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Online decision aids for cardiovascular disease prevention: Systematic review and evaluation of quality

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3 Online decision aids for cardiovascular disease prevention:
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5 Systematic review and evaluation of quality
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9 Authors: Carissa Bonner^{1,2}, Pinika Patel^{1,2}, Michael Fajardo^{1,2}, Ruixuan Zhuang¹, Lyndal
10 Trevena^{1,2}
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12
13

14
15 Affiliations:
16

- 17 1. Sydney School of Public Health, The University of Sydney, NSW, Australia
18
19 2. ASK-GP Centre of Research Excellence, The University of Sydney, NSW, Australia
20
21
22
23
24
25

26 Corresponding Author:
27

28 Mr Michael Fajardo
29

30 Rm 128C, Edward Ford Building A27, The University of Sydney, NSW 2006, Australia
31

32 Email: michael.fajardo@sydney.edu.au
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Abstract

Objectives: Recent guideline changes for cardiovascular disease (CVD) prevention medication have resulted in calls to implement shared decision making rather than arbitrary treatment thresholds. Less attention has been paid to existing tools that could facilitate this. Decision aids are well established tools that enable shared decision making and have been shown to improve CVD prevention adherence. However, it is unknown how many CVD decision aids are publicly available for clinicians and patients online, what their quality is like and whether they are suitable for patients with lower health literacy, for whom the burden of CVD is greatest. This study aimed to identify and evaluate all publicly available online CVD prevention decision aids based on: 1) suitability for low health literacy populations (understandability, actionability and readability); and 2) International Patient Decision Aid Standards.

Design: Systematic review of public websites in August-November 2016 using an environmental scan methodology, with updated evaluation in April 2018.

Primary outcome measures: Understandability and actionability using the validated PEMAT-P scale; readability using Gunning-Fog and Flesch Kincaid indices; and quality using IPDAS versions 3 and 4.

Results: A total of 25 unique decision aids were identified. On the PEMAT-P scale, the decision aids scored well on understandability (mean 87%) but not on actionability (mean 61%), readability was also higher than recommended levels (mean Gunning Fog index = 10.1; suitable for Grade 10 students). Four DAs met all qualifying criteria and one met certification criteria.

Conclusions: Publicly available CVD prevention decision aids are not suitable for low literacy populations and only one met international standards for certification. Given that patients with lower health literacy are at increased risk of CVD this urgently needs to be addressed.

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Key words: cardiovascular disease, decision support, decision aid, prevention, shared decision making, health literacy

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Strengths and Limitations of this Study

- First systematic search to identify and evaluate freely available online CVD Decision Aids using the International Patient Decision Aid Standards (IPDAS), the most credible and internationally recognised measure for evaluating patient decision aids
- Patient decision aids were evaluated using the multiple versions of IPDAS as well as the validated Patient Education Materials Assessment Tool for Printed Materials measure relating to health literacy, extracted independently by two reviewers where discrepancies were resolved via discussion to reduce bias
- Google results are not replicable due to the changing nature of the search algorithm and websites; but using Known Repositories may assist researchers and clinicians to conduct similar searches
- We did not assess the accuracy of the information provided by these decision aids

Introduction

Cardiovascular disease (CVD) prevention is a key issue for primary care, as one of the most common problems managed in general practice¹ and the leading cause of mortality and morbidity in developed nations.² Clinical guidelines recommend lifestyle interventions with the addition of medication to lower blood pressure and/or cholesterol if CVD risk becomes high.³⁻⁵ However, recent guideline changes for cardiovascular disease (CVD) prevention medication have increasingly lowered the threshold for treatment: statin initiation has reduced from 20% absolute CVD risk over 10 years down to 10% in the UK and 7.5% in the US;^{6,7} and the latest US hypertension guidelines recommend a very low threshold of 130mmHg for blood pressure medication.⁸ These changes have led to wide debate in leading medical journals (e.g. BMJ, JAMA, Lancet), with calls to implement shared decision-making based on both benefits and harms as well as patient preferences, rather than arbitrary treatment thresholds for CVD prevention.⁶⁻¹⁰

Shared decision making is important in this context, because there are many ways to reduce risk and weighing up the benefits and harms of different options is dependent on individual preferences.^{7,9} For example, a 60 year old female smoker with elevated blood pressure (130/80 mmHg) and cholesterol (5/1.8 total/HDL) will have a 10% chance of a CVD event in the next 10 years based on the Framingham model (see <http://chd.bestsciencemedicine.com/calc2.html> for risk and intervention estimates using different models). She may prefer to avoid the side effects and costs of medication and focus on changing her lifestyle,¹¹ which could reduce her risk to 6% if she quit smoking, or 7% if she adopted a Mediterranean diet or increased her physical activity to high levels. Alternatively, she may be unwilling or unable to make these changes,¹¹ and would prefer to reduce her risk to 7% with either low-moderate intensity statins¹² or blood pressure lowering medication.¹³ Although these options have different *relative* risk reduction benefits, when the baseline CVD risk is only 10% the *absolute* benefit is very similar, so patient preferences must be taken into account.

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3 Little attention has been paid to existing tools that could facilitate shared decision making in
4 this context. Decision aids are well established as an effective tool to help patients engage in
5 shared decision making about their health. International standards have been developed to
6 ensure they provide evidence-based, unbiased information about benefits and harms, using
7 multiple formats to enhance patient understanding (available at
8 <http://ipdas.ohri.ca/using.html>). The latest Cochrane review on this topic found 105 RCTs
9 evaluating decision aids, with positive effects on knowledge about options, value
10 clarification and feelings of being better informed.¹⁴ Patient decision aids for CVD
11 prevention have been shown to improve uptake and self-reported adherence to preventive
12 interventions¹⁵, however not all decision aids have reported similar effects on adherence.
13 The *Statin Choice* decision aid aimed at CVD prevention in diabetes did not report similar
14 adherence to statins but did report that patients accurately perceived their risk for heart
15 attack.¹⁶

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28 The availability of high quality, understandable health information is particularly important
29 considering the burden of CVD is greater for people with low health literacy. This means
30 they do not have adequate skills to access, understand and use resources to manage their
31 own health. The majority of the general population falls into this category, and this is
32 associated with less regular healthcare access, lower uptake of prevention services, poorer
33 self-management, greater medication errors, worse CVD outcomes and increased all-cause
34 mortality.¹⁷⁻¹⁹ It is therefore important to consider the needs of patients with low health
35 literacy skills when developing online shared decision making tools, which are likely to be
36 accessed with little support from health professionals.

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46 This study aimed to systematically review the online environment for patient decision aids
47 relating to primary CVD prevention, and evaluate their quality based on international
48 patient decision aid standards and health literacy criteria.

49 50 51 52 53 54 Methods

Inclusion and exclusion criteria

Decision aids were considered if they met all inclusion criteria: 1) focus on primary prevention (i.e. not secondary prevention or treatment for established CVD), 2) provides information about blood pressure medication, cholesterol lowering medication, and/or aspirin, 3) freely available, and 4) written in English. Exclusion criteria included: 1) could not be viewed due to technical problems after 2 attempts, 2) developed by a company with a vested interest in medication (e.g. pharmaceutical), or 4) targeted at health professionals.

Search methods

This rationale behind this search strategy originated from the innovative methodology of an environmental scan. This originated in a business context and was developed to retrieve and organise data from varying contexts to make decisions about the future.²⁰ An environmental scan can be described as an efficient and organised means to collect specific information a given topic/institution that is pertinent to its internal workings and external influences/surrounding. Part of the process involves a purposive approach to a search from which the search is then exploded. For this study we identified known online decision aid repositories (see Table 1) as the most likely sources to contain relevant information pertinent to this study. Our second source was from Google Australia.

Table 1. List of known decision aid 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 Das	http://www.mayoclinic.org/
MAGIC SHARE-IT Public Guidelines/Das	https://www.magicapp.org/app#/guidelines
Decision Boxes at Laval University	http://www.decisionbox.ulaval.ca/
Annalisa DAs at Sydney University	http://healthdecisions.org.au/team/
CeMPED DAs 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 DAs for Musculoskeletal group	http://musculoskeletal.cochrane.org/decision-aids
Patient DA site (mostly NHS, OG, M)	http://patient.info/decision-aids
NHS (restricted access)	http://sdm.rightcare.nhs.uk/pda/
Annalisa DAs at Norway (restricted access)	https://mybetterdecisions.org/

Two independent searchers (PP and RZ) were instructed to reset their Cache in their web browsers before each Google search to minimise the effect of Google search optimisation. The final search terms after piloting included 11 for CVD/Medication and 2 for Decision Aids. The lead researchers (CB, LT) and the two independent searchers agreed upon 11 specific terms for CVD/Medication: cardiovascular disease; heart disease; stroke; heart attack; hypertension; hypercholesterolemia; hypercholesterolaemia; aspirin; blood pressure medication; cholesterol medication and statin, and two specific terms for Decision Aids: decision aid and decision support. Additional terms were pilot tested before settling on the final list. A single CVD/Medication term and a single Decision Aids term were combined for each search, resulting in 22 unique Google searches. The first 50 results were considered (not including web advertisements), providing a pool of 1100 results to be title scanned for each searcher (2200 results in total). Scanning the first 100 search results for the first few

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3 searches found no additional resources after the first 50 results, so the cut-off of 50 was
4 retained.
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9 The two independent searchers conducted this search as part of a Master of Public Health
10 degree capstone unit during August to November 2016. In March 2017, an independent
11 rater (CB) reconciled these search results at the earliest stage feasible (see Figure 1), and
12 the original searchers completed any missing ratings for the final dataset. Only websites that
13 were still working when the third independent rater reconciled the lists were included.
14 Duplicates were considered either as identical web addresses or identical PDFs.
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22 *Evaluation and data extraction*

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26 The two independent searchers rated the content of each decision aid using a validated tool
27 to assess whether printed materials are suitable for people with low health literacy, the
28 Patient Education Material Evaluation Tool for Print Materials (PEMAT-P).²¹ PEMAT-P
29 includes two subscales: 1) understandability, which is a measure of how well a person is
30 able to process and explain the key message of the material, where higher percentages
31 indicate better understandability; and 2) actionability, which is a measure of how well a
32 person is able to identify what to do based on the information in presented, where higher
33 percentages indicate better actionability. For the two independent searchers, the
34 correlation between understandability scores was .53 and the correlation between
35 actionability scores was .46. Conflicts were therefore resolved by the third rater (MF, after
36 discussion with CB) to finalise the PEMAT-P score for each individual decision aid. A
37 threshold of 70% was used to determine whether the decision aid was understandable or
38 actionable.²¹
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51 *Readability*

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3 Each decision aid's readability was measured using the Gunning Fog index, which is an index
4 that estimates the formal years of (US) education an individual needs to understand the
5 text.²² Scores range from 0 to 20 which corresponds to the US grade level that the text
6 should be easily understood by, for example a score of 6 would indicated the test should be
7 easily understood by those educated to the 6th grade level in the US schooling system. The
8 Flesch Kincaid Reading Ease score was also calculated with higher scores indicating greater
9 ease of comprehension. Scores range from 0 to 100 where a score of about 70-80 is the
10 equivalent to school grade 7.²³ The correlation between two independent ratings was high
11 (Gunning Fog Index was 0.91 and Flesch Kincaid was 0.94) so the average of the two scores
12 were used as the final index.
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22 *IPDAS Checklist*

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26 The two independent researchers (PP and RZ) each completed a checklist based on version
27 3 of the IPDASi items, with discrepancies resolved by a third rater (MF, after discussion with
28 CB). In addition, two independent raters (PP and MF) used the International Patient Decision
29 Aids Standards Instrument-Short Form (IPDASi-SF) to assess the same decision aids on a
30 quantitative scale.²⁴ Each item is rated on a 4 point Likert scale (1 = Strongly Disagree, 4 =
31 Strongly Agree). Total scores are calculated by the sum of all items and then converted into
32 a value out of 100. Higher values indicate closer agreement with meeting the criteria of a
33 decision aid. The IPDAS-SF is a shortened version of the third iteration of the IPDAS. The
34 short form has demonstrated a 0.87 correlation with the IPDASi 47-item version.²⁴ In April
35 2018 the evaluation was repeated by two researchers (CB and MF) using IPDAS v4, an
36 updated version of IPDAS v3 that reclassified the items into three domains with some
37 revised wording: qualifying, certification and quality. All decision aids in the original
38 evaluation were still publicly available at this time. Qualifying criteria are measures on a
39 binary yes-no scale and certification and quality criteria are measured on a 4 point Likert
40 scale. To qualify as a decision aid, all 6 qualifying criteria must be met. To be certified as a
41 decision aid, all 6 certifying criteria must score at least 3. Agreement for the qualifying
42 criteria items ranged from 64% to 100% and the average correlation between certification
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3 and qualifying items were .35 and .61 respectively. Questions relating to screening tests
4 were not used.
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8 9 Results

10 The search of 15 known repositories and 2200 google search results yielded 25 unique CVD
11 prevention decision aids (see Figure 1). Table 2 details the overall evaluation of the decision
12 aids; and Table 3 presents scores by individual decision aid. The Appendix provides the full
13 IPDAS checklist item results and web archive URLs for the included decision aid webpages.
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16 ***Evaluation of the quality of the decision aids***

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18 For the version 3 IPDASi-SF (short form) scale, the correlation between the two raters was
19 0.76 and the mean (SD) score was 64.56 (10.80) out of a maximum 100. For the version 3
20 IPDAS evaluation, none of the decision aids met all qualifying criteria to *be defined as a*
21 *patient decision aid* and the median was 71% (5 out of 7 criteria met). None of the decision
22 aids met all criteria to *lower the risk of making a biased decision*, and the median was 33%.
23 None of the decision aids met all criteria to *indicate quality*, and the median was 85%. For
24 the version 4 IPDAS evaluation, four decision aids met the criteria to *qualify* for a decision
25 aid and the median was 83% (5 out of 6 criteria met) ranging from 2 to 6. One decision aid
26 scored 3 or above on all six items to *certified* as a decision aid and the median was 50% (3
27 out of 6 items) ranging from 1 to 6. The median quality criteria that scored 3 or above was
28 30% (7 out of 23 criteria) ranging from 1 to 12 items.
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31 A central component of decision aids is to present all options, risks and benefits in a
32 balanced and unbiased way, with visual representation of numerical information. Nineteen
33 decision aids provided only one intervention option (73%), whereas the remaining six
34 provided 2-7 different options (27%). The presentation of harms versus benefits in icon
35 arrays was highly variable. Of the 12 decision aids that used icon arrays, 5 (42%) presented
36 only benefits in icon arrays and 7 (58%) presented benefits and harms in icon arrays. Of the
37 7 that presented benefits and harms in icon arrays, 4 (57%) combined benefits and harms in
38 one icon array and 3 (43%) separated them. Of the 4 that combined benefits and harms in
39 one icon array, 1 (25%) separated the benefits and harms and 3 (75%) overlapped the
40 benefits and harms.
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Evaluation of suitability for low health literacy populations

For the PEMAT-P evaluation, the decision aids generally scored well on understandability but lower on actionability. The average understandability score was 87% (SD = 7.1%) and actionability was 61% (SD = 24.6%). For readability, the average Gunning Fog index was 9.9 (SD=1.9) and Flesch Kincaid was 61.8 (SD=10.3), indicating that a US school grade of 9 is required to understand the information. The correlation between understandability and readability was -0.60 for Gunning Fog and 0.59 for Flesch Kincaid.

