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Where Is the Evidence? A Systematic Review of Shared Decision Making and Patient Outcomes

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Background. *Despite widespread advocacy for shared decision making (SDM), the empirical evidence regarding its effectiveness to improve patient outcomes has not been systematically reviewed. The purpose of this study was to systematically review the empirical evidence linking patient outcomes and SDM, when the decision-making process has been explicitly measured, and to identify under what measurement perspectives SDM is associated with which types of patient outcomes (affective-cognitive, behavioral, and health).* ***Data Sources.*** *PubMed (through December 2012) and hand search of article bibliographies.* ***Study Selection.*** *Studies were included if they empirically 1) measured SDM in the context of a patient-clinician interaction and 2) evaluated the relationship between SDM and at least 1 patient outcome.* ***Data Extraction.*** *Study results were categorized by SDM measurement perspective (patient-reported, clinician-reported, or observer-rated) and outcome type (affective-cognitive, behavioral, or health).* ***Data Synthesis.*** *Thirty-nine studies met inclusion criteria. Thirty-three used patient-reported measures of SDM, 6 used observer-rated measures, and 2 used clinician-reported measures. Ninety-seven unique patient outcomes were assessed; 51% affective-cognitive, 28% behavioral, and 21% health. Only 43% of assessments (*n *= 42) found a significant and positive relationship between SDM and the patient outcome. This proportion varied by SDM measurement perspective and outcome category. It was found that 52% of outcomes assessed with patient-reported SDM were significant and positive, compared with 21% with observer-rated and 0% with clinician-reported SDM. Regardless of measurement perspective, SDM was most likely to be associated with affective-cognitive patient outcomes (54%), compared with 37% of behavioral and 25% of health outcomes.* ***Limitations.*** *The relatively small number of studies precludes meta-analysis. Because the study inclusion and exclusion criteria required both an empirical measure of SDM and an assessment of the association between that measure and a patient outcome, most included studies were observational in design.* ***Conclusions.*** *SDM, when perceived by patients as occurring, tends to result in improved affective-cognitive outcomes. Evidence is lacking for the association between empirical measures of SDM and patient behavioral and health outcomes.* ***Keywords:*** *shared decision making; medical decision making; patient outcomes; systematic review.* ***(Med Decis Making 2015;35:114–131)***

Since the early 1980s, shared decision making (SDM) has been suggested as an optimal approach to making health care decisions.[1–3] Both the Institute of Medicine and the U.S. Preventive Services Task Force have advocated for clinicians to use SDM when making preventive health and treatment recommendations.[4,5] Most recently, language contained in the Affordable Care Act specifically called for programs to facilitate SDM and for the establishment of the Patient Centered Outcomes Research Institute.[6] Furthermore, a recent systematic review of patient decision-making preferences found that the majority of patients prefer to be actively involved in decision making and that the trend for a preference for shared decisions has increased over time.[7]

Although historically, SDM was advocated as a means of protecting patient autonomy[8,9] and of understanding regional variation in the use of medical treatment,[10] there has been a shift in focus over time to investigating the effects of SDM and other communication processes on health-related patient outcomes.[11] For example, the National Cancer Institute published a monograph in 2007 that specifically focused on how patient-centered communication may help to promote health and reduce suffering.[12]

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Additionally, many evaluations of SDM interventions cite the possible benefits of SDM on patient outcomes as a justification for the study (e.g., Hamann and others[13]; Wilkins and others[14]; Légaré and others[15]). Furthermore, models have been developed that specifically hypothesize the way that SDM and other patient-provider communication may affect health-related patient outcomes.[16,17] Thus, although the aim of SDM has not always been to improve patient health outcomes, it is valuable to systematically evaluate the empirical evidence supporting the impact of SDM on a range of patient outcomes.

Previous systematic reviews have pointed to the effectiveness of decision aids for improving patient outcomes,[18] but as evidenced by these reviews, use of a decision aid does not ensure that SDM occurs. For example, in the most recent Cochrane review of decision aids (2011), only 16 of the 86 randomized trials reviewed explicitly measured the effects of decision aids on patient participation in decision making. Among these studies, there were no differences in patient reports of having participated in SDM between those given a decision aid or those receiving usual care.[18] Thus, the positive effects of decision aids on patient outcomes may not be attributable to SDM. Moreover, the empirical evidence surrounding SDM is not confined to studies of decision aids only.

Despite widespread advocacy for SDM and a growing body of literature evaluating its use, the empirical evidence regarding its effectiveness as a mechanism to improve patient outcomes has not been systematically summarized. Additionally, SDM has been measured in a variety of ways across studies, and these measurement perspectives may represent different perceptions about the meaning of SDM. Given the current lack of synthesis of the literature, whether these different measurement perspectives are differentially associated with patient outcomes is not known. The objectives of this systematic review are twofold. The first is to describe the patient outcomes that have been studied in relation to SDM, when the decision-making process has been explicitly measured with an SDM measurement tool and the relationship between that measure of SDM and at least 1 patient outcome was evaluated. The second objective is to identify under what measurement perspectives (patient-reported, clinician-reported, or observer-rated) SDM is associated with which types of patient outcomes.

METHODS

Conceptual Framework

The conceptual framework guiding this systematic review was adapted from models by Street and colleagues[16] and Kreps and colleagues[17] (Figure 1). In their model of pathways in which clinician-patient communication can lead to better health, Street and colleagues posited that while communication between clinicians and patients, including SDM, can lead to improved health outcomes directly, in most cases communication affects health indirectly through proximal and intermediate outcomes. As proposed by Kreps and colleagues[17] in their Transformation Model of Communication and Health Outcomes, we changed the categorization of outcomes from a temporal classification to a conceptual classification. This latter model asserts that patient outcomes should be categorized by their impact on the individual across 3 categories: affective-cognitive, behavioral, and physiological. Affective-cognitive outcomes include knowledge, attitudinal, and affective-emotional effects. Behavioral outcomes include both adherence to recommended treatments and adoption of health behaviors. Physiological outcomes (which we have broadened to label as ''health outcomes'') include measures quality of life, self-rated health, and biological measures of health (e.g., blood pressure).[17]

