Development and Validation of UCD-11: An 11-item Measure of User-Centered Design for Patient-Centered Tools

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Abstract (300 words)

Background: Researchers developing health-related tools for patients and families employ a range of approaches to involve prospective users in design and development.

Objective: To develop a validated measure of the human- or user-centeredness of design and development processes for patient-centered tools.

Design: Cross-sectional data from a previous systematic review of the design and development processes of 348 tools.

Methods: Using a conceptual framework of user-centered design, our team of patients, caregivers, health professionals, tool developers, and researchers analyzed how specific practices in tool design and development might be combined and used as a measure. We prioritized variables according to their importance within the conceptual framework and validated the resultant measure using principal component analysis with Varimax rotation, classical item analysis, and confirmatory factor analysis.

Results: We retained 11 items in a 3-factor structure explaining 68% of the variance in the data. Cronbach's alpha was .72. Confirmatory factor analysis supported our hypothesis of a latent construct of user-centeredness. Items were whether or not: (1) patient, family, caregiver or surrogate users were involved in steps to understand users or (2) develop a prototype, (3) asked their opinions, (4) observed using the tool, or (5) involved in steps intended to evaluate the tool, (6) the process had three or more iterative cycles, (7) changes between cycles were explicitly reported, (8) health professionals were asked their opinion, (9) consulted before a first prototype was developed or (10) between initial and final prototypes, and (11) a panel of other experts was involved.

Conclusion: The measure UCD-11 may be used to quantitatively document the user- and human-centeredness of design and development processes of patient-centered tools. By building an evidence base about such processes, we can help ensure that tools are adapted to the people who will use them, rather than requiring people to adapt to tools.

Keywords (MeSH)

Patient-Centered Care; Patient Participation; Health Services Research; Validation Studies as Topic; Surveys and Questionnaires*; Humans

Keywords (non-MeSH)

user-centred design, human-centred design, user-centered design, human-centered design, codesign, instrument, scale, index, patient and public involvement

Main Text

Introduction

Products and applications increasingly aim to support patients in managing one's health and living one's life. These include physical tools like wheelchairs[1] or eating utensils[2], medical devices like insulin pumps[3] or home dialysis equipment[4], assistive devices like screen readers[5] or voice aids[6], digital applications like eHealth tools[7] or mHealth tools[8,9], tools for collecting patient-reported outcome or experience measures[10,11], patient decision aids[12], and a variety of other patient-facing tools, that is, tools intended to be used by patients and caregivers.

None of these tools can achieve their intended impact if they are not usable by and useful to their intended users. Although recommendations for patient involvement are increasing in health care and health research[13–18] and evidence exists regarding what people value as characteristics of some of these tools[19], there are few practical recommendations regarding how to best design and develop tools or products that patients and caregivers will use[20] [21]. Terms like co-design, user-centred design, human-centred design, and design thinking appear in publications without definitions, with few details about how these terms were operationalized, and without frameworks or metrics to capture the process. This suggests that there is both interest in and efforts toward involving users in tool design and development processes, but little structure informing such involvement.

Our study sought to inform this knowledge gap. We previously synthesized a framework of user-centered design[22], shown in Figure 1, and used it to extract data from 623 articles in a systematic review describing the design and development of 348 patient-facing tools[23]. In this framework, a user is any person who interacts with (in other words, “uses”) a system, service, or product for some purpose.

Figure 1. User-Centered Design Framework

User-centered design is sometimes referred to as human-centered design[24] and is both conceptually and methodologically related to terms like design thinking and co-design[25]. It is intended to optimize the user experience of a system, service, or product [18,28-30]. In this work, we define user-centered design as a fully- or semi-structured approach in which people who currently use or who could in future use a system, service, or product are involved in an iterative process of optimizing its user experience. This iterative process includes one or more steps to understand prospective users, including their needs, goals, strengths, limitations, contexts, and intuitive processes (e.g., the ways in which they currently address the issue at hand or use similar systems, services, or products.) The iterative process also includes one or more steps to develop or refine prototypes, and one or more steps to observe prospective users interactions with versions of the tool.

livari & livari[26] noted that the different ways in which user-centeredness is described in the literature imply four distinct meanings or dimensions: user focus, meaning that the system is designed and developed around users' needs and capabilities; work-centredness, meaning that the system is designed and developed around users' workflow and tasks; user involvement or participation, meaning that the design and development process involves users or users participate in the process; and system personalization, meaning the system is individualized by or for individual users. Our definition of user-centeredness and framework of user-centered design draw most strongly upon the third of these (user involvement or participation) as a means to achieve the first (user focus) and fourth (system personalization). The second meaning (work-centeredness) is less relevant here as it refers to paid work in the original definition. However, it may be worth noting the considerable work that people may need to undertake to make health decisions or to live with illness or disability.[27–30]

In this study, using this existing structured dataset describing the design and development of 348 patient-facing tools[23], we aimed to derive a measure of the user- or human-centeredness of the design and development of patient-centered tools.