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Figure 1. PRISMA Flow Diagram of searcher results (Search 1 PP, Searcher 2 RZ)

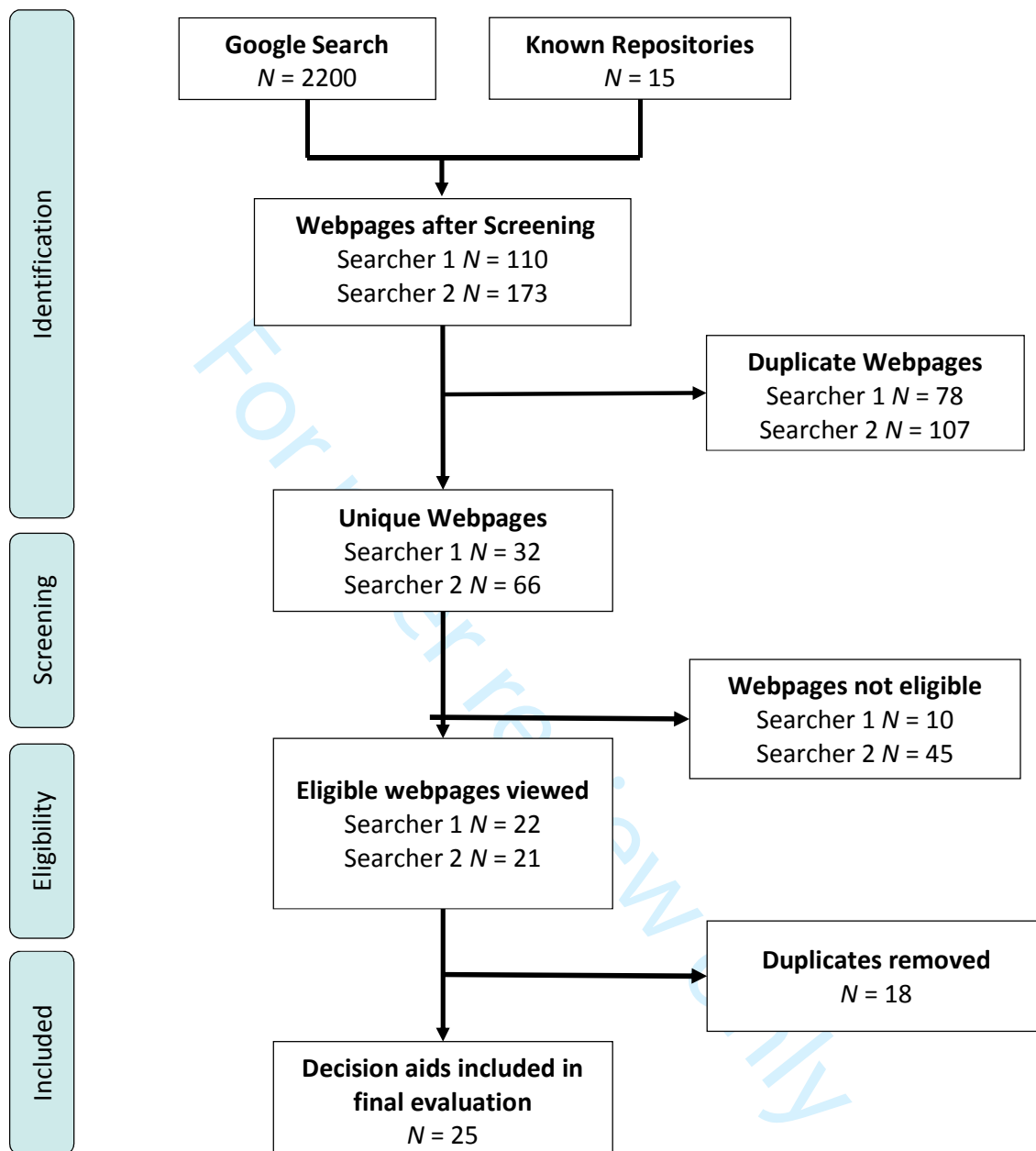


Table 2. Evaluation for included decisions aids (n=25)

Decision Aid Evaluation			
Intervention options		Count (%)	
Medication	Cholesterol-lowering	14 (56)	
	Blood pressure lowering	5 (20)	
	Aspirin	8 (32)	
Lifestyle ^a	Any lifestyle change included	7 (28)	
	Quit smoking	3 (12)	
	Improve diet	2 (8)	
	Increase physical activity	2 (8)	
	Lose weight	2 (8)	
IPDAS ^b		Median	Min–Max
V3	Criteria used to be defined as a patient DA	5 or 71%	3–6 or 43–86%
	Criteria to lower risk of making a biased decision	33%	11–86%
	Other criteria indicating quality	82%	0–100%
V4	Qualifying criteria met (6 items, yes or no)	5 or 83%	2–6 or 33–100%
	Certification criteria met (6 items, score $\geq 3/4$)	3 or 50%	1–6 or 17–100%
	Quality criteria met (23 items, score $\geq 3/4$)	7 or 30%	1–12 or 4–52%
Health Literacy Evaluation			
PEMAT-P		Mean (SD)	
	Understandability	87 (7.1) ^c	
	Actionability	61 (24.6) ^c	
Readability		Mean (SD)	
	Gunning Fog	9.9 (1.9)	
	Flesch Kincaid	61.8 (10.3)	

^a Lifestyle changes will be less than the total sum of its subcategories as one decision aid may have multiple options

^b Percentages for the Criteria to lower the risk of making a biased decision and Criteria for indicating quality in IPDAS V3 don't have counts because these items have an N/A response option, so using raw counts wouldn't be an appropriate comparison

^c These are mean and SD percentage values

Table 3. Individual evaluation of included decision aids (n=25)

ID	Readability Ratings		PEMAT-P Ratings		IPDAS Ratings	
	Gunning Fog (0-20)	Flesch Reading Ease (0-100)	Understandability (0-100)	Actionability (0-100)	V3-SF Overall Score (0-100)	V4 Quality Criteria Rated ≥3 (23 items)
DA_01	8.295	63.915	94.12	66.67	60.94	10
DA_02	9.94	63.68	93.75	83.33	72.66	9
DA_03	7.765	73.85	92.86	71.43	81.25	11
DA_04	8.84	70.935	92.86	71.43	81.25	12
DA_05	8.49	65.37	92.86	71.43	81.25	6
DA_06	8.03	69.72	85.71	60.00	51.56	4
DA_07	10.91	55.35	92.86	16.67	64.84	7
DA_08	9.7	63.35	85.71	20.00	64.84	7
DA_09	10.28	59.445	82.35	66.67	65.63	9
DA_10	11.76	46.095	75.00	60.00	46.09	1
DA_11	11.07	48.625	76.92	60.00	46.88	2
DA_12	7.155	76.025	88.24	83.33	61.72	7
DA_13	7.245	75.695	88.24	83.33	61.72	7
DA_14	7.085	76.315	88.24	83.33	61.72	7
DA_15	11.1	63.415	81.25	33.33	63.28	7
DA_16	11.09	62.335	81.25	33.33	63.28	7
DA_17	11.42	61.945	81.25	33.33	63.28	7
DA_18	13.725	37.05	73.33	60.00	71.88	10
DA_19	13.15	40.405	80.00	60.00	71.88	11
DA_20	11.75	56.745	94.12	100.00	69.53	9
DA_21	11.43	63.01	81.25	33.33	69.53	8
DA_22	11.55	57.775	87.50	20.00	65.63	7
DA_23	8.965	66.905	100.00	100.00	78.91	6
DA_25	10.045	60.525	94.12	80.00	53.13	6
DA_26	7.68	66.47	94.12	80.00	41.41	3

Discussion

Principal findings

This review found 25 CVD prevention decision aids available to the public online, with the majority of them focussing on a single medication as the primary line of prevention against a potential future CVD event. Overall the decision aids were very understandable but only had moderate actionability and a high readability level beyond the health literacy level of the general population. Of particular concern is that only 1 of the 25 decision aids met the most recent international criteria for certification, but the short form scores and quality checklist were reasonably high indicating decent quality overall.

Strengths and weaknesses

The strengths of this study include a systematic review and evaluation process with multiple independent searchers/raters. The main limitation is the replicability of conducting a systematic search using online search engines like Google. The dynamic nature of the web with constant variation in website content and metadata means that no search is perfectly replicable even though the cache was cleared between search terms. However, the methods used are likely to have captured the most common and popular search results, since many duplicates were removed between the two searchers. Additional decision aids could have been found by a different searcher, search engine or geographical location.

Comparison to other research

The methods and findings of this study are comparable to two other environmental scans of prenatal decision aids, which also identified issues with presenting unbiased information about both benefits and harms.^{25 26} Other studies using PEMAT-P for patient education materials have found poor results (CVD decision aids in this study: 87% and 61%; CVD risk calculators: 64% and 19%; online heart failure websites: 56% and 35%; printed lifestyle information for chronic kidney disease: 52% and 37%; for understandability and actionability respectively).²⁷⁻²⁹ The IPDAS criteria for decision aid development may have led to higher quality patient education materials, but there is still room for improvement on actionability and readability levels.

Implications and future research

CVD prevention decision aids could be improved to better meet quality criteria and make them suitable for low health literacy populations. This needs to include a basic explanation of what CVD is and what CVD risk means, inclusion of both medication and lifestyle intervention options to enable a fully informed choice, and balanced presentation of risks and benefits using visual communication aids such as icon arrays.³⁰ Several IPDAS items required substantial discussion between raters to decide on the best way to apply them consistently, indicating that further work is needed to provide a reliable tool for certifying decision aids. Work on this issue is ongoing, with particular attention in the US following legislative changes to certify DAs.³¹ The IPDAS criteria were more reliable when used by raters who were more familiar with decision aids at a later stage of the project.

Conclusion

To meet the needs of the general population who are likely to have low health literacy, CVD prevention decision aids need to improve actionability and readability, and better address basic certifying criteria such as explaining CVD and ensure that all options are presented in an unbiased way with visual support for benefits and harms.

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3 **Declarations**

4 *Ethical approval and consent to participate*

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6 Not applicable.

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9 *Consent for Publication*

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11 Not applicable.

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13 *Availability of data and material*

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15 Available on request.

16
17 *Competing interests*

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19 The authors declare that they have no competing interests.

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31 *Authors Contributions*

32 CB contributed to the conceptualisation, methodology, data analysis and interpretation, and
33 drafting the manuscript. PP contributed to the methodology, data collection and revising
34 the manuscript. RZ contributed to the methodology, data collection and revising the
35 manuscript. MF contributed to the data analysis and revising the manuscript. LT contributed
36 to the conceptualisation, methodology and revising the manuscript.

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Multimedia Appendix 1: List of included web addresses a decision aid.

