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Medical Decision Making

Minimum standards for the certification of patient decision support interventions: Feasibility and application

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ABSTRACT

Objective: Patient decision support interventions are not currently subject to standardized quality control. The current study aims to assess the feasibility of applying a proposed set of minimum standards (previously developed as part of a possible certification process) to a selection of existing patient decision support interventions.
Methods: A convenience sample of interventions selected from those included in the 2009 Cochrane systematic review of patient decision aids was scored by trained raters using the International Patient Decision Aids Standards (IPDAS) instrument. Scores were then evaluated against the published proposed minimum standards.
Results: Twenty-five out of thirty included interventions met all qualifying criteria while only three met the proposed certification criteria. The changes required for an intervention to meet the proposed certification standards were relatively minor. There was considerable variation between raters' mean scores.
Conclusions: Most interventions did not meet the certification criteria due to lack of information on modifiable items such as update policy and funding source.
Practice implications: Specifying minimum standards for patient decision support interventions is a feasible development. However, it remains unclear whether the minimum standards can be applied to interventions designed for use within clinical encounters and to those that target screening and diagnostic tests.

1. Introduction

Shared decision-making and the use of patient decision support interventions (also called patient decision aids) have been important innovations in healthcare [1,2], and have recently become part of health policy developments worldwide [3–5]. In the UK, the 2010 White Paper: 'Liberating the NHS' [3] and the NHS operating framework [6] promote the development and implementation of patient decision support interventions to support shared decision-making. These interventions are designed to help patients make informed decisions about their health care [8–10]. They can have substantial effects on patient decision-making and may influence health outcomes insofar as they increase knowledge and accuracy of risk perceptions, decrease decisional conflict and improve the match between personal values and choice [7].

Although decision support interventions are becoming increasingly popular, their design and development processes are not routinely subjected to quality assessment to ensure they have been competently developed and can be trusted by patients. Hence, their quality varies substantially [11]. There is an increased risk that their contents may be inaccurate, inappropriate or biased, or open to undeclared conflicts of interest or influences. To improve consistency in how these interventions are developed, and reduce the risk of harmful bias, the possibility of introducing a certification process has been considered [5].

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To date, several attempts have been made to define a set of quality criteria for these interventions [11–13]. Notably, the International Patient Decision Aid Standards (IPDAS) collaboration have developed a checklist [11] and the IPDAS instrument (IPDASi) [12]. Application of such quality assessments has shown considerable variability in the quality scores achieved [12,14]. However, on reflection it may not be realistic to expect interventions to meet all the quality criteria set out in the IPDAS checklist and listed in IPDASi; some items are more important than others. Neither the IPDAS checklist nor the instrument provide an overall indication of a quality threshold or define a cut-off value that indicates what would constitute a minimum acceptable quality.

To address this issue, Joseph-Williams and colleagues [14] proposed a set of minimum standards based on items included in the 47-item IPDASi (v3.0) [12] that could start discussions about a possible certification process for those interventions. These minimum standards, in contrast to previous efforts, were specifically developed to define a quantitative threshold at which a tool might qualify as an acceptable, and possibly, certified patient decision support intervention. More information about the methods used to develop these standards can be found elsewhere [14]. Items within IPDASi (v3.0) were stratified into qualifying, certification and quality categories according to the importance attributed to them in the Delphi consensus process. To 'qualify', it was proposed that the interventions would have to cover *all* the specified qualification items ($n = 6$). They act as gatekeeper items, identifying those materials that qualify as decision support interventions. Certification items ($n = 10$) encompass criteria found to be essential to avoid harmful bias, such as disclosure of funding source and evidence used. Interventions that 'qualified' to enter a certification process, and subsequently met *all* certification criteria, could be potentially certified as adequate for use by patients, by an agency as yet not identified. Joseph-Williams et al. proposed that the remaining items ($n = 28$) be regarded as items that indicated quality (i.e., additional criteria which confer higher quality but that are not considered mandatory for potential certification). Table 1 provides an overview of each category, the items contained within it and the corresponding item(s) in IPDASi (v3.0).

