminal illness, visual or hearing disability, other kind of disability, etc.)
 - Comments _____

- ☐ People who may be disadvantaged and/or underserved due to **psychological** characteristics (e.g., mental illness, lack of social support, etc.)
 - Comments _____
- ☐ People who may be disadvantaged and/or underserved due to **cognitive** characteristics (e.g., low literacy or health literacy, low numeracy, learning differences, dementia, etc.)
 - Comments _____
- ☐ People who may be disadvantaged and/or underserved due to **socioeconomic** characteristics (e.g., education, income, rural or remote location, recent immigrants, housing insecurity, food insecurity, less access to care, speak a different language than the local language, low Internet access, etc.)
 - Comments _____
- ☐ People who may be disadvantaged and/or underserved due to potential **discrimination or stigma** in the health care system (e.g., people who are obese, who have alcohol or drug dependencies, who are sex workers, etc.)
 - Comments _____
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____
- ☐ None of the above

29. How were **PFCS users** recruited? (check all that apply)

- ☐ Convenience sample (“our clinic”, “3 clinics”)
- ☐ Snowball sampling (authors will use this word)
- ☐ Purposive sampling (authors may use this word, may refer to quotas)
- ☐ Community groups (e.g., support groups, community centres)
- ☐ Registries
- ☐ Flyers/posters
- ☐ Online panel (includes MTurk)
- ☐ Random sample
- ☐ Not reported
- ☐ Unclear
- ☐ Comments _____

30. Were **PFCS users** compensated/incentivized in any way?

- ☐ Yes (check all that apply)
 - cash
 - gift cards/points
 - parking/transportation
 - drawings/lottery
 - refreshments
 - unclear
 - other _____
- ☐ No, no funds or equivalent exchanged hands in any way
- ☐ Not reported
- ☐ Comments _____

31. Did the research team consult with **clinician users** who were **not researchers with a stake in the tool** and **who might potentially see patients who would need the decision aid/tool**? (check one)

- ☐ Yes

- ☐ No
- ☐ Not reported
- ☐ Unclear

Comments _____

32. (Display logic: only include if 31 is yes) How many **clinician users** were consulted in total?

Number : _____

Total not clear but it was at least this many : _____

- ☐ Not reported
- ☐ Unclear

Comments _____

33. (Display logic: only include if 31 is yes) When were **clinician users** consulted? (check all that apply)

- ☐ Before first prototype was developed
- ☐ After first prototype was developed, but before final prototype was developed
- ☐ After final prototype was developed
- ☐ Not reported
- ☐ Unclear

Comments _____

34. (Display logic: only include if 31 is yes) Did the developers make any changes to tool based on **clinician users'** feedback? (check all that apply)

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear

Comments _____

35. (Display logic: only include if 31 is yes) Were **clinician users** compensated/incentivized in any way?

- ☐ Yes (check all that apply)
 - ☐ cash
 - ☐ gift cards/points
 - ☐ parking/transportation
 - ☐ drawings/lottery
 - ☐ refreshments
 - ☐ unclear
 - ☐ other _____

☐ No, no funds or equivalent exchanged hands in any way

☐ Not reported

☐ Comments _____

36. Was there an **expert panel** (panel of academics, clinicians, etc.) involved? (check one)

- ☐ Yes
- ☐ No
- ☐ Not reported
- ☐ Unclear
- ☐ Not applicable

Comments _____

37. Did any users have formal links with specific patient/consumer organization (ex. employee or volunteer within disease-specific patient)?

- ☐ Yes, describe: _____
- ☐ Yes, describe: _____
- ☐ Yes, describe: _____
- ☐ Yes, describe: _____
- ☐ No/Not reported
- ☐ Unclear

38. Did any users have formal links with specific clinical organization? (e.g. Royal College of Physicians, American Medical Association, American Association of Clinical Radiologists, etc.)