ID	Web Address	WebCite
1	https://www.med-decisions.com/h2hv2/	http://www.webcitation.org/6rBGRO6iB
2	https://www.healthdecision.org/tool.html#/tool/cholesterol	http://www.webcitation.org/6rBNTNikC
3	https://www.healthwise.net/cochrane/decisionaid/Content/StdDocument.aspx?DOCHWID=aa44406	http://www.webcitation.org/6rBNe4456
4	https://www.healthwise.net/cochrane/decisionaid/Content/StdDocument.aspx?DOCHWID=uf9825	http://www.webcitation.org/6rBNxy94W
5	https://www.healthwise.net/cochrane/decisionaid/Content/StdDocument.aspx?DOCHWID=zx1768	http://www.webcitation.org/6rBO2SKKf
6	http://optiongrid.org/option-grids/grid-landing/51	http://www.webcitation.org/6rBOAo7I9
7	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/high-cholesterol/	PDF available on request
8	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/high-blood-pressure/	PDF available on request
9	https://statindecisionaid.mayoclinic.org http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013	http://www.webcitation.org/6rB7TxoW4
10	http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statins/art-20045772	http://www.webcitation.org/6rBOGLM1U
11	http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statins/art-20045772	http://www.webcitation.org/6rBOJ16bl
12	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_avg21.pdf	http://www.webcitation.org/6rBOMEgar
13	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_elevated2.pdf	http://www.webcitation.org/6rBOTnZeo
14	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_high2.pdf	http://www.webcitation.org/6rBOXs845
15	http://shareddecisions.mayoclinic.org/files/2014/11/Aspirin_DA_avg.pdf	http://www.webcitation.org/6rBOZwelz
16	http://shareddecisions.mayoclinic.org/files/2011/08/Aspirin_DA_elevated1.pdf	http://www.webcitation.org/6rBOgzuyd
17	http://shareddecisions.mayoclinic.org/files/2011/08/Aspirin_DA_high.pdf	http://www.webcitation.org/6rBOKUTgM
18	http://www.decisionbox.ulaval.ca/index.php?id=883&L=2	http://www.webcitation.org/6rBPG2Gjh
19	http://www.decisionbox.ulaval.ca/index.php?id=817&L=2	http://www.webcitation.org/6rBPG9pij
20	https://www.nice.org.uk/guidance/cg181/resources/patient-decision-aid-243780157 http://www.parksmed.co.uk/wp-content/uploads/2013/09/Antiplatelets_Aspirin-for-Primary-Prevention-of-CVD_Patient-Decision-Aid.pdf	http://www.webcitation.org/6rBPImWde
21	http://www.parksmed.co.uk/wp-content/uploads/2013/09/Statin_Patient-decision-aids.pdf	http://www.webcitation.org/6rBPOedwZ
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23	http://www.viha.ca/NR/rdonlyres/ADE60ED3-7BFC-4394-A793-9BA65CD5922F/0/CVRRPatientChoicesPamphlet.pdf	http://www.webcitation.org/6rBPazRce
24	https://archive.ahrq.gov/patients-consumers/prevention/disease/aspirinwom.html	http://www.webcitation.org/6rBPfPLDL
25	http://www.drugepi.org/wp-content/uploads/2013/11/DoPE_Toolkit_brochure_REV21.pdf	http://www.webcitation.org/6rBPI1kyO



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Recorded on Page
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Page 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 5-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 7-8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 8-9
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 9



PRISMA 2009 Checklist

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Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 9-11
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 9-11
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 9-11
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Page 9-11

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Page 11, PRISMA Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 3 (for individual decision aids rather than studies)
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence	Table 2 (for summary of decision aids rather than studies)



PRISMA 2009 Checklist

		intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Page 11-12
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Page 16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Page 16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Page 17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Page 18

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

For more information, visit: www.prisma-statement.org.

BMJ Open

Online decision aids for primary cardiovascular disease prevention: Systematic search, evaluation of quality, and suitability for low health literacy patients

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-025173.R1
Article Type:	Research
Date Submitted by the Author:	01-Dec-2018
Complete List of Authors:	Bonner, Carissa; The University of Sydney, School of Public Health; The University of Sydney, Ask, Share, Know: Rapid Evidence for General Practice Decisions Centre for Research Excellence Patel, Pinika; The University of Sydney, School of Public Health; The University of Sydney, Ask, Share, Know: Rapid Evidence for General Practice Decisions Centre for Research Excellence Fajardo, Michael; The University of Sydney, School of Public Health; The University of Sydney, Ask, Share, Know: Rapid Evidence for General Practice Decisions Centre for Research Excellence Zhuang, Ruixuan; The University of Sydney, School of Public Health Trevena, Lyndal; The University of Sydney, School of Public Health; The University of Sydney, Ask, Share, Know: Rapid Evidence for General Practice Decisions Centre for Research Excellence
Primary Subject Heading:	Communication
Secondary Subject Heading:	Cardiovascular medicine, General practice / Family practice, Health services research, Public health
Keywords:	Cardiovascular disease, Decision Support, Decision Aid, Prevention, Shared Decision Making, Health Literacy

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Manuscripts

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3 Online decision aids for primary cardiovascular disease prevention:
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5 Systematic search, evaluation of quality, and suitability for low health literacy patients
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10 Authors: Carissa Bonner^{1,2}, Pinika Patel^{1,2}, Michael Fajardo^{1,2}, Ruixuan Zhuang¹, Lyndal
11 Trevena^{1,2}
12
13
14
15

16 Affiliations:
17

- 18
19 1. Sydney School of Public Health, The University of Sydney, NSW, Australia
20
21 2. ASK-GP Centre of Research Excellence, The University of Sydney, NSW, Australia
22
23
24
25
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27

28 Corresponding Author:
29

30 Mr Michael Fajardo
31

32 Rm 128C, Edward Ford Building A27, The University of Sydney, NSW 2006, Australia
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35 Email: michael.fajardo@sydney.edu.au
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45 **Word count: 3541**
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Abstract

Objectives: Recent guideline changes for cardiovascular disease (CVD) prevention medication have resulted in calls to implement shared decision making rather than arbitrary treatment thresholds. Less attention has been paid to existing tools that could facilitate this. Decision aids are well established tools that enable shared decision making and have been shown to improve CVD prevention adherence. However, it is unknown how many CVD decision aids are publicly available for clinicians and patients online, what their quality is like and whether they are suitable for patients with lower health literacy, for whom the burden of CVD is greatest. This study aimed to identify and evaluate all English-language, publicly available online CVD prevention decision aids based on: 1) suitability for low health literacy populations (understandability, actionability and readability); and 2) International Patient Decision Aids Standards (IPDAS).

Design: Systematic review of public websites in August-November 2016 using an environmental scan methodology, with updated evaluation in April 2018.

Primary outcome measures: Understandability and actionability using the validated Patient Education Materials Assessment Tool for Printed Materials (PEMAT-P scale); readability using Gunning-Fog and Flesch Kincaid indices; and quality using IPDAS versions 3 and 4.

Results: A total of 25 unique decision aids were identified. On the PEMAT-P scale, the decision aids scored well on understandability (mean 87%) but not on actionability (mean 61%). Readability was also higher than recommended levels (mean Gunning Fog index = 10.1; suitable for Grade 10 students). Four decision aids met criteria to be considered a decision aid (i.e. met IPDAS qualifying criteria) and one sufficiently minimised major bias (i.e. met IPDAS certification criteria).

Conclusions: Publicly available CVD prevention decision aids are not suitable for low literacy populations and only one met international standards for certification. Given that patients with lower health literacy are at increased risk of CVD this urgently needs to be addressed.

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3 **Key words:** cardiovascular disease, decision support, decision aid, prevention, shared
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For peer review only

Strengths and Limitations of this Study

- First systematic search to identify and evaluate freely available online CVD Decision Aids using the International Patient Decision Aids Standards (IPDAS), the most credible and internationally recognised measure for evaluating patient decision aids
- Patient decision aids were evaluated using the multiple versions of IPDAS as well as the validated Patient Education Materials Assessment Tool for Printed Materials measure relating to health literacy, extracted independently by two reviewers where discrepancies were resolved via discussion to reduce bias
- Google results are not replicable due to the changing nature of the search algorithm and websites; but using Known Repositories may assist researchers and clinicians to conduct similar searches
- We did not assess the accuracy of the information provided by these decision aids

Introduction

Cardiovascular disease (CVD) prevention is a key issue for primary care, as one of the most common problems managed in general practice¹ and the leading cause of mortality and morbidity in developed nations.² Clinical guidelines recommend lifestyle interventions with the addition of medication to lower blood pressure and/or cholesterol if CVD risk becomes high.³⁻⁵ However, recent guideline changes for cardiovascular disease (CVD) prevention medication have increasingly lowered the threshold for treatment: statin initiation has reduced from 20% absolute CVD risk over 10 years down to 10% in the UK and 7.5% in the US;^{6,7} and the latest US hypertension guidelines recommend a very low threshold of 130mmHg for blood pressure medication.⁸ These changes have led to wide debate in leading medical journals (e.g. BMJ, JAMA, Lancet), with calls to implement shared decision-making based on both benefits and harms as well as patient preferences, rather than arbitrary treatment thresholds for CVD prevention.⁶⁻¹⁰

Shared decision making is important in this context, because there are many ways to reduce risk and weighing up the benefits and harms of different options is dependent on individual preferences.^{7,9} For example, a 60 year old female smoker with elevated blood pressure (130/80 mmHg) and cholesterol (5/1.8 total/HDL mmol/L) will have a 10% chance of a CVD event in the next 10 years based on the Framingham model (see <http://chd.bestsciencemedicine.com/calc2.html> for risk and intervention estimates using different models). She may prefer to avoid the side effects and costs of medication and focus on changing her lifestyle,¹¹ which could reduce her risk to 6% if she quit smoking, or 7% if she adopted a Mediterranean diet or increased her physical activity to high levels. Alternatively, she may be unwilling or unable to make these changes,¹¹ and would prefer to reduce her risk to 7% with either low-moderate intensity statins¹² or blood pressure lowering medication.¹³ Although these options have different *relative* risk reduction benefits, when the baseline CVD risk is only 10% the *absolute* benefit is very similar, so patient preferences must be taken into account.

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3 Little attention has been paid to existing tools that could facilitate shared decision making in
4 this context. Decision aids are well established as an effective tool to help patients engage in
5 shared decision making about their health. International standards have been developed to
6 ensure they provide evidence-based, unbiased information about benefits and harms, using
7 multiple formats to enhance patient understanding (available at
8 <http://ipdas.ohri.ca/using.html>).^{14 15} The latest Cochrane review on this topic found 105
9 RCTs evaluating decision aids, with positive effects on knowledge about options, value
10 clarification and feelings of being better informed.¹⁶ Patient decision aids for CVD
11 prevention have been shown to improve uptake and self-reported adherence to preventive
12 interventions¹⁷; however not all decision aids have reported similar effects on adherence.
13 The *Statin Choice* decision aid aimed at CVD prevention in diabetes did not report similar
14 adherence to statins but did report that patients accurately perceived their risk for heart
15 attack.¹⁸

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30 The availability of high quality, understandable health information is particularly important
31 considering the burden of CVD is greater for people with low health literacy. This means
32 they do not have adequate skills to access, understand or use resources to manage their
33 own health. The majority of the general population falls into this category, and this is
34 associated with less regular healthcare access, lower uptake of prevention services, poorer
35 self-management, greater medication errors, worse CVD outcomes and increased all-cause
36 mortality.¹⁹⁻²¹ It is therefore important to consider the needs of patients with low health
37 literacy skills when developing online shared decision making tools, which are likely to be
38 accessed with little support from health professionals.

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49 This study aimed to systematically review the online environment for patient decision aids
50 relating to primary CVD prevention, and evaluate their quality based on international
51 patient decision aid standards and health literacy criteria.
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Methods

Inclusion and exclusion criteria

Decision aids were considered if they met all inclusion criteria: 1) focus on primary prevention (i.e. not secondary prevention or treatment for established CVD), 2) provides information about blood pressure medication, cholesterol lowering medication, and/or aspirin, 3) freely available, and 4) written in English. Exclusion criteria included: 1) could not be viewed due to technical problems after 2 attempts, 2) developed by a company with a vested interest in medication (e.g. pharmaceutical), or 4) targeted at health professionals or clinicians.

Search methods

An environmental scan can be described as an efficient and organised means to collect specific information on a given topic/institution that is pertinent to its internal workings and external influences/surrounding.²² Part of the process involves a purposive approach to a search from which the search is then exploded. For this study we identified known online decision aid repositories (see Table 1) as the most likely sources to contain relevant information pertinent to this study. Our second source was from Google Australia.

Table 1. List of known decision aid 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://healthdecisions.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 Aids 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/

Two independent searchers (PP and RZ) were instructed to reset their Cache in their web browsers before each Google search to minimise the effect of Google search optimisation. The final search terms after piloting included 11 for CVD/Medication and two for Decision Aids. The lead researchers (CB, LT) and the two independent searchers agreed upon 11 specific terms for CVD/Medication: cardiovascular disease; heart disease; stroke; heart attack; hypertension; hypercholesterolemia; hypercholesterolaemia; aspirin; blood pressure medication; cholesterol medication; and statin, and two specific terms for Decision Aids: decision aid and decision support (see Appendix Table A1 for search strategy). Additional terms were pilot tested before settling on the final list. A single CVD/Medication term and a single Decision Aids term were combined for each search, resulting in 22 unique Google

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3 searches. The first 50 results for each unique Google search were exported (not including
4 web advertisements), providing a pool of 1100 results to be title scanned for each searcher
5 (2200 results in total). Scanning the first 100 search results for the first few searches found
6 no additional resources after the first 50 results, so the cut-off of 50 was retained.
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13 The two independent searchers conducted this search as part of a Master of Public Health
14 degree capstone unit during August to November 2016. In March 2017, an independent
15 rater (CB) reconciled these search results at the earliest stage feasible (see Figure 1), and
16 the original searchers completed any missing ratings for the final dataset. Only websites that
17 were still working when the third independent rater reconciled the lists were included.
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19 Duplicates were considered either as identical web addresses or identical PDFs.
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27 *Evaluation and data extraction*

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32 The two independent searchers rated the content of each decision aid using a validated tool
33 to assess whether printed materials are suitable for people with low health literacy, the
34 Patient Education Material Evaluation Tool for Print Materials (PEMAT-P).²³ PEMAT-P
35 includes two subscales: 1) understandability, which is a measure of how well a person is
36 able to process and explain the key message of the material; and 2) actionability, which is a
37 measure of how well a person is able to identify what to do based on the information in
38 presented. Items were rated on a binary scale (Yes/No) with some items provided a “Not
39 Applicable” option. Final understandability and actionability scores were calculated as a
40 percentage of “Yes” ratings for all items not including “not applicable” ratings; higher
41 percentages indicate better understandability or actionability. Intraclass correlations were
42 calculated using SPSS v25. For the two independent searchers, the intraclass correlation for
43 final understandability scores was .51 and for actionability scores was .48. Conflicts for
44 individual PEMAT-P items were therefore resolved by the third rater (MF, after discussion
45 with CB) to finalise the PEMAT-P score for each individual decision aid. A threshold of 70%
46 was used to determine whether the decision aid was understandable or actionable.²¹
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Readability

Each decision aid's readability was measured using the Gunning Fog index, which is an index that estimates the formal years of (US) education an individual needs to understand the text.²⁴ 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. The Flesch Kincaid Reading Ease score was also calculated with higher scores indicating greater ease of comprehension. Scores range from 0 to 100 where a score of about 70-80 is the equivalent to school grade 7.²⁵ The intraclass correlation between two independent ratings was high (Gunning Fog Index was 0.91 and Flesch Kincaid was 0.94) so the average of the two scores were used as the final index.

