

Interventions to facilitate shared decision-making using decision aids with patients in Primary Health Care

A systematic review

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Abstract

Background: Shared decision making (SDM) is a process within the physician–patient relationship applicable to any clinical action, whether diagnostic, therapeutic, or preventive in nature. It has been defined as a process of mutual respect and participation between the doctor and the patient. The aim of this study is to determine the effectiveness of decision aids (DA) in primary care based on changes in adherence to treatments, knowledge, and awareness of the disease, conflict with decisions, and patients' and health professionals' satisfaction with the intervention.

Methods: A systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines was conducted in Medline, CINAHL, Embase, the Cochrane Central Register of Controlled Trials, and the NHS Economic Evaluation Database. The inclusion criteria were randomized clinical trials as study design; use of SDM with DA as an intervention; primary care as clinical context; written in English, Spanish, and Portuguese; and published between January 2007 and January 2019. The risk of bias of the included studies in this review was assessed according to the Cochrane Collaboration's tool.

Results: Twenty four studies were selected out of the 201 references initially identified. With the use of DA, the use of antibiotics was reduced in cases of acute respiratory infection and decisional conflict was decreased when dealing with the treatment choice for atrial fibrillation and osteoporosis. The rate of determination of prostate-specific antigen (PSA) in the prostate cancer screening decreased and colorectal cancer screening increased. Both professionals and patients increased their knowledge about depression, type 2 diabetes, and the perception of risk of acute myocardial infarction at 10 years without statins and with statins. The satisfaction was greater with the use of DA in choosing the treatment for depression, in cardiovascular risk management, in the treatment of low back pain, and in the use of statin therapy in diabetes. Blinding of outcomes assessment was the most common bias.

Conclusions: DA used in primary care are effective to reduce decisional conflict and improve knowledge on the disease and treatment options, awareness of risk, and satisfaction with the decisions made. More studies are needed to assess the impact of shared decision making in primary care.

Abbreviations: DA = decision aids, PSA = prostate-specific antigen, SDM = shared decision making.

Keywords: decision aids, primary health care, shared decision making

1. Introduction

Decision making in primary care is sometimes complex for patients and health professionals. Clinical information with

scientific evidence about the various options for diagnosis and treatment is not always clearly available. However, decision-making process involves more than providing information; it means that the patients play an active role in decisions concerning

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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their health, and that they fully engage in the decision-making process.^[1]

Shared decision making (SDM) intends to balance the patients' right of autonomy with the practitioners' responsibility to protect patients' safety.^[2] SDM is a process within the physician–patient relationship applicable to any clinical action, whether diagnostic, therapeutic, or preventive in nature. It has been studied mainly in the areas of healthy lifestyle and adherence to treatment in chronic diseases, breast and prostate cancer, and palliative care. It is considered a manifestation of patient-centered care, a health care approach that is guided by the patients' needs instead of the health professionals' priorities.^[3] The components of SDM have many elements in common with patient-centered care, such as providing information about patients' choices, showing consideration for their values, and decision-making involvement.^[4] Its practice is fundamental when all the hoped-for benefits of an intervention cannot be guaranteed or when there is great risk involved. Different instruments have been developed to measure patient participation and how professionals facilitate the involvement of patients in decision making, which has important ethical implications with respect to their autonomy.^[5,6] This participation in the decision-making process is possible through a deliberative model of the physician–patient relationship, which involves information exchange and subsequent deliberation in order to achieve the best choice.^[7] In this paper, we distinguish “shared decision making” from “informed decision making,” even if they have common characteristics.

Interventions to support SDM either aim to prepare health professionals through actions like coaching or training interventions, or to help the practitioners and patients to proceed with the decision making by implementing procedures such as DA.^[8] DA strategies facilitate patients' decision-making involvement and play an essential role in SDM as informative tools. They contribute to the respect of personal values in the decision-making process by increasing the patients' knowledge of their conditions and reducing passivity in decision making.^[9]

The use of DA can help patients participate in the decisions to improve the quality of the decision-making process and the satisfaction with the chosen option.^[10] Benefits from DA compared with usual care have already been described. DA increase knowledge regarding options and reduce the decisional conflict related to feeling uninformed. DA also encourages patients to be actively involved in decision making and provide an accurate perception of the actual risks. The use of DA foster valued-based choices and patient–practitioner communication.^[9] A number of barriers to the application of DA by professionals in primary care have been described, such as time restraints, lack of familiarity, and the existence of an of inadequate clinical reporting system that does not allow these tools to be included. Facilitators include automation the use of DA, making them available for patient's prior consultation, and their use by nonclinical personnel.^[11]

Evidence has been published that shows that SDM promotes appropriate care, decreases overtreatment, meliorates health outcomes and, by extension, reduces health-care costs.^[8] SDM has shown to be effective in many scenarios including Primary Care, Mental Health, Pediatrics, Palliative Care, Medicine, and Surgery.^[12] SDM assumes that patients are willing and prepared to choose the best option, although in practice patients are not often in a position to make a good decision and practitioners have to lead the decision-making process. In these cases, Brown and Salmon^[2] suggest contextualizing the decision and assessing

patients by making judgements of reasonableness. Although many training programs towards improving health care professionals' competence in SDM have been identified, its routine use remains limited.^[13] Boland et al^[14] identified barriers in the implementation of SDM beside training, such as low practitioners' perception of self-efficacy in SDM, time constrains, inappropriate settings, and a lack of team-based approach. Kalsi et al^[12] pointed high-quality DA, cultural shift towards a more patient-centered care, and adequate training as challenges in the implementation of SDM.