- ☐ Yes, describe: _____
- ☐ Yes, describe: _____
- ☐ Yes, describe: _____
- ☐ Yes, describe: _____
- ☐ No/Not reported
- ☐ Unclear

39. What **other (i.e. other than patients, family and friends, caregivers, surrogates and clinician users)** kinds of relevant people were involved? (what they report in article, do not infer, but look for synonyms and flag for discussion at team meeting by adding a comment)

- ☐ Human factors. usability experts
- ☐ Designers (e.g., interaction designers, interface designers, user experience designers, human computer interaction experts, etc.)
- ☐ Graphic designers (e.g. illustrators, data display experts, photographers, videographers)
- ☐ Web/app/system developers
- ☐ Data security experts
- ☐ Plain language, literacy experts
- ☐ Decision experts, decision science experts
- ☐ Experts in counseling
- ☐ Patient education experts
- ☐ Social media experts
- ☐ Online community managers
- ☐ Managers, administrators, and organisational decision-makers
- ☐ Policymakers and planners
- ☐ Communication campaign experts
- ☐ Other _____
- ☐ Other _____
- ☐ Other _____
- ☐ Not reported
- ☐ Not applicable
- ☐ Comments _____

Quality appraisal (i.e., can we have confidence in the data?)

40. Check all sections apply to this article, then answer the subquestions:

- ☐ (automatically checked) For **all** studies, check whether the article describes (check all that apply):
 - ☐ Description of the context (clinical context, setting, etc.)
 - ☐ Description of the purpose of the study
- ☐ For **development** studies, check whether the article describes (check all that apply):
 - ☐ Description of how development occurred (i.e., at least one step described in full, not just, “we developed a decision aid,”)
 - ☐ Description of how **content** was developed and/or refined
 - ☐ Description of how **format** was developed and/or refined
 - ☐ Description of how data were used to refine tool
- ☐ Does the article **report results** relating to human study participants? If yes, check whether the article describes (check all that apply):
 - ☐ Description of participants (age, gender, clinical characteristics, etc.)
 - ☐ Justification of sampling (why they recruited the people they recruited)
 - ☐ Description of data collection and analysis (what data did they collect and what did they do with it)
 - ☐ Justification of measurements (e.g., validated measures, standard measures, reasons for choices, etc.) (look for: citations, “validated measure”, Cronbach alpha)
- ☐ For **non-experimental evaluation** studies, check whether the article describes (check all that apply):
 - ☐ Control of potentially confounding variables (look for: age, education, literacy, etc.)
- ☐ For **experimental evaluation** studies (e.g., randomized controlled studies), check whether the article describes (check all that apply):
 - ☐ Method of randomization and/or sequence generation
 - ☐ Allocation concealment and/or blinding (i.e., study participants don’t know to which arm they were assigned)
 - ☐ Reported number of dropouts or complete outcome data

Comments _____

Quality score = $100 * \text{number of checked items} / \text{number of possible checked items}$.

N.B. We will collect this for descriptive reasons but won’t set a threshold (yet) because part of the point of this whole review is that we don’t know what the best methods are, so things like, “appropriate sampling,” are impossible to judge.

Appendix 3. Full details of data, analyses, and study quality

(Text in grey and in parentheses gives the variable name in the dataset for readers who wish to further explore the provided data.)

Table S3.1 Theories, models, frameworks, or standards guiding the development process

	Patient decision aid projects (n=325) n (%) (da = 1)	User-centered design projects (n=65) n (%) (da = 0)
No theory/model/framework/standard reported (ThmoFr16)	167 (51)	0 (0)
Other theory/model/framework/standard: PtDA: social cognitive theory, CREDIBLE criteria, Janis and Mann conflict model of decision making; UCD: Bates' model for information seeking behavior, Human Factors techniques, Information theory; Medical Research Council (MRC) framework, Patient-Clinician-Designer (PCD) Framework. ^{ne} (ThmoFr13)	67 (21)	11 (17)
International Patient Decision Aids Standard (IPDAS) ^{ne} (ThmoFr1)	63 (19)	0 (0)
Ottawa Decision Support Framework ^{ne} (ThmoFr9)	56 (17)	0 (0)
Stages of Change ^{ne} (ThmoFr12)	9 (3)	1 (2)
Theory of Planned Behaviour ^{ne} (ThmoFr14)	9 (3)	2 (3)
Multiattribute Utility Theory ^{ne} (ThmoFr8)	5 (2)	0 (0)