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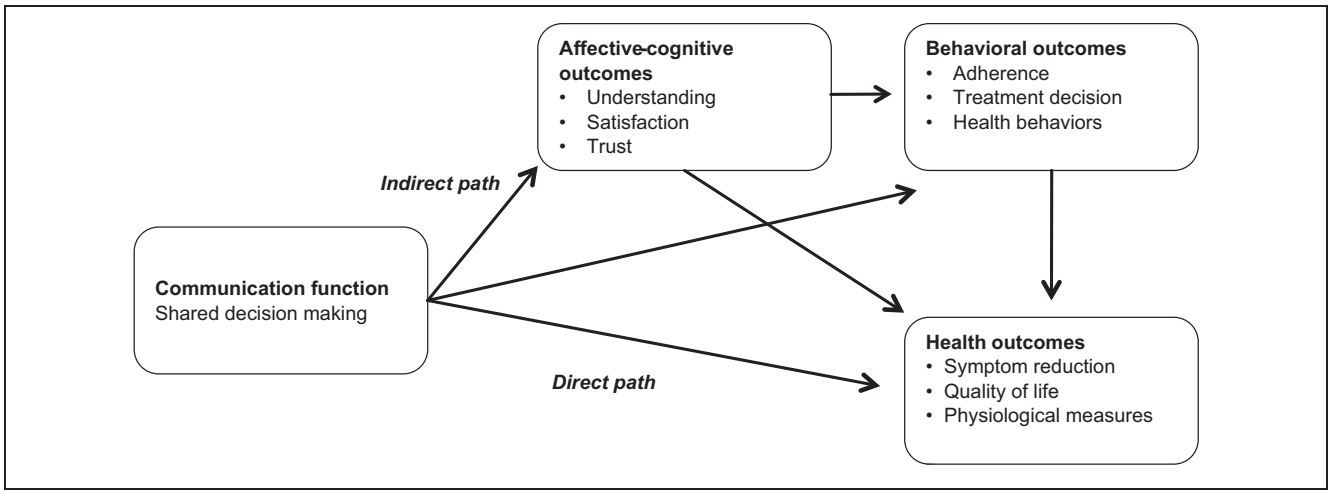

Figure 1 Conceptual framework linking shared decision making (SDM) to patient outcomes. Adapted from Street and others[16] with permission from Elsevier and from Kreps and others[17] with permission from SAGE Publications.

Inclusion and Exclusion Criteria

Studies were included in this review if they empirically 1) measured the decision-making process with an SDM measurement tool in the context of a patient-clinician interaction and 2) evaluated the relationship between SDM and at least 1 explicitly measured patient outcome. Excluded studies were those that reported only qualitative data or were reviews or commentaries. Also excluded were studies that did not explicitly measure both the decision-making process using an SDM measure and at least 1 patient outcome as well as those that did not quantitatively model the relationship between measured SDM at least 1 patient outcome.

Search Strategy

We began with the primary search strategy outlined by Makoul and Clayman[19] in their 2006 systematic review of the SDM literature. Specifically, in January 2013, we conducted a PubMed search for English-language articles published through December 31, 2012, with the words *shared decision making* in the title or abstract. Makoul and Clayman reasoned that this search strategy captured articles with a clear focus on SDM in the medical literature and that the simple approach allows for reproducibility for future studies. Due to the lack of agreement across studies regarding how to best define, and thus measure, the occurrence of SDM, we opted to include all studies that explicitly measured SDM, regardless of the tool used. In so doing, we did not prescribe an operational definition of SDM per se but rather assessed all studies that specifically mentioned ''shared decision making'' in the abstract. No start date was specified, so that all studies published up through the end of 2012 would be included. One reviewer (L.A.S.) screened the resulting abstracts for the inclusion and exclusion criteria. The full text of all potentially eligible articles was read and reviewed, and any non-redundant references to SDM were collected. A second reviewer (J.E.L.) reviewed any articles for which eligibility was not clear, and a final inclusion-exclusion decision was made by consensus. Because a number of study-eligible articles evaluated more than 1 patient outcome in relation to SDM, the unit of analysis for this review is a patient outcome.

Classification Framework

There are multiple ways that SDM can be measured.[19,20] A priori, we expected the measurement of SDM to fall into 2 primary categories: patient self-reports of SDM or observer ratings of the use of SDM (usually via structured coding of audio-recordings). Our review of the literature also revealed a third category: clinician reports of using SDM with patients. In addition to considering the SDM measurement perspective, as indicated in the conceptual framework (Figure 1), we considered the type of outcome evaluated. Because a diversity of outcomes have been assessed in association with SDM, it is helpful to categorize these outcomes to provide for more meaningful discussion of results across studies. Thus, we used an adaptation of the 3 classifications proposed in the Transformation Model of Communication and Health Outcomes[17]: affective-cognitive, behavioral,

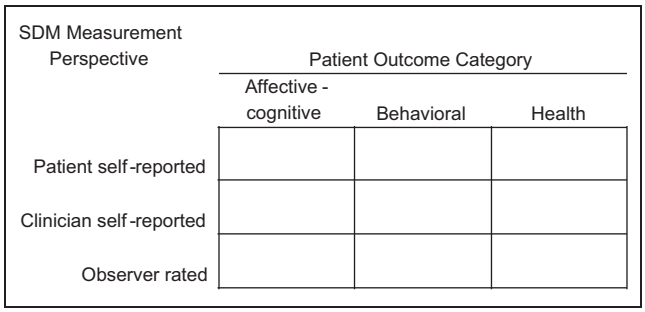

Figure 2 Categorization framework of patient outcome categories by shared decision making (SDM) measurement type.

and health outcomes. Combined, these categorizations resulted in a 3 × 3 classification framework that was used to structure the results of the systematic review (Figure 2).

Assessment of the Quality of Studies

We used a modified version of the Systematic Appraisal of Quality in Observational Research (SAQOR) tool to assess the quality of included studies.[21] SAQOR was created for use in systematic reviews to assess the quality of observational studies. Each study was rated as adequate, inadequate, or unclear across 6 categories: sample, research design, quality of measures, follow-up, distorting influences (confounders), and reporting of data. A total score for each study is computed by counting the number of categories marked adequate. Thus, the total quality score has a range of 0–6, with higher scores indicating higher quality studies. Total scores of 5 or 6 represent high-quality observational studies, scores of 3 or 4 represent moderate-quality observational studies, and scores of 0, 1, or 2 represent low-quality observational studies.[22] After training together on 3 studies, 2 reviewers independently rated each remaining study according to the above criteria. Cohen's kappa was calculated as a measure of interrater reliability of quality ratings at the category level for each study. Interrater reliability of the independent rating of quality scores was high (Cohen's kappa = 0.7). Any discrepancies in scoring were discussed until consensus was reached.