The benefits from SDM have already been reviewed, but none of these papers focuses on the primary care context. Considering the proven effectiveness and the scarce implementation of SDM, there is a need for summarizing published evidence on the practice of SDM in primary care, considering whether the use of DA with patients treated in primary care, as compared with the usual clinical practice, improve adherence to the treatment, knowledge and awareness of the illness, patients and health professionals' satisfaction with the intervention, and also reduces decisional conflict.

The aims of this study are: to determine whether SDM using DA in primary care consultations improve adherence to the treatment, knowledge and awareness of the illness, satisfaction of both professionals and patients with the intervention, and reduces decisional conflict. To identify the appropriate tools for decision making in primary care. To assess evidence quality for these tools.

2. Methods

A systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.^[15] In order to identify primary studies, the following databases were consulted: MEDLINE via PubMed, CINAHL, EMBASE, Cochrane Central Register of Controlled Trials (CENTRAL), and NHS Economic Evaluation Database. The PubMed search strategy was “Decision Making” [Mesh] AND “Primary Health Care” [Mesh] AND (Randomized Controlled Trial[ptyp] odds ratio (OR) “before and after” [tiab]) AND (English[lang] OR Portuguese[lang] OR Spanish[lang]) AND (“2007/01/01” [PDAT]: “2020/01/31” [PDAT]). The following search terms were used with the remaining databases: “Shared decision making” AND “Primary care,” with publication limit dates added. Additionally, the reference lists of the selected articles were manually reviewed, and those that met the established inclusion criteria were included. Additionally, the reference lists of the included papers were manually reviewed, in case any study that met the established inclusion criteria had not been identified in the initial search due to the specific search terms used or for being published in journals that are not indexed in the consulted databases.

A literature search was conducted between January 2007 and January 2019.

This systematic revision includes randomized clinical trials that assess DA for shared decision making in primary care. The articles may be written in English, Spanish, or Portuguese. The inclusion criteria were: DA used for any diagnostic or therapeutic intervention in primary care; DA in any format; patients of any age who were assisted in primary care consultations for any disease.

As exclusion criteria it was established duplicated references; non access to full text article; not relevant for the aim of the study;

Table 1
Assessment of the methodological quality according to the Cochrane Collaboration's tool.

Study, year	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting
Loh et al ^[12] 2007	1	1	2	2	2	1
Thomson et al ^[13] 2007	1	1	2	1	1	1
Krones et al ^[14] 2008	1	2	2	3	1	2
Koelewijn-Van Loon et al ^[15] 2009	1	2	1	3	1	1
Myers et al ^[16] 2010	2	2	2	3	2	1
Légaré et al ^[17] 2010	1	1	3	3	2	2
Montori et al ^[18] 2011	1	1	1	3	1	1
Legare et al ^[19] 2012	1	1	2	3	1	1
Sheridan et al ^[20] 2012	2	2	1	2	2	2
Wilkes et al ^[21] 2013	2	1	1	3	1	1
Branda et al ^[22] 2013	2	1	2	2	1	2
Miller et al ^[23] 2014	2	2	3	2	2	1
Patel et al ^[24] 2014	1	1	2	2	1	2
Price-Haywood et al ^[25] 2014	1	2	3	2	1	2
Fiks et al ^[26] 2015	2	2	1	1	3	2
Lewis et al ^[27] 2015	1	1	1	2	2	2
Leblanc et al ^[28] 2015	1	1	3	3	3	1
Perestelo-Perez et al ^[29] 2016	1	1	2	3	2	2
Karagiannis et al ^[30] 2016	2	1	3	3	2	2
Reuland et al ^[31] 2017	1	1	3	3	2	2

1 = low risk, 2 = unclear risk, 3 = high risk, RR = relative risk.

and studies with low methodological quality after assessing the risk of bias.

Randomized and controlled clinical trials that included patients using primary care consultations for treatment, diagnosis, prevention, or health promotion activities related to acute or chronic diseases were selected. The Intervention group was programs making use of DA in SDM. The Control group was standard practice, which means that SDM strategies were not used. After discarding duplicates, references were screened according to title and abstract. Then, the full texts of the selected articles were retrieved for assessment. Two researchers selected the studies independently. Discrepancies were resolved by consensus.

One researcher collected the following data through specially designed forms: types of conditions for which SDM was used, health care professionals involved, DA, clinical outcomes of the intervention, adherence to treatment, patients' knowledge of the different treatment options, adverse effects resulting from the interventions, decisional conflict, satisfaction of professionals and patients. Information obtained after data extraction was analyzed and a narrative synthesis were carried out describing the results.

The assessment of risk of bias was conducted using the Cochrane Collaboration's tool.^[16] This tool allows evaluating the studies according to the random sequence generation, the allocation concealment, the blinding of participants and personnel, the blinding of outcome assessment, the incomplete outcome data and the selective reporting. Review authors' judgements were categorized as "low risk" of bias, "high risk" of bias, or "unclear risk" of bias. The risk was assessed as "unclear risk" when details about methods followed were not described in the article. Studies with a score "high risk" in >3 items were excluded. It is estimated that randomized clinical trials with a medium quality assessment may overestimate the effect size by up to 35%, as compared with those with high quality.^[17]

The quality appraisal was performed by 2 researchers independently, and consensus was reached regarding the results. Given the heterogeneity of the interventions and measurement methods, it was not considered appropriate to perform a statistical analysis of the study results. Table 1 shows the methodological quality of the trials included in this review. Blinding of outcomes assessment was the most common bias. This research activity does not involve human subjects or animals. Neither human data have been used. IRB approval has not been required.