Analytic Hierarchy Process ^{ne} (Thmofr2)	3 (1)	1 (2)
Edutainment Decision Aid Model (EDAM) ^{ne} (Thmofr4)	3 (1)	0 (0)
User-Centered Design ^{ne} (Thmofr15)	2 (1)	65 (100)
Elaboration Likelihood Model ^{ne} (Thmofr5)	2 (1)	0 (0)
Expected Utility Theory ^{ne} (Thmofr6)	2 (1)	0 (0)
Differentiation and Consolidation Theory ^{ne} (Thmofr3)	1 (<1)	0 (0)
Fast and Frugal Heuristics ^{ne} (Thmofr7)	1 (<1)	0 (0)
Precaution Adoption Model ^{ne} (Thmofr10)	1 (<1)	0 (0)
Preventive Health Model ^{ne} (Thmofr11)	0 (0)	0 (0)

^{ne}except for "No theory/model/framework/standards reported", categories are not mutually exclusive

Table S3.2 Tool characteristics

		Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Format of the tool ^{ne}	Paper (Format1)	198 (61)	2 (3)
	Recording (Format2)	89 (27)	0 (0)
	Requires multiple formats (Format7)	77 (24)	14 (22)
	Electronic application (Format10)	72 (22)	8 (12)

	Offered in multiple formats (Format6)	71 (22)	6 (9)
	Online application (Format17)	70 (22)	27 (42)
	Conversation (Format3)	55 (17)	3 (5)
	Paper delivered online (Format9)	18 (6)	0 (0)
	Other (PtDA: self-examination tutorial; UCD: virtual environment, appointment reminders, assistive device...) (Format5)	2 (1)	23 (35)
	Mobile App (Format11)	1 (<1)	23 (35)
	Unclear or Not reported (Format4, Format8)	0 (0)	0 (0)
Clinical context addressed by the tool ^{ne}	Breast Cancer (Clincon9)	64 (20)	1 (2)
	Reproductive Health (Clincon3)	61 (19)	1 (2)
	Prostate Cancer (Clincon1)	47 (14)	1 (2)
	Other: PtDA: Benign prostatic hyperplasia, smoking, dementia; UCD: elderly, dementia (Clincon8)	35 (11)	14 (22)
	Other (Chronic): PtDA: Knee osteoarthritis, Multiple sclerosis, osteoporosis; UCD:	35 (11)	11 (17)

	Obesity (Clincon17)		
	Cardiovascular Health (Heart disease, stroke, etc...) (Clincon15)	29 (9)	5 (8)
	Colorectal Cancer (Clincon11)	26 (8)	0 (0)
	Ovarian Cancer (Clincon10)	17 (5)	0 (0)
	Mental health (Clincon18)	11 (3)	7 (11)
	Advance Care Planning (Clincon4)	10 (3)	0 (0)
	Diabetes (Clincon2)	8 (2)	7 (11)
	Vaccine-Preventable Disease (Clincon5)	7 (2)	2 (3)
	Lung Cancer (Clincon12)	7 (2)	0 (0)
	Cancer in general, not specific (Clincon_anycancer)	7 (2)	2 (3)
	Disability (Clincon16)	6 (2)	16 (25)
	Other Cancer: PtDA: cervical cancer, Ductal carcinoma in situ (DCIS), melanoma, Papillary Thyroid Cancer (Clincon13)	4 (1)	0 (0)
	Chronic Obstructive Pulmonary Disorder (COPD) (Clincon14)	2 (1)	3 (5)

	Not reported (Clincon6)	0 (0)	1 (2)
Type of decision or health issue addressed by the tool ^{ne}	Treatment (Typdec5)	184 (57)	7 (11)
	Screening (Typdec3)	68 (21)	1 (2)
	Prevention (Typdec1)	38 (12)	5 (8)
	Genetic Testing (Typdec2)	20 (6)	0 (0)
	Other: PtDA: clinical trial participation, smoking cessation; UCD: monitoring, self-management, self-monitoring... (Typdec9)	16 (5)	26 (40)
	Diagnostic Testing (Typdec4)	12 (4)	0 (0)
	Management (therapeutic, risk...) (Typdec10)	9 (3)	8 (12)
	Dealing with barriers in one's everyday life (Typdec6)	4 (1)	29 (45)
	Unclear (Typdec8)	2 (1)	0 (0)
	Not reported (Typdec7)	1 (<1)	0 (0)
Context of tool usage ^{ne}	At home or in a private setting (Contex1)	148 (46)	16 (25)
	During an in-person clinical encounter (Contex3)	102 (31)	4 (6)
	In a health care setting but not during a clinical encounter	93 (29)	1 (2)