The results of our review are presented below in accordance with the Institute of Medicine's standards for reporting reviews.[23]

RESULTS

Overview of Studies

Forty-one publications[24–64] representing 39 unique studies met the inclusion criteria (Figure 3, Table 1). Thirty-four of the 41 articles meeting inclusion criteria were published in the last 10 years, and the earliest study meeting the inclusion criteria was published in 1989 (Brody and others[24]).

The 39 studies were conducted across a variety of clinical contexts. Fourteen studies (36%) were conducted in the context of cancer care, and almost three-quarters of these (n = 10) focused specifically on breast cancer treatment and surgery decisions. Other clinical contexts studied included mental health (n = 5), diabetes (n = 5), serious injury (n = 3), heart disease (n = 2), HIV (n = 2), and general primary care (n = 2) among others (n = 6).

Quality Assessment

The SAQOR quality scores ranged from 2 to 6, with a median score of 4 (Table 1). Across the 39 studies, 3 (8%) received a high quality rating, 30 (77%) moderate, and 6 (15%) low. Most of the studies were either a cross-sectional or prospective survey in which data were collected either before and after, or only after, a consultation with a clinician. Only 9 of the studies used a pretest–posttest design,[24,27,39,40,42,44,60–62] and 19 studies measured SDM at the same time as measuring the outcome of interest.[25,26,28,29,31–34,37,41,45–47,49–53] Nine of the 39 studies were conducted in the context of a clinical trial.[27,32,38,39,42,44,46,51,56] Eight of these were a secondary analysis of a previous randomized controlled trial (RCT).[27,32,38,39,42,46,51,56] In these studies, either the analysis was conducted without regard to group assignment,[51,56] group assignment was used as a predictor variable in the model,[32,38,42,46] or the results were tested separately to see whether group assignment confounded the relationship between measured SDM and patient outcomes.[27,39] The ninth study included a patient self-report of participation in SDM but only tested the association of patient-reported SDM with a patient outcome among those in the experimental group.[44] Thus, none of the included RCTs evaluated the association between SDM and a patient outcome with a randomized design.

SDM Measurement Perspective

Eighty-five percent of studies measured SDM from the patient's perspective (n = 33), 15% (n = 6) measured via observer rating, and 2 (8%) used clinician-reports to measure SDM. In 2 studies,[48,55] the same patient outcome was assessed for its association with SDM from different SDM measurement perspectives, and these analyses are considered separately.

(*text continues on p. 124)*

Table 1 Summary of Included Studies by Shared Decision Making (SDM) Measurement Perspective

First Author, Ref. No.	Year	Diseases Context	*N*[a]	Design	SDM Measurement	Patient Outcomes Measured	Summary of Results[b]	Quality Rating: SAQOR Score and Rating
Patient self-reported SDM								
Brody[24]	1989	Primary care, various	117	Survey at baseline, 1 day, and 1 week postconsultation	1-item variant of Control Preference Scale (CPS)	Sense of personal control; concern regarding illness; satisfaction with the physician; experiencing discomfort; experiencing dysfunction; symptom improvement; general medical improvement	SDM associated with greater sense of personal control, lower postvisit levels of concern regarding illness, less discomfort, greater symptom improvement, and greater improvements in overall medical condition 1 week after visit. No association between SDM and experiencing dysfunction 1 week after visit.	4 Moderate
Lerman[25]	1990	Primary care, various	83	Cross-sectional survey after primary care visit	13-item Perceived Involvement in Care Scale (PICS)	Satisfaction with the art of care; satisfaction with the technical aspects of care; understanding about illness; reassurance regarding health status; perceived control over medical problem; predicted discomfort; predicted functional capacity	SDM associated with satisfaction with the technical aspects of care, understanding about illness, reassurance regarding health status, perceived control over medical problem, and predicted functional capacity. No association between SDM and satisfaction with the art of care or predicted discomfort.	4 Moderate
Chambers[26]	1999	Asthma (primary care)	394	Cross-sectional survey, SDM questions are not about one specific interaction	1-item variant of CPS	Regular use of inhaled corticosteroids	SDM associated with regular use of inhaled corticosteroids as prescribed.	4 Moderate
Gattellari[27]	2001	Cancer, various	233; 9	Audio-recorded consultation and surveys at baseline, immediately after consultation and 1 week and 2 weeks postconsultation	1-item variant of CPS	Anxiety immediately after the consultation; anxiety 2 weeks after the consultation; satisfaction with the consultation; satisfaction with the information and emotional support received; recall of information	SDM associated with satisfaction with the consultation and satisfaction with the information and emotional support received. No association between SDM and anxiety at either time point or recall of information.	6 High
Golin[28]	2002	Diabetes	198	Face-to-face interviews before and after consultation	9-item Facilitation of Patient Involvement in Care Scale (FPI)	Satisfaction with the visit	SDM associated with satisfaction with the visit. In a subgroup analysis, this association was found to be true only for women.	5 High
Heisler[29]	2002	Diabetes	1431	Cross-sectional mailed survey	4-item Provider Participatory Decision-Making Style Scale (PDMstyle)	Patient-reported diabetes self-management	In separate multivariate analyses, both components of SDM are positively associated with patient-reported diabetes self-management. When both components of SDM are included in 1 model, only information-giving remains significant.	3 Moderate

(continued)

Table 1 (continued)

