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Systematic review and evaluation of freely available online diabetes medication decision aids

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Abstract

Rationale, aims and objectives: Diabetes mellitus is likely to be in the top 10 leading global burden of diseases by 2030, where self-management of diabetes is one avenue to alleviate burden. Shared decision-making processes and the use of decision aids may help facilitate self-management in patients with diabetes. We aimed to identify and assess all publicly available online diabetes medication decision aids, for suitability for low health literate patients, in terms of their understandability and actionability.

Methods: Systematic review of public websites in August-November 2017 using an environmental scan methodology, assessment of clinical validity using a high-risk patient profile, assessment of understandability and actionability using the PEMAT-P subscales, readability using the Gunning Fog Index and Flesch-Kincaid Reading score and ratings against the International Patient Decision Aids Standards Instrument Short Form (IPDASi-SF) and Version 4.

Results: Seven diabetes medication decision aids were identified in this study. The mean understandability score was 88% (SD = 10%) the mean actionability score was 52% (SD = 24%) which ranged from 17 to 80%. The mean Gunning Fog index was 10.8 (SD = 0.7), the mean Flesch-Kincaid Reading Score was 10.1 (SD = 0.7) the mean IPDASi-SF score was 57.34 (*SD*=9.86). The Development subscale scores for the IPDASi-SF were poor (mean 1).

Conclusions: Understandability of the decision aids overall was good however with the US 10th grade reading levels they may not be suitable for a low health literacy audience. Actionability was also less than favourable.

Keywords

Diabetes, decision aid evaluation, decision aids, economic burden, evaluation, health literacy, international decision aid criteria, patient-centered care, patient communication, patient education, person-centered healthcare, shared decision-making

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Introduction

Diabetes mellitus is an increasing epidemic projected to be the seventh leading burden of disease by 2030 [1] with a large economic burden that is highly variable across and within countries [2]. Lifestyle change such as increased physical activity and improved nutritional intake can help reduce diabetic complications arising from poor glycemic control [3,4]. Daily pharmacological intervention has also been demonstrated to be an effective measure for glycemic control [5]. Due to the natures of these effective interventions, self-management of diabetes has become a major proponent of most Western clinical management guidelines [6-8].

The Royal Australian College of General Practitioners, the UK National Institute for Health Care and Excellence and the American Diabetes Association all recommend pharmacological and lifestyle intervention through patient-centred care for individuals with type 2 diabetes [6-8]. This involves communication that incorporates patient's values, preferences and which provides information based on patients' numeracy and literacy capacities. It can also

involve diabetes self-management education and support to facilitate the knowledge and skills needed by the patient for ongoing management [6-8]. Most of the self-management is directed at glycemic control *via* lifestyle change (physical activity, nutritional intake) and pharmacological intervention. All 3 guidelines have very similar recommendations for pharmacological interventions with all indicating metformin as the initial choice and dual and triple therapies (i.e., additional medication combined with metformin) if metformin alone does not produce favourable outcomes [6-8]. Additional drugs that are recommended in these guidelines as second line therapies include sulphonylureas, dipeptidyl peptidase inhibitors and sodium glucose co-transporter 2 inhibitors. Third line therapies include insulin and glucagon-like peptide-1 receptor agonists. However, unlike lifestyle interventions, medications can come with complications. For example, long term use of metformin has been associated with B12 deficiency and anemia [9]. Metformin and sulfonylureas have demonstrated higher rates of hypogylcaemia compared to other metformin-based combination second line therapy [5]. This uncertainty created by medication use for glycemic control is a prime circumstance wherein patient preferences and values should be used to guide their final decision [10]. Shared decision-making, which is consistent with the patient-centred approach to diabetes management endorsed by all 3 guidelines, provides the implementation framework for this guidance.