	(Contex2)		
	Not reported (Contex5)	40 (12)	3 (5)
	Unclear (Contex7)	20 (6)	4 (6)
	Other: PtDA: at school, training; UCD: at school (Contex4)	7 (2)	3 (5)
	Daily life (Contex6)	3 (1)	44 (68)
	During a virtual clinical encounter (Contex8)	2 (1)	0 (0)
Timing of tool usage ^{ne}	Before clinical encounter (Timing1)	124 (38)	3 (5)
	During clinical encounter (Timing2)	102 (31)	4 (6)
	Between clinical encounters (Timing4)	75 (23)	1 (2)
	Not reported (Timing7)	46 (14)	9 (14)
	Unclear (Timing3)	24 (7)	7 (11)
	Other (Timing6)	14 (4)	6 (9)
	After clinical encounter (Timing8)	12 (4)	2 (3)
	Not associated with clinical encounter (Timing5)	9 (3)	22 (34)
	Everyday life (Timing9)	1 (<1)	16 (25)

^{ne}except for "Unclear/Not reported", categories are not mutually exclusive

Table S3.3 Iteration

	Patient decision aid projects with development data (n=283) n (%)	User-centered design projects with development data (n=65) n (%)
Development was iterative (iterative)	210 (74)	60 (92)
Number of cycles when iterative: Median (IQR) (Range) (ltcycles_nb)	3 (2-4) (1-50)	3 (2-3) (1-33)
Description of changes between versions/prototypes (ltchnages)	64 (23)	34 (52)

Table S3.4 Clinician users' involvement

		Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)	Patient decision aid projects (n=325) Median (IQR) (Range)	User-centered design projects (n=65) Median (IQR) (Range)
Clinician were consulted by the research team ^e	Yes (clins_y)	205 (63)	36 (55)		
	No (clins_no)	12 (4)	1 (2)		
	Not reported (clins_nr)	104 (32)	28 (43)		

	Unclear (clins_un)	4 (1)	0 (0)		
	Total	325 (100)	65 (100)		
When clinicians involved (n=205, n=36), total number involved ^e	Total was clear (Clistot_1, Clistot_nb)	47 (23)	8 (22)	13 (5-26) (2-1280)	14 (7-37)(3-102)
	Total was not clear, but it was at least this many (Clistot_2, Clistot_nb)	46 (22)	10 (28)	9 (5-16) (1-143)	7 (3-15)(2-20)
	Not reported (Clistot_3)	99 (48)	17 (47)		
	Unclear (Clistot_4)	13 (6)	1 (3)		
	Total	205 (100)	36 (100)	10 (5-22) (1-1280)	9 (4-20) (2-102)
When clinicians involved (n=205, n=36), timing of consultation ^{ne}	Before initial prototype developed (Clinsbef)	131 (64)	23 (64)		
	Between initial and final prototypes (Clinsbtw)	141 (69)	19 (53)		
	After final prototype developed (Clinsaft)	38 (19)	0 (0)		
	Unclear (Clinsun)	4 (2)	1 (3)		
	Not reported	14 (7)	3 (8)		

	(Clinsnr)				
When clinicians involved (n=205, n=36), changes were made to the tool based on clinician users' feedback (Clinschg)		150 (73)	26 (72)		

^ecategories are mutually exclusive

^{ne}except for "Unclear/Not reported", categories are not mutually exclusive

Table S3.5 User characteristics

		Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Patients, members of the public were involved ^{ne}	Any patients or members of the public (kuinvp)	310 (95)	64 (98)
	Faced this situation in the past (kuinvp_past)	70 (22)	4 (6)
	Are currently facing this situation (kuinvp_now)	275 (85)	61 (94)
	Might face this situation in the future (kuinvp_fut)	82 (25)	9 (14)
	Have not and will not face this situation (kuinvp_nev)	0 (0)	3 (5)
	Not reported / Unclear (kuinvp_nrun)	3 (1)	2 (3)