3. Results

The database search produced 201 references, 15 of which were duplicates. After reading the title and abstract of the identified references, 138 references were discarded for not fulfilling the inclusion criteria. The resulting 48 articles were full-text screened, and 24 were excluded for their poor methodological quality. Finally, 24 studies were included in this review.^[18–41]

According to the aim of the review, the results were organized regarding effectiveness of the intervention on adherence to treatment, knowledge and awareness of the disease, absence of conflict, and patients' and professionals' satisfaction. The results from the reviewed studies are summarized in Table 2. Table 3 shows the articles obtained from each database.

3.1. Patients' conditions

The mean age of the participants in the reviewed studies ranged from 8 years^[32] to 73 years.^[33] The study population involved adults or older people, except for 1 study on children with asthma.^[32] The interventions were performed by family physicians in all the trials, except for 2 where nurses^[21] and pediatricians^[32] took part. The interventions were used in cancer screening,^[22,26,27,31,33,37] type 2 diabetes,^[28,35,36] cardiovascular

Table 2
Characteristics and results from the included clinical trials.

Authors, year	Participants (n, age, % males)	Type of DA, Goal	Disease, Professional involved	Intervention (G1) Control (G2)	Assessment tools	Main outcome measures	Outcomes: adherence to treatment	Outcomes: knowledge and awareness	Outcomes: decisional conflict	Outcomes: satisfaction
Loh et al ^[18] 2007	105; 45 years; 29.7% males	Personal interview, DA. To assess whether SDM improves outcomes without increasing consultation time.	Depression FFs	G1: DAs for monitoring and treatment of depression. G2: Standard care.	PICS and MSH-scale. Treatment adherence: self-report. CSO-8 questionnaire.	G1: easier participation in consultation. Greater effectiveness in patient involvement. PICS (P=.02). No differences in consultation time.	No differences in treatment adherence.	Not assessed	Not assessed	G1: Greater satisfaction in post-intervention patients (P=.014).
Thomson R et al ^[19] 2007	109; 73, 4 years; 56% males	Computerized DA. Efficacy in the choice of aspirin or warfarin treatment in FA patients by using SDM.	Atrial fibrillation FFs	G1: DAs used in the decision to start treatment with OACs. G2: Standard care (paper guidelines).	Knowledge scale. Degner's decision-making preference scale. Decision Conflict Scale (DCS).	Higher mean warfarin knowledge score than participants on aspirin, P<.001. Patients in G1 were significantly much less likely to start warfarin.	Not assessed	Less conflict with decision in post-consultation G1 (P=.036).	Not assessed	Not assessed
Krones et al ^[20] 2008	1132; 58.8 years; 43.8% males	Paper-based DA. To evaluate the impact of communication of the CVRFs by using SDM.	Cardiovascular risk. FFs	G1: DAs in prevention of CVRFs: effective in lifestyle changes, satisfaction, etc. G2: Standard care.	Short form of Shared Decision-Making Q (SDM-Q) Patient Participation Scale (MSH-scale).	Reported patients' participation and SDM step was higher in G1 (P<.001).	CVD risk decreased in both groups without a significant difference.	Not assessed	Not assessed	Decisional regret was significantly lower at follow-up (P .02) in the intervention group. Greater satisfaction in G1 (P<.001).
Koehnli-van Loon et al ^[1] 2009	615; 57 years; 47% males	Personal interview, DA. To determine the effect of changes in lifestyle in CV risk through SDM.	Cardiovascular risk. Nurses	G1: Use of DAs in cardiovascular risk factor prevention G2: Standard care.	Validated questionnaires, the score risk table and UKPDS risk.	G1: Better coping with anxiety, statistically significant. No significant differences between groups (food consumption, smoke, alcohol).	Not assessed	Greater perception of risk (P<.001).	Lower decision conflict was found in G1 (higher confidence about decision making P<.001). G1: More trust in decision making process (P<.001).	G1: Greater patient satisfaction with the decisions made (P<.001).