Shared decision-making can be described as the midpoint between "paternalistic" decision-making (e.g., the health professional telling patients what to do) and "consumerist" decision-making (e.g., the patients telling the doctor what to do) [11]. It is the process wherein patients and health professionals both contribute to the final healthcare decision for the patient [11]. A significant part of this process involves the health professional and patient engaging in a balanced discussion of the harms and benefits for each possible option, which can be facilitated by the use of a decision aid [12]. Decision aids are designed to facilitate shared decision-making and informed choice and have improved knowledge, more accurate risk perceptions, better congruency between values and their decision and decreased decisional conflict, compared to usual care [10]. In the context of type 2 diabetes, decision aids have also been demonstrated to improve patient involvement in their health decisions [13,14] as well as improve medication adherence [15]. These studies also identified that the effective decision aids were ones that were short and succinct. This suggests an important role of health literacy which identifies short and succinct text as a principle for low health literacy materials [16].

Health literacy is the capacity to obtain, process, comprehend, appraise and act on health information [16-18]. Decision aids in general have a greater difficulty in engaging patients with low health literacy in the shared decision-making process [19]. Lower health literacy patients have been associated with increased decision uncertainty and increased decision regret compared to higher health literacy patients [19]. Low health literacy is also associated with poor self-management and worse chronic disease outcomes [20]. Type 2 diabetic patients with poor health literacy have demonstrated poorer glycaemic control compared to those with adequate health literacy [21]. Given that low health literacy rates in the general populations across some major Western countries are high (Australia: 59% [22], Europe: 47% [23], Canada: 60% [24]), it is critical to address the health literacy demand for providing patient education materials catered to a low health literacy audience.

With the demonstrable positive effects of decision aids it is evident that they are an effective tool to engage patients in their decision-making around medications to manage their diabetes. To address whether there are high quality decision aids for a low health literacy population, this study aimed to identify publicly available diabetes medication decision aids and evaluate their quality in terms of international decision aid criteria and suitability for patients with low health literacy.

Methods

An environmental scan was employed to address this research question. Environmental scans have been used previously due to their wider reach compared to that of a traditional systematic review to answer this type of research question [25-28].

Ethical approval

Since there were no participants in this study and the data was based on publicly available websites, an ethics application was not required.

Inclusion and exclusion criteria

Decision aids were considered if they met all inclusion criteria: (1) focus on decision about diabetes medication or for glycemic control, (2) provides information about the diabetes medication, (3) freely available and (4) written in English. Exclusion criteria included: (1) paid material, (2) developed by a company with a vested interest in medication (e.g., pharmaceutical), (3) targeted at health professionals, (4) focuses on insulin delivery methods, (5) focuses on gestational diabetes or pregnancy decisions, (6) focuses on childhood diabetes or (7) focuses on non-medication management options (e.g., bariatric surgery).

Search strategy

There were 2 main sources for identifying web addresses that inventoried diabetes decision aids. One source was from known online decision aid repositories (see Table 1) and the second was a systematic internet search using Google Australia with English-language terms. The 2 independent reviewers (LH and NN) were instructed to reset their Cache in their web browsers before each Google search to minimise the effect of Google search optimisation. The 2 search term themes were Diabetes