Methods

Validity Framework

Guided by an established validity framework[31], we developed and validated a measure using Classical Test Theory[32,33]. The framework reflects consensus in the field of measurement and evaluation about what indicates the validity of a measure.

Specifically, the validity framework proposes five ways in which a measure may or may not demonstrate validity: its content validity, its response process, its internal structure, its relationship to other variables, and the consequences of the measure[31,34]. Because our aim was to develop a new measure in an area with few metrics, our study directly addresses the first three of these five. We discuss how related and future research might inform the fourth and fifth ways of assessing validity.

Content Validity

The data extraction process had been designed to result in a complete dataset of items, with the items prioritized according to their relevance within our conceptual framework. Thus, to do this prioritization and ensure content validity of items (point 1 in the validity framework[31]), we used seminal literature[24,35–39] and held monthly or bimonthly consultations in person and by teleconference over the course of two years within our interdisciplinary group of patients, caregivers, health professionals, academic researchers, and other stakeholders.

Response Process

We refined the response process for each item (point 2 in the validity framework[31]) through an iterative process of data extraction and data validation. This included consultation with fifteen outside experts and four rounds of pilot data extraction and refinement of response processes[23].

Internal Structure

Regarding the internal structure of the measure (point 3 in the validity framework[31]), we identified which prioritized items formed a positive definite matrix of tetrachoric correlations, meaning that the items were sufficiently independent of each other to allow the matrix to be inverted. Tetrachoric correlations are correlations between dichotomous variables. Positive definite matrices are matrices that are able to be inverted. This is possible when the vectors (in our case, vectors of tetrachoric correlations between potential items in the measure) that make up the matrix are sufficiently independent of each other. Matrix inversion is required to conduct principal component analysis. We identified the items to make up the matrix by first rank ordering possible items in the dataset according to their priority in our conceptual framework,

using the expertise of our interdisciplinary team (see Patient Partnership section below). We then built the matrix in a stepwise fashion, adding items until the matrix of correlations was no longer invertible. Then, based on classical item analysis in which we required discrimination indices over 0.2[40–42], we formed a group of items with an acceptable value of Kaiser’s measure of sampling adequacy (over 0.6[43]), meaning that they share enough common variance to allow principal component analysis. We then conducted such analysis with Varimax rotation. Using the resultant scree plot and content expertise based on our conceptual framework, we identified components that explained sufficient variance in the data, retaining items with loadings over 0.4 on at least one factor. We also performed classical item analysis to assess the resultant psychometric properties of the items in the measure. Finally, we used confirmatory factor analysis with unweighted least squares estimation to test our hypothesis of the existence of a latent construct of user-centeredness explaining the variance in the three components. In other words, we tested whether or not our data suggested that the components we found in our analysis shared a common root.

Applying the Measure Within the Dataset

We applied the resulting measure to the dataset to examine and compare scores for the two groups of projects within the original study: patient decision aids, which could have been developed in any way, and other patient-facing tools that specifically described their design and development method as user- or human-centered design. To explore potential changes in design and development methods over time, we plotted scores within the two groups according to the year of publication of the first paper published about each project.

We conducted analyses in SAS, version 9.4 (Cary, North Carolina, United States) and in R, version 3.3.2.

Patient Partnership

Patients and other stakeholders participated in every aspect of the research for this overall project as members of the research team. For the development of the measure, patient and caregiver partners were most involved in the prioritization of items for analysis.

Results

Retained Items

Out of 19 identified potential variables, we retained 11 items in a three-factor structure explaining 68% of the variance in the data. Kaiser’s measure of sampling accuracy was 0.68, considered acceptable[43]. Each item is binary and is scored as either present or absent. Table 1 shows the 11 retained items and factor structure. Cronbach’s alpha for all 11 items was .72, indicating acceptable internal consistency, particularly for a measure of only 11 items[44].