Myers et al ^[21] 2010	313; 56.5 years	Personal interview, DA. To assess the impact of SDM in prostate cancer screening	Prostate cancer screening. FFs and Nurses	G1: DAs in prostate cancer screening with PSA test. G2: Standard care.	Cancer screening knowledge measured on baseline and endpoint surveys. OPTON scale. Control Preferences Scale.	No significant difference in requests for PSA tests between both groups. There was no impact in physicians' engagement with the SDM-program. G1: reduction in antibiotic use (P=.08).	Not assessed	Not assessed	No differences in decisional conflict (P=.620). G1: Fewer decisional conflict. Not statistically significant.	Not assessed
Legaré et al ^[23] 2013	459; 32 years; 29% males	Web-based DA, personal interview. To evaluate the impact of SDM-program on antibiotic treatment and physicians' intention to engage SDM.	Acute respiratory infection. FFs	G1: DAs in prescription of antibiotic therapy. G2: Standard care.	Decisional Conflict Scale. Haynes. OPTON scale.	Discreet improvement in drug treatment with bisphosphonates in G1 (P=.009). Not statistically significant differences between groups in patient involvement; only patient involvement was more intensive.	Not assessed	Not assessed	Decisional conflict was similar in both groups (P=.725).	Greater patient satisfaction in G2 (not statistically significant).
Montori et al ^[24] 2011	100; 67 years	Paper-based DA. To assess the effectiveness of osteoporosis treatment in at-risk women using SMD.	Osteoporosis. FFs	G1: DAs for intensifying treatment and knowledge of osteoporosis. G2: Standard care.	Decisional Conflict Scale. Haynes.	Decision to use antibiotics: 52.2% in G1 versus 27.2% in G2. RR = 0.48, 95% CI (0.34-0.68). Greater patient involvement in G1 (P<.01).	Not assessed	Not assessed	No significant differences (P=.29) in decisional conflict.	Not assessed
Legaré et al ^[25] 2012	359; 41.6 years; 28.2% males	Personal interview and web-based on DA. To evaluate the effectiveness of a training SDM program to reduce the use of antibiotic in ARI.	Acute respiratory infection. FFs	G1: DAs for antibiotic therapy in ARI. G2: Standard care.	Ad-hoc questionnaire about the use of antibiotics immediately after consultation. The modified Control Preference Scale. Phone call for adherence to decision and to repeat consultation.	Decision to use antibiotics: 52.2% in G1 versus 27.2% in G2. RR = 0.48, 95% CI (0.34-0.68). Greater patient involvement in G1 (P<.01).	Not assessed	Not assessed	No significant differences (P=.29) in decisional conflict.	Not assessed
Sheridan et al ^[26] 2012	128; 57.5 years	Video-based DA, personal interview. To examine the effects of a prostate cancer screening intervention using SDM.	Prostate cancer screening. FFs	G1: DAs in video format for prostate cancer screening. G2: Standard care.	SDM questionnaire of 5-points Likert-scale. Follow-up decision about PSA screening for 9 months.	G1: Lower screening rates (RR = 0.42; 95% CI 0.14-1.24). Patients in G1 considered that PSA test in screening was a personal decision (RR = 2.79 95% CI 1.56-3.47).	Not assessed	Not assessed	No differences in patient satisfaction.	Not assessed
Wilkes et al ^[27] 2013	581; 63 years	Web-based program, DA. To assess the effect of training primary care physicians in SDM and activating their patients to ask about prostate cancer screening.	Prostate cancer screening. FFs	G1: 2 DAs in prostate cancer screening; medical training and patient activation. G2: Standard care.	Modified Kaplan questionnaire. SDM satisfaction, attitudes and behaviors were measured by questionnaires, pre and post intervention.	G1 had higher discussion rates about the screening procedure (P<.01). Physicians in G1 were more neutral during prostate cancer screening recommendations (P<.05).	Not assessed	Not assessed	Not assessed	High level of patient satisfaction in both groups.