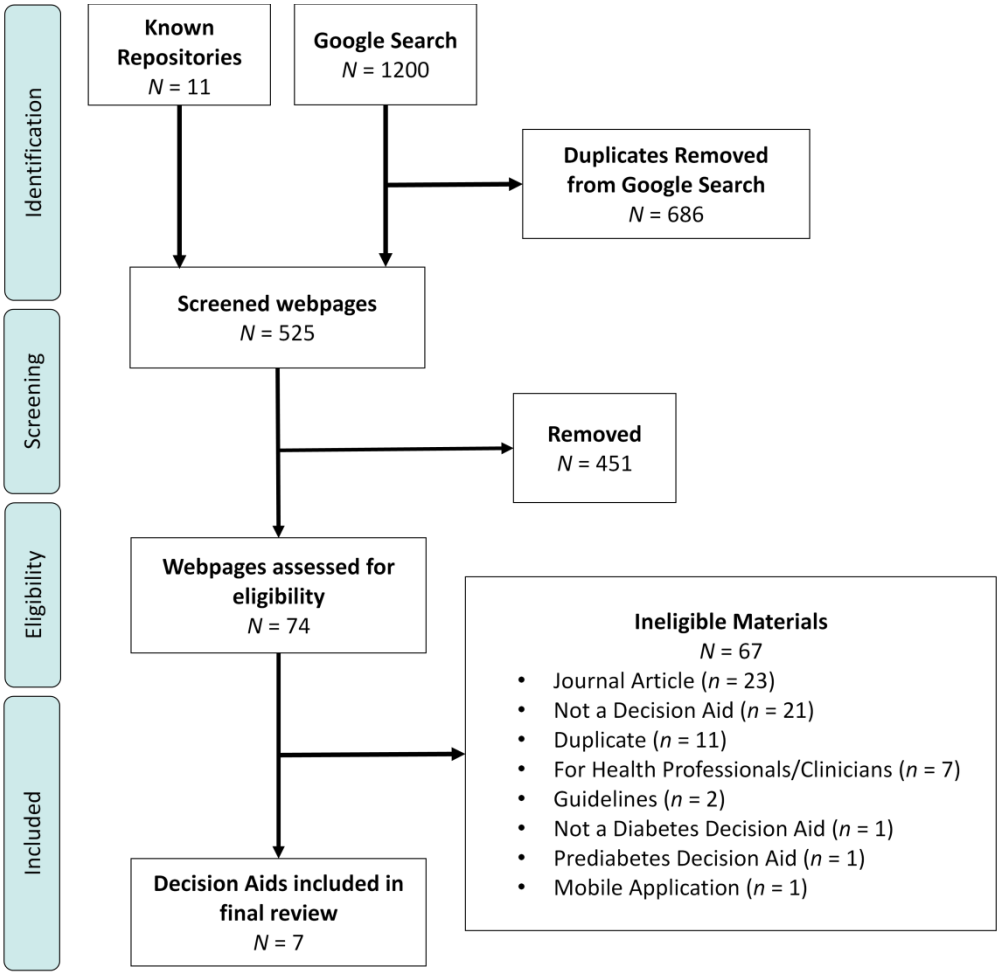
Table 1 List of Known Repositories

Organisation	Website
The Decision Aid Library Inventory (DALI) – Ottawa Research Institute	https://decisionaid.ohri.ca/AZlist.html
Option grids	http://optiongrid.org/
Agency for Healthcare Research and Quality	http://www.effectivehealthcare.ahrq.gov/tools-and-resources/patient-decision-aids/
NHS (accessible)	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/
NICE Decision Aids	https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making
Mayo Clinic Decision Aids	http://www.mayoclinic.org/
MAGIC SHARE-IT Public Guidelines/ Decision Aids	https://www.magicapp.org/app#/guidelines
Decision Boxes at Laval University	http://www.decisionbox.ulaval.ca/
Annalisa Decision Aids at Sydney University	http://healthedecisions.org.au/team/
CeMPED Decision Aids at Sydney University	http://www.psych.usyd.edu.au/cemped/com_decision_aids.shtml
Health fact boxes at the Harding Centre for Risk Literacy	https://www.harding-center.mpg.de/en/health-information/fact-boxes
Cochrane Decision Aids for Muskuloskeletal group	http://musculoskeletal.cochrane.org/decision-aids
Patient Decision Aid site (mostly NHS, OG, M)	http://patient.info/decision-aids
NHS (restricted access)	http://sdm.rightcare.nhs.uk/pda/
Annalisa Decision Aids at Norway (restricted access)	https://mybetterdecisions.org/

Table 2 Percentage agreement between reviewers (LH and NN) Google search results for each set of terms