Family members/Friends were involved ^{ne}	Any family members or friends (kuinvfmf)	35 (11)	13 (20)
	Faced this situation in the past (kuinvfmf_past)	5 (2)	0 (0)
	Are currently facing this situation (kuinvfmf_now)	30 (9)	13 (20)
	Might face this situation in the future (kuinvfmf_fut)	5 (2)	0 (0)
	Have not and will not face this situation (kuinvfmf_nev)	0 (0)	0 (0)
	Not reported / Unclear (kuinvfmf_nrun)	0 (0)	0 (0)
Caregivers were involved ^{ne}	Any caregivers (kuinvcar)	15 (5)	14 (22)
	Faced this situation in the past (kuinvcar_past)	1 (<1)	0 (0)
	Are currently facing this situation (kuinvcar_now)	13 (4)	14 (22)
	Might face this situation in the future (kuinvcar_fut)	2 (1)	1 (2)
	Have not and will not face this situation (kuinvcar_nev)	0 (0)	0 (0)
	Not reported / Unclear (kuinvcar_nrun)	0 (0)	0 (0)
Surrogate decision-makers were involved ^{ne}	Any surrogate decision-makers (kuinvsur)	8 (2)	0 (0)

	Faced this situation in the past (kuinvsur_past)	2 (1)	0 (0)
	Are currently facing this situation (kuinvsur_now)	6 (2)	0 (0)
	Might face this situation in the future (kuinvsur_fut)	2 (1)	0 (0)
	Have not and will not face this situation (kuinvsur_nev)	0 (0)	0 (0)
	Not reported / Unclear (kuinvsur_nrun)	0 (0)	0 (0)

^{ne}except for "Not reported/Unclear", categories are not mutually exclusive

Table S3.6 Reporting of users' sociodemographic characteristics

		Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Age	Yes ^e (charage_y)	284 (87)	45 (69)
	Not reported ^e (charage_nr)	39 (12)	20 (31)
	Unclear ^e (charage_un)	2 (1)	0 (0)
Sex/Gender	Yes ^e (chargen_y)	287 (88)	41 (63)
	Not reported ^e (chargen_nr)	36 (11)	24 (37)
	Unclear ^e (chargen_un)	2 (1)	0 (0)
Race/Ethnicity	Yes ^e (charetn_y)	144 (44)	11 (17)

	Not reported ^e (charetn_nr)	178 (55)	54 (83)
	Unclear ^e (charetn_un)	3 (1)	0 (0)
Education	Yes ^e (charedu_y)	227 (70)	19 (29)
	Not reported ^e (charedu_nr)	94 (29)	46 (71)
	Unclear ^e (charedu_un)	4 (1)	0 (0)
Income	Yes ^e (charinc_y)	58 (18)	5 (8)
	Not reported ^e (charinc_nr)	264 (81)	60 (92)
	Unclear ^e (charinc_un)	3 (1)	0 (0)
Literacy/Health literacy	Yes ^e (charlit_y)	21 (6)	4 (6)
	Not reported ^e (charlit_nr)	304 (94)	61 (94)
	Unclear ^e (charlit_un)	0 (0)	0 (0)
Numeracy	Yes ^e (charnum_y)	7 (2)	2 (3)
	Not reported ^e (charnum_nr)	317 (98)	63 (97)
	Unclear ^e (charnum_un)	1 (<1)	0 (0)
Clinical characteristics	Yes ^e (charclin_y)	258 (79)	34 (52)
	Not reported ^e (charclin_nr)	65 (20)	31 (48)
	Unclear ^e (charclin_un)	2 (1)	0 (0)