(continued)

Table 2
(Continued).

Authors, year	Participants (n, age, % males)	Type of DA, Goal	Disease Professional involved	Intervention (G1) Control (G2)	Assessment tools	Main outcome measures	Outcomes: adherence to treatment	Outcomes: knowledge and awareness	Outcome: decisional conflict	Outcomes: satisfaction
Brandt et al ^[28] 2013	103; 57.6 years; 61% males	Paper-based DA. To analyze the efficacy of non-academic and rural care in DM2 using SDM.	Type 2 diabetes. FPs.	G1: DAs for treatment intensification. G2: Standard care.	Patient knowledge, comfort with decision making and questionnaires. Decisional Conflict Scale. Patient self-report. End points were ascertained at baseline and at follow-up with designed questionnaires.	G1: More interactive in the consultation (77% vs 45%; $P=0.01$). More involved in decision making (60% vs 28%; $P=0.1$). No significant differences in the study variables between groups.	Not assessed	More knowledge about options in decision making (67% vs 33%; $P=0.1$).	Not assessed	Similar level of patient satisfaction in both groups.
Miller et al ^[29] 2014	347; 68.7 years; 26.78% males	Paper-based DA. To test the SDM intervention for increasing patient-reported awareness of NSAID risk.	Risks of NSAID use. FPs.	G1: DAs with information on taking NSAIDs. G2: Standard care.	Decisional Conflict Scale. Patient self-report. End points were ascertained at baseline and at follow-up with designed questionnaires.	None	Not assessed	Not assessed	Not assessed	Not assessed
Patel et al ^[30] 2014	148; 47 years; 33% males	Paper-based DA and personal interview. To pilot an SDM package about treatments for low back pain patients.	Low back pain. FPs and physical therapists.	G1: DAs with information on treatment options. G2: Standard care.	Roland Morris Questionnaire after 4 months post intervention.	Degree of disability. Less disability in G1. 2.3 (CI 95%: 0.08–4.47).	Not assessed	Not assessed	Not assessed	Patient satisfaction was measured by a 5-point Likert scale: G1 53%, G2 67%. RR=1.28 (CI 95%: 0.79–2.03). Not assessed
Price-Haywood et al ^[31] 2014	168; 58.3 years; 34.5% males	Personal interview DA. It evaluates an SDM program for FPs to improve cancer communication and increase cancer screening in illiterate patients.	Cervical, breast, and colon cancer screening in illiterate patients. FPs.	G1: FPs undergo a training program + feedback audits to enhance communication and improve screening rates. G2: FPs only undergo feedback audits.	Perceived involvement in Care Scale. They look over differences between groups by using behavior checklists and feedback over 12 and 24 months.	G1: Better communication and SDM in colon cancer screening. The screening rates increased in both groups, but significant differences were only found with breast cancer screening. Communication did not improve screening rates.	Not assessed	Not assessed	Not assessed	Not assessed
Fiks et al ^[32] 2015	60; 8.3 years.	Web-based DA. To assess a DA tool (MyAsthma, an EHR-linked patient portal) supporting shared decision-making for pediatric asthma.	Asthma. Primary care pediatricians.	G1: MyAsthma website with interactive tool for parents and physicians. The aim was to raise awareness of symptoms and optimize treatments. G2: Standard care.	Outcomes were measured by the proportion of participants who completed the portal survey each month. Acceptability was measured by a Likert-type scale.	G1: Reduction in the following 6 months in the number of consultations (0% vs 4%), hospital admissions (8% vs 29%), visits to pneumologist (31% vs 44%), and pediatrician (62% vs 67%). No significant differences in asthma control or quality of life.	Not assessed	Not assessed	Not assessed	Patient satisfaction with care, evaluated by 2 questions: no significant differences.
Lewis et al ^[33] 2015	2550; 50–75 years	To evaluate effectiveness of 3 SDM interventions (personal and group interviews, and DVD) on PSA screening in primary care.	PSA testing in colon cancer screening. FPs	G1: Three groups: a) DVD with information. b) Invitation to participate in a group with professionals and other patients. c) Both. G2: Standard care.	PSA testing was measured via electronic medical record at 12 months. Use of SDM strategies was evaluated by self-report at 4 months post intervention.	Compared to the control group, PSA testing took place more frequently in G1 in the following 12 months (30% vs 21%) $P=0.1$. No differences between SDM strategies.	Not assessed	There was greater awareness in G1-DVD ($P<0.001$) and a less positive attitude toward the routine of PSA testing ($P=0.06$).	Not assessed	Not assessed
LeBlanc et al ^[34] 2015	297; 43.5 years; 33% males	Personal interview DA, and paper-based. To estimate the effect of a DA tool (encounter DA) on the quality of the decision-making process and depression outcomes.	Depression. FPs	G1: DAs for the choice of antidepressant medication. G2: Standard care.	Decisional Conflict Scale. PHO-9 questionnaire. OPTON scale.	Patient involvement was higher in G1, $P<0.001$. No differences in clinical outcomes.	Not assessed	G1: Improved knowledge of the medication OR=9.5 (95% CI: 0.8–18.2).	Not assessed	G1: Physicians were more satisfied with the decision (RR=1.64) $P=0.2$.
Penstelo-Perez et al ^[35] 2016	168; >18 years.	Personal interview and paper-based DA. To explore the efficacy of a DA tool (Statin Choice, an encounter DA) in the use of statins in DM2 patients.	Type 2 diabetes. FPs.	G1: DAs for choosing statin therapy to reduce cardiovascular risk. G2: Standard care.	Knowledge, CARFs, decisional conflict, and anxiety were assessed through validated questionnaires. Self-report after intervention.	None	Not assessed	G1: Improved knowledge ($P=0.001$), perception of risk of AMI at 10 years without statins ($P=0.1$) and with statins ($P=0.08$).	Not assessed	G1: Greater patient satisfaction (assessed by using an adapted Barry et al questionnaire) ($P=0.001$).
Karagiannis et al ^[36] 2016	204; 65 years; 43% males	Paper-based DA. To assess the efficacy of a DA tool (Diabetes Medication Choice Decision Aid) in DM2 patients.	Type 2 diabetes. FPs, nurses.	G1: DAs for choice of treatment in paper format. G2: Standard care.	Ad-oc questionnaires, an adaptation of the Decisional Conflict Scale and self-reporting after intervention.	HA1c was reduced after 12 weeks by 33% in G1 ($P=0.051$). BMI for G1 was 2.1 points lower than control at 24 weeks ($P=0.41$).	Not assessed	There were no differences in patient knowledge about the disease ($P=0.234$).	Not assessed	There were no differences in patient satisfaction with the decision made ($P=0.06$).
Reiland et al ^[37] 2017	265; 58 years; 35% males	Personal interview, video-based DA. To determine the combined effect of an SDM tool on CRC screening completion.	Colon cancer screening. FPs.	G1: DAs with information on colon cancer screening. G2: Video on healthy diet and standard care.	A blinded medical record review evaluated the CRC screening completion evidence within 6 months after intervention.	68% of G1 underwent colon cancer screening versus 27% of G2 (95% CI: 29–51). The intervention was more effective in women (50% vs 21%, $P=0.2$).	Not assessed	Not assessed	Not assessed	Not assessed

(continued)

Table 2
(Continued).