Search Terms	**Agreement (%)**
Diabetes Glucose decision aid	40%
Diabetes Glucose decision support	36%
Diabetes Glycaemic decision aid	39%
Diabetes Glycaemic decision support	39%
Diabetes Glycemic decision aid	40%
Diabetes Glycemic decision support	40%
Diabetes insulin decision aids	38%
Diabetes insulin decision support	39%
Diabetes medication decision aid	0%
Diabetes medication decision support	42%
Diabetes metformin decision aid	3%
Diabetes metformin decision support	40%

Figure 1 Search strategy and results



Medications and Decision Aids. The lead researchers (MF and CB) and the 2 independent reviewers agreed upon 6 specific terms for Diabetes Medication: diabetes medication, diabetes metformin, diabetes insulin, diabetes glucose, diabetes glycemic and 2 terms for Decision Aids: decision aid and decision support. Each unique pairing of a diabetes and decision aid term generated 12 Google searches. The first 50 results not including web advertisements were exported using browser plugins (SEOQuake for Mozilla Firefox or GLChrome Extension for Google Chrome), providing 2 pools of 600 webpages to be screened. The percentage of results that were identical within each search term set from the independent reviewers are shown in Table 2. Duplicates were then removed from the initial pools. Independent reviewers screened webpages for inclusion and conflicts were discussed and resolved at a meeting with the lead researchers (MF and CB) where reasons for exclusions are provided in Figure 1. The reviewers conducted this search as part of a Master of Public Health degree capstone unit during August to November 2017.

Evaluation and data extraction

The 2 independent reviewers (LH and NN) rated the content of each decision aid using the validated Patient Education Material Evaluation Tool for Print Materials (PEMAT-P) [29]. PEMAT-P provides 2 sub-measures that are particularly relevant to health literacy: (1) understandability, which is a measure of how well a health consumer is able to process and explain the key message of the material, where higher percentages indicate better understandability and (2) actionability, which is a measure of how well a health consumer is able to identify what to do based on the information presented, where higher percentages indicate better actionability. Reviewers were instructed to read the PEMAT User guide and conduct the evaluation on 2 decision aids. Once completed, reviewers met with a third researcher (CB) to discuss concerns with the items before continuing to evaluate subsequent decision aids. The correlation between initial understandability and actionability for the independent reviewers were 0.87 and 0.41 respectively. The percentage agreement ranged from 57% to 100% and Cohen kappa's ranged from 0.22 to 1. Conflicts were resolved by discussion and resolved by a third rater (CB) if consensus was not reached.

Readability

Each decision aid's readability was measured using the Gunning Fog index, which is an index that estimates the

Table 3 Decision aid characteristics and evaluations

ID	URL	Medication	Understandability	Actionability	Gunning Fog Index	Flesch–Kincaid Grade Level	Final IPDASi-SF
DA47	http://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/diabetes-medication-management/	Insulin	100	80	9.8	8	56.46
DA35	https://cdn1.scrvt.com/08ab3606b0b7a8ea53fd0b40b1c44f86/fa4ec74ada67bbab/cdebc5170953/Lifestyle-and-metformin-for-type-2-diabetes.pdf	Insulin	86	29	9	8.2	59.74
DA33	https://decisionaid.ohri.ca/AZsearch.php?criteria=diabetes	Metformin	93	60	10.9	9.6	68.65
DA40	https://diabeteswa.com.au/manage-your-diabetes/resources/	Multiple	100	80	10.5	10.2	47.76
DA42	https://innovation.cms.gov/Files/x/cpcipsl-rc4.pdf	Multiple	87	17	8	7.3	45.26
DA17	https://prezi.com/wvzjedfagkia/insulin-decision-aid/	Multiple	81	40	10.5	8.3	52.5
DA48	https://southwest.devonformularyguidance.nhs.uk/formulary/chapters/6.-endocrine/type-2-diabetes-treatment-guidance	Multiple	71	60	11.6	10	71.04

formal years of (US) education an individual needs to understand the text [30]. Scores range from 0 to 20 which corresponds to the US grade level that the text should be easily understood by, for example, a score of 6 would indicate the test should be easily understood by those educated to the 6th grade level in the US schooling system. Similarly, the Flesch-Kincaid Grade level was obtained for each decision aid. This score indicates the number of years of US education that may be required to understand the text [31]. One author obtained readability scores (MF).