Table 1
Qualifying ($n = 6$), certification ($n = 10$) and quality ($n = 28$) criteria including corresponding IPDASi (v3.0) dimension and item number (right column).

Category	Code	Item	IPDASi item
Qualifying	Q1	Describes health condition or problem for which index decision is required	Information 1*
	Q2	Explicitly states decision under consideration (index decision)	Information 2
	Q3	Describes the options available for the index decision	Information 3
	Q4	Describes the positive features of each option	Information 5
	Q5	Describes the negative features of each option	Information 6
	Q6	Describes the features of options to help patients imagine the physical, social and/or psychological effects	Value 1 (value items 1, 2 and 3 from IPDASI v3.0 merged)
Certification	C1	Shows positive and negative features of options with equal detail	Information 8
	C2	Provides information about the funding source used for development	Disclosure 1
	C3	Provides citations to the evidence selected	Evidence 1
	C4	Provides a production or publication date	Evidence 3
	C5	Provides information about update policy	Evidence 4
	C6	Provides information about the level of uncertainty around outcome probabilities	Probability 6
	CT1	Describes what the test is designed to measure	Test 1
	CT2	Describes next steps taken if test detects a condition/problem	Test 6
	CT3	Describes next steps if no condition/problem detected	Test 7
	CT4	Describes consequences of detection that would not have caused problems if the screen was not done	Test 9
Quality	QA1	Development included needs assessment to determine what patients need to make the decision	Development 1
	QA2	Development included needs assessment to determine what health professionals need to discuss decision	Development 2
	QA3	Development included review by patients not involve in producing the DSI	Development 3
	QA4	Development included review by professionals not involve in producing the DSI	Development 4
	QA5	DSI was field tested with patients facing the decision	Development 5
	QA6	DSI was field tested with practitioners who counsel patients facing the decision	Development 6
	QA7	Includes author/developers credentials or qualifications	Disclosure 2
	QA8	Evidence that DSI improves match between patient preferences and chosen option	Evaluation 1
	QA9	Evidence that DSI helps patient improve knowledge about options' features	Evaluation 2
	QA10	Describes how research evidence was selected/synthesized	Evidence 2
	QA11	Describes the quality of research evidence used	Evidence 5
	QA12	Provides step by step way to make decision	Guidance 1
	QA13	Includes tools to use when discussing options with practitioner	Guidance 2
	QA14	Describes the natural course of the condition	Information 4
	QA15	Makes it possible to compare features of available options	Information 7
	QA16	Reports readability levels	Language 1
	QA17	Provides information about outcome probabilities (OPs)	Probability 1
	QA18	Specifies reference class of patient for which OPs apply	Probability 2
	QA19	Specifies event rates for Ops	Probability 3
	QA20	Specifies the time period over which OPs apply	Probability 4
	QA21	Allows to compare OPs using the same denominator	Probability 5
	QA22	Provides more than one way of viewing probabilities	Probability 7
	QA23	Asks patients to consider which positive and negative features matter most to them	Value 4
	QAT1	Includes information about chances of having a true positive result	Test 2
	QAT2	Includes information about chances of having a true negative result	Test 3
	QAT3	Includes information about chances of having a false positive result	Test 4
	QAT4	Includes information about chances of having a false negative result	Test 5
	QAT5	Describes the chance the disease is detected with and without use of the test	Test 8

* 'Information 1' refers to the first item in the information domain of the IPDAS instrument V4.0. For the full list of items, see Joseph-Williams et al. [14].

The aim of the present study was to examine the feasibility of applying the minimum standards proposed by Joseph-Williams et al. [14], to a selection of patient decision support interventions included in the 2009 Cochrane Review [9]. We defined feasibility as the extent to which the proposed minimum standards can be applied to existing interventions and whether those standards can realistically be met. The objectives of the study were: (1) to determine the proportion of interventions that would meet what Joseph-Williams et al. call 'qualifying' and 'certification' criteria, and thereby assess whether the application of minimum standards is feasible and (2) to better understand the additional efforts that would be required to modify existing interventions in order to meet the proposed threshold.