IPDAS Checklist

The two independent researchers (PP and RZ) each completed a checklist based on version 3 of the IPDASi items, with discrepancies resolved by a third rater (MF, after discussion with CB). IPDASi v3 has three domains: *Criteria used to be defined as a patient decision aid* (7-items), *Criteria to lower risk of making a biased decision* (9-items), *Other criteria indicating quality* (13 items). Criteria used to be defined as a patient decision aid items were rated on a Yes/No scale and the other two domains were rated on a 4-point Likert scale (1=Strongly Disagree to 4=Strongly Agree). In addition, two independent raters (PP and MF) used the International Patient Decision Aids Standards Instrument-Short Form (IPDASi-SF) to assess the same decision aids on a quantitative scale.¹⁴ Each item is rated on a 4-point Likert scale (1 = Strongly Disagree, 4 = Strongly Agree). 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 IPDAS. The short form has demonstrated a 0.87 correlation with the IPDASi 47-item version.¹⁴ In April 2018 the evaluation was repeated by two researchers (CB and MF) using IPDAS v4, an updated version of IPDAS v3 that reclassified the items into three

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3 domains with some revised wording and had collapsed some items into one. The new
4 domains were *qualifying*, *certification* and *quality*. Qualifying criteria, if all met, identify the
5 material as a decision aid. Certification criteria are those deemed essential to avoid harmful
6 bias and all six criteria need to be met (i.e. scored 3 or more) for the decision aid to be
7 considered certified. Quality criteria on the other hand were items considered desirable but
8 not essential to avoid harmful bias. All decision aids in the original evaluation were still
9 publicly available at this time. Qualifying criteria are measured on a binary yes-no scale and
10 certification and quality criteria are measured on a 4-point Likert scale. To qualify as a
11 decision aid, all 6 qualifying criteria must be met. To be certified as a decision aid, all 6
12 certifying criteria must score at least 3. Agreement for the qualifying criteria items ranged
13 from 64% to 100% and the average correlation between *certification* and *qualifying* items
14 were .35 and .61 respectively. Questions relating to screening tests were not used.
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28 ***Patient and Public Involvement***

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30 The development of this research question was informed by the International Patient
31 Decision Aids Standards, which has involved an extensive consultation process over many
32 years to produce health decision making tools that are useful and effective for patients. This
33 study did not recruit patients or members of the public, so they were not specifically
34 involved.
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43 **Results**

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45 The search of 15 known repositories and 2200 google search results yielded 25 unique CVD
46 prevention decision aids (see Figure 1). Table 2 details the overall evaluation of the decision
47 aids; and Table 3 presents scores by individual decision aid. Appendix Table A2 provides the
48 full IPDAS checklist item results and web archive URLs for the included decision aid
49 webpages.
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55 ***Evaluation of the quality of the decision aids***

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57 For the version 3 IPDASi-SF (short form) scale, the correlation between the two raters was
58 0.76 and the mean (SD) score was 64.56 (10.80) out of a maximum 100. For the version 3
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3 IPDAS evaluation (see appendix Table A3 for individual scoring per item for each decision
4 aid), none of the decision aids met all qualifying criteria to *be defined as a patient decision*
5 *aid* and the median was 71% (5 out of 7 criteria met). None of the decision aids met all
6 criteria to *lower the risk of making a biased decision*, and the median was 33%. None of the
7 decision aids met all criteria to *indicate quality*, and the median was 85%. For the version 4
8 IPDAS evaluation (see Appendix Table A4 for individual scoring per item for each decision
9 aid), four decision aids met the criteria to *qualify* for a decision aid and the median was 83%
10 (5 out of 6 criteria met) ranging from 2 to 6. One decision aid scored 3 or above on all six
11 items to *certified* as a decision aid and the median was 50% (3 out of 6 items) ranging from 1
12 to 6. The median quality criteria that scored 3 or above was 30% (7 out of 23 criteria)
13 ranging from 1 to 12 items.

14
15 A central component of decision aids is to present all options, risks and benefits in a
16 balanced and unbiased way, with visual representation of numerical information. Nineteen
17 decision aids provided only one intervention option (73%), whereas the remaining six
18 provided 2-7 different options (27%). The presentation of harms versus benefits in icon
19 arrays was highly variable. Icon Arrays are graphic representations to show abstract
20 probabilities as more concrete frequencies (e.g. 2% = 2 coloured dots out of 100 black dots),
21 and are considered best practice for risk communication.²⁶ Of the 12 decision aids that used
22 icon arrays, 5 (42%) presented only benefits in icon arrays and 7 (58%) presented benefits
23 and harms in icon arrays. Of the 7 that presented benefits and harms in icon arrays, 4 (57%)
24 combined benefits and harms in one icon array and 3 (43%) separated them. Of the 4 that
25 combined benefits and harms in one icon array, 1 (25%) separated the benefits and harms
26 and 3 (75%) overlapped the benefits and harms.

27 ***Evaluation of suitability for low health literacy populations***

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29 For the PEMAT-P evaluation, the decision aids generally scored well on understandability
30 but lower on actionability. The average understandability score was 87% (SD = 7.1%) and
31 actionability was 61% (SD = 24.6%). For readability, the average Gunning Fog index was 9.9
32 (SD=1.9) and Flesch Kincaid was 61.8 (SD=10.3), indicating that a US school grade of 9 is
33 required to understand the information. The correlation between understandability and
34 readability was -0.60 for Gunning Fog and 0.59 for Flesch Kincaid.

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[Insert Figure 1. PRISMA Flow Diagram of searcher results (Search 1 PP, Searcher 2 RZ)]

For peer review only

Table 2. Evaluation for included decisions aids (n=25)

Decision Aid Evaluation			
Intervention options		Count (%)	
Medication	Cholesterol-lowering	14 (56)	
	Blood pressure lowering	5 (20)	
	Aspirin	8 (32)	
Lifestyle ^a	Any lifestyle change included	7 (28)	
	Quit smoking	3 (12)	
	Improve diet	2 (8)	
	Increase physical activity	2 (8)	
	Lose weight	2 (8)	
IPDAS ^b		Median	Min–Max
V3	Criteria used to be defined as a patient DA	5 or 71%	3–6 or 43–86%
	Criteria to lower risk of making a biased decision	33%	11–86%
	Other criteria indicating quality	82%	0–100%
V4	Qualifying criteria met (6 items, yes or no)	5 or 83%	2–6 or 33–100%
	Certification criteria met (6 items, score $\geq 3/4$)	3 or 50%	1–6 or 17–100%
	Quality criteria met (23 items, score $\geq 3/4$)	7 or 30%	1–12 or 4–52%
Health Literacy Evaluation			
PEMAT-P		Mean (SD)	
	Understandability	87 (7.1) ^c	
	Actionability	61 (24.6) ^c	
Readability		Mean (SD)	
	Gunning Fog	9.9 (1.9)	
	Flesch Kincaid	61.8 (10.3)	

^a Lifestyle changes will be less than the total sum of its subcategories as one decision aid may have multiple options

^b Percentages for the Criteria to lower the risk of making a biased decision and Criteria for indicating quality in IPDAS V3 don't have counts because these items have an N/A response option, so using raw counts wouldn't be an appropriate comparison

^c These are mean and SD percentage values

Table 3. Individual evaluation of included decision aids (n=25)

ID	PEMAT-P Ratings		IPDAS Ratings		Readability Ratings	
	Understand- ability (0-100)	Actionability (0-100)	V3-SF Overall Score (0-100)	V4 Quality Criteria Rated ≥3 (23 items)	Gunning Fog (0-20)	Flesch Reading Ease (0-100)
DA_01	94.1	66.7	60.9	10	8.3	63.9
DA_02	93.8	83.3	72.7	9	9.9	63.7
DA_03	92.9	71.4	81.3	11	7.8	73.9
DA_04	92.9	71.4	81.3	12	8.8	70.9
DA_05	92.9	71.4	81.3	6	8.5	65.4
DA_06	85.7	60.0	51.6	4	8.0	69.7
DA_07	92.9	16.7	64.8	7	10.9	55.4
DA_08	85.7	20.0	64.8	7	9.7	63.4
DA_09	82.4	66.7	65.6	9	10.3	59.4
DA_10	75.0	60.0	46.1	1	11.8	46.1
DA_11	76.9	60.0	46.9	2	11.1	48.6
DA_12	88.2	83.3	61.7	7	7.2	76.0
DA_13	88.2	83.3	61.7	7	7.2	75.7
DA_14	88.2	83.3	61.7	7	7.1	76.3
DA_15	81.3	33.3	63.3	7	11.1	63.4
DA_16	81.3	33.3	63.3	7	11.1	62.3
DA_17	81.3	33.3	63.3	7	11.4	61.9
DA_18	73.3	60.0	71.9	10	13.7	37.1
DA_19	80.0	60.0	71.9	11	13.2	40.4
DA_20	94.1	100.0	69.5	9	11.8	56.7
DA_21	81.3	33.3	69.5	8	11.4	63.0
DA_22	87.5	20.0	65.6	7	11.6	57.8
DA_23	100.0	100.0	78.9	6	9.0	66.9
DA_24	94.1	80.0	41.4	3	7.7	66.5
DA_25	94.1	80.0	53.1	6	10.0	60.5

Discussion

Principal findings

This review found 25 CVD prevention decision aids available to the public online, with the majority of them focussing on a single medication as the primary line of prevention against a potential future CVD event. Overall the decision aids were very understandable but only had moderate actionability and a high readability level beyond the health literacy level of the general population. Most people would therefore have difficulty taking action based on the information in these decision aids, even though their primary purpose is to help the decision making process. Of particular concern is that only 1 of the 25 decision aids met the most recent international criteria for certification, but the short form scores and quality checklist were reasonably high indicating decent quality overall. This means many decision aids would only require minor additions to reach certification standards; but the issues for low health literate patients would remain.

Strengths and weaknesses

The strengths of this study include a systematic review and evaluation process with multiple independent searchers/raters. The main limitation is the replicability of conducting a systematic search using online search engines like Google. The dynamic nature of the web with constant variation in website content and metadata means that no search is perfectly replicable even though the cache was cleared between search terms. However, the methods used are likely to have captured the most common and popular search results, since many duplicates were removed between the two searchers. Additional decision aids could have been found by a different searcher, search engine or geographical location, and in other languages, which could produce different findings about the overall suitability for low health literate patients. However, this paper provides a list of known repositories of decision aids, including the primary source of IPDAS-assessed decision aids, to guide future researchers. This may improve the consistency of current and future findings. It also highlights the need for a central reputable location for decision aids that consumers could be referred to rather than search for their own.

Comparison to other research

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3 The methods and findings of this study are comparable to two other environmental scans of
4 prenatal decision aids, which also identified issues with presenting unbiased information
5 about both benefits and harms.^{27 28} Other studies using PEMAT-P for patient education
6 materials have found poor results (CVD decision aids in this study: 87% and 61%; CVD risk
7 calculators: 64% and 19%; online heart failure websites: 56% and 35%; printed lifestyle
8 information for chronic kidney disease: 52% and 37%; for understandability and actionability
9 respectively).²⁹⁻³¹ The IPDAS criteria for decision aid development may have led to higher
10 quality patient education materials, but there is still room for improvement on actionability
11 and readability levels.
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20 *Implications and future research*

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22 CVD prevention decision aids could be improved to better meet quality criteria and make
23 them suitable for low health literacy populations. In particular, this needs to include: 1) a
24 basic explanation of what CVD is and what CVD risk means, since the mechanism for how
25 this leads to events like heart attack and stroke was rarely explained; 2) inclusion of both
26 medication and lifestyle intervention options to enable a fully informed choice, as there
27 tended to be a focus on single medication options; 3) balanced presentation of risks and
28 benefits using visual communication aids such as icon arrays, since few decision aids used
29 best practice risk communication strategies in an equal way for both the benefit and harm
30 of options (e.g. reduced chance of CVD event versus chance of side effects); and 4) more
31 support for what actions to take based on the decision made.²⁶
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41 Several IPDAS items required substantial discussion between raters to decide on the best
42 way to apply them consistently, indicating that further work is needed to provide a reliable
43 tool for certifying decision aids. For example, decision aids that compared a single
44 medication option versus doing nothing were easier to rate highly on balanced presentation
45 than those with multiple options, even though the latter enables a more fully informed
46 choice. In addition, the items did not cover: 1) health literate design issues (e.g. use of white
47 space, images that are consistent with text, and clear direction for next steps); 2)
48 assessment of the accuracy of the information provided (e.g. whether the risks and benefits
49 presented were based on the latest systematic review, if available); 3) ease of access for the
50 intended audience, particularly for low health literacy populations; or 4) how effective the
51 decision aid was, even when an evaluation had been conducted. Work on these issues is
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3 ongoing, with particular attention in the US following legislative changes to certify decision
4 aids.³² The IPDAS criteria were more reliable when used by raters who were more familiar
5 with decision aids at a later stage of the project, suggesting a need for structured training in
6 using IPDAS rating scales.
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10 *Conclusion*

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13 To meet the needs of the general population who are likely to have low health literacy, CVD
14 prevention decision aids need to improve actionability and readability, and better address
15 basic certifying criteria such as explaining CVD and ensure that all options are presented in
16 an unbiased way with visual support for benefits and harms.
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Declarations

Ethical approval and consent to participate

Not applicable.