Factor “pre-prototype involvement” included two items: (1) whether prospective users (meaning patient, family, caregiver, or surrogate users) were involved in steps that help tool developers

understand users, and (2) whether prospective users were involved in steps of developing a prototype. Factor “iterative responsiveness” included 5 items: (3) whether prospective users were asked their opinions; (4) whether they were observed using the tool; (5) whether they were involved in steps intended to evaluate the tool; (6) whether the development process had three or more iterative cycles; and (7) whether changes between iterative cycles were explicitly reported. Factor “other expert involvement” included four items: (8) whether health professionals were asked their opinion; (9) whether health professionals were consulted before a first prototype was developed; (10) whether health professionals were consulted between initial and final prototypes; and (11) whether an expert panel of non-users was involved.

Table 1. Final Measure with Factor Loadings

		Factors ^b		
Items ^a	Explanations and Examples	Pre-Prototype Involvement	Iterative Responsiveness	Other Expert Involvement
1. Were potential end users (e.g., patients, caregivers, family and friends, surrogates) involved in any steps to help understand users and their needs?	Such steps could include various forms of user research, including formal or informal needs assessment, focus groups, surveys, contextual inquiry, ethnographic observation of existing practices, development of personas, literature review in which users were involved in appraising and interpreting existing literature, or other activities.	0.82		
2. Were potential end users involved in any steps of designing, developing, and/or refining a prototype?	Such steps could include storyboarding, reviewing the draft design or content prior to starting to develop the tool, and designing, developing, or refining a prototype.	0.83		

3. Were potential end users involved in any steps intended to evaluate prototypes or a final version of the tool?	Such steps could include feasibility testing, usability testing with iterative prototypes, pilot testing, a randomized controlled trial of a final version of the tool, or other activities.		0.78	
4. Were potential end users asked their opinions of the tool in any way?	For example, they might be asked to voice their opinions in a focus group, interview, survey, or through other methods.		0.80	
5. Were potential end users observed using the tool in any way?	For example, they might be observed in a think-aloud study, cognitive interviews, through passive observation, logfiles, or other methods.		0.71	
6. Did the development process have 3 or more iterative cycles?	The definition of a cycle is that the team developed something and showed it to at least one person outside the team before making changes; each new cycle leads to a version of the tool that has been revised in some small or large way.		0.64	
7. Were changes between iterative cycles explicitly reported in any way?	For example, the team might have explicitly reported them in a peer-reviewed paper or in a technical report. In the case of rapid prototyping, such reporting could be, for example, a list of design decisions made and the rationale for the decisions.		0.87	

8. Were health professionals asked their opinion of the tool at any point?	Health professionals could be any relevant professionals, including physicians, nurses, allied health providers, etc. These professionals are not members of the research team. They provide care to people who are likely users of the tool. Asking their opinion means simply asking for feedback, in contrast to, for example, observing their interaction with the tool or assessing the impact of the tool on health professionals' behavior.			0.80
9. Were health professionals consulted at any point before a first prototype was developed?	Consulting before a first prototype means consulting prior to developing anything. This may include a variety of consultation methods.	0.49		0.75
10. Were health professionals consulted between initial and final prototypes?	Consulting between initial and final prototypes means some initial design of the tool was already created when consulting with health professionals.			0.91
11. Was an expert panel involved?	An expert panel is typically an advisory panel composed of experts in areas relevant to the tool if such experts are not already present on the research team; for example, plain language experts, accessibility experts, designers, engineers, industrial designers, digital security experts, etc. These			0.56

	experts may be health professionals, but not health professionals who would provide direct care to end users.			
Cronbach alpha for factor ^c		0.51	0.65	0.67

^aAll items are scored as yes = 1, no = 0.

^bFactor loadings lower than 0.40 are not shown.

^cCronbach alpha values are presented with item 9 included in Factor 3. Cronbach alpha overall for all 11 items was 0.72.

Non-Retained Items

The eight items non-retained due to lack of sufficient explanation of variance were whether or not: (1) users involved were currently dealing with the health situation; (2) a formal patient organization was involved; (3) an advisory panel of users was involved; (4) there were users who were formal members of the research team; (5) users were offered incentives or compensation of any kind for their involvement (e.g., cash, gift cards, paying for parking); (6) people who were members of any vulnerable population were explicitly involved[45]; (7) users were recruited as a convenience sample; and (8) users were recruited using methods that one might use to recruit from populations that may be harder to reach (e.g., community centers, purposive sampling, snowball sampling).