First Author, Ref. No.	Year	Diseases Context	*N*[a]	Design	SDM Measurement	Patient Outcomes Measured	Summary of Results[b]	Quality Rating: SAQOR Score and Rating
Keating[30]	2002	Breast cancer	1081	Cross-sectional phone survey	1-item rating of decision-making role developed for this study	Satisfaction with treatment information provided; satisfaction with treatment choice; receipt of breast-conserving surgery (v. mastectomy)	SDM associated with satisfaction with the amount of treatment information provided. No association between SDM and satisfaction with treatment choice or receipt of breast conserving surgery.	3 Moderate
Heisler[31]	2003	Diabetes	127; 50	Cross-sectional survey of patient and physician	1-item variant of CPS	Number of treatment strategies agreed upon by patient and provider	No association in multivariate analysis. In a bivariate analysis, SDM was positively associated with the number of treatment strategies agreed upon by the patient and provider. After multivariate adjustment, the association was no longer significant.	4 Moderate
Legare[32]	2003	Menopause	167	Cross-sectional survey of both the patient and physician immediately after consultation	1-item variant of CPS	Difference between physician and patient decisional conflict	SDM associated with the physician experiencing greater decisional conflict that then patient (unexpected direction).	3 Moderate
Ananian[33]	2004	Breast cancer	181	Cross-sectional survey after decision before surgery	1-item variant of CPS	Decision about surgery (mastectomy alone or mastectomy with reconstruction); decision about timing of reconstruction among those receiving mastectomy with breast reconstruction (immediate or delayed reconstruction)	No associations in multivariate analysis. In bivariate analysis, SDM associated with choice of having breast reconstruction.	3 Moderate
Lantz[34] (also Katz 2005[35] and Bleicher 2008[36])[c]	2005	Breast cancer	1633	Cross-sectional mailed survey study on average 7 months after diagnosis	1-item variant of CPS	Satisfaction with surgery received; satisfaction with decision process; decisional conflict; decision about surgery (mastectomy or breast conserving surgery)	SDM associated with greater satisfaction with surgery received, greater satisfaction with the decision process, and less decisional regret. Patients who reported SDM were more likely to receive mastectomy. In a subgroup analysis, this association was only supported for white women and not for racial groups (Katz).	3 Moderate
Nekhlyudov[37]	2005	Breast cancer	431	Cross-sectional mailed survey study	1-item variant of CPS	Satisfaction with decision 6 months after surgery; current satisfaction with decision; current breast cancer concern; current depressive symptoms	SDM (v. patient-controlled decisions) associated with lower satisfaction 6 months after surgery and lower current concern about breast cancer. No associations between SDM and current satisfaction or current depressive symptoms.	4 Moderate

(continued)

Table 1 (continued)

First Author, Ref. No.	Year	Diseases Context	*N*[a]	Design	SDM Measurement	Patient Outcomes Measured	Summary of Results[b]	Quality Rating: SAQOR Score and Rating
Thapar[38]	2005	Epilepsy	975; 115	Cross-sectional survey study; secondary analysis of RCT	Not described beyond ''patient-rated shared decision making''	Satisfaction with physician care of epilepsy	SDM associated with satisfaction with physician epilepsy care.	3 Moderate
Clever[39,d]	2006	Depression (primary care)	1706	Survey at baseline, 6, 18, and 24 months postconsultation; secondary analysis of 4 RCTs combined	1-item rating of involvement in decision making developed for this study	Receipt of guideline concordant depression care (antidepressant medication or counseling); depressive symptoms	SDM associated with receipt of guideline concordant depression care and resolution of major depression symptoms over 18 months of follow-up.	5 High
Loh[40]	2007	Depression (primary care)	207; 30	Longitudinal survey study—data collected at initial consultation and 6–8 weeks later	6-item patient participation scale first used by Mah-Son-Hing and others (1999)	Depressive symptoms; treatment adherence	SDM associated with treatment adherence. No direct association between SDM and depressive symptoms, but there was an indirect effect of SDM on depressive symptoms through treatment adherence.	5 High
Mandelblatt[41]	2006	Breast cancer	718	Cross-sectional in-person survey	4-item subscale of PICS	Decision about surgery (mastectomy or breast conserving surgery); receipt of adjuvant therapy; satisfaction with care; impact of breast cancer on life	SDM associated with adjuvant treatment use, satisfaction with care, and with impact of breast cancer on life (unexpected direction). In a subgroup analysis, SDM only associated with adjuvant treatment use among women aged 67–74, and not among those aged 75 and older. No association between SDM and decision about type of surgery.	4 Moderate
Swanson[42,d]	2007	Depression (primary care)	1317	Survey at baseline and at 6, 18, and 24 months postconsultation; secondary analysis of 4 RCTs combined	3-item rating of involvement in SDM developed for this study	Satisfaction with care	SDM associated with satisfaction with care.	5 High
Mahone[43]	2008	Serious mental illness	85	Cross-sectional survey	1-item variant of CPS	Medication adherence in the past 1 month; medication adherence in the past 6 months; quality of life	No associations	3 Moderate
Deinzer[44]	2009	Hypertension (primary care)	86; 15	Prospective controlled clinical trial	Combined Outcome Measure for Risk Communication and Treatment Decision Making Effectiveness scale (COMRADE)	Blood pressure (diastolic and systolic)	No association. In a subgroup analysis, patients with a high interest in participating in SDM who reported an increase in SDM had a decrease in diastolic and systolic blood pressure.	3 Moderate
Hawley[45]	2009	Breast cancer	1651	Cross-sectional mailed survey	1-item variant of CPS	Receipt of mastectomy as the initial surgery treatment	No association between SDM and rates of mastectomy as the initial surgery in multivariate model. In bivariate analysis, women who reported SDM were less likely to receive mastectomy initially than those who reported a patient-based decision.	4 Moderate

(continued)

Table 1 (continued)

First Author, Ref. No.	Year	Diseases Context	*N*[a]	Design	SDM Measurement	Patient Outcomes Measured	Summary of Results[b]	Quality Rating: SAQOR Score and Rating
Janssen[46]	2009	Serious injury, various	90	Cross-sectional survey	4-item scale measuring SDM as part of the larger Cologne-Patient-Questionnaire (CPQ)	Self-rated health: ''Would you say your health in general is excellent, very good, good, fair, or poor?''	SDM associated with better self-related health.	4 Moderate
van den Bergh[47]	2009	Prostate cancer	129	Cross-sectional mailed survey study	1-item rating of involvement in decision making developed for this study	Decisional conflict; depressive symptoms; generic anxiety; prostate cancer–specific anxiety	SDM associated with decreased decision conflict. No association between SDM and depressive symptoms, generic anxiety, or prostate cancer–specific anxiety.	4 Moderate
Burton[48,e]	2010	Heart disease	85	Surveyed before and after consultation. Medical students observed interaction and coded using OPTION scale.	13-item PICS	Confidence in the decision	SDM associated with confidence in decision.	3 Moderate
Ommen[49]	2011	Injury or illness requiring hospitalization, various	2197	Secondary analysis of a cross-sectional, retrospective mailed survey study	4-item scale measuring SDM as part of the larger CPQ	Trust in physician	SDM associated with trust in physician.	4 Moderate
Glass[50]	2012	Various	499	Secondary analysis of a cross-sectional survey study	9-item SDM-Q-9 scale	Satisfaction with decision	SDM associated with satisfaction with the decision.	4 Moderate
Johnson[51,f]	2012	HIV	254	Cross-sectional analysis from a longitudinal cohort study	1-item variant of CPS	Health care empowerment	SDM positively associated with health care empowerment.	3 Moderate
Johnson[51,f]	2012	HIV	148	Cross-sectional analysis of a larger RCT	1-item variant of CPS	Health care empowerment	No association.	3 Moderate
Lim[52]	2012	Breast cancer	206	Secondary analysis of a cross-sectional survey	1-item variant of CPS	Exercise, diet, stress management behaviors	SDM positively associated with engagement in exercise. No association between SDM and diet or stress management.	2 Low
Mo[53]	2012	Terminal cancer	93	Cross-sectional survey	2-item rating of involvement in decision making developed for this study	Physical functioning; emotional functioning; quality of life; quality of death	No associations.	4 Moderate
Schleife[54]	2012	Breast cancer	107	Cross-sectional survey	1-item rating of involvement in decision making developed for this study	Anxiety and depression; quality of life	No associations.	3 Moderate