Consent for Publication

Not applicable.

Availability of data and material

Website URLs containing the CVD Decision Aids are available in Supplementary Files.

Descriptive and evaluative data are also available within Supplementary Files.

Competing interests

The authors declare that they have no competing interests.

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Authors Contributions

CB contributed to the conceptualisation, methodology, data analysis and interpretation, and drafting the manuscript. PP contributed to the methodology, data collection and revising the manuscript. RZ contributed to the methodology, data collection and revising the manuscript. MF contributed to the data analysis and revising the manuscript. LT contributed to the conceptualisation, methodology and revising the manuscript.

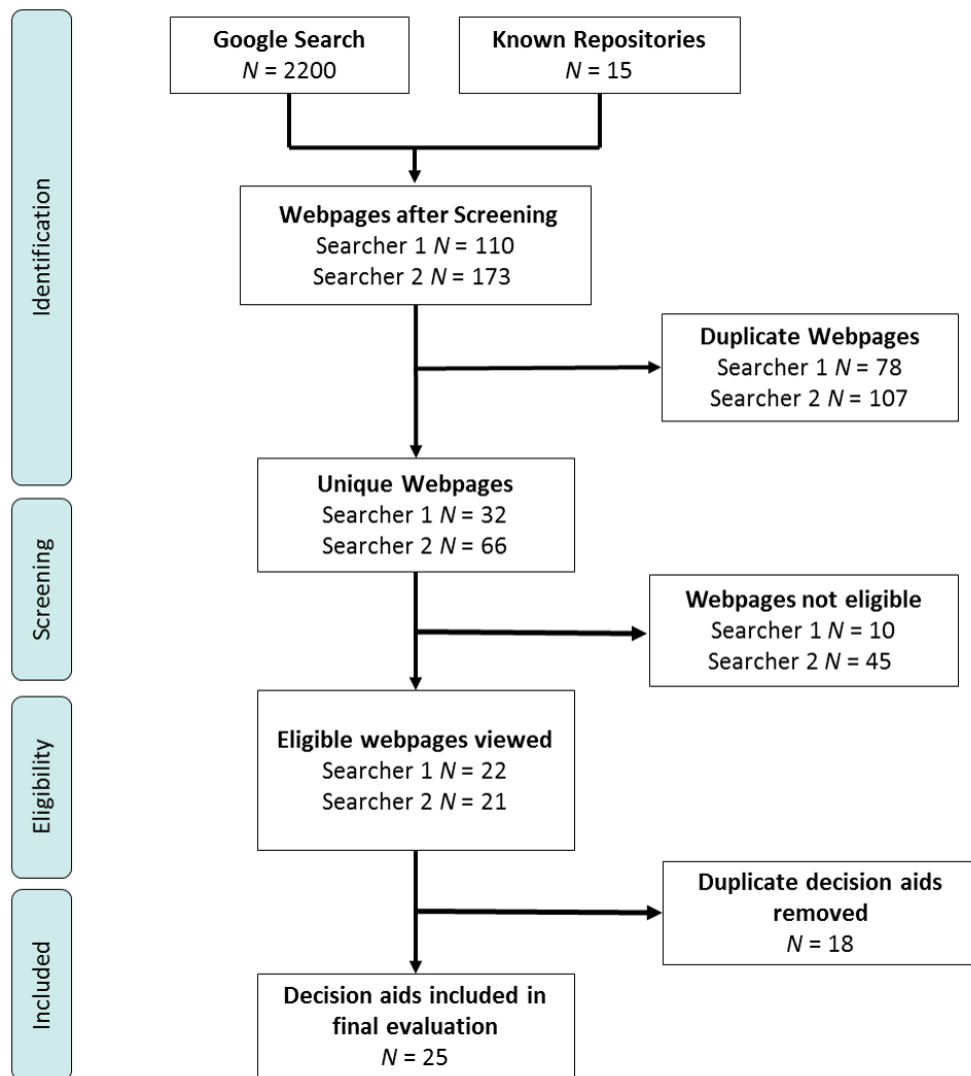
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PRISMA Flow Diagram of searcher results (Search 1 PP, Searcher 2 RZ)

Appendix

Table A1. Google Search Strategy

	Search String
Google Search 1	Cardiovascular disease decision aid
Google Search 2	Heart disease decision aid
Google Search 3	Stroke decision aid
Google Search 4	Heart attack decision aid
Google Search 5	Hypertension decision aid
Google Search 6	Hypercholesterolemia decision aid
Google Search 7	Hypercholestoerlaemia decision aid
Google Search 8	Aspirin decision aid
Google Search 9	Blood pressure medication decision aid
Google Search 10	Cholesterol medication decision aid
Google Search 11	Statin decision aid
Google Search 12	Cardiovascular disease decision support
Google Search 13	Heart disease decision support
Google Search 14	Stroke decision support
Google Search 15	Heart attack decision support
Google Search 16	Hypertension decision support
Google Search 17	Hypercholesterolemia decision support
Google Search 18	Hypercholestoerlaemia decision support
Google Search 19	Aspirin decision support
Google Search 20	Blood pressure medication decision support
Google Search 21	Cholesterol medication decision support
Google Search 22	Statin decision support

Table A2. List of included web addresses a decision aid.

ID	Web Address	WebCite
1	https://www.med-decisions.com/h2hv2/	http://www.webcitation.org/6rBGRO6iB
2	https://www.healthdecision.org/tool.html#/tool/cholesterol	http://www.webcitation.org/6rBNTNlKc
3	https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=aa44406	http://www.webcitation.org/6rBNe4456
4	https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=uf9825	http://www.webcitation.org/6rBNxy94W
5	https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=zx1768	http://www.webcitation.org/6rBO2SKKf
6	http://optiongrid.org/option-grids/grid-landing/51	http://www.webcitation.org/6rBOAo7l9
7	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/high-cholesterol/	PDF available on request
8	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/high-blood-pressure/	PDF available on request
9	https://statindecisionaid.mayoclinic.org	http://www.webcitation.org/6rB7TxoW4
10	http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013	http://www.webcitation.org/6rBOGLM1U
11	http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statins/art-20045772	http://www.webcitation.org/6rBOJ16bl
12	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_avg21.pdf	http://www.webcitation.org/6rBOMEgar
13	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_elevated2.pdf	http://www.webcitation.org/6rBOTnZeo
14	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_high2.pdf	http://www.webcitation.org/6rBOXs845
15	http://shareddecisions.mayoclinic.org/files/2014/11/Aspirin_DA_avg.pdf	http://www.webcitation.org/6rBOZwelz
16	http://shareddecisions.mayoclinic.org/files/2011/08/Aspirin_DA_elevated1.pdf	http://www.webcitation.org/6rBOgzuyd
17	http://shareddecisions.mayoclinic.org/files/2011/08/Aspirin_DA_high.pdf	http://www.webcitation.org/6rBOKUTgM
18	http://www.decisionbox.ulaval.ca/index.php?id=883&L=2	http://www.webcitation.org/6rBPG2Gjh
19	http://www.decisionbox.ulaval.ca/index.php?id=817&L=2	http://www.webcitation.org/6rBPG9pij
20	https://www.nice.org.uk/guidance/cg181/resources/patient-decision-aid-243780157	http://www.webcitation.org/6rBPImWde
21	http://www.parksmed.co.uk/wp-content/uploads/2013/09/Antiplatelets_Aspirin-for-Primary-Prevention-of-CVD_Patient-Decision-Aid.pdf	http://www.webcitation.org/6rBPOedwZ
22	http://www.parksmed.co.uk/wp-content/uploads/2013/09/Statin_Patient-decision-aids.pdf	http://www.webcitation.org/6rBPY4nHf
23	http://www.viha.ca/NR/rdonlyres/ADE60ED3-7BFC-4394-A793-9BA65CD5922F/0/CVRRPatientChoicesPamphlet.pdf	http://www.webcitation.org/6rBPaZRce
24	https://archive.ahrq.gov/patients-consumers/prevention/disease/aspirinwom.html	http://www.webcitation.org/6rBPfPLDL
25	http://www.drugepi.org/wp-content/uploads/2013/11/DoPE_Toolkit_brochure_REV21.pdf	http://www.webcitation.org/6rBPi1kyO

Table A3: International Patient Decision Aid Standards Inventory Version 3 Ratings for all Cardiovascular Decision Aids (n=25).

ID:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
<i>Criteria to be defined as a patient decision aid</i>																										
1.	The decision aid describes the condition (health or other) related to the decision.	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1	1	1	1
2.	The decision aid describes the decision that needs to be considered (the index decision).	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1
3.	The decision aid identifies the target audience.	0	1	1	1	0	1	0	1	0	1	0	0	0	0	0	0	0	1	1	0	1	1	1	0	1
4.	The decision aid lists the options (health care or other).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0
5.	The decision aid has information about the positive features of the options (e.g. benefits, advantages).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6.	The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1
7.	The decision aid helps patients clarify their values for outcomes of options by: a) asking people to think about which positive and negative features of the options matter most to them AND/OR b) describing each option to help patients imagine the physical, social, and /or psychological effect.	1	0	1	1	1	1	1	0	0	1	0	0	0	0	0	0	0	1	1	1	0	0	0	0	1
<i>Criteria to lower the risk of making a biased decision</i>																										
1.	The decision aid makes it possible to compare the positive and negative features of the available options.	1	0	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	0	1	1	0	0	0
2.	The decision aid shows the negative and positive features of the options with equal detail.	0	1	1	1	1	1	1	0	0	0	0	0	0	0	1	1	1	1	1	0	1	0	0	0	0
3.	The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.	0	1	2	2	2	1	1	0	1	2	2	0	0	0	1	1	1	1	1	1	1	1	0	0	
4.	The decision aid (or available technical documents) reports funding sources for development.	3	3	3	0	0	3	0	0	0	3	3	0	0	0	0	0	0	0	0	0	0	1	1	0	
5.	The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.	0	1	1	1	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0
6.	The decision aid includes authors/developers' credentials or qualifications.	1	3	1	1	1	3	0	0	0	3	3	0	0	0	0	0	0	0	0	0	0	0	1	1	0
7.	The decision aid reports the date when it was last updated.	0	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1
8.	The decision aid (or available technical document) reports readability levels.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9.	The decision aid provides references to scientific evidence used.	0	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	0	1	1	0	1	1	1	0	0
<i>Other criteria indicating quality</i>																										
1.	The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.	1	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	0	0
2.	The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option).	2	0	1	1	1	1	1	1	0	1	1	1	1	0	0	0	0	1	1	1	0	0	0	0	0
3.	The information about outcomes of options (positive and negative) includes the chances they may happen.	0	1	0	0	0	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	0	
4.	The decision aid presents probabilities using event rates in a defined group of people for a specified time.	1	1	2	2	2	0	1	1	1	2	2	1	1	1	1	1	1	0	1	1	1	1	1	0	0
5.	The decision aid compares probabilities of options over the same period of time.	1	1	2	2	2	0	0	1	2	2	1	1	1	1	1	1	0	1	1	1	1	1	0	0	
6.	The decision aid uses the same scales in diagrams comparing options.	1	1	2	2	2	0	0	1	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	0	2
7.	Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.	1	1	0	0	0	1	2	2	3	1	1	3	3	3	2	2	2	0	0	2	2	2	2	2	2
8.	The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing.	3	1	1	1	1	1	2	2	3	3	3	3	3	3	2	2	2	3	3	3	2	2	2	2	2
9.	People who were facing the decision field tested the decision aid.	1	1	1	1	1	1	2	2	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
10.	Field testing showed that the decision aid was acceptable to users (the general public & practitioners).	1	1	1	1	1	1	2	2	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
11.	Field testing showed that people who were undecided felt that the information was presented in a balanced way.	1	1	1	1	1	3	2	2	3	3	3	3	3	3	2	2	2	3	3	3	2	2	2	2	2
12.	There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.	1	3	1	1	1	3	3	3	1	3	3	1	1	1	3	3	3	3	3	3	3	3	3	3	2
13.	There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.	1	3	3	3	3	3	3	1	3	3	1	1	1	1	3	3	3	3	3	3	3	2	3	3	2

Table A4: International Patient Decision Aid Standards Inventory Version 4 Ratings for all Cardiovascular Decision Aids (n=25).