IPDAS Checklist

Two independent raters (LH and NN) used the International Patient Decision Aids Standards Instrument-Short Form (IPDASi-SF) to assess the included decision aids [32]. Each item is rated on a 4 point Likert scale (1 = Strongly Disagree, 4 = Strongly Agree). Items are divided into 8 sections: information (4 items), probabilities (3 items), values (1 item), development (3 items), disclosure (1 item), evaluation (2 items) and evidence (2 items). Total scores are calculated by the sum of all items and then converted into a value out of 100. Higher values indicate closer agreement with meeting the criteria of a decision aid. The IPDASi-SF is a shortened version of the third iteration of the International Patient Decision Aids (IPDAS) Checklist. The short form has demonstrated a 0.87 correlation with the IPDAS 47-item version [32]. Two independent raters (MF and CB) also used the IPDAS v4 [33] without screening test items was also used. IPDAS v4 has 3 subsections: qualifying, certifying and quality criteria. Qualifying criteria are measured on a binary yes-no scale and certification and quality criteria are measured on a 4 point Likert scale. To qualify as a decision aid, all 6 qualifying criteria must be met. To be certified as a decision aid, all 6 certifying criteria must score at least 3. Agreement for the qualifying criteria items ranged from 43% to 86% and the correlations between certification items ranged from 0.27 to 0.86 and for quality items ranged from 0.35 and 0.61.

Results

This search yielded 7 unique decision aids for a diabetes medication (see Figure 1). Two decision aids were specific to insulin, one decision aid was specific to metformin and 4 decision aids explored multiple medication options such as sulphonylureas or insulin as alternatives to metformin [5].

Decision Aid Evaluation

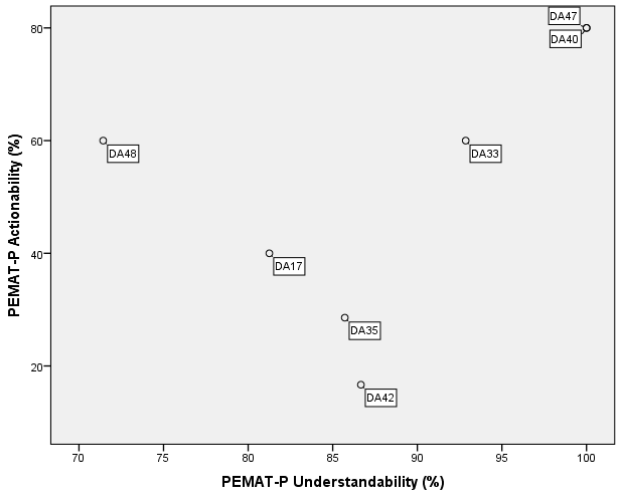
Table 3 details individual PEMAT-P, readability and IPDASi-SF final scores. The mean understandability score was 88% (*SD* = 10%) which ranged from 71% to 100% and the mean actionability score was 52% (*SD* = 24%) which ranged from 17% to 80%. The average Gunning Fog

index was 10.8 (*SD* = 0.7) and the average Flesch was 10.1 (*SD* = 0.7). For the IPDAS checklist, the correlation between the 2 raters was 0.95 and the mean IPDASi score was 57.34 (*SD*=9.86). Table 4 provides the mean IPDAS-SF scores per section of the checklist. Figure 2 graphically depicts the relationship between understandability and actionability for each decision aid. For the version 4 IPDAS evaluation, 2 decision aids met the criteria to qualify for a decision aid and the median was 83% (5 out of 6 criteria met) ranging from 50% (3 criteria) to 100% (6 criteria). No decision aid scored 3 or above on all 6 items to be certified as a decision aid and the median was 50% (3 out of 6 items) ranging from 33% (2 criteria) to 67% (4 criteria). The median quality criteria that scored 3 or above was 22% (5 out of 23 criteria) ranging from 9% (2 criteria) to 35% (8 criteria).