Authors, year	Participants (n, age, % males)	Type of DA, Goal	Disease, Professional involved	Intervention (G1) Control (G2)	Assessment tools	Main outcome measures	Outcomes: adherence to treatment	Outcomes: knowledge and awareness	Outcome: decisional conflict	Outcomes: satisfaction
Sanders et al ^[9] 2018.	68; 45.4 years; 47% males	Personal interview in DA; SMD and positive reinforcement in the chosen therapy. To increase expectations of favorable outcomes.	Non-chronic low back pain.	G1: DAs for positive reinforcement. G2: standard care.	Physical disability measured with the Roland-Morris disability questionnaire (RMD).	The mean disability score declined to 4.1 (G1) and 4.3 (G2) after 2 weeks (difference 0.2; <i>P</i> = .789), 2.1 (G1) and 2.3 (G2) after 12 weeks (<i>P</i> = .720) and 2.0 for both groups after 26 weeks (<i>P</i> = .949). Patients made informed choices regarding statin intake, 34% versus 3%, OR 16.6 (95% CI 4.4 to 63.0), blood pressure control, 39% versus 3%, OR 22.2 (95% CI 5.3–93.3) and glycated hemoglobin, 43% versus 3%, OR 26.0 (95% CI 6.5–104.8).	Not assessed	Patients in the intervention group reported a significantly higher level of patient involvement (2.92 (SD: 1.21) than the controls (2.44 SD1:23) (difference 0.48; <i>P</i> = .005).	Conflict: not assessed.	Not assessed
Buhse et al ^[9] 2018	279; 59 years;	SDM programme for DM2 includes: a patient decision teaching session and a personal encounter.	DM2 cases	G1: SDM programme G2: standard care	Patients adherence to treatment and life style.	Patients made informed choices regarding statin intake, 34% versus 3%, OR 16.6 (95% CI 4.4 to 63.0), blood pressure control, 39% versus 3%, OR 22.2 (95% CI 5.3–93.3) and glycated hemoglobin, 43% versus 3%, OR 26.0 (95% CI 6.5–104.8).	Mean drug adherence rates were high for both groups (80% for antihypertensive and 91% for statin treatment).	Patients in the intervention group achieved higher levels of risk knowledge, with a mean score of 6.96 versus 2.86, difference 4.06 (95% CI 2.96–5.17).	Not assessed	Not assessed
Schwartz et al ^[4] 2018.	728; 59 years; 60% female	Different DA in SDM.	CRC screening.	G1: Verbal information. G2: quantitative information.	Perceived CRC risk using a Test: intend to be screened; test preferences.	Patients in G2 had a larger increase in intent to undergo fecal immunochemical test (FIT) (<i>P</i> = .011) and were more likely to switch their preferred test from non-FIT to FIT (28% vs 19%, <i>P</i> = .010).	Not assessed	There were no significant differences between group and subjective numeracy for perceived risk.	There was a significant decrease for decision conflict and perceived barriers for FIT and colonoscopy (<i>P</i> < .001)	Not assessed
Penisteb-Perez et al ^[4] 2019.	107; 59 years; 57.9% female	Web format as a DA in SDM. To make informed decisions about CRC screening.	CRC screening.	G1: DAs in CRC screening. G2: standard care.	Decisional conflict measured with the Spanish version of the Decisional Conflict Scale (DCS). Knowledge of colorectal cancer and screening options was assessed using a test	No significant differences in the mean scores for any outcome were observed.	Not assessed	Patients in the intervention group reported more knowledge (<i>P</i> < .001).	Lower decisional conflict in DA group (<i>P</i> < .001)	Not assessed

AF = atrial fibrillation, AMI = acute myocardial infarction, ARI = acute respiratory infection, BMI = body mass index, CI = confidence interval, CRC = colorectal cancer, CSQ-8 = Client Satisfaction Questionnaire, CVRFs = cardiovascular risk factors, DAs = decision aids, FPs = family physicians, INSH = patient participation scale, NSAID = Non-steroidal anti-inflammatory drug, OACs = oral anticoagulants, OPTION scale = "observing patient involvement in decision making" and D-OPTION: dyadic. Haynes: have you missed any of your pills in the last week?, OR = odds ratio, PICS = Patient perception of involvement in care scale, RR = relative risk, SDM = shared decision making, UKPDS = UK Prospective Diabetes Study.

Table 3
List of articles obtained from each database.

Database	Articles identified	
Medline	Loh et al ^[18] 2007	
	Krones et al ^[20] 2008	
	Myers et al ^[22] 2010	
	Légaré et al ^[23] 2010	
	Montori et al ^[24] 2011	
	Legare et al ^[25] 2012	
	Sheridan et al ^[26] 2012	
	Wilkes et al ^[27] 2013	
	Branda et al ^[28] 2013	
	Miller et al ^[29] 2014	
	Fiks et al ^[32] 2015	
	Leblanc et al ^[34] 2015	
	Perestelo-Perez et al ^[35] 2016	
	Karagiannis et al ^[36] 2016	
	Reuland et al ^[37] 2017	
	Sanders et al ^[38] 2018	
	Buhse et al ^[39] 2018 Schwartz et al ^[40] 2018	
	Perestelo-Perez et al ^[41] 2019	
	Embase	Thomson et al ^[9] 2007
		Central
Patel et al ^[30] 2014		
Price-Haywood et al ^[31] 2014		
Lewis et al ^[33] 2015		
Perestelo-Perez et al ^[41] 2019		
CINAHL	0	
NHS	0	

disease,^[19,20,21] respiratory disease,^[23,25,32] and depression.^[18,34]

3.2. Decision aids format

There was great variability in the DA format used among the reviewed studies, including paper,^[20,24,28,29,30,34,35,36] video,^[26,33,37] and digital formats like web sites and computer-based formats.^[19,23,27,32,41] Reporting systems and group meetings were sometimes used, or a combination of both.^[31,33]

A paper-based DA implied that an informative sheet was given during the consultation, with a self-report procedure. A personal interview was considered as an encounter and dialogue between the health professional (doctor, nurse, physical therapists) and the patient, but the patient did not necessarily receive written information. When the meeting was in group, this meant >1 patient at the same consultation. It is better called Shared Medical Appointment, understood as a doctor-patient visits in which groups of patients are seen by one or more health care providers in a concurrent session.

Web-based DA referred to online information that was given to the patient, so it could be read by their own at home. Computerized DA meant graphic information, numerical, and information using computer systems. An e-book could be considered a format that uses computer language and that can be used as a tool in DA. Another DA mentioned in the reviewed articles was DVD or video-based techniques. They were commonly used for teaching patients about some medical condition or treatment options. The reviewed results did not show any differences when comparing the strategies.

3.3. Effectiveness regarding clinical outcomes: adherence to the treatment

Studies that did not measure adherence to the treatment, but its consequences, were reviewed.

The intervention reduced the use of antibiotics in cases of acute respiratory infection (relative risk [RR]=0.48; confidence interval (CI) 95%: 0.34–0.48).^[19] In a trial, the use of DA improved osteoporosis treatment ($P=.009$).