(continued)

Table 1 (continued)

First Author, Ref. No.	Year	Diseases Context	*N*[a]	Design	SDM Measurement	Patient Outcomes Measured	Summary of Results[b]	Quality Rating: SAQOR Score and Rating
Schoenthaler[55,e]	2012	Diabetes	608;41	Cross-sectional mailed survey of patients and physicians and review of electronic health record	13-item PICS	Medication adherence	No association. In an additional analysis there was a significant interaction effect between social support and SDM so that the association between patient perceptions of SDM and medication adherence was stronger as social support increased.	4 Moderate
Thum[56]	2012	Serious injury, various	91	Cross-sectional analysis of a larger RCT	3-item scale measuring SDM as part of the larger CPQ	Trust in physician	SDM associated with trust in physician.	4 Moderate
Wallen[57]	2012	Rheumatic disease	109	Cross-sectional survey study	3-item rating of involvement in SDM as part of the larger Complementary and Alternative Medicine Use in Arthritis (I-CAMP) questionnaire	Use of CAM; disclosure of use of CAM to provider	SDM associated with use of CAM and disclosure of use of CAM to provider.	3 Moderate
Clinician self-reported SDM								
Heisler[58]	2009	Diabetes	4198; 1217	Cross-sectional mailed survey and medical record review	1-item variant of CPS	Satisfaction with provider communication; receipt of dilated eye examinations; assessment of A1c; assessment of lipids; elevated A1c; elevated lipids; elevated systolic blood pressure	No associations.	4 Moderate
Schoenthaler[55,e]	2012	Diabetes	608;41	Cross-sectional mailed survey of patients and physicians and review of electronic health record	9-item Self-Assessment Questionnaire	Medication adherence	No association.	4 Moderate
Observer rated SDM								
Goossensen[59]	2007	Mental Illness	61;8	Audio-recorded visits with postconsultation surveys	OPTION scale (codes for 12 physician communication behaviors); consultation was audio-recorded and coded.	Satisfaction with involvement in decision	No association.	2 Low
Burton[48,e]	2010	Heart disease	85	Surveyed before and after consultation. Medical students observed interaction and coded using OPTION scale.	OPTION scale; consultation was observed and coded.	Confidence in the decision	No association.	3 Moderate

(continued)

Table 1 (continued)

First Author, Ref. No.	Year	Diseases Context	*N*[a]	Design	SDM Measurement	Patient Outcomes Measured	Summary of Results[b]	Quality Rating: SAQOR Score and Rating
Singh[60]	2010	Cancer, various	63	Audio-recorded visits with pre- and postconsultation surveys	Coding system containing 20 physician communication behaviors developed for this study	Satisfaction with consultation; anxiety	No associations.	5 High
Politi[61]	2011	Breast surgery —both prevention and cancer treatment	57	Patient visits were observed and rated on the OPTION scale; patients completed 2 surveys (immediately after consultation and 1–2 weeks late via phone).	OPTION scale; consultation was observed and coded.	Decision satisfaction; treatment decision consistent with recommenda-tion from physician; aggressiveness of treatment chosen	No associations.	3 Moderate
Smith[62] (Also Butow 2010[63])	2011	Breast cancer	55	Audio-recorded visits with preconsultation surveys and then follow-up mailed surveys at 2 weeks and 4 months postconsultation	OPTION scale; consultation was audio-recorded and coded.	Postconsultation anxiety; decisional conflict; satisfaction with the consultation; satisfaction with the physician's SDM skills; satisfaction with decision (after 2 weeks); satisfaction with the decision (after 4 months)	SDM positively associated with satisfaction with the decision after 4 months and satisfaction with the physician's SDM skills. No association between SDM and postconsultation anxiety, decisional conflict, satisfaction with the consultation, or satisfaction with decision after 2 weeks.	4 Moderate
Langseth[64]	2012	Heart disease	49; 2	Audio-recorded visits with postconsultation surveys	OPTION scale; consultation was audio recorded and coded.	Treatment decision (invasive or noninvasive)	SDM associated with choice of noninvasive treatment.	2 Low

Note: CAM = complementary and alternative medicine; RCT = randomized controlled trial.
a. Number of patients; number of provider if reported.
b. Unless noted, the association was significant in the expected direction in a multivariate model.
c. In 2 cases, the results from 1 study were published separately in 2 articles, but the patient outcomes evaluated and the measurement of SDM used overlapped entirely (Butow and Smith; Bleicher and Katz). The results for each of these pairs of publications are considered only once in the context of this review.
d. Two publications (Clever and Swanson) are secondary analyses of the same sample but use different measures of SDM modeled with different outcomes. Each unique SDM measurement and patient outcome assessment is listed separately here and throughout the review.
e. Two studies measured SDM from multiple perspectives. Each unique SDM measurement and patient outcome assessment is listed separately here and throughout the review.
f. Johnson and others[51] report the results from 2 separate studies in 1 publication. Each study is listed separately here and throughout the review.

Patient-reported SDM was measured in a variety of ways across studies. The most commonly used measure was a modified version of the Control Preference Scale[65] in which patients rate their perceptions about their level of involvement in decision making ($n = 13$ studies). In its original form, the Control Preference Scale measures an individual's preferences for his or her role in decision making, and it has been validated across several different patient and clinical contexts and shown to have good reliability.[66,67] The second most commonly used patient-reported measure of SDM was the multi-item Patient Involvement in Care Scale,[25] which was used in 4 studies. The Patient Involvement in Care Scale has been validated across a number of studies, most commonly in the context of cancer care.[66,67] A variety of other single and multi-item measures of SDM were used ($n = 16$ studies), including 5 studies that developed new measures of SDM for their study.

Five of the 6 studies that included observer ratings of SDM used the OPTION scale, in which observers rate the communication between patient and clinician on 12 items.[68] The OPTION scale either is completed by an in-person observer in real time or is used to rate audio-recordings of patient-clinician interactions.