Classical Test Theory and Confirmatory Factor Analysis Results

Classical item difficulty parameters ranged from .28 to .85 on a scale ranging from 0 to 1 and discrimination indices from .29 to .46, indicating good discriminating power[40–42]. Confirmatory factor analysis demonstrated that a second-order model provided an acceptable to good fit[46] (SRMR=.09, GFI=.96, AGFI=.94, NFI=.93), supporting our hypothesis of a latent construct of user-centeredness that explains the three factors.

Scores Within the Dataset

As expected when applying a measure to the dataset used to develop it, scores within the dataset were distributed across the full range of possible scores, meaning from 0 to 11. Median scores were 5 out of a possible 11 (interquartile range: IQR 3-8) for the design and development of patient decision aids, and 7 out of a possible 11 (IQR 5-8) for patient-facing tools in which the authors specifically described their design and development method as user- or human-centered design. The 95% confidence interval of the difference in mean scores for patient decision aid projects compared to projects that described their approach as user- or human-centered design was (-1.5,-0.3). Figure 2 shows scores over time within the two groups. There were no discernable time trends in UCD-11 scores.

Figure 2. UCD-11 scores by year of publication of first paper describing a project

PtDA = Patient decision aids; UCD = Other tools created using user- or human-centered design

Discussion

Principal Results and Comparisons with Prior Work

Our study aimed to derive a measure of user-centeredness of the design and development processes for patient-centered tools. Applying a conceptual framework of user-centered design allowed us to identify indicators of this construct and develop an internally valid measure. This measure includes items that address the involvement of users and health professionals at every stage of a framework of user-centeredness[22] as well as the importance of designing and developing tools in iterative cycles. Given the creative nature of design and development and a wide range of possible tools, the items are high-level assessments of whether or not particular aspects of involvement were present or absent, not assessments of the quality of each aspect.

To the best of our knowledge, ours is the first such validated measure for health applications. Other broadly applicable measures exist that assess the usability or ease of use of tools; for example, the System Usability Scale[47,48]. However, this measure assesses the quality of the resulting tool or system, not the process of arriving at the end product. Process measures also exist; for example, in software, consumer product development, and information systems[49–51].

Barki & Hartwick[49] developed measures centered around the design and development of information systems in professional contexts. They distinguished between user participation and user involvement, defining user participation as, “the assignments, activities and behaviors that users or their representatives perform during the system development process,” and user involvement as, “a subjective psychological state reflecting the importance and personal relevance that a user attaches to a given system.” (Note that, rather than Barki & Hartwick’s definition, in this paper, when we refer to user involvement, we are using livari & livari’s[26] definition of user involvement, “as a broader concept in which users are somehow involved in the systems development process.” livari & livari further specify that user participation, “is a special case of user involvement in which users (or their representatives) actively participate in the process.”) Barki & Hartwick’s user participation items intended to be assessed by users included, for example, “I was able to make changes to the formalized agreement of work to be done during system definition,” and, “I formally reviewed work done by Information Systems/Data Processing staff during implementation.” User involvement items were also assessed by users by having them indicate, for example, to what extent they felt the system was needed or relevant to them. Our measure has some items similar to the items in their user participation scale; however, in our measure, users themselves do not need to indicate whether or not a step occurred.

Kujala[50] offers a measure intended to assess the quality of system specifications after these have been developed. Items include, for example, “Customer or user requirements are completely defined,” and, “The correctness of the requirements is checked with real users,” assessed on a 4-point Likert scale from disagree to agree. This measure assesses the quality of user research outputs, which should typically be generated early in a project. In contrast, our measure offers a means of measuring user involvement by the aspects of a design and development process that were or were not done during the entire process.

Subramanyam and colleagues[51] assessed user participation in software development using data collected from time sheets and surveys across 117 projects conducted over four years at a large manufacturing firm. Projects often consisted of developing manufacturing and supply chain software. They found that users reported higher satisfaction in a projects developing new software when the demands on their time were lowest, whereas developers reported higher satisfaction when users’ time spent in the project was highest. Users in this case were employees in the firm, who presumably had other work-related tasks to do as well. Our measure differs from this approach in that we assess involvement in a variety of steps as well as other factors (e.g., three or more iterative cycles) rather than total time spent by users.