No effects were found in the control of childhood asthma, but admissions to hospital were reduced in 21% after the interventions, and pediatrics consultations were also reduced in 5%.^[26]

In the screening programmes, the rate of determination of prostate-specific antigen (PSA) in the prostate cancer screening was reduced (RR=0.48; CI 95%: 0.14–1.24)^[20] and colorectal cancer screening increased in 41% (CI 95%: 29–51).^[31] In a trial, prostate cancer screening increased with the intervention, although patients changed their attitudes towards the benefits of determining PSA ($P=.008$).^[27]

Loh et al^[18] did not find any differences in adherence to treatment among patients with depression, but they did find greater patient involvement when SDM was used.

Type 2 diabetes patients reduced their HbA1 and body mass index when DA was provided, due to adherence to treatment.^[36] In Buhse et al,^[39] mean drug adherence rates were high for both groups (80% for antihypertensive and 91% for statin treatment).

Patients who engaged an SDM process reduced their cardiovascular risk because of lifestyle changes. Reported patients' participation and SDM step was higher when DA was used ($P<.001$).^[20]

3.4. Effectiveness regarding clinical outcomes: knowledge and awareness of the disease

The interventions improved knowledge on medication of depression (OR=9.5; CI 95%: 0.8–18.2).^[28]

In type 2 diabetes, DA improved knowledge ($P=.001$) and the perception of risk of acute myocardial infarction at 10 years without statins ($P=.01$) and with statins ($P=.08$).^[35] However, there were no differences regarding the patient's knowledge about the disease ($P=.234$). Patients in the intervention group reported a significantly higher level of patient involvement (2.92 [SD: 1.21] than the controls (2.44 [SD 1:23]) (difference 0.48; $P=.005$).^[38]

As for awareness of the health status, the perception of cardiovascular risk ($P=.001$)^[21,35] and prostate cancer risk^[33] increased when patients went through SDM. In prostate cancer screening, PSA testing was reduced when using SDM, as it was considered a personal decision.^[26] On the contrary, colon cancer screening increased, especially among women, after a video-based DA: 68% of intervention group underwent colon cancer screening versus 27% of control group (95% CI: 29–51).^[37]

3.5. Effectiveness regarding clinical outcomes: conflict with the decision

Decisional conflict was considered a state of uncertainty about a course of action. Such uncertainty is more likely when a person is confronted with decisions involving risk or uncertainty of outcomes, when high stakes choices with significant potential gains and losses are entertained, when there is a need to make

Table 4
Effectiveness regarding clinical evidence in the included clinical trials.

Effective measure	Evidence
Adherence to the treatment	Krones et al ^[20] 2008, Thomson et al ^[19] 2007, Sheridan et al ^[26] 2012, Karagiannis et al ^[36] 2016, Buhse et al ^[39] 2018, Loh et al ^[18] 2007, Price-Haywood et al ^[31] 2014.
Satisfaction	Loh et al ^[18] 2007, Krones et al ^[20] 2008, Koelewijn-van Loon et al ^[21] 2009, Légaré F et al ^[25] 2012, 2013, Patel et al ^[30] 2014, Fiks et al ^[32] 2015, LeBlanc et al ^[34] 2015, Perestelo-Pérez et al ^[35] 2016.
Decisional conflict	Thomson et al ^[19] 2007, Krones et al ^[20] 2008, Koelewijn-van Loon et al ^[21] 2009, Legaré et al ^[23] 2013, Légaré et al ^[25] 2012, Schwartz et al ^[40] 2018, Perestelo-Perez et al ^[41] 2019.
Improvement in knowledge and greater awareness	Koelewijn-van Loon et al ^[21] 2009, Lewis et al ^[33] 2015, Perestelo-Pérez et al ^[35] 2016, Perestelo-Perez et al ^[41] 2019, Sheridan et al ^[26] 2012, Branda et al ^[28] 2013, Reuland et al ^[37] 2017, Sanders et al ^[38] 2018.

value tradeoffs in selecting a course of action, or when anticipated regret over the positive aspects of rejected options is probable.^[19]

Decisional conflict was reduced in the decision that regarded the treatment choice for atrial fibrillation ($P < .036$)^[19] and respiratory infection.^[23,25] Patients at cardiovascular risk showed higher confidence about decision making ($P = .001$)^[21] and lower decisional regret^[20] when SDM was implemented. There was a significant decrease for decisional conflict and perceived barriers for faecal immunochemical test and colonoscopy in colorectal cancer screening ($P < .001$).^[40]

In contrast, no differences were found in decisional conflict associated to SDM when interviewing patients for prostate cancer screening ($P = .620$),^[22] when dealing with women at osteoporosis risk ($P = .725$),^[24] or when informing type 2 diabetes patients about treatment choices ($P = .305$).^[36]

3.6. Effectiveness regarding clinical outcomes: satisfaction

The satisfaction was greater with the use of DA in choosing the treatment for depression ($P = .014$)^[18,34] in cardiovascular risk management ($P = .001$),^[20,21] the treatment of low back pain (intervention group: 53%, control group: 67%. RR = 1.28 (CI 95%: 0.79–2.03),^[30] and the use of statin therapy in diabetes ($P = .001$).^[35] No differences were found among type 2 diabetes patients,^[28,36] children with asthma^[32] or men interviewed for prostate cancer screening.^[26,27] Satisfaction of physicians was measured in only one of the reviewed studies. They were more satisfied with the decision when using a DA tool (RR = 1.64) $P = .02$.^[34]

Patients reported to be more involved in the decision-making process due to SDM for choosing the treatment for depression^[18,34] and acute respiratory infection.^[25] It was also reported that SDM facilitated better communication between physicians and patients^[31] and further discussing the options.^[27] Table 4 shows the reports of effectiveness regarding clinical evidence.