^ecategories are mutually exclusive

Table S3.7 Type and level of user involvement

		Patient decision aid projects with development data (n=283) n (%)	User-centered design projects with development data (n=65) n (%)
Literature review	Individually ^e (pfcsinvmod_lit_in)	0 (0)	0 (0)
	In group ^e (pfcsinvmod_lit_fg)	0 (0)	0 (0)
	Both ^e (pfcsinvmod_lit_both)	0 (0)	0 (0)
	Other ^e (pfcsinvmod_lit_other)	0 (0)	0 (0)
Observation of existing processes	Individually ^e (pfcsinvmod_obs_in)	10 (4)	18 (28)
	In group ^e (pfcsinvmod_obs_fg)	2 (1)	2 (3)
	Both ^e (pfcsinvmod_obs_both)	2 (1)	2 (3)
	Other ^e (pfcsinvmod_obs_other)	0 (0)	1 (2)
Formal needs assessment	Individually ^e (pfcsinvmod_fna_in)	12 (4)	11 (17)
	In group ^e (pfcsinvmod_fna_fg)	10 (4)	3 (5)
	Both ^e (pfcsinvmod_fna_both)	7 (2)	5 (8)
	Other ^e (pfcsinvmod_fna_other)	0 (0)	0 (0)
Informal needs assessment	Individually ^e (pfcsinvmod_ina_in)	39 (14)	11 (17)
	In group ^e (pfcsinvmod_ina_fg)	28 (10)	15 (23)

	Both ^e (pfcsinvmod_ina_both)	25 (9)	11 (17)
	Other ^e (pfcsinvmod_ina_other)	0 (0)	0 (0)
Develop and/or validate underlying model	Individually ^e (pfcsinvmod_mod_in)	0 (0)	0 (0)
	In group ^e (pfcsinvmod_mod_fg)	0 (0)	0 (0)
	Both ^e (pfcsinvmod_mod_both)	0 (0)	0 (0)
	Other ^e (pfcsinvmod_mod_other)	0 (0)	0 (0)
Storyboarding / wireframing	Individually ^e (pfcsinvmod_sto_in)	4 (1)	2 (3)
	In group ^e (pfcsinvmod_sto_fg)	1 (<1)	4 (6)
	Both ^e (pfcsinvmod_sto_both)	1 (<1)	2 (3)
	Other ^e (pfcsinvmod_sto_other)	0 (0)	0 (0)
Adapt/translate tool	Individually ^e (pfcsinvmod_ada_in)	1 (<1)	0 (0)
	In group ^e (pfcsinvmod_ada_fg)	1 (<1)	0 (0)
	Both ^e (pfcsinvmod_ada_both)	0 (0)	0 (0)
	Other ^e (pfcsinvmod_ada_other)	0 (0)	0 (0)
Content/format review prior	Individually ^e (pfcsinvmod_crp_in)	6 (2)	2 (3)
	In group ^e (pfcsinvmod_crp_fg)	16 (6)	8 (12)

	Both ^e (pfcsinvmod_crp_both)	6 (2)	3 (5)
	Other ^e (pfcsinvmod_crp_other)	0 (0)	0 (0)
Prototype development	Individually ^e (pfcsinvmod_prot_in)	17 (6)	1 (2)
	In group ^e (pfcsinvmod_prot_fg)	11 (4)	2 (3)
	Both ^e (pfcsinvmod_prot_both)	1 (<1)	4 (6)
	Other ^e (pfcsinvmod_prot_other)	3 (1)	0 (0)
Content/format review after	Individually ^e (pfcsinvmod_cra_in)	27 (10)	10 (15)
	In group ^e (pfcsinvmod_cra_fg)	30 (11)	8 (12)
	Both ^e (pfcsinvmod_cra_both)	13 (5)	1 (2)
	Other ^e (pfcsinvmod_cra_other)	1 (<1)	0 (0)
Pilot/usability testing	Individually ^e (pfcsinvmod_pil_in)	141 (50)	43 (66)
	In group ^e (pfcsinvmod_pil_fg)	8 (3)	5 (8)
	Both ^e (pfcsinvmod_pil_both)	11 (4)	2 (3)
	Other ^e (pfcsinvmod_pil_other)	0 (0)	0 (0)
Second round of pilot/usability testing	Individually ^e (pfcsinvmod_pilot2_in)	25 (9)	11 (17)
	In group ^e (pfcsinvmod_pilot2_fg)	0 (0)	0 (0)

	Both ^e (pfcsinvmod_pilot2_both)	0 (0)	0 (0)
	Other ^e (pfcsinvmod_pilot2_other)	0 (0)	0 (0)