In summary, our measure aligns somewhat with work from other contexts to measure user-centeredness. The key differences between our measure and previous measures is that ours assesses the process of design and development rather than the quality of the end product, is specific to the context of health-related tools rather than that of information systems or more general contexts, and may be reported or assessed by anyone with sufficient knowledge of the design and development process rather than requiring reporting by users. This latter difference offers flexibility of administration and feasibility for assessing the design and development of completed projects. However, this also means that our measure does not capture the quality of involvement from the perspectives of those involved. Future research should compare the relationship—or lack thereof—between whether or not specific steps occurred in a design and development process and users' perspectives on the quality of the design and development process.

In addition to the strengths within our study, the first external use of our measure, conducted through advance provision of the measure to colleagues, offered some additional promising indications of its validity, specifically with respect to the fourth and fifth items of the validity framework (relationship to other variables, consequences of the measure) that were not possible to assess in our study. Higgins and colleagues conducted a systematic review of 26 electronic tools for managing children's pain. They aimed to investigate the characteristics of tools still available for patients and families to use versus those no longer in use. They found that higher UCD-11 scores were associated with the tools still being available for use after the grant and project had ended[52].

Although case reports suggest that involving users in the design and development of health-related tools can lead to more usable, accepted, or effective tools[53,54], and, as mentioned above, emerging evidence suggests that higher scores on our measure are associated with more sustained availability of tools[52], we lack definitive evidence about the extent to which increasing user-centeredness may improve tools. It may be that there is a point beyond which it is either not feasible or not a good use of limited time and resources to increase involvement. For these reasons, UCD-11 should be considered descriptive, not normative.

Limitations

Our study has two main weaknesses. First, our data came from published reports, not direct capture of design and development processes. Although we have reason to believe the data are of high quality given our rigorous data validation[23], data from a systematic review of this nature may not contain full details of design and development processes. Second, because our largest data source came from reports of the design and development of patient decision aids, our findings may be overly influenced by practices in the field of shared decision making and patient decision aids. We believe that this focus is appropriate for increasing patient-centeredness. Shared decision making has been noted as “the pinnacle of patient-centered care”[55] and patient-centered care has been defined as, “care that is respectful of and responsive to individual patient preferences, needs, and values,” such that, “patient values guide all clinical decisions,”[56] a definition that aligns precisely with the goals of shared decision making[57]. The role of patient decision aids as an intervention to facilitate informed

choice via shared decision making suggests that these are particularly important patient-centered tools to consider. However, it is possible that, because patient decision aids are intended to be used to complement consultation with a health professional, this focus in our data may have led to an over-emphasis on the role of health professionals in developing tools for use by patients, caregivers, and others.

Conclusions

Using a framework of user-centered design synthesized from foundational literature, we were able to derive UCD-11, an internally valid descriptive measure of the user-centeredness of the design and development processes of tools intended for use by patients and families. This measure offers a structured way to consider design and development methods (for example, co-design) when creating tools with and for patients and caregivers. Through measurement and reporting, this measure can help collect evidence about user involvement in order that future research might better specify how we can make the best possible use of the time and effort of all people involved in design and development of tools intended for patients and families to use. We hope this measure will help generate structured data towards this goal and help foster more creation of tools that are adapted to the people who will use them, rather than requiring people to adapt to the tools.

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Conflicts of interest

During the course of this project, Carrie A. Levin (patient decision aid developer team member, 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 that creates products including patient decision aids.

Abbreviations

None

Ethics Approval, Consent to Participate and Consent for Publication

Not applicable.

Authors' Contributions

Conceptualization and methodology: HOW, GV, JSR; Validation: JSR; Formal analysis: HOW, GV, JSR; Investigation: HOW, GV, SCD, HC, MD, AF, AMCG, LH, AH, NMI, FL, TP, DS, MET, RJV, JSR; Data curation: GV, TP; Writing - Original Draft: HOW, JSR; Writing - Review and editing: HOW, GV, SCD, HC, MD, AF, AMCG, LH, AH, NMI, FL, TP, DS, MET, RJV, JSR; Project administration: HOW, SCD; Funding acquisition: HOW, SCD, HC, AF, AMCG, LH, AH, NMI, FL, DS, RJV, JSR

Availability of Data and Materials

Data used in this study are available at {link to be made public when manuscript is accepted}.