	ID	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
<i>Criteria to qualify as a decision aid</i>																											
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1	The development process included review by professionals not involved in producing the decision support intervention.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	The patient decision aid was field tested with patients who were facing the decision.	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1
3	The patient decision aid was field tested with practitioners who counsel patients who face the decision.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
4	The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5	The patient decision aid (or associated documentation) describes the quality of the research evidence used.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6	The patient decision aid includes authors' / developers' credentials or qualifications.	4	4	4	4	4	2	1	1	1	1	1	1	1	1	3	3	1	1	1	4	4
7	The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
8	There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	1	1	1	1	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1
9	There is evidence that the patient decision aid helps patients improve their knowledge about options' features.	1	1	1	1	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1

*Note: Scores of 1.5 and 3.5 indicate instances when the two reviewers did not agree on between 1 or 2, or between 3 and 4 respectively, so the average was taken instead.

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PRISMA 2009 Checklist

Section/topic	#	Checklist item	Recorded on Page
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Page 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 5-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 7-8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 8-9
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 9



PRISMA 2009 Checklist

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Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 9-11
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 9-11
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 9-11
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Page 9-11

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Page 11, PRISMA Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 3 (for individual decision aids rather than studies)
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence	Table 2 (for summary of decision aids rather than studies)



PRISMA 2009 Checklist

		intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Page 11-12
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Page 16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Page 16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Page 17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Page 18

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

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BMJ Open

Online decision aids for primary cardiovascular disease prevention: Systematic search, evaluation of quality, and suitability for low health literacy patients

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Primary Subject Heading:	Communication
Secondary Subject Heading:	Cardiovascular medicine, General practice / Family practice, Health services research, Public health
Keywords:	Cardiovascular disease, Decision Support, Decision Aid, Prevention, Shared Decision Making, Health Literacy

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3 Online decision aids for primary cardiovascular disease prevention:
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5 Systematic search, evaluation of quality, and suitability for low health literacy patients
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10 Authors: Carissa Bonner^{1,2}, Pinika Patel^{1,2}, Michael Fajardo^{1,2}, Ruixuan Zhuang¹, Lyndal
11
12 Trevena^{1,2}
13
14
15

16 Affiliations:
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- 18
19 1. Sydney School of Public Health, The University of Sydney, NSW, Australia
20
21 2. ASK-GP Centre of Research Excellence, The University of Sydney, NSW, Australia
22
23
24
25
26
27

28 Corresponding Author:
29

30 Mr Michael Fajardo
31

32 Rm 128C, Edward Ford Building A27, The University of Sydney, NSW 2006, Australia
33
34

35 Email: michael.fajardo@sydney.edu.au
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Abstract

Objectives: Recent guideline changes for cardiovascular disease (CVD) prevention medication have resulted in calls to implement shared decision making rather than arbitrary treatment thresholds. Less attention has been paid to existing tools that could facilitate this. Decision aids are well established tools that enable shared decision making and have been shown to improve CVD prevention adherence. However, it is unknown how many CVD decision aids are publicly available for patients online, what their quality is like and whether they are suitable for patients with lower health literacy, for whom the burden of CVD is greatest. This study aimed to identify and evaluate all English-language, publicly available online CVD prevention decision aids.

Design: Systematic review of public websites in August–November 2016 using an environmental scan methodology, with updated evaluation in April 2018. The decision aids were evaluated based on: 1) suitability for low health literacy populations (understandability, actionability and readability); and 2) International Patient Decision Aids Standards (IPDAS).

Primary outcome measures: Understandability and actionability using the validated Patient Education Materials Assessment Tool for Printed Materials (PEMAT-P scale); readability using Gunning–Fog and Flesch–Kincaid indices; and quality using IPDAS versions 3 and 4.

Results: A total of 25 unique decision aids were identified. On the PEMAT-P scale, the decision aids scored well on understandability (mean 87%) but not on actionability (mean 61%). Readability was also higher than recommended levels (mean Gunning–Fog index = 10.1; suitable for Grade 10 students). Four decision aids met criteria to be considered a decision aid (i.e. met IPDAS qualifying criteria) and one sufficiently minimised major bias (i.e. met IPDAS certification criteria).

Conclusions: Publicly available CVD prevention decision aids are not suitable for low literacy populations and only one met international standards for certification. Given that patients with lower health literacy are at increased risk of CVD this urgently needs to be addressed.

1
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3 **Key words:** cardiovascular disease, decision support, decision aid, prevention, shared
4 decision making, health literacy
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Strengths and Limitations of this Study

- First systematic search to identify and evaluate freely available online CVD Decision Aids using the International Patient Decision Aids Standards (IPDAS), the most credible and internationally recognised measure for evaluating patient decision aids
- Patient decision aids were evaluated using the multiple versions of IPDAS as well as the validated Patient Education Materials Assessment Tool for Printed Materials measure relating to health literacy, extracted independently by two reviewers where discrepancies were resolved via discussion to reduce bias
- Google results are not replicable due to the changing nature of the search algorithm and websites; but using Known Repositories may assist researchers and clinicians to conduct similar searches
- We did not assess the accuracy of the information provided by these decision aids

Introduction

Cardiovascular disease (CVD) prevention is a key issue for primary care, as one of the most common problems managed in general practice¹ and the leading cause of mortality and morbidity in developed nations.² Clinical guidelines recommend lifestyle interventions with the addition of medication to lower blood pressure and/or cholesterol if CVD risk becomes high.³⁻⁵ However, recent guideline changes for cardiovascular disease (CVD) prevention medication have increasingly lowered the threshold for treatment: statin initiation has reduced from 20% absolute CVD risk over 10 years down to 10% in the UK and 7.5% in the US;^{6,7} and the latest US hypertension guidelines recommend a very low threshold of 130mmHg for blood pressure medication.⁸ These changes have led to wide debate in leading medical journals (e.g. BMJ, JAMA, Lancet), with calls to implement shared decision-making based on both benefits and harms as well as patient preferences, rather than arbitrary treatment thresholds for CVD prevention.⁶⁻¹⁰

Shared decision making is important in this context, because there are many ways to reduce risk and weighing up the benefits and harms of different options is dependent on individual preferences.^{7,9} For example, a 60 year old female smoker with elevated blood pressure (130/80 mmHg) and cholesterol (5/1.8 total/HDL mmol/L) will have a 10% chance of a CVD event in the next 10 years based on the Framingham model (see <http://chd.bestsciencemedicine.com/calc2.html> for risk and intervention estimates using different models). She may prefer to avoid the side effects and costs of medication and focus on changing her lifestyle,¹¹ which could reduce her risk to 6% if she quit smoking, or 7% if she adopted a Mediterranean diet or increased her physical activity to high levels. Alternatively, she may be unwilling or unable to make these changes,¹¹ and would prefer to reduce her risk to 7% with either low-moderate intensity statins¹² or blood pressure lowering medication.¹³ Although these options have different *relative* risk reduction benefits, when the baseline CVD risk is only 10% the *absolute* benefit is very similar, so patient preferences must be taken into account.

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3 Little attention has been paid to existing tools that could facilitate shared decision making in
4 this context. Decision aids are well established as an effective tool to help patients engage in
5 shared decision making about their health. International standards have been developed to
6 ensure they provide evidence-based, unbiased information about benefits and harms, using
7 multiple formats to enhance patient understanding (available at
8 <http://ipdas.ohri.ca/using.html>).^{14 15} The latest Cochrane review on this topic found 105
9 RCTs evaluating decision aids, with positive effects on knowledge about options, value
10 clarification and feelings of being better informed.¹⁶ Patient decision aids for CVD
11 prevention have been shown to improve uptake and self-reported adherence to preventive
12 interventions¹⁷; however not all decision aids have reported similar effects on adherence.
13 The *Statin Choice* decision aid aimed at CVD prevention in diabetes did not report similar
14 adherence to statins but did report that patients accurately perceived their risk for heart
15 attack.¹⁸

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30 The availability of high quality, understandable health information is particularly important
31 considering the burden of CVD is greater for people with low health literacy. This means
32 they do not have adequate skills to access, understand or use resources to manage their
33 own health. The majority of the general population falls into this category, and this is
34 associated with less regular healthcare access, lower uptake of prevention services, poorer
35 self-management, greater medication errors, worse CVD outcomes and increased all-cause
36 mortality.¹⁹⁻²¹ It is therefore important to consider the needs of patients with low health
37 literacy skills when developing online shared decision making tools, which are likely to be
38 accessed with little support from health professionals.

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49 This study aimed to systematically review the online environment for patient decision aids
50 relating to primary CVD prevention, and evaluate their quality based on international
51 patient decision aid standards and health literacy criteria.

52 53 54 55 56 57 58 59 60 Methods

Inclusion and exclusion criteria

Decision aids were considered if they met all inclusion criteria: 1) focus on primary prevention (i.e. not secondary prevention or treatment for established CVD), 2) provides information about blood pressure medication, cholesterol lowering medication, and/or aspirin, 3) freely available, and 4) written in English. Exclusion criteria included: 1) could not be viewed due to technical problems after 2 attempts, 2) developed by a company with a vested interest in medication (e.g. pharmaceutical), or 4) targeted at health professionals or clinicians.

Search methods

An environmental scan can be described as an efficient and organised means to collect specific information on a given topic/institution that is pertinent to its internal workings and external influences/surrounding.²² Part of the process involves a purposive approach to a search from which the search is then exploded. For this study we identified known online decision aid repositories (see Table 1) as the most likely sources to contain relevant information pertinent to this study. Our second source was from Google Australia.

Table 1. List of known decision aid 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://healthdecisions.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 Aids 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/

Two independent searchers (PP and RZ) were instructed to reset their Cache in their web browsers before each Google search to minimise the effect of Google search optimisation. The final search terms after piloting included 11 for CVD/Medication and two for Decision Aids. The lead researchers (CB, LT) and the two independent searchers agreed upon 11 specific terms for CVD/Medication: cardiovascular disease; heart disease; stroke; heart attack; hypertension; hypercholesterolemia; hypercholesterolaemia; aspirin; blood pressure medication; cholesterol medication; and statin, and two specific terms for Decision Aids: decision aid and decision support (see Appendix Table A1 for search strategy). Additional terms were pilot tested before settling on the final list. A single CVD/Medication term and a single Decision Aids term were combined for each search, resulting in 22 unique Google

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3 searches. The first 50 results for each unique Google search were exported (not including
4 web advertisements), providing a pool of 1100 results to be title scanned for each searcher
5 (2200 results in total). Scanning the first 100 search results for the first few searches found
6 no additional resources after the first 50 results, so the cut-off of 50 was retained.
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13 The two independent searchers conducted this search as part of a Master of Public Health
14 degree capstone unit during August to November 2016. In March 2017, an independent
15 rater (CB) reconciled these search results at the earliest stage feasible (see Figure 1), and
16 the original searchers completed any missing ratings for the final dataset. Only websites that
17 were still working when the third independent rater reconciled the lists were included.
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19 Duplicates were considered either as identical web addresses or identical PDFs.
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24 25 26 27 *Evaluation and data extraction* 28

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31 The two independent searchers rated the content of each decision aid using a validated tool
32 to assess whether printed materials are suitable for people with low health literacy, the
33 Patient Education Material Evaluation Tool for Print Materials (PEMAT-P).²³ PEMAT-P
34 includes two subscales: 1) understandability, which is a measure of how well a person is
35 able to process and explain the key message of the material; and 2) actionability, which is a
36 measure of how well a person is able to identify what to do based on the information in
37 presented. Items were rated on a binary scale (Yes/No) with some items provided a “Not
38 Applicable” option. Final understandability and actionability scores were calculated as a
39 percentage of “Yes” ratings for all items not including “not applicable” ratings; higher
40 percentages indicate better understandability or actionability. Intraclass correlations were
41 calculated using SPSS v25. For the two independent searchers, the intraclass correlation for
42 final understandability scores was 0.51 and for actionability scores was 0.48. Conflicts for
43 individual PEMAT-P items were therefore resolved by the third rater (MF, after discussion
44 with CB) to finalise the PEMAT-P score for each individual decision aid. A threshold of 70%
45 was used to determine whether the decision aid was understandable or actionable.²¹
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Readability

Each decision aid's readability was measured using the Gunning Fog index, which is an index that estimates the formal years of (US) education an individual needs to understand the text.²⁴ 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. The Flesch Kincaid Reading Ease score was also calculated with higher scores indicating greater ease of comprehension. Scores range from 0 to 100 where a score of about 70-80 is the equivalent to school grade 7.²⁵ The intraclass correlation between two independent ratings was high (Gunning Fog Index was 0.91 and Flesch Kincaid was 0.94) so the average of the two scores were used as the final index.

IPDAS Checklist

The two independent researchers (PP and RZ) each completed a checklist based on version 3 of the IPDASi items, with discrepancies resolved by a third rater (MF, after discussion with CB). IPDASi v3 has three domains: *Criteria used to be defined as a patient decision aid* (7-items), *Criteria to lower risk of making a biased decision* (9-items), *Other criteria indicating quality* (13 items). Criteria used to be defined as a patient decision aid items were rated on a Yes/No scale and the other two domains were rated on a 4-point Likert scale (1=Strongly Disagree to 4=Strongly Agree). In addition, two independent raters (PP and MF) used the International Patient Decision Aids Standards Instrument-Short Form (IPDASi-SF) to assess the same decision aids on a quantitative scale.¹⁴ Each item is rated on a 4-point Likert scale (1 = Strongly Disagree, 4 = Strongly Agree). 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 IPDAS. The short form has demonstrated a 0.87 Pearson's *r* correlation with the IPDASi 47-item version.¹⁴ In April 2018 the evaluation was repeated by two researchers (CB and MF) using IPDAS v4, an updated version of IPDAS v3 that reclassified the items into three domains with some revised wording and had collapsed some items into one. The new

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3 domains were *qualifying*, *certification* and *quality*. Qualifying criteria, if all met, identify the
4 material as a decision aid. Certification criteria are those deemed essential to avoid harmful
5 bias and all six criteria need to be met (i.e. scored 3 or more) for the decision aid to be
6 considered certified. Quality criteria on the other hand were items considered desirable but
7 not essential to avoid harmful bias. All decision aids in the original evaluation were still
8 publicly available at this time. Qualifying criteria are measured on a binary yes-no scale and
9 certification and quality criteria are measured on a 4-point Likert scale. To qualify as a
10 decision aid, all 6 qualifying criteria must be met. To be certified as a decision aid, all 6
11 certifying criteria must score at least 3. Agreement for the *qualifying* items ranged from 64%
12 to 100% and the average intraclass correlation coefficient between independent ratings for
13 *qualifying* and *certifying* items were 0.16 and 0.34 respectively. Questions relating to
14 screening tests were not used.