3.7. Risk assessment of biases

The Cochrane Collaboration's tool was used to evaluate the risk of bias. Seven trials showed a high risk of bias regarding the "blinding of participants and personnel," once in "blinding of outcome assessment," and twice in "incomplete outcome data." The rest of studies showed a low or uncertain risk of bias.

4. Discussion

This systematic review about the effectiveness of SDM using DA identified an improvement in the satisfaction with the intervention, showing greater patient involvement and better knowledge of the disease, decreasing decisional conflict.

The findings of this review were consistent with the results of other studies on the use of DA for the screening and treatment of specific conditions.^[9] There is evidence that the DA improve knowledge of options and reduce decisional conflict when compared with usual care. Knowledge about the different options for diagnosis and treatment is relevant to the clinical context as it helps patients take a more active role in the decisions, improving the risk perception when the options are complex.^[42]

SDM using DA in primary care was frequently used in screening programs, mainly for prostate, colon, and breast cancer. The DA used to make decisions in the screening and treatment of oncological processes help choose the less invasive procedures and start treatments earlier.^[43] Despite this, oncologists involve patients in decision making less often than they would like.^[44] About the use of DA for prostate cancer screening, while the rate of PSA testing was significantly reduced in one trial compared with the control group, it increased in another. Nonetheless, its effectiveness was shown in the increased use of colonoscopy procedures in colon cancer screening.

Few studies assessed the impact of SDM using DA on health outcomes. In one trial where its effectiveness was determined for the control of asthma and quality of life in children, with the reduction in the number of consultations, hospital admissions, visits to the pulmonologist and pediatrician, there were no relevant differences between the groups.^[32] More research is needed to know the effectiveness of DA on clinical outcomes of the most common processes treated in primary care consultations. SDM, when put into practice in primary care consultations, improves patients' knowledge regarding the prevention and treatment of highly prevalent diseases. However, while patients want to play a more active role in decision making,^[45] there is no evidence of interventions that improve the participation of health care professionals in SDM.^[46] In long term patients, which is the most common patient profile in primary care, a moderate evidence of lack of effect of SDM on medication adherence has been identified, and conflicting evidence for the effectiveness of SDM on the patients' clinical parameters and health-related quality of life.^[47]

Evidence of SDM effectiveness in depression identified in this review is congruent with previous studies. Benefits from the SDM in mental health have been identified such as symptoms reduction, improved self-esteem, increased service satisfaction, improved treatment adherence, improved patient knowledge, increased confidence in decisions, and decreased rates of hospitalization.^[48] Due to the complexity inherent to mental health and the lack of decisional capacity of some mental health patients, SDM occurs less frequently than in other medical areas.^[49] Hamann et al^[50] pointed out self-stigma and shame as

barriers for SDM in mental health. These behaviors hinder physician–patient communication and critical attitudes that lead to SDM. Fisher et al^[51] reviewed decision making in mental health, particularly in bipolar disorder patients. Findings showed that they desired to get more actively involved, both themselves and their families, in the decisions concerning their treatment. DA was considered a useful tool for informed decision making based on scientific evidence.

Regarding type 2 diabetes patients, this review identified benefits from the use of SDM that are consistent with previous reviews. The meta-analysis conducted by Saheb et al^[52] highlighted an association between SDM and decision quality, patient knowledge and patient risk perception in type 2 diabetes. SDM is appropriate for diabetes care because of the impact of treatment in patients' lifestyle, the lifelong term measures to be adopted, and the multiple treatment options available. SDM allows sharing evidence with patients and engaging them in their choice.^[53]

It was found evidence of the usefulness of SDM for the reduction of antibiotic consumption in acute respiratory infections. As Coxeter et al^[54] highlighted in their Cochrane review, evidence available to support this finding remains moderate. However, patients reported high decision involvement and self-efficacy, and low decisional conflict when SDM was used in the general practitioners' consultations for acute respiratory infections.^[55] SDM has been particularly suggested for reducing antibiotic prescribing for acute respiratory infections. In these situations, benefits and harms are practically balanced, so patients' preferences become a priority; they need to be fully informed about evidence in favor and against antibiotic use.^[56]

The main limitations of this review are determined by the variability of the DA, the way in which they were applied, and the measurement of outcomes, which made comparing studies difficult. Although the search strategies were broad, they may not have identified all the studies in which SDM appears in primary care. Improving the methodology quality of future clinical trials carried out on DA in primary care is recommended, especially about the double blind and the blind method.

Overall, this review found evidence of SDM effectiveness in improving knowledge about the disease and patients' options, reducing the decisional conflict and fostering patient satisfaction with the decision process and the final choice in primary care settings. Findings from this review could help facilitate SDM implementation in primary care.

Comparability of results was compromised due to the variability of DA formats included in this review. Although evidence of SDM effectiveness was identified, some of the reviewed studies did not provide solid conclusions. There is a need for more studies to assess the impact of SDM in primary care, health outcomes, and patient quality of life, also for designing and validating DA for treatments and diagnostic tests for chronic conditions.

5. Conclusions

Some decision aids (DA) used in primary care consultations by family physicians and nurses have proven their clinical potential for improving knowledge on the disease, decisional conflict, and professionals and patients' satisfaction. Future research should assess the effectivity of DA as regards outcomes of the most frequent diseases treated in primary care consultations.

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