References

1. Carrington P, Hurst A, Kane SK. Wearables and Chairables: Inclusive Design of Mobile Input and Output Techniques for Power Wheelchair Users. [doi: 10.1145/2556288.2557237]
2. Renda G, Jackson S, Kuys B, Whitfield TWA. The cutlery effect: do designed products for people with disabilities stigmatise them? *Disabil Rehabil Assist Technol* Taylor & Francis; 2016 Nov;11(8):661–667. PMID:25936430
3. Heller S, White D, Lee E, Lawton J, Pollard D, Waugh N, Amiel S, Barnard K, Beckwith A, Brennan A, Campbell M, Cooper C, Dimairo M, Dixon S, Elliott J, Evans M, Green F, Hackney G, Hammond P, Hallowell N, Jaap A, Kennon B, Kirkham J, Lindsay R, Mansell P, Papaioannou D, Rankin D, Royle P, Smithson WH, Taylor C. A cluster randomised trial, cost-effectiveness analysis and psychosocial evaluation of insulin pump therapy compared with multiple injections during flexible intensive insulin therapy for type 1 diabetes: the REPOSE Trial. *Health Technol Assess* 2017 Apr;21(20):1–278. PMID:28440211
4. Wallace EL, Lea J, Chaudhary NS, Griffin R, Hammelman E, Cohen J, Sloand JA. Home Dialysis Utilization Among Racial and Ethnic Minorities in the United States at the National, Regional, and State Level. *Perit Dial Int* pdiconnect.com; 2017;37(1):21–29. PMID:27680759
5. Shilkrot R, Huber J, Liu C, Maes P, Nanayakkara SC. FingerReader: A Wearable Device to Support Text Reading on the Go. *CHI '14 Extended Abstracts on Human Factors in Computing Systems* New York, NY, USA: ACM; 2014. p. 2359–2364.
6. Hawley MS, Cunningham SP, Green PD, Enderby P, Palmer R, Sehgal S, O'Neill P. A voice-input voice-output communication aid for people with severe speech impairment. *IEEE Trans Neural Syst Rehabil Eng* 2013 Jan;21(1):23–31. PMID:22875259
7. Markham SA, Levi BH, Green MJ, Schubart JR. Use of a Computer Program for Advance Care Planning with African American Participants. *J Natl Med Assoc* 2015 Feb;107(1):26–32. PMID:27282525
8. Hightow-Weidman LB, Muessig KE, Pike EC, LeGrand S, Baltierra N, Rucker AJ, Wilson P. HealthMpowerment.org: Building Community Through a Mobile-Optimized, Online Health Promotion Intervention. *Health Educ Behav* 2015 Aug;42(4):493–499. PMID:25588932
9. Sridhar A, Chen A, Forbes ER, Glik D. Mobile application for information on reversible contraception: a randomized controlled trial. *Am J Obstet Gynecol Elsevier*; 2015 Jun 1;212(6):774.e1–774.e7.
10. Hartzler AL, Izard JP, Dalkin BL, Mikles SP, Gore JL. Design and feasibility of integrating personalized PRO dashboards into prostate cancer care. *J Am Med Inform Assoc* 2016 Jan;23(1):38–47. PMID:26260247

11. Sanchez-Morillo D, Fernandez-Granero MA, Jiménez AL. Detecting COPD exacerbations early using daily telemonitoring of symptoms and k-means clustering: a pilot study. *Med Biol Eng Comput Springer Berlin Heidelberg*; 2015 May 1;53(5):441–451.
12. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev John Wiley & Sons, Ltd*; 2017 Apr 12;4:CD001431. PMID:28402085
13. Macaulay AC, Commanda LE, Freeman WL, Gibson N, McCabe ML, Robbins CM, Twohig PL. Participatory research maximises community and lay involvement. *North American Primary Care Research Group. BMJ* 1999 Sep 18;319(7212):774–778. PMID:10488012
14. Cargo M, Mercer SL. The value and challenges of participatory research: strengthening its practice. *Annu Rev Public Health* 2008;29:325–350. PMID:18173388
15. Légaré F, Boivin A, van der Weijden T, Pakenham C, Burgers J, Légaré J, St-Jacques S, Gagnon S. Patient and public involvement in clinical practice guidelines: a knowledge synthesis of existing programs. *Med Decis Making* 2011 Nov;31(6):E45–74. PMID:21959267
16. Gagnon M-P, Desmartis M, Lepage-Savary D, Gagnon J, St-Pierre M, Rhainds M, Lemieux R, Gauvin F-P, Pollender H, Légaré F. Introducing patients' and the public's perspectives to health technology assessment: A systematic review of international experiences. *Int J Technol Assess Health Care* 2011 Jan;27(1):31–42. PMID:21262085
17. Selby JV. The patient-centered outcomes research institute: a 2013 agenda for “research done differently.” *Popul Health Manag* 2013 Apr;16(2):69–70. PMID:23565922
18. Gagnon M-P, Desmartis M, Gagnon J, St-Pierre M, Gauvin F-P, Rhainds M, Lepage-Savary D, Coulombe M, Dipankui MT, Légaré F. Introducing the patient's perspective in hospital health technology assessment (HTA): the views of HTA producers, hospital managers and patients. *Health Expect* 2014 Dec;17(6):888–900. PMID:23046439
19. Olmsted MG, Massoudi BL, Zhang Y. What consumers want in personal health applications: findings from Project HealthDesign. *Pers Ubiquit Comput Springer London*; 2015 Jan 1;19(1):79–83.
20. Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, Gyte G, Oakley A, Stein K. Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach. *Health Technol Assess* 2004 Apr;8(15):1–148, III–IV. PMID:15080866
21. Coulter A, Stilwell D, Kryworuchko J, Mullen PD, Ng CJ, van der Weijden T. A systematic development process for patient decision aids. *BMC Med Inform Decis Mak* 2013 Nov 29;13 Suppl 2(Suppl 2):S2. PMID:24625093