27 28 ***Patient and Public Involvement***

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30 The development of this research question was informed by the International Patient
31 Decision Aids Standards, which has involved an extensive consultation process over many
32 years to produce health decision making tools that are useful and effective for patients. This
33 study did not recruit patients or members of the public, so they were not specifically
34 involved.

41 42 **Results**

43
44 The search of 15 known repositories and 2200 google search results yielded 25 unique CVD
45 prevention decision aids (see Figure 1). Table 2 details the overall evaluation of the decision
46 aids; and Table 3 presents scores by individual decision aid. Appendix Table A2 provides the
47 full IPDAS checklist item results and web archive URLs for the included decision aid
48 webpages.

53 54 ***Evaluation of the quality of the decision aids***

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56 For the version 3 IPDASi-SF (short form) scale, the Pearson's r correlation between the two
57 raters was 0.76 and the mean (SD) score was 64.56 (10.80) out of a maximum 100. For the
58 version 3 IPDAS evaluation (see appendix Table A3 for individual scoring per item for each
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3 decision aid), none of the decision aids met all qualifying criteria to *be defined as a patient*
4 *decision aid* and the median was 71% (5 out of 7 criteria met). None of the decision aids met
5 all criteria to *lower the risk of making a biased decision*, and the median was 33%. None of
6 the decision aids met all criteria to *indicate quality*, and the median was 85%. For the
7 version 4 IPDAS evaluation (see Appendix Table A4 for individual scoring per item for each
8 decision aid), four decision aids met the criteria to *qualify* for a decision aid and the median
9 was 83% (5 out of 6 criteria met) ranging from 2 to 6. One decision aid scored 3 or above on
10 all six items to *certified* as a decision aid and the median was 50% (3 out of 6 items) ranging
11 from 1 to 6. The median quality criteria that scored 3 or above was 30% (7 out of 23 criteria)
12 ranging from 1 to 12 items.

13
14 A central component of decision aids is to present all options, risks and benefits in a
15 balanced and unbiased way, with visual representation of numerical information. Nineteen
16 decision aids provided only one intervention option (73%), whereas the remaining six
17 provided 2-7 different options (27%). The presentation of harms versus benefits in icon
18 arrays was highly variable. Icon Arrays are graphic representations to show abstract
19 probabilities as more concrete frequencies (e.g. 2% = 2 coloured dots out of 100 black dots),
20 and are considered best practice for risk communication.²⁶ Of the 12 decision aids that used
21 icon arrays, 5 (42%) presented only benefits in icon arrays and 7 (58%) presented benefits
22 and harms in icon arrays. Of the 7 that presented benefits and harms in icon arrays, 4 (57%)
23 combined benefits and harms in one icon array and 3 (43%) separated them. Of the 4 that
24 combined benefits and harms in one icon array, 1 (25%) separated the benefits and harms
25 and 3 (75%) overlapped the benefits and harms.

26 ***Evaluation of suitability for low health literacy populations***

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28 For the PEMAT-P evaluation, the decision aids generally scored well on understandability
29 but lower on actionability. The average understandability score was 87% (SD = 7.1%) and
30 actionability was 61% (SD = 24.6%). For readability, the average Gunning Fog index was 9.9
31 (SD=1.9) and Flesch Kincaid was 61.8 (SD=10.3), indicating that a US school grade of 9 is
32 required to understand the information. The Pearson's *r* correlation between
33 understandability and readability was -0.60 for Gunning Fog and 0.59 for Flesch Kincaid.
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[Insert Figure 1. PRISMA Flow Diagram of searcher results (Search 1 PP, Searcher 2 RZ)]

Table 2. Evaluation for included decisions aids (n=25)

Decision Aid Evaluation			
Intervention options		Count (%)	
Medication	Cholesterol-lowering	14 (56)	
	Blood pressure lowering	5 (20)	
	Aspirin	8 (32)	
Lifestyle ^a	Any lifestyle change included	7 (28)	
	Quit smoking	3 (12)	
	Improve diet	2 (8)	
	Increase physical activity	2 (8)	
	Lose weight	2 (8)	
IPDAS ^b		Median	Min–Max
V3	Criteria used to be defined as a patient DA	5 or 71%	3–6 or 43–86%
	Criteria to lower risk of making a biased decision	33%	11–86%
	Other criteria indicating quality	82%	0–100%
V4	Qualifying criteria met (6 items, yes or no)	5 or 83%	2–6 or 33–100%
	Certification criteria met (6 items, score $\geq 3/4$)	3 or 50%	1–6 or 17–100%
	Quality criteria met (23 items, score $\geq 3/4$)	7 or 30%	1–12 or 4–52%
Health Literacy Evaluation			
PEMAT-P		Mean (SD)	
	Understandability	87 (7.1) ^c	
	Actionability	61 (24.6) ^c	
Readability		Mean (SD)	
	Gunning Fog	9.9 (1.9)	
	Flesch Kincaid	61.8 (10.3)	

^a Lifestyle changes will be less than the total sum of its subcategories as one decision aid may have multiple options

^b Percentages for the Criteria to lower the risk of making a biased decision and Criteria for indicating quality in IPDAS V3 don't have counts because these items have an N/A response option, so using raw counts wouldn't be an appropriate comparison

^c These are mean and SD percentage values

Table 3. Individual evaluation of included decision aids (n=25)

ID	PEMAT-P Ratings		IPDAS Ratings		Readability Ratings	
	Understand-ability (0-100)	Actionability (0-100)	V3-SF Overall Score (0-100)	V4 Quality Criteria Rated ≥3 (23 items)	Gunning Fog (0-20)	Flesch Reading Ease (0-100)
DA_01	94.1	66.7	60.9	10	8.3	63.9
DA_02	93.8	83.3	72.7	9	9.9	63.7
DA_03	92.9	71.4	81.3	11	7.8	73.9
DA_04	92.9	71.4	81.3	12	8.8	70.9
DA_05	92.9	71.4	81.3	6	8.5	65.4
DA_06	85.7	60.0	51.6	4	8.0	69.7
DA_07	92.9	16.7	64.8	7	10.9	55.4
DA_08	85.7	20.0	64.8	7	9.7	63.4
DA_09	82.4	66.7	65.6	9	10.3	59.4
DA_10	75.0	60.0	46.1	1	11.8	46.1
DA_11	76.9	60.0	46.9	2	11.1	48.6
DA_12	88.2	83.3	61.7	7	7.2	76.0
DA_13	88.2	83.3	61.7	7	7.2	75.7
DA_14	88.2	83.3	61.7	7	7.1	76.3
DA_15	81.3	33.3	63.3	7	11.1	63.4
DA_16	81.3	33.3	63.3	7	11.1	62.3
DA_17	81.3	33.3	63.3	7	11.4	61.9
DA_18	73.3	60.0	71.9	10	13.7	37.1
DA_19	80.0	60.0	71.9	11	13.2	40.4
DA_20	94.1	100.0	69.5	9	11.8	56.7
DA_21	81.3	33.3	69.5	8	11.4	63.0
DA_22	87.5	20.0	65.6	7	11.6	57.8
DA_23	100.0	100.0	78.9	6	9.0	66.9
DA_24	94.1	80.0	41.4	3	7.7	66.5
DA_25	94.1	80.0	53.1	6	10.0	60.5

Discussion

Principal findings

This review found 25 CVD prevention decision aids available to the public online, with the majority of them focussing on a single medication as the primary line of prevention against a potential future CVD event. Overall the decision aids were very understandable but only had moderate actionability and a high readability level beyond the health literacy level of the general population. Most people would therefore have difficulty taking action based on the information in these decision aids, even though their primary purpose is to help the decision making process. Of particular concern is that only 1 of the 25 decision aids met the most recent international criteria for certification, but the short form scores and quality checklist were reasonably high indicating decent quality overall. This means many decision aids would only require minor additions to reach certification standards; but the issues for low health literate patients would remain.

Strengths and weaknesses

The strengths of this study include a systematic review and evaluation process with multiple independent searchers/raters. The main limitation is the replicability of conducting a systematic search using online search engines like Google. The dynamic nature of the web with constant variation in website content and metadata means that no search is perfectly replicable even though the cache was cleared between search terms. However, the methods used are likely to have captured the most common and popular search results, since many duplicates were removed between the two searchers. Additional decision aids could have been found by a different searcher, search engine or geographical location, and in other languages, which could produce different findings about the overall suitability for low health literate patients. However, this paper provides a list of known repositories of decision aids, including the primary source of IPDAS-assessed decision aids, to guide future researchers. This may improve the consistency of current and future findings. It also highlights the need for a central reputable location for decision aids that consumers could be referred to rather than search for their own.

Comparison to other research

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3 The methods and findings of this study are comparable to two other environmental scans of
4 prenatal decision aids, which also identified issues with presenting unbiased information
5 about both benefits and harms.^{27 28} Other studies using PEMAT-P for patient education
6 materials have found poor results (CVD decision aids in this study: 87% and 61%; CVD risk
7 calculators: 64% and 19%; online heart failure websites: 56% and 35%; printed lifestyle
8 information for chronic kidney disease: 52% and 37%; for PEMAT-P understandability and
9 actionability scores respectively).²⁹⁻³¹ The IPDAS criteria for decision aid development may
10 have led to higher quality patient education materials, but there is still room for
11 improvement on actionability and readability levels.

20 *Implications and future research*

21 CVD prevention decision aids could be improved to better meet quality criteria and make
22 them suitable for low health literacy populations. In particular, this needs to include: 1) a
23 basic explanation of what CVD is and what CVD risk means, since the mechanism for how
24 this leads to events like heart attack and stroke was rarely explained; 2) inclusion of both
25 medication and lifestyle intervention options to enable a fully informed choice, as there
26 tended to be a focus on single medication options; 3) balanced presentation of risks and
27 benefits using visual communication aids such as icon arrays, since few decision aids used
28 best practice risk communication strategies in an equal way for both the benefit and harm
29 of options (e.g. reduced chance of CVD event versus chance of side effects); and 4) more
30 support for what actions to take based on the decision made.²⁶

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41 Several IPDAS items required substantial discussion between raters to decide on the best
42 way to apply them consistently, indicating that further work is needed to provide a reliable
43 tool for certifying decision aids. For example, decision aids that compared a single
44 medication option versus doing nothing were easier to rate highly on balanced presentation
45 than those with multiple options, even though the latter enables a more fully informed
46 choice. In addition, the items did not cover: 1) health literate design issues (e.g. use of white
47 space, images that are consistent with text, and clear direction for next steps); 2)
48 assessment of the accuracy of the information provided (e.g. whether the risks and benefits
49 presented were based on the latest systematic review, if available); 3) ease of access for the
50 intended audience, particularly for low health literacy populations; or 4) how effective the
51 decision aid was, even when an evaluation had been conducted. Work on these issues is
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3 ongoing, with particular attention in the US following legislative changes to certify decision
4 aids.³² The IPDAS criteria were more reliable when used by raters who were more familiar
5 with decision aids at a later stage of the project, suggesting a need for structured training in
6 using IPDAS rating scales.
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10 *Conclusion*

11 To meet the needs of the general population who are likely to have low health literacy, CVD
12 prevention decision aids need to improve actionability and readability, and better address
13 basic certifying criteria such as explaining CVD and ensure that all options are presented in
14 an unbiased way with visual support for benefits and harms.
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3 **Declarations**

4
5 *Ethical approval and consent to participate*

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7 Not applicable.

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10 *Consent for Publication*

11
12 Not applicable.

13
14 *Availability of data and material*

15
16 Website URLs containing the CVD Decision Aids are available in Supplementary Files.

17
18 Descriptive and evaluative data are also available within Supplementary Files.

19
20 *Competing interests*

21
22 The authors declare that they have no competing interests.

23
24
25 *Funding*

26
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28
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30
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32
33
34 *Authors Contributions*

35
36 CB contributed to the conceptualisation, methodology, data analysis and interpretation, and
37 drafting the manuscript. PP contributed to the methodology, data collection and revising
38 the manuscript. RZ contributed to the methodology, data collection and revising the
39 manuscript. MF contributed to the data analysis and revising the manuscript. LT contributed
40 to the conceptualisation, methodology and revising the manuscript.