^ecategories are mutually exclusive

Table S3.8 Type of user involvement

	Patient decision aid projects with development data (n=283) n (%)	User-centered design projects with development data (n=65) n (%)
PFCS users involved as participants in study ^{ne} (pfcspts)	282 (>99)	63 (97)
PFCS users involved in advisory capacity ^{ne} (pfcsadv)	77 (27)	14 (22)
PFCS advisory panel ^{ne} (pfcsadvpan)	26 (9)	4 (6)
PFCS users involved on research/development team ^{ne} (pfcsres)	23 (8)	9 (14)
Other ^{ne} (pfcs23_2, pfcs23_5, pfcs23_6)	0 (0)	0 (0)
Not reported or unclear (pfcs23_7, pfcs23_8)	0 (0)	2 (3)

PFCS users = Patients/public, family members/friends, caregivers, surrogate users

^{ne}except for "Not reported or unclear", categories are not mutually exclusive

Table S3.9 Methods of eliciting users' responses to the tool

		Patient decision aid projects with development data (n=283)	User-centered design projects with development data (n=65)
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		n (%)	n (%)
Asked thoughts & opinions of the tool ^{ne}	PFCS users (askpfcs)	211 (75)	61 (94)
	Clinician users (askclin)	118 (42)	21 (32)
	Non-users (asknon)	56 (20)	24 (37)
Observed interacting with the tool ^{ne}	PFCS users (obspfcs)	117 (41)	47 (72)
	Clinician users (obsclin)	16 (6)	2 (3)
	Non-users (obsnon)	3 (1)	3 (5)
Assessed impact on ^{ne}	PFCS users (asspfcs)	248 (88)	29 (45)
	Clinician users (assclin)	22 (8)	2 (3)
	Non-users (assnon)	1 (<1)	0 (0)

^{ne}categories are not mutually exclusive

Table S3.10 Evaluation

	Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Evaluation of feasibility, acceptability, satisfaction with tool/decision aid, usability, other preliminary metric of evaluation ^{ne} (eval1)	216 (66)	58 (89)
Evaluation of efficacy ^{ne} (eval2)	288 (89)	29 (45)
Evaluation of implementation ^{ne} (eval3)	28 (9)	8 (12)

^{ne}categories are not mutually exclusive

Table S3.11 Advisory panels and organizations' involvement

		Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Formal involved organizations (at least one) ^{ne}	Formal links with specific patient/consumer organization (linkorgapt1, linkorgapt2, linkorgapt3, linkorgapt4)	38 (12)	9 (14)
	Formal links with specific clinical organization (linkorgaclin1, linkorgaclin2, linkorgaclin3, linkorgaclin4)	8 (2)	1 (2)
Expert panel (panel of academics, clinicians, etc.)	Yes ^e (exptpan_y)	153 (47)	25 (38)
	No ^e (exptpan_n)	8 (2)	2 (3)
	Not reported ^e (exptpan_nr)	114 (35)	35 (54)
	Unclear ^e (exptpan_un)	8 (2)	3 (5)
	Not applicable ^e (evaluation projects) (exptpan_na)	42 (13)	0 (0)

^{ne}categories are not mutually exclusive

^ecategories are mutually exclusive

Table S3.12 Patients/public, family members/friends, caregivers, surrogate users' recruitment

	Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
--	--	---

Convenience sample ^{ne} (reconc)	266 (82)	36 (55)
Community groups ^{ne} (recomm)	40 (12)	9 (14)
Registries ^{ne} (recreg)	37 (11)	0 (0)
Advertisement ^{ne} (recadv)	35 (11)	0 (0)
Flyers, posters ^{ne} (recfly)	31 (10)	4 (6)
Other type of recruitment: PtDA: Letters, consecutive sample, telephone, health insurance; UCD: schools, Daycare facilities ^{ne} (recother)	30 (9)	3 (5)
Not reported (recnr)	15 (5)	21 (32)
Online panel ^{ne} (recpanel)	11 (3)	0 (0)
Purposive ^{ne} (recpurp)	10 (3)	7 (11)
Snowball sampling ^{ne} (recsnow)	9 (3)	5 (8)
Random sample ^{ne} (recrand)	8 (2)	0 (0)
Unclear (recun)	2 (1)	0 (0)

^{ne}except for "Not reported/Unclear", categories are not mutually exclusive

Table S3.13 Patients/public, family members/friends, caregivers, surrogate users' compensation

	Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Any kind of compensation ^{ne} (comp)	89 (27)	17 (26)
Cash ^{ne} (Compcash)	61 (19)	8 (12)

Gift cards/points ^{ne} (Compcards)	29 (9)	3 (5)
Parking/transportation ^{ne} (Comppark)	15 (5)	4 (6)
Refreshments ^{ne} (Comprefresh)	11 (3)	1 (2)
Other kind of compensation: PtDA: 1-month access to the decision support, Gift, Small incentives (e.g. key ring flashlights), Telephone-administered GC and BRCA1/2 testing; UCD: Complimentary registration for The Cooper Institute's Active Living Every Day program ^{ne} (Compothor)	4 (1)	3 (5)
Drawings/Lottery ^{ne} (Complott)	4 (1)	0 (0)
Unclear (Compun)	0 (0)	2 (3)

PFCS users = Patients/public, family members/friends, caregivers, surrogate users

^{ne}except for "Unclear", categories are not mutually exclusive

Table S3.14 Clinician users' compensation when clinician users were involved

	Patient decision aid projects (n=325) n (%)	User-centered design projects (n=65) n (%)
Yes ^e (clinscomp_y)	13 (4)	3 (5)
Cash ^{ne} (Clinscomp_1)	8 (2)	2 (3)
Gift cards/points ^{ne} (Clinscomp_2)	2 (1)	0 (0)
Refreshments ^{ne} (Clinscomp_5)	2 (1)	0 (0)
Parking/transportation ^{ne} (Clinscomp_3)	1 (<1)	0 (0)

Unclear (Clinscomp_7)	1 (<1)	1 (2)
Drawings/lottery ^{ne} (Clinscomp_4)	0 (0)	0 (0)
Other ^{ne} (Clinscomp_6)	0 (0)	0 (0)
No, no funds or equivalent exchanged hands in any way ^e (clinscomp_n)	0 (0)	0 (0)
Not reported ^e (clinscomp_nr)	191 (59)	31 (48)
Unclear ^e (clinscomp_un)	1 (<1)	0 (0)

^ecategories are mutually exclusive

^{ne}except for "Unclear", categories are not mutually exclusive

Table S3.15 Quality of included articles

		Papers describing patient decision aid projects (n=490)* n (%)	Papers describing user-centered design projects (n=133)* n (%)
Ethics ^{ne} (ethics)		362 (74)	68 (51)
Description of the context ^{ne} (descrcon)		489 (>99)	133 (100)
Description of the purpose of the study ^{ne} (descrpurp)		489 (>99)	133 (100)
Experimental evaluation studies ^{ne} (studexp)		276 (56)	14 (11)
	Method of randomization and/or sequence generation (descrrand)	214 (44)	12 (9)

	Allocation concealment and/or blinding (describind)	156 (32)	7 (5)
	Reported number of dropouts or complete outcome data (descridrop)	213 (43)	12 (9)
Non-experimental evaluation studies ^{ne} (studeva)		206 (42)	106 (80)
	Control of potentially confounding variables (descriconf)	35 (7)	9 (7)
Studies relating to human participants ^{ne} (studhum)		484 (99)	129 (97)
	Description of participants (descripart)	451 (92)	107 (80)
	Justification of sampling (descrisamp)	207 (42)	56 (42)
	Description of data collection and analysis (descricoll)	478 (98)	125 (94)
	Justification of measurements (descrimeas)	368 (75)	57 (43)
Development studies ^{ne} (studdev)		282 (58)	103 (77)
	Description of how development occurred (descridev)	243 (50)	99 (74)
	Description of how content	220 (45)	93 (70)

	was developed and/or refined (descrcont)		
	Description of how format was developed and/or refined (descrform)	132 (27)	78 (59)
	Description of how data were used to refine tool (descrref)	158 (32)	83 (62)

**n for this table is a descriptive overview of all included articles not combined into projects.*

^{ne}categories are not mutually exclusive.

Appendix 4. PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5, 6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	NA
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7 & 8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7 & Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9-12
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	10, 11
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	11
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	13
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	12

Appendix 4. PRISMA 2009 Checklist

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	NA
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	14, Figure 2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	NA
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	NA
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Tables 3 & 4
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	NA
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	24-27
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	27, 28
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	29
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	30

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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