Table 4 IPDASi-SF Mean ratings per IPDAS section

IPDAS-SF Section	Mean rating
Information	3.2
Probabilities	1.8
Values	3
Development	1
Disclosure	1.9
Evaluation	2.5
Evidence	2.2

Figure 2 Scatterplot of understandability scores against actionability scores for each decision aid



Discussion

Seven diabetes medication decision aids were identified in this study. Four decision aids addressed multiple medication options, two addressed insulin and one addressed metformin. The decision aids that addressed multiple medication options all contained metformin as a choice alongside alternatives recommended in guidelines such as sulphonylureas, dipeptidyl peptidase inhibitors and sodium glucose co-transporter 2 inhibitors and one decision aid addressed a second medication to supplement metformin monotherapy (i.e., second line as outlined in each of the UK, American and Australian guidelines). However, our review did not identify any decision aid that addresses triple therapy.

Generally, these decision aids performed well on understandability; however, reading scores on average were US 10th grade reading levels so despite favourable understandability scores, these decision aids may not be suitable for patients with low health literacy. Actionability, however, was only moderate and sometimes poor, which is concerning given that these tools are marketed as decision aids. However, given that IPDASi-SF ratings on average were only 57.34, a lot of the checklist items were not adequately met. Within the IPDASi-SF, the decisions aids adequately met criteria about the information and values though begin to decline in the areas of probabilities, disclosure, evidence and evaluation and fail in development. The poor adherence to the IPDASi-SF appears to lie in the lack of "behind the scenes" reporting of how the decision aid had been developed. Moreover, IPDASi-SF criteria does not necessarily put an emphasis on the capacity of decision aids to communicate actions compared to the balancing information about the harms and benefits of each option, so the low actionability may be a by-product of decision aid development. This is echoed in the how poorly these decision aids meet the IPDASi-SF criteria specific to the development of the decision aid (i.e., development, evidence and evaluation sections) compared to the informational content (i.e., information, values and probabilities sections). Moreover, this trend is reflected in the IPDAS v4 scores where certification criteria and quality criteria, both of which comprise development and communication components, were scored low overall.

Meetings to resolve conflicts and using multiple searchers strengthens the confidence in the final results of this study. Notwithstanding the difficulty with Google searches due to the dynamic nature of websites and their low reproducibility of results (0-42% agreement), we believe we have obtained a temporally representative sample of available diabetes medication decision aids. PEMAT-P reliability is difficult to assess given a small sample size; however, the use of a third reviewer to resolve conflicts provides a greater confidence in the final reliability of the PEMAT-P ratings. In terms of the small sample, the summary statistics for the IPDASi-SF sections are easily swayed by a single observation and so caution should be exercised in these interpretations despite the IPDASi-SF demonstrating good inter-rater reliability.

Conclusion

Freely available diabetes medication decision aids are consistently understandable, but due to their 10th grade reading levels may still not be suitable for patients with

low health literacy. These decision aids also vary in their actionability thus increasing the difficulty for patients to easily take action based on the information provided. Health professionals should be aware of the limitation of these decision aids and aim to supplement these areas, particularly in the case of the patient with low health literacy, with further individualised explanations and actionable items in the consultation room. Future diabetes decision aids or updates would benefit through the incorporation of a goal to lower reading levels and to improve actionability with more tailored information to better suit a low health literacy audience and communicating information using visual aids.

Acknowledgements and Conflicts of Interest

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