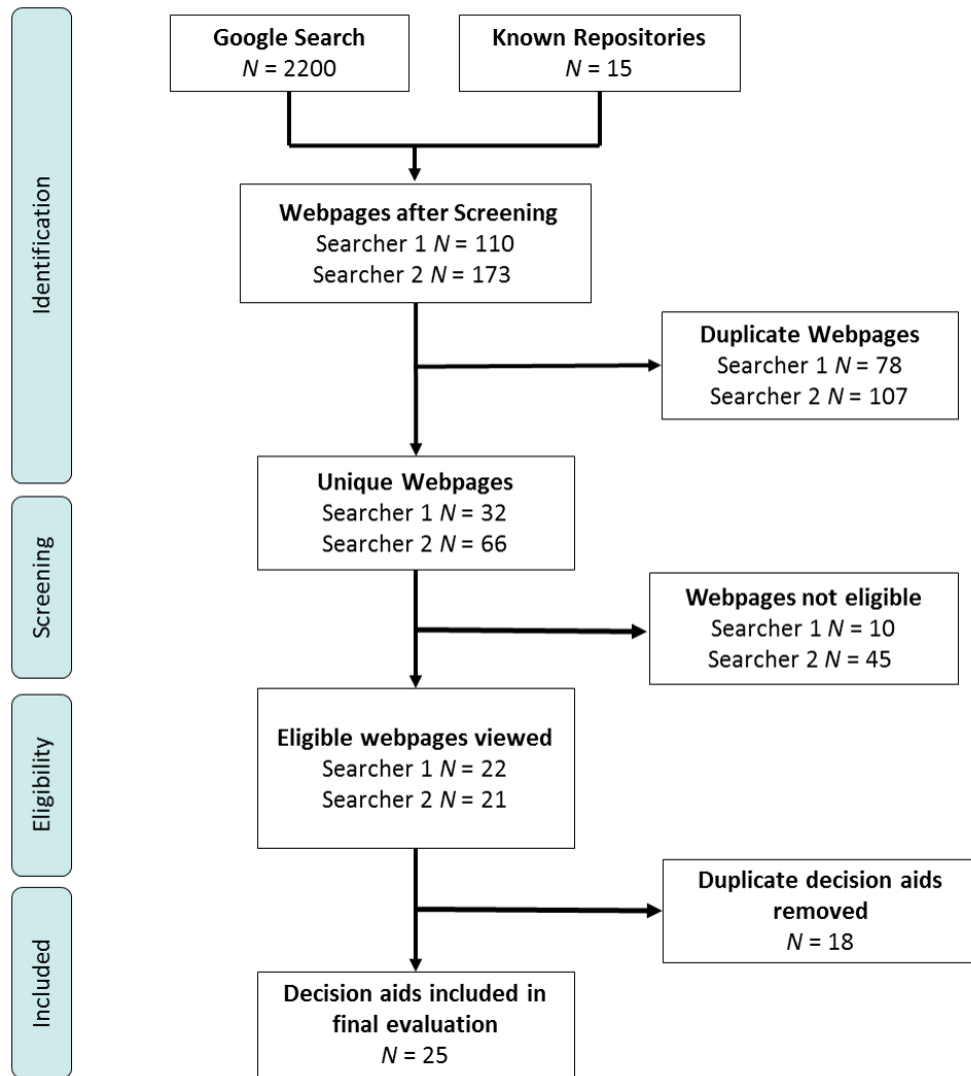
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46 *Acknowledgements*

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41 PRISMA Flow Diagram of searcher results (Search 1 PP, Searcher 2 RZ)

Appendix

Table A1. Google Search Strategy

	Search String
Google Search 1	Cardiovascular disease decision aid
Google Search 2	Heart disease decision aid
Google Search 3	Stroke decision aid
Google Search 4	Heart attack decision aid
Google Search 5	Hypertension decision aid
Google Search 6	Hypercholesterolemia decision aid
Google Search 7	Hypercholestoerlaemia decision aid
Google Search 8	Aspirin decision aid
Google Search 9	Blood pressure medication decision aid
Google Search 10	Cholesterol medication decision aid
Google Search 11	Statin decision aid
Google Search 12	Cardiovascular disease decision support
Google Search 13	Heart disease decision support
Google Search 14	Stroke decision support
Google Search 15	Heart attack decision support
Google Search 16	Hypertension decision support
Google Search 17	Hypercholesterolemia decision support
Google Search 18	Hypercholestoerlaemia decision support
Google Search 19	Aspirin decision support
Google Search 20	Blood pressure medication decision support
Google Search 21	Cholesterol medication decision support
Google Search 22	Statin decision support

Table A2. List of included web addresses a decision aid.

ID	Web Address	WebCite
1	https://www.med-decisions.com/h2hv2/	http://www.webcitation.org/6rBGRO6iB
2	https://www.healthdecision.org/tool.html#/tool/cholesterol	http://www.webcitation.org/6rBNTNlKc
3	https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=aa44406	http://www.webcitation.org/6rBNe4456
4	https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=uf9825	http://www.webcitation.org/6rBNxy94W
5	https://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=zx1768	http://www.webcitation.org/6rBO2SKKf
6	http://optiongrid.org/option-grids/grid-landing/51	http://www.webcitation.org/6rBOAo7l9
7	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/high-cholesterol/	PDF available on request
8	http://sdm.rightcare.nhs.uk/shared-decision-making-sheets/high-blood-pressure/	PDF available on request
9	https://statindecisionaid.mayoclinic.org	http://www.webcitation.org/6rB7TxoW4
10	http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013	http://www.webcitation.org/6rBOGLM1U
11	http://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statins/art-20045772	http://www.webcitation.org/6rBOJ16bl
12	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_avg21.pdf	http://www.webcitation.org/6rBOMEgar
13	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_elevated2.pdf	http://www.webcitation.org/6rBOTnZeo
14	http://shareddecisions.mayoclinic.org/files/2011/08/Statin_DA_high2.pdf	http://www.webcitation.org/6rBOXs845
15	http://shareddecisions.mayoclinic.org/files/2014/11/Aspirin_DA_avg.pdf	http://www.webcitation.org/6rBOZwelz
16	http://shareddecisions.mayoclinic.org/files/2011/08/Aspirin_DA_elevated1.pdf	http://www.webcitation.org/6rBOgzuyd
17	http://shareddecisions.mayoclinic.org/files/2011/08/Aspirin_DA_high.pdf	http://www.webcitation.org/6rBOKUTgM
18	http://www.decisionbox.ulaval.ca/index.php?id=883&L=2	http://www.webcitation.org/6rBPG2Gjh
19	http://www.decisionbox.ulaval.ca/index.php?id=817&L=2	http://www.webcitation.org/6rBPG9pij
20	https://www.nice.org.uk/guidance/cg181/resources/patient-decision-aid-243780157	http://www.webcitation.org/6rBPImWde
21	http://www.parksmed.co.uk/wp-content/uploads/2013/09/Antiplatelets_Aspirin-for-Primary-Prevention-of-CVD_Patient-Decision-Aid.pdf	http://www.webcitation.org/6rBPOedwZ
22	http://www.parksmed.co.uk/wp-content/uploads/2013/09/Statin_Patient-decision-aids.pdf	http://www.webcitation.org/6rBPY4nHf
23	http://www.viha.ca/NR/rdonlyres/ADE60ED3-7BFC-4394-A793-9BA65CD5922F/0/CVRRPatientChoicesPamphlet.pdf	http://www.webcitation.org/6rBPaZRce
24	https://archive.ahrq.gov/patients-consumers/prevention/disease/aspirinwom.html	http://www.webcitation.org/6rBPfPLDL
25	http://www.drugepi.org/wp-content/uploads/2013/11/DoPE_Toolkit_brochure_REV21.pdf	http://www.webcitation.org/6rBPi1kyO

Table A3: International Patient Decision Aid Standards Inventory Version 3 Ratings for all Cardiovascular Decision Aids (n=25).

ID:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
<i>Criteria to be defined as a patient decision aid</i>																										
1.	The decision aid describes the condition (health or other) related to the decision.	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1	1	1	1
2.	The decision aid describes the decision that needs to be considered (the index decision).	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1
3.	The decision aid identifies the target audience.	0	1	1	1	0	1	0	1	0	1	0	0	0	0	0	0	1	1	0	1	1	1	0	1	1
4.	The decision aid lists the options (health care or other).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0
5.	The decision aid has information about the positive features of the options (e.g. benefits, advantages).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6.	The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1
7.	The decision aid helps patients clarify their values for outcomes of options by: a) asking people to think about which positive and negative features of the options matter most to them AND/OR b) describing each option to help patients imagine the physical, social, and /or psychological effect.	1	0	1	1	1	1	1	0	0	1	0	0	0	0	0	0	1	1	1	0	0	0	0	1	1
<i>Criteria to lower the risk of making a biased decision</i>																										
1.	The decision aid makes it possible to compare the positive and negative features of the available options.	1	0	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1	0	1	1	0	0	0	0
2.	The decision aid shows the negative and positive features of the options with equal detail.	0	1	1	1	1	1	1	0	0	0	0	0	0	1	1	1	1	1	0	1	0	0	0	0	0
3.	The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.	0	1	2	2	2	1	0	1	2	2	0	0	0	1	1	1	1	1	1	1	1	0	0	0	0
4.	The decision aid (or available technical documents) reports funding sources for development.	3	3	3	0	0	3	0	0	0	3	3	0	0	0	0	0	0	0	0	0	0	1	1	0	0
5.	The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.	0	1	1	1	1	1	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0
6.	The decision aid includes authors/developers' credentials or qualifications.	1	3	1	1	1	3	0	0	0	3	3	0	0	0	0	0	0	0	0	0	0	1	1	0	0
7.	The decision aid reports the date when it was last updated.	0	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1	1
8.	The decision aid (or available technical document) reports readability levels.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
9.	The decision aid provides references to scientific evidence used.	0	1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	1	1	0	1	1	1	0	0	0
<i>Other criteria indicating quality</i>																										
1.	The decision aid describes what happens in the natural course of the condition (health or other) if no action is taken.	1	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	0	0
2.	The decision aid has information about the procedures involved (e.g. what is done before, during, and after the health care option).	2	0	1	1	1	1	1	1	0	1	1	1	1	0	0	0	1	1	1	0	0	0	0	0	0
3.	The information about outcomes of options (positive and negative) includes the chances they may happen.	0	1	0	0	0	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0
4.	The decision aid presents probabilities using event rates in a defined group of people for a specified time.	1	1	2	2	2	0	1	1	1	2	2	1	1	1	1	1	1	0	1	1	1	1	1	0	0
5.	The decision aid compares probabilities of options over the same period of time.	1	1	2	2	2	0	0	1	2	2	1	1	1	1	1	1	0	1	1	1	1	1	0	0	0
6.	The decision aid uses the same scales in diagrams comparing options.	1	1	2	2	2	0	0	1	2	2	1	1	1	1	1	1	1	1	1	1	1	1	0	2	2
7.	Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.	1	1	0	0	0	1	2	2	3	1	1	3	3	3	2	2	2	0	2	2	2	2	2	2	2
8.	The decision aid was reviewed by people who previously faced the decision who were not involved in its development and field testing.	3	1	1	1	1	1	2	2	3	3	3	3	3	3	2	2	2	3	3	3	2	2	2	2	2
9.	People who were facing the decision field tested the decision aid.	1	1	1	1	1	1	2	2	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
10.	Field testing showed that the decision aid was acceptable to users (the general public & practitioners).	1	1	1	1	1	1	2	2	3	3	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2
11.	Field testing showed that people who were undecided felt that the information was presented in a balanced way.	1	1	1	1	1	3	2	2	3	3	3	3	3	3	2	2	2	3	3	3	2	2	2	2	2
12.	There is evidence that the decision aid (or one based on the same template) helps people know about the available options and their features.	1	3	1	1	1	3	3	3	1	3	3	1	1	1	3	3	3	3	3	3	3	3	3	3	2
13.	There is evidence that the decision aid (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.	1	3	3	3	3	3	3	1	3	3	1	1	1	1	3	3	3	3	3	3	3	2	3	3	2

Table A4: International Patient Decision Aid Standards Inventory Version 4 Ratings for all Cardiovascular Decision Aids (n=25).

	ID	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	
<i>Criteria to qualify as a decision aid</i>																											
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1	The development process included review by professionals not involved in producing the decision support intervention.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	The patient decision aid was field tested with patients who were facing the decision.	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
3	The patient decision aid was field tested with practitioners who counsel patients who face the decision.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
4	The patient decision aid (or associated documentation) describes how research evidence was selected or synthesized.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5	The patient decision aid (or associated documentation) describes the quality of the research evidence used.	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
6	The patient decision aid includes authors'/ developers' credentials or qualifications.	4	4	4	4	4	2	1	1	1	1	1	1	1	1	1	3	3	1	1	1	4	1	4
7	The patient decision aid (or associated documentation) reports readability levels (using 1 or more of the available scales).	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
8	There is evidence that the patient decision aid improves the match between the preferences of the informed patient and the option that is chosen.	1	1	1	1	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
9	There is evidence that the patient decision aid helps patients improve their knowledge about options' features.	1	1	1	1	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

*Note: Scores of 1.5 and 3.5 indicate instances when the two reviewers did not agree on between 1 or 2, or between 3 and 4 respectively, so the average was taken instead.



PRISMA 2009 Checklist

Section/topic	#	Checklist item	Recorded on Page
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	Page 1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	Page 2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Page 5-6
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Page 6
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Page 7-8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Page 8-9
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Page 9



PRISMA 2009 Checklist

4	Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Page 9-11
8	Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Page 9-11
12	Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
16	Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	Page 9-11
18	Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Page 9-11

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Page 11, PRISMA Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 3 (for individual decision aids rather than studies)
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence	Table 2 (for summary of decision aids rather than studies)



PRISMA 2009 Checklist

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intervals, ideally with a forest plot.

		intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Page 11-12
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Page 16
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Page 16
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Page 17
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Page 18

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

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