2. Methods

The 2009 Cochrane systematic review of 45 patient decision support interventions, evaluated in 55 randomized controlled trials, was used to identify a convenience sample of 30 interventions written in English. Decision support interventions were included if they had been evaluated in a trial that measured and reported at least one of the selected outcome measures: knowledge, accurate risk perceptions, value congruence with choice, participation in decision-making, satisfaction with decision-making process. We asked the developers of the decision support intervention to provide a copy of the tool that was used in the reported trial and to supply all supporting documents (development protocols and relevant publications). If the original decision support intervention was not available, and an alternative version was submitted, the developers were asked to describe the main differences between the versions. We included the first 30 interventions we received, out of the 45 interventions included in the Cochrane review. The Cochrane review was chosen to ensure that included tools were decision support interventions of varying formats, clinical contexts, development processes and quality that had already met the review's inclusion criteria and were therefore expected to meet the qualification items. Developers were invited to take part in the study in November 2009 and asked to provide copies of the interventions and associated background materials (e.g. development documents, relevant publications).

Four trained IPDASi raters (NJ-W, MP, SS, M-AD) assessed the interventions: each was independently assessed by two of the raters using IPDASi (v3.0). Details about the IPDASi dimensions, items and scoring methods are reported elsewhere [12]. If tools were developed for use during a consultation, a sample transcript was requested. Items were scored on a scale of 1–4 (1 = *strongly disagree* to 4 = *strongly agree*). Interventions were required to score positively, i.e. score 3 (*agree*) or 4 (*strongly agree*), in order to meet the item satisfactorily. Where the discrepancy between scores awarded by each rater for the same item differed across the agree/disagree boundary (i.e. difference of two or more points), both raters were consulted and discussed the scores until consensus was achieved. The discussion was overseen and moderated by an independent rater. In addition, inter-rater reliability was examined.

To determine which interventions would potentially qualify and meet certification thresholds, the interventions were classified as 'qualified' and 'certified' if they scored 3 or above on *all* items within the qualification and certification categories. Interventions concerned with screening or diagnostic tests had to meet four additional certification items (CT1-4, see Table 1). An overall quality score out of 100 was also awarded to the interventions.

For interventions that failed to qualify and/or meet certification thresholds, we assessed the type of qualifying and certification criteria that were not met, and how frequently these were not covered by the interventions. These criteria were then reviewed to determine how easy or difficult it might be for developers to modify their interventions in order to meet the proposed threshold.

All analyses were performed using SPSS. Descriptive statistics were used to summarize total quality scores. To examine inter-rater reliability, we used a two-way ANOVA model for global score by tool and rater. Since each intervention was rated by two out of four raters, we needed to de-confound rater and intervention as sources of variation. The ANOVA uses a 'type 1 sum of squares' criterion where the sum of squares component for each factor, and corresponding *F*-test and *p*-value, are duly adjusted for confounding with the other factor.

3. Results

Thirty interventions were assessed using a copy of the tool as well as published evidence describing the development of the tool and/or its evaluation. Six out of those 29 interventions also provided supplementary materials such as a transcript or a link to a website detailing the development process. Only one out of six interventions designed for use in the consultation provided a transcript [15].

The two-way ANOVA analysis, and in particular the estimated mean differences between raters (Table 2), revealed considerable systematic variation between raters ($F = 7.8$, $p = 0.001$). The residual SD in the ANOVA model was 6.6, demonstrating the degree of random disagreement between pairs of raters for the global score.

Nine out of 30 interventions covered screening or testing decisions [15–27], and 21 focused on surgical or medical treatment decisions [28–50]. Table 3 shows how the interventions performed when assessed using qualifying and certification criteria. 83% ($n = 25$) met all the specified qualifying criteria. All the interventions described the options available and associated features in order to help patients imagine the physical effects (qualifying items Q3 and Q6). However, four interventions (13%) did not cover the positive features of each option (qualifying item Q4) [21,27,41,48]. Additionally, one intervention (3%) failed to describe the condition or problem for which the index decision was required (qualifying item Q1) [27]. Two interventions (7%) did not explicitly state the decision under consideration (qualifying item Q2) [27,28] and one intervention (3%) omitted to discuss the negative features of each option (qualifying item Q5) [27].