22. Witteman HO, Dansokho SC, Colquhoun H, Coulter A, Dugas M, Fagerlin A, Giguere AM, Glouberman S, Haslett L, Hoffman A, Ivers N, Légaré F, Légaré J, Levin C, Lopez K, Montori VM, Provencher T, Renaud J-S, Sparling K, Stacey D, Vaisson G, Volk RJ, Witteman W. User-centered design and the development of patient decision aids: protocol for a systematic review. *Syst Rev* 2015 Jan 26;4:11. PMID:25623074
23. Vaisson, G., Provencher, T., Dugas, M., Trottier, M.-È., Chipenda Dansokho, S., Colquhoun, H., Fagerlin, A., Giguère, A. M. C., Hakim, H., Haslett, L., Hoffman, A., Ivers, N. M., Julien, A.-S., Légaré, F., Légaré, J., Levin, C. A., Renaud, J-S., Stacey, D., Volk, R. J., Witteman, H. O. User Involvement in the Development of Patient Decision Aids: A Systematic Review.
24. ISO DIS. 9241-210: 2010. Ergonomics of human system interaction-Part 210: Human-centred design for interactive systems. International Standardization Organization (ISO). Switzerland.; 2009.
25. Sanders EB-N, Stappers PJ. Co-creation and the new landscapes of design. *CoDesign* Taylor & Francis; 2008 Mar 1;4(1):5–18.
26. Iivari J, Iivari N. Varieties of user-centredness: An analysis of four systems development methods. *Information Systems Journal Wiley Online Library*; 2011;21(2):125–153.
27. Strauss AL, Fagerhaugh S, Suczek B, Wiener C. The work of hospitalized patients. *Soc Sci Med* 1982;16(9):977–986. PMID:7112176
28. Corbin J, Strauss A. Managing chronic illness at home: Three lines of work. *Qual Sociol* 1985 Sep 1;8(3):224–247.
29. Valdez RS, Holden RJ, Novak LL, Veinot TC. Transforming consumer health informatics through a patient work framework: connecting patients to context. *J Am Med Inform Assoc* 2015 Jan;22(1):2–10. PMID:25125685
30. Ancker JS, Witteman HO, Hafeez B, Provencher T, Van de Graaf M, Wei E. The invisible work of personal health information management among people with multiple chronic conditions: qualitative interview study among patients and providers. *J Med Internet Res* 2015 Jun 4;17(6):e137. PMID:26043709
31. American Educational Research Association, American Psychological Association, National Council on Measurement in Education, Joint Committee on Standards for Educational and Psychological Testing (U.S.). Standards for Educational and Psychological Testing. American Educational Research Association; 2014. ISBN:9780935302356
32. Novick MR. The axioms and principal results of classical test theory. *J Math Psychol* 1966/2;3(1):1–18.
33. Lord FM, Novick MR, Birnbaum A. Statistical theories of mental test scores. Addison-Wesley; 1968 [cited 2017 May 13]; Available from: <http://doi.apa.org/psycinfo/1968-35040-000>