Clinician-reported SDM was used in 2 studies, both in the context of diabetes.[55,58] One of these used a modified version of the Control Preference Scale[65] and the other used a 9-item Self-Assessment Questionnaire.[69]

Patient Outcomes Evaluated

The number of patient outcomes evaluated per study ranged from 1 to 7, with a total of 95 unique patient outcomes and 97 unique patient outcome–SDM measurement pairs assessed across the 39 studies (Table 2). Among the 97 outcome assessments, 51% ($n = 50$) were affective-cognitive outcome assessments, 28% ($n = 27$) behavioral outcome assessments, and 21% ($n = 20$) health outcome assessments. Half of the affective-cognitive variables studied were related to patient satisfaction ($n = 25$). Beyond satisfaction, affective-cognitive variables included concerns and anxieties about the illness ($n = 5$), decisional conflict ($n = 4$), anxiety following the consultation ($n = 4$), confidence in the decision ($n = 2$), and knowledge ($n = 2$), among others. The most frequent behavioral variable assessed concerned the treatment decision itself ($n = 10$), with 9 of these regarding breast cancer treatment decisions. Other behavioral variables include treatment and medication adherence ($n = 7$), health behaviors ($n = 3$), and others. Health outcomes included patient ratings of overall health ($n = 6$) and quality of life ($n = 3$), depressive symptoms ($n = 5$), and other patient-reported measures ($n = 2$), as well as a blood pressure ($n = 2$) and other physiological measures ($n = 2$).

Associations between SDM and Patient Outcomes

As can be seen in Table 3, fewer than half ($n = 42$; 43%) of assessments revealed a statistically significant and positive relationship between SDM and the patient outcome. Results varied by both the SDM measurement perspective and the category of patient outcome. When SDM was measured from the perspective of the patient, regardless of the outcome category, assessments were more likely to result in significant associations. Across all outcomes assessed, 52% were significantly and positively associated with patient-reported SDM, compared with only 21% of outcomes when SDM was observer-rated and 0% when SDM was clinician reported.

Similarly, regardless of how SDM was measured, affective-cognitive patient outcomes were most likely to be associated with SDM. Because a full half of the affective-cognitive outcomes were patient satisfaction variables, we compared the results and conclusions between satisfaction outcomes and those using other affective-cognitive outcomes (online Appendix Table A1). As neither the results nor conclusions were altered, we continue to categorize the outcome variables according to our original categorization framework throughout the remainder of the review. In total, 54% of affective-cognitive outcomes were positively associated with SDM, compared with 37% of behavioral and 25% of health patient outcomes. Three studies found negative effects of SDM on patient outcomes including an increase in decisional conflict,[32] a decrease in patient satisfaction,[37] and an increase in patient reports of the impact of breast cancer on their life.[41] All 3 were affective-cognitive patient outcomes in the context of patient self-reports of SDM.

All 5 health outcomes that were found to be associated with SDM were patient self-reported outcomes, including 1-item ratings of general health rating,[46] discomfort,[24] symptom improvement,[24] general medical improvement,[24] and measure of depressive symptoms rated on the Center for Epidemiologic Studies-Depression scale.[39] Among these, only depressive symptoms were measured using a multi-item, previously validated scale.[39] None of the 4

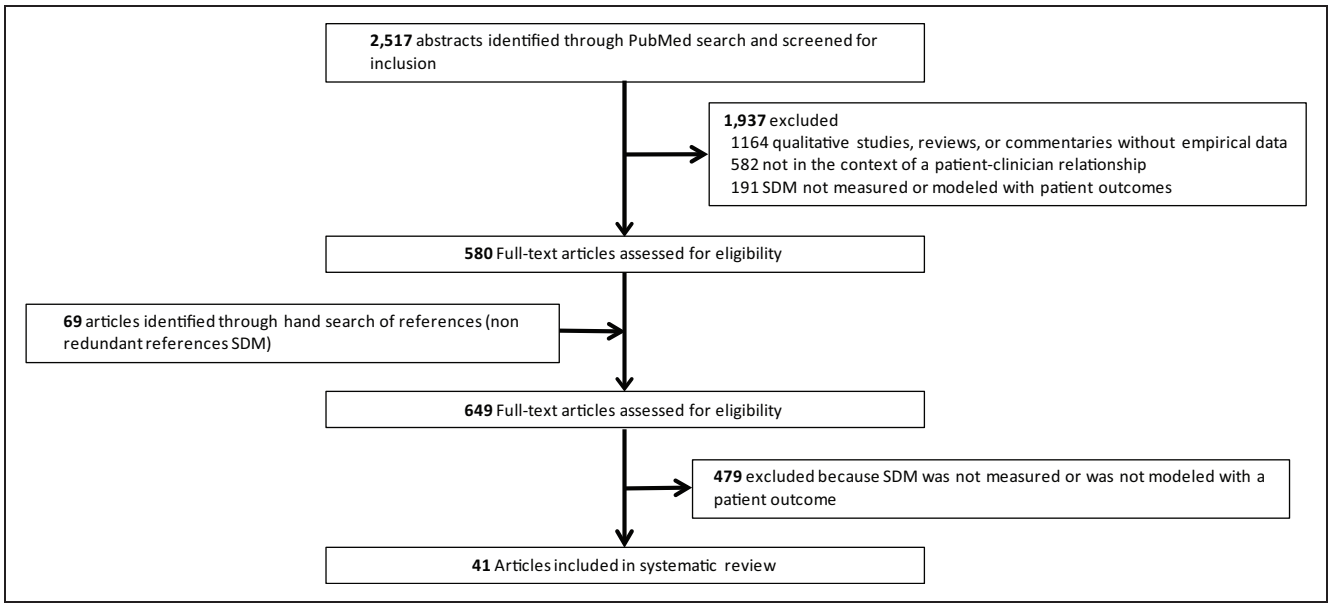

Figure 3 Search strategy and selection results.

physiological measures assessed were associated with SDM.[44,58]

DISCUSSION

Relatively few evaluations have been conducted between SDM and patient outcomes when both the decision-making process and patient outcome have been empirically measured. We found a total of 39 unique studies, which included 97 assessments of the relationship between an empirical measure of SDM and a subsequent empirical measure of a patient outcome. Affective-cognitive outcomes were assessed most often and were primarily patient reports of satisfaction, decisional conflict, or other perceptions immediately after an interaction with a clinician. Furthermore, relative to behavioral and health outcomes, affective-cognitive outcomes were most often found to be significantly and positively associated with SDM. While affective-cognitive outcomes are important and represent SDM's origins as an ethical call to increase patient autonomy,[3,8] there has been a shift toward understanding how patient-clinician communication, including SDM, may be associated with more distal behavioral and health outcomes.[12,16,70]