When certification criteria were applied, only a minority of interventions ($n = 3$: 10%) satisfactorily met the proposed certification threshold and would achieve certification, if such a system were to be introduced. The items most frequently omitted were the update policy (certifying item C5; not included in 25 interventions: 83%), provision of selected citations (certifying item C3; not included in 14 interventions: 47%), information about the level of uncertainty (certifying item C6; not included in 12 interventions: 40%) and disclosure of the funding source (certifying item C2; not included in 9 interventions: 30%).

Interventions concerned with screening or diagnostic tests ($n = 9$) were required to meet four additional certification items. All nine interventions covered what the test was designed to measure (certifying item CT1). However, one (11%) intervention did not describe the steps to be taken if a condition or problem was

Table 2
Estimated mean differences between scores (on 0–100 scale) awarded by individual raters and the corresponding mean scores that would have been obtained using all four raters. From 2-way ANOVA model for global score by tool and rater.

Rater	Estimated difference	95% confidence interval
1	−0.1	−3.8 to +3.6
2	+2.4	−1.3 to +6.1
3	+2.3	−1.4 to +6.0
4	−4.6	−8.2 to −0.9

Table 3
Decision aid qualifying and certification outcomes and quality assessment score.

Developer	Patient decision	Qualified	Certified	Quality score
IMDF [29, 43]	Benign prostatic hyperplasia	•	•	83.33
IMDF [33]	Back surgery	•	•	75.36
Shorten [46]	Birth choice after cesarean	•		69.57
Cranney [31]	Osteoporosis treatment options	•		68.84
Lalonde [36, 37]	Cardiovascular health treatment	•		68.12
IMDF [54]	Hormone replacement therapy	•		67.39
Goel [34]	Breast cancer treatment	•		65.94
IMDF [17, 23,26]	PSA screening	•		64.29
O'Connor [44]	Hormone replacement therapy	•		60.14
Hunter [21]	Prenatal screening			60.12
IMDF [30, 42]	Ischemic heart disease	•	•	58.70
McAlister [39]	Atrial fibrilation treatment	•		57.97
Laupacis [38]	Blood transfusion heart surgery	•		57.25
Whelan [49]	Adjuvant chemotherapy	•		56.52
Gattellari [18]	Prostate cancer screening	•		55.95
Whelan [48]	Breast cancer treatment			53.62
Wong [50]	Pregnancy termination	•		52.90
O'Connor [45]	Hormone replacement therapy	•		52.17
McBride [40]	Hormone replacement therapy	•		52.17
Green [19, 20]	Breast cancer genetic testing	•		42.86
Dolan [16]	Colon cancer screening	•		39.29
Lerman [22]	Genetic breast cancer testing	•		38.69
Johnson [35]	Endodontic treatment	•		37.68
Wolf [27]	Colon cancer screening			35.12
Montgomery [41]	Hypertension treatment			34.78
Bekker [15]	Prenatal screening	•		31.55
Pignone [24, 25]	Colon cancer screening	•		29.17
Street [47]	Breast cancer treatment	•		28.26
Davison [32]	Prostate cancer treatment	•		26.81
Auvinen [28]	Prostate cancer treatment			24.64

detected (certifying item CT2), two (22%) interventions did not describe the steps to be taken if the test did not detect a condition or problem (certifying item CT3) and five (56%) interventions did not disclose the consequences of detection that would not have caused problems if the screen was not done (certifying item CT4). Only two interventions covered all proposed test-related certification criteria satisfactorily. However, these interventions did not meet the proposed certification threshold as other core certification criteria had not been met.