34. Downing SM. Validity: on meaningful interpretation of assessment data. *Med Educ* 2003 Sep;37(9):830–837. PMID:14506816
35. Abras C, Maloney-Krichmar D, Preece J. User-centered design. *Encyclopedia of Human-Computer Interaction* Thousand Oaks: Sage Publications; 2004;37(4):445–456.
36. Gould JD, Lewis C. Designing for Usability: Key Principles and What Designers Think. *Commun ACM* 1985;28(3):300–311. PMID:5495722
37. Mao J-Y, Vredenburg K, Smith PW, Carey T. The State of USER-CENTERED DESIGN PRACTICE. *Commun ACM* 2005;48(3):105–109.
38. Nielsen J. The usability engineering life cycle. *Computer* 1992 Mar;25(3):12–22.
39. Norman DA. *The Design of Everyday Things*. Basic Books; 2002. ISBN:9780465067107
40. Nunnally J, Bernstein L. *Psychometric theory*. 3rd ed. New York: McGraw Hill; 1994.
41. Schmeiser CB, Welch CJ. Test development. *Educational measurement* 2006;4:307–353.
42. Everitt BS, Skrondal A. *The Cambridge Dictionary of Statistics*. Cambridge: Cambridge University Press; 2010. ISBN:9780511779633
43. Kaiser HF. An index of factorial simplicity. *Psychometrika* Springer-Verlag; 1974 Mar 1;39(1):31–36.
44. DeVellis RF. *Scale Development: Theory and Applications*. 3rd ed. Thousand Oaks, CA: SAGE Publications; 2011. ISBN:9781506341583
45. Dugas M, Trottier M-È, Chipenda Dansokho S, Vaisson G, Provencher T, Colquhoun H, Dogba MJ, Dupéré S, Fagerlin A, Giguere AMC, Haslett L, Hoffman AS, Ivers NM, Légaré F, Légaré J, Levin CA, Menear M, Renaud J-S, Stacey D, Volk RJ, Witteman HO. Involving members of vulnerable populations in the development of patient decision aids: a mixed methods sequential explanatory study. *BMC Med Inform Decis Mak BMC Medical Informatics and Decision Making*; 2017;17(1):12. PMID:28103862
46. Schermelleh-Engel K, Moosbrugger H, Müller H. Evaluating the Fit of Structural Equation Models: Tests of Significance and Descriptive Goodness-of-Fit Measures. *MPR-online* 2003 May 25;8(8):23–74.
47. Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. *Int J Hum Comput Interact* 2008 Jul 29;24(6):574–594.
48. Bangor A, Kortum P, Miller J. Determining What Individual SUS Scores Mean: Adding an Adjective Rating Scale. *J Usability Studies* Bloomingdale, IL: Usability Professionals' Association; 2009 May;4(3):114–123.
49. Barki H, Hartwick J. Measuring User Participation, User Involvement, and User Attitude.

Miss Q Management Information Systems Research Center, University of Minnesota; 1994;18(1):59–82.

50. Kujala S. Effective user involvement in product development by improving the analysis of user needs. *Behav Inf Technol* Taylor & Francis; 2008 Nov 1;27(6):457–473.
51. Subramanyam R, Weisstein FL. User participation in software development projects. *Commun ACM* [Internet] dl.acm.org; 2010; Available from: <http://dl.acm.org/citation.cfm?id=1666455>
52. Kristen S. Higgins, Perri Tutelman, Christine T. Chambers, Holly O. Witteman, Melanie Barwick, Penny Corkum, Doris Grant, Jennifer N. Stinson, Chitra Laloo. Availability of E-Health Tools for Pediatric Pain Assessment and Management: Barriers, Facilitators, Costs, and Design (under review).
53. Kilsdonk E, Peute LW, Riezebos RJ, Kremer LC, Jaspers MWM. From an expert-driven paper guideline to a user-centred decision support system: a usability comparison study. *Artif Intell Med Elsevier*; 2013 Sep;59(1):5–13. PMID:23684240
54. Wilkinson CR, De Angeli A. Applying user centred and participatory design approaches to commercial product development. *Design Studies* 2014 Nov 1;35(6):614–631.
55. Barry MJ, Edgman-Levitan S. Shared Decision Making — The Pinnacle of Patient-Centered Care. *N Engl J Med* 2012;366(9):780–781.
56. Committee on Quality of Health Care in America. Crossing the Quality Chasm: A New Health System for the 21st Century. *J Healthc Qual* 2002;24(5):52.
57. Légaré F, Witteman HO. Shared Decision Making: Examining Key Elements And Barriers To Adoption Into Routine Clinical Practice. *Health Aff* 2013 Feb 1;32(2):276–284.