Although there are strong ethical and interpersonal reasons to advocate for SDM, our findings illustrate the continued uncertainty surrounding SDM as a mechanism to improve patient outcomes. Regardless of the type of patient outcome considered or the SDM measurement used, empirical evaluations that have included an explicit measure of the shared decision-making process and a patient outcome more often than not have found no positive and statistically significant relationship between SDM and the patient outcome. The one exception is among assessments that evaluated an affective-cognitive patient outcome in relation to patient-reported SDM. Within these assessments, the majority (66%) found a significant and positive relationship between SDM and a subsequent patient outcome. Notably lacking were any studies that evaluated the association between observer-rated SDM and patient health outcomes. Clinician reports of SDM were also rare, with the 8 such associations evaluated here coming from only 2 independent studies, with none found to have a significant association with a patient outcome.

Notably, 85% of the studies identified for review measured SDM via a patient self-report. As previously reported,[19,20] within the patient-reported SDM measurement category, a wide range of measures of patient perceptions of SDM are currently being used. While variations of the Control Preference Scale[65] are most commonly used, we found 16 different instruments used across the 33 studies that measured SDM via patient self-report. Regardless of whether the Control Preference Scale or some other instrument is used to capture patient-reported use of SDM, more often than not the items contained in

Table 2 Patient Outcomes Assessed by Shared Decision Making (SDM) Measurement Perspective and Outcome Category (n = 97)

SDM Measurement Category	Patient Outcome Category		
	Affective-Cognitive (n = 50)	**Behavioral (n = 27)**	**Health (n = 20)**
Patient reported	Satisfaction with care (× 7)	Decision about breast cancer treatment (× 7)	Patient-rated health/ symptoms (× 6)
SDM	Concern/anxiety about illness (× 5)	Medication/treatment adherence (× 6)	Depressive symptoms (× 5)
	Satisfaction with decision (× 5)	Diet	Quality of life (× 3)
	Decisional conflict (× 3)	Disclosure of CAM use	Anxiety
	Satisfaction with consultation (× 3)	Exercise	Blood pressure
	Anxiety after consultation (× 2)	Number of treatment strategies agreed upon	Emotional functioning
	Control over medical problem (× 2)	Receipt of depression care	
	Health care empowerment (× 2)	Stress management behaviors	
	Knowledge (× 2)	Use of CAM	
	Satisfaction with information received (× 2)		
	Trust in physician (× 2)		
	Confidence in decision		
	Predicted discomfort		
	Predicted functional capacity		
Clinician reported	Satisfaction with provider communication	Medication adherence	Blood pressure
SDM		Receipt of dilated eye exam	Hemoglobin A1c
		Receipt of hemoglobin A1c assessment	Lipid level
		Receipt of lipid assessment	
Observer rated	Satisfaction with decision (× 4)	Decision about breast cancer treatment (× 2)	
SDM	Anxiety immediately after consultation (× 2)	Decision about treatment for arrhythmia	
	Satisfaction with consultation (× 2)		
	Confidence in decision		
	Decisional conflict		
	Satisfaction with physician's SDM skills		

Note: CAM = complementary and alternative medicine.

these instruments do not reveal what it is about the decision-making process that leads a patient to report that it was shared. Additionally, many of the patient-reported measures of SDM used were not previously validated or were not validated for the population for which they were being used. Taken together, these observations are particularly troubling as several recent studies have found that observer ratings of SDM do not predict patient reports of having participated in a shared decision.[48,66,67] These findings may represent differences in conceptual definitions of SDM or may highlight problems with the current tools for measuring SDM. Regardless, these results (combined with our findings that when positively associated with a patient outcome, it is patient-perceived SDM and not observer-rated SDM that is important) highlight the importance of understanding the patient's perspective as critical to the

Table 3 Summary of Results by SDM Measurement Perspective and Patient Outcome Category

	Patient Outcome Category											
	Affective-Cognitive			Behavioral			Health			Total		
SDM Measurement Perspective		*n*	%		*n*	%		*n*	%		*n*	%
Patient reported	Positive[a]	25	66%	Positive	11	55%	Positive	5	29%	Positive	39	52%
	NS[a]	10	26%	NS	9	45%	NS	12	71%	NS	33	44%
	Negative[a]	3	8%	Negative	0	0%	Negative	0	0%	Negative	3	4%
	Total measured	38		Total measured	20		Total measured	17		Total measured	75	
Clinician reported	Positive	0	0%	Positive	0	0%	Positive	0	0%	Positive	0	0%
	NS	1	100%	NS	4	100%	NS	3	100%	NS	8	100%
	Negative	0	0%	Negative	0	0%	Negative	0	0%	Negative	0	0%
	Total measured	1		Total measured	4		Total measured	3		Total measured	8	
Observer rated	Positive	2	18%	Positive	1	33%	Positive	0	—	Positive	3	21%
	NS	9	82%	NS	2	67%	NS	0	—	NS	11	79%
	Negative	0	0%	Negative	0	0%	Negative	0	—	Negative	0	0%
	Total measured	11		Total measured	3		Total measured	0		Total measured	14	
Total	Positive	27	54%	Positive	10	37%	Positive	5	25%	Positive	42	43%
	NS	20	40%	NS	17	63%	NS	15	75%	NS	52	54%
	Negative	3	6%	Negative	0	0%	Negative	0	0%	Negative	3	3%
	Total measured	50		Total measured	27		Total measured	20		Total measured	97	

a. *Positive* refers to a significant, positive (i.e., beneficial) association between SDM and the patient outcome. *NS* refers to a nonsignificant association. *Negative* refers to a significant, negative (i.e., nonbeneficial) association between SDM and the patient outcome.

science of measuring SDM. As better tools are developed to measure SDM, it will be critical understand what leads a patient to label a decision as ''shared.'' Without such an understanding, our ability to foster SDM processes in practice will continue to be hindered as will our ability to fully understand the impact of SDM on patient outcomes.

Our review highlights several important points regarding the assessment of SDM and patient health outcomes. First, health outcomes were least studied. Second, when health outcomes have been assessed in relation to SDM, the outcomes have most often been measured via patient self-report and often with unvalidated instruments. In total, only 5 of the 20 (25%) health outcomes evaluated were found to be associated with SDM, and 4 of these used single-item unvalidated measures. Furthermore, we identified only 4 physiological measures of patient health (blood pressure, hemoglobin A1c, and lipid level) that have been evaluated for their association with SDM, and none of these evaluations identified a statistically significant relationship.[44,58] Results from this review thus indicate that the link between SDM and health patient outcomes, in particular, has yet to be fully established.