Table 3 shows the overall quality scores out of 100 for all interventions in this sample, adjusted for variation between raters. The mean quality score was 51.64 and the median was 54.79 (ranging from 24.64 to 83.33). The majority of interventions provided information about outcome probabilities ($n = 28$: 93%) and described the natural course of the condition ($n = 27$: 90%). Eighty-seven percent ($n = 26$) made it possible to compare features of available options and 83% ($n = 25$) asked patients to consider which positive and negative features matter most to them, offered step-by-step guidance on making the decision and provided evidence that patients' knowledge about options had improved after using the interventions.

The majority of interventions had not been field-tested with practitioners ($n = 20$: 67%) and did not provide evidence that the intervention improved the match between informed patient preferences and the chosen option ($n = 19$: 63%). Nineteen interventions (63%) did not describe the quality of research evidence used. Other criteria that were often unmet included reviews by patients not involved in development and descriptions of how evidence was selected and synthesized ($n = 18$: 60%).

4. Discussion and conclusion

4.1. Discussion

In this hypothetical application of a proposed set of minimum standards, most interventions met the qualifying criteria while only 10% met the proposed certification threshold. Their failure to do so was primarily explained by the lack of information about disclosure of update policy and funding source(s), or the lack of an explicit acknowledgement of uncertainty about risks and benefits of treatment options. Therefore, the changes required to meet the suggested certification thresholds are relatively minor, and would make certification possible if developers were prepared to make such changes.

Five interventions out of 30 did not meet the proposed qualifying criteria despite being included in the 2009 Cochrane review [9]. This was because the Cochrane review requirements for inclusion as a 'decision aid' differ from those developed for the proposed minimum standards [9,12,14]. For instance, the Cochrane review checklist includes a single item asking whether positive and negative features of options are presented, which may be considered met if an intervention covers *either* positive *or* negative features. In the qualifying criteria suggested by Joseph-Williams et al., this item is dichotomized, requiring that both positive and negative features be presented. In this hypothetical application, none of the interventions that failed to meet the qualifying criteria went on to meet the full set of certification criteria. This supports the potential of qualifying criteria as 'gatekeeper' items to identify candidate interventions.

Further, many of the interventions that failed to 'qualify' were designed for use within clinical encounters, and are typically accompanied by additional verbal information not included in the intervention itself [21,27,28]. The supplementary materials that were requested as part of the evaluation were often unavailable ($n = 24$) and the assessment was based on the published articles and copy of the intervention only. Interventions designed for use in the clinic that were accompanied by additional materials met the qualifying criteria [15,35,49]. These results suggest that interventions designed for use by a skilled facilitator and/or health professional could meet the qualifying criteria should the context and additional materials be taken into account. The increasing range of interventions and processes that fall within the spectrum

of patient decision support interventions does pose challenges for the design of a fair and acceptable certification process. Further investigation is therefore required.

Surprisingly, only three interventions satisfactorily met the certification criteria after minimum standards had been applied [33,42,43]. This may indicate that the certification criteria set out in the proposed minimum standards may be too critical, as they would preclude a large number of decision support interventions from being certified. However, on closer inspection, most of the missing certification items could be addressed relatively easily. The addition of update policy, citations and funding source information in the interventions or associated background documents would more than triple the rate of those reaching certification (from 10% to 37%). Provision of probability ranges or addition of statements that describe the level of uncertainty would further increase the certification rate to 57%. Minor changes, unlikely to add a heavy burden to the development process, would be needed to increase certification rates. Importantly, the standards do not require that these items be covered in the intervention itself; inclusion in the relevant background documents is sufficient to meet the standard. Therefore, despite the low achievement of potential certification observed, we consider the items included in the certification category to be feasible.

Additional certification items for interventions concerned with screening or diagnostic tests, which were only met by a minority of test-related interventions, may be less feasible. To score 3 or above on these items, and hence certify as patient decision support interventions, descriptions of the next steps following a negative or positive test result, as well as the consequences of detection, would need to be added. Meeting these criteria would require more substantial amendments than those needed to meet core certification items. Therefore, we suggest that the test related certification criteria be reviewed, as the present results undeniably questions their applicability.