Notably lacking among the SDM literature are randomized trials evaluating the impact of a communication/decision-making intervention on patient outcomes that empirically measure the communication/decision-making process used. Many RCTs in recent years have evaluated the effects of some type of communication or decision-making intervention on patient outcomes. These interventions most often center on a decision aid but also include patient or clinician communication training interventions.[71,72] Decision aid studies, in particular, have shown decision aids to be effective at improving patient outcomes.[18] However, many of these intervention studies have not included an empirical measure of SDM, instead assuming SDM to have occurred based on group assignment, or they have included a measure of SDM as means of quality control but have not modeled the empirical measure of SDM with patient outcomes. Without an evaluation of the empirical measure of SDM with patient outcomes, it is not clear that SDM (or something else) is what led to an improvement in the patient outcome. The Cochrane review's finding that there were no differences in patient self-reports of SDM by group assignment among decision aid studies that included an empirical measure of SDM highlights the uncertainty of what led to the changes in patient outcomes.[19] Our review identified only 9 studies conducted in the context of a randomized trial,[27,32,38,39,42,44,46,51,56] and despite the design of the parent study, none reported the association of SDM and a patient outcome in the context of the randomized design.

Until now, SDM has almost always been measured cross-sectionally in the context of one interaction or discussion. This may explain, in part, the general lack of association between SDM and patient outcomes. That is, one discussion between a clinician and patient may not lead to improved health outcomes. Instead, a long-standing relationship between a clinician and patient marked by patient-centered care and SDM may affect outcomes over time. To complement thoughtful conceptual models that hypothesize the paths between patient and clinician communication behaviors and patient outcomes (e.g., Street and others[16]), well-designed studies are needed that measure multiple patient and physician interactions and patient outcomes over time to formally test whether decision-making and communication interventions lead to increased SDM, and then whether it is these increases in SDM (or something else) that are associated with health outcomes. SDM may mediate or even moderate the relationship between communication or decision-making interventions and patient outcomes. For example, SDM may improve patient satisfaction, which over time may lead to trust in the physician, followed by adherence to physician recommendations and ultimately improved health.[73] However, these relationships remain largely untested in the empirical literature.

In the meantime, SDM may be better advocated on ethical grounds. Patient-centered care, including SDM, is important outside of its potential effect on patient health outcomes. The US Preventive Task Force highlighted the multiple perspectives on which SDM can be recommended. These included an ethical mandate to protect patient autonomy and self-determination, an interpersonal benefit of promoting trust in the patient-clinician relationship, and an educational gain of increasing patient knowledge about treatment options, benefits, and harms through an SDM process.[5] Thus, despite only limited evidence that SDM improves patient outcomes, there are still important reasons to advocate for an SDM process when making healthcare decisions.

Limitations

Our conceptual framework examines the impact of SDM when explicitly measured on patient outcomes across 2 important domains—the perspective from which SDM was measured and the type of patient

outcome. However, undoubtedly there are other dimensions that are important to understanding the relationship between SDM and patient outcomes. For example, the clinical context in which the decision was made and the nature of the decision itself (prevention v. acute treatment v. chronic treatment decisions, etc.) may influence the impact of SDM on patient outcomes. Given the relatively small number of studies identified as eligible for study inclusion, we were not able to further categorize studies for this first systematic review.

We recognize that SDM (particularly patient perceptions of SDM) may not be limited to the context of one visit between a patient and clinician, but rather patient reports of SDM may be influenced by the prior relationship between the patient and clinician or by the influence of other parties in the decision.[66] This is especially likely to be true in primary care and chronic disease contexts in which patients and their clinicians often make multiple decisions over the course of many visits. However, none of the studies identified here measured SDM across a long-standing relationship, and thus we are unable to discuss how SDM may affect patient outcomes over time. Additionally, all of the studies reviewed here examined SDM in the context of a patient and clinician only, limiting our ability to examine the effects of having family members or others participate in decision making.

The study inclusion and exclusion criteria may have also affected our findings. Our aim in the current review was to understand how SDM is currently measured and how SDM using these different measures is (or is not) associated with various patient outcomes. As such, the study inclusion criteria required both an empirical measure of SDM and an assessment of the association between that measure and a patient outcome. Based on these criteria, most of the included studies were observational studies rather than randomized clinical trials, as most intervention studies did not include an evaluation of the association of an empirical measure of SDM and patient outcomes. Rather, if the investigators in those studies chose to draw conclusions specific to SDM, they did so by evaluating the effect of intervention group assignment on patient outcomes. Thus, there may be additional patient outcomes that have been assessed in relationship to an SDM intervention that are not discussed in this review. Our findings are also limited by the psychometric properties of both the SDM and outcome measures used in the studies meeting our inclusion criteria. Although we cannot formally assess the impact of such measurement limitations on our findings, it is important to acknowledge that the psychometric properties of both the SDM and outcome measures were varied or, at times, not reported.

Finally, the results and conclusions presented here may be influenced by publication biases. Although we were careful to review articles identified as eligible for inclusion for additional nonredundant references, we did not attempt to identify and include results from unpublished studies. Additionally, due to the diversity of patient outcomes assessed across studies combined with the relative paucity of studies, we were not able to use meta-analysis methods. As consensus is built around the measurement of SDM and the patient outcomes most salient to SDM, future systematic reviews may be able to use a meta-analysis to formally combine and assess the evidence across studies.

CONCLUSION

Our review suggests that when patients report that they have participated in SDM, they are likely to enjoy better affective-cognitive outcomes, such as improved satisfaction and less decisional conflict. Furthermore, patient reports are the only SDM measurement perspective found to be associated with patient health outcomes, albeit in a minority of those studies. The challenge with these findings is that we do not know what leads a patient to report a decision as shared and, thus, we do not know how to foster SDM and its associated benefits in practice. Thus, not only should future studies continue to address the impact of SDM across a continuum of patient outcomes and clinical settings, but they should also address the methodological challenges associated with such evaluations, including how best to measure SDM. Patients increasingly report a desire to engage in SDM, and SDM remains an important tool to promote patient autonomy and satisfaction. However, our findings indicate that with the measures of SDM currently available, the link between SDM and patient behavioral and health outcomes has yet to be fully established.

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