The wide range of quality scores is consistent with previous studies [12,14], and demonstrates the considerable variability in content. Quality items included in the proposed set of minimum standards should be seen as a guide rather than a mandatory requirement. Interventions that meet these criteria may be of superior quality, and it is recommended that developers attempt to cover as many items in this category as is appropriate. However, similarly to the IPDASi (v3.0), there should be no defined cut-off point in this category at which interventions would fail assessment.

Our assessment was limited to interventions identified in the 2009 Cochrane review [9], and may therefore not fully represent the greater number of interventions recently developed and included in subsequent updates of the Cochrane Review. However, we believe that our sample was, overall, reasonably representative, since it included a variety of developers (small and large academic institutions and healthcare organizations as well as not for profit organizations), formats, and clinical decisions addressed. Further, many of the tools were developed before publication of the IPDAS checklist in 2006 [11]. Interventions could not, therefore, be expected to meet all these criteria. Despite the fact that every effort was made to obtain supporting materials from developers, these were often unavailable, which may well explain the inability to meet the suggested threshold. The 2014 Cochrane review includes decision support interventions developed after the publication of the IPDAS checklist and instrument [7], and we expect that overall qualification and certification rates would increase if the proposed minimum standards were applied to interventions developed more recently. Further research is needed to investigate this assumption.

It was not possible to ascertain the accuracy and appropriateness of the scientific content of these interventions. As noted elsewhere [14], one of the drawbacks of the IPDAS process is the absence of evidence appraisal. Therefore, the possibility remains that even interventions that meet the proposed certification criteria may not contain information that is deemed scientifically sound. This is an unresolved issue and will remain a challenge if attempts are made to set up a certification process.

Finally, the inter-rater reliability analysis demonstrated considerable variation between raters, which warrants further investigation. Although all raters had been trained in using the IPDAS instrument and were experts in this area, inter-rater variation would justify standardizing the rating procedure further and providing additional training, should the minimum standards be implemented.

Despite repeated calls for a certification process to be established, and the efforts of the IPDAS Collaboration [11,12,51], this is the first study to report on the feasibility of a set of proposed minimum standards [14]. Critics have questioned whether standards can or should be set to cover the diverse range of possible interventions, decisions, settings and goals [52]. There are questions about whether a more tailored approach might be required; different standards for different types of interventions. Concerns have also been voiced about whether standards can accurately judge the effectiveness of interventions, and that developers should not adhere to such standards uncritically [53]. Others have called for further theoretical and empirical support for quality measures of patient decision support interventions before implementation [52]. These issues remain unresolved.

4.2. Conclusion

Owing to the steady increase of patient decision support interventions developed over the last decade, and the proven variability in their quality, calls for quality control and certification have emerged [5,11,12,14]. Quality control may help to ensure that these interventions are appropriate and of a necessary standard for intended use and free from harmful bias. Therefore, a set of standards that define a threshold for certification may be beneficial. The qualifying and certification criteria set out in the proposed minimum standards by Joseph-Williams et al. [14] aim to provide such a threshold. This analysis offers a first insight into the feasibility of a set of proposed minimum standards applied to selected interventions suggesting that when hypothetically applied to a range of patient decision support interventions, most qualification items were met. None of the interventions that failed to meet the qualifying criteria met the full set of certification criteria, hence confirming the potential of qualifying criteria as 'gatekeeper' items for the certification process. However, certification was rarely achieved, with only three interventions meeting this threshold. Our analysis revealed that the changes required for an intervention to certify were minor, and could be implemented by developers with minimum effort.

4.3. Practice implications

Therefore, we suggest that it is feasible to apply the current minimum criteria to most but not all patient decision support interventions. Before a certification process can be realized, further investigation is needed for interventions concerned with screening or diagnostic tests and for those designed for use in the clinical encounter. Considerable inter-rater variation suggests that additional training and standardization of the assessment procedures may be required. The latter highlights the importance of the present study in assessing the feasibility of such standards before even considering implementing a certification process. In the meantime, developers of decision support interventions may want to consider the minimum standards when conceptualizing, designing and evaluating new interventions.

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