A systematic review of patient-practitioner communication interventions involving treatment decisions.

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Abstract

Objectives: To examine the: 1) methodological quality of interventions examining strategies to improve patient-practitioner communication involving treatment decisions; 2) effectiveness of strategies to improve patient-practitioner communication involving treatment decisions; and 3) types of treatment decisions (emergency/non-emergency) in the included studies.

Methods: Medline, PsychINFO, CINAHL, and Embase were searched to identify intervention studies. To be included studies were required to examine patient-practitioner communication related to decision making about treatment. Study methodological quality was assessed using Cochrane's Effective Practice and Organisation of Care risk of bias criteria. Study design, sample characteristics, intervention details, and outcomes were extracted.

Results: Eleven studies met the inclusion criteria. No studies were rated low risk on all nine risk of bias criteria. Two of the three interventions aimed at changing patient behaviour, two of the five practitioner directed, and one of the three patient-practitioner directed interventions demonstrated an effect on decision-making outcomes. No studies examined emergency treatment decisions.

Conclusions: Existing studies have a high risk of bias and are poorly reported. There is some evidence to suggest patient-directed interventions may be effective in improving decision-making outcomes.

Practice Implications: It is imperative that an evidence-base is developed to inform clinical practice.

Key words: communication; decision making; treatment; systematic review

Introduction

The importance of patient-practitioner communication in treatment decision making

High quality patent-practitioner communication is associated with numerous affective and behavioural patient outcomes.[1] The content and process of patient-practitioner communication is particularly important in circumstances where treatment decisions are required,[2] and even more so when these may hold long-term health consequences. The provision of information that enables accurate perceptions of the risks and benefits of treatment options is therefore essential for informed decision making.[3]

Effective communication about treatment options has the potential to increase accurate risk perceptions, confidence and satisfaction, and reduce anxiety and negative emotions.[4] Poor communication and lack of information has been associated with poor patient outcomes such as distress, anxiety, decisional uncertainty, dissatisfaction, and non-adherence to treatment recommendations.[5] To ensure the provision of high-quality health care, effective patient-practitioner communication is required.

Challenges in effective patient-practitioner communication

Facilitating patient involvement in decision making is a complex task. Firstly, patient preferences for the amount and type of information, as well as their involvement in treatment decision making, may vary.[6] Thus, a one-size-fits-all approach is not appropriate. Secondly, clinicians may not accurately assess preferences for information or involvement in decision making,[7] which can result in conflict between the ideal and actual care received.

Lastly, the provision of information about treatment options and their outcomes may be difficult for patients to comprehend. Patients frequently express dissatisfaction with the information provided to them and may experience difficulty in retaining and processing information,[8] leading to exacerbated feelings of fear and misinterpretation of treatment side effects.[9] As perceptions of risk and benefit have been found to influence treatment decision making,[10] accurate perceptions are crucial.[3]

Practitioners face unique challenges in communicating treatment options, particularly when a decision is urgently required, and/or a patient lacks capacity to consent. In emergencies, clinicians need to quickly convey information about treatment options in order for patients to make informed decisions. In some circumstances, treatment decisions may become the responsibility of a patient's family member.[11] However, family members are not always able to accurately represent patients' preferences.[12] In such high-stake situations, feelings of uncertainty are common,[13] and accurate comprehension of information and clarity of decision making may be poor. In light of the communication challenges faced by practitioners, it is imperative a strong evidence-base exists to guide this process.

Evidence-based recommendations to guide communication about treatment decision making are needed

Face-to-face consultations are the most common form of patient-practitioner communication regarding treatment options, and have been identified as a valuable and preferable method of communication by patients and healthcare providers.[14, 15] However currently, evidence-based guidelines for optimal patient-practitioner communication regarding treatment decision making do not exist. Healthcare providers must therefore

rely on expert consensus recommendations and general communication guidelines to inform practice. General guidelines stipulate face-to-face communication about treatment decision making should encompass verbal and non-verbal components,[16] which can be augmented by information delivered in various formats.[15] Due to the absence of evidence-based clinical practice guidelines, information is likely to be delivered in a non-standardised manner, potentially resulting in suboptimal patient outcomes.

Several reviews have examined strategies for improving patient-practitioner communication. These, however, focussed on: shared decision making;[1] communication training for healthcare providers;[17, 18] breaking bad news;[19] use of decision aids;[20, 21] decisions about health screening (as opposed to treatment alone);[21] and observational or quasi-experimental studies.[22] These reviews lack high-quality experimental evidence, and none have explicitly examined the face-to-face interaction of patients and providers when treatment decision making takes place. The existing literature is also restricted in its generalisability, as most studies have focussed on specific populations (most commonly cancer patients),[17] with little evidence to guide communication regarding treatment options for other diseases or emergencies.

Therefore, the purpose of the review is to examine the: 1) methodological quality of interventions examining strategies to improve patient-practitioner communication involving treatment decisions; 2) effectiveness of strategies to improve patient-practitioner communication involving treatment decisions; and 3) types of treatment decisions (emergency/non-emergency) examined in the included studies.

Methods

Searches of the Medline, PsychINFO, CINAHL, and Embase databases were completed on the 19th April 2016 to identify publications on communicating treatment choices. The search was limited to humans, adults, and English language publications using the "Advanced Ovid Search" function. The search used a combination of the following terms to identify publications: Communication AND Physician-Patient Relations AND Decision Making (see Supplementary Material S1 for complete search strategy). Search findings were combined prior to removal of duplicates. Reference lists of relevant reviews and included studies were searched manually to identify additional relevant publications.

Inclusion and exclusion criteria

Participants and setting

Studies involving adult participants aged 18 years and above in any setting were eligible for inclusion. Studies conducted with children as participants or involving parents making treatment decisions for children were excluded.

Relevance

Studies that aimed to evaluate the effect of interventions designed to influence face-to-face patient-practitioner communication regarding treatment decision making on patient decision-making outcomes were included. Studies that were: a) not specific to patient-practitioner communication; b) did not involve a discussion of treatment options or treatment decisions; or c) used only web-based, graphical or written forms of communication, were excluded. Studies examining decision aids alone were excluded as a review of this literature has been conducted.[21]

Outcomes

Eligible studies focussed on real or hypothetical treatment decisions, and included patient decision-related outcomes such as treatment decision, or outcomes associated with improving patient-practitioner communication involving treatment decisions, for example decisional conflict, decision regret, satisfaction with decision, and knowledge.

Study design

Studies that met Cochrane's Effective Practice and Organisation of Care (EPOC) research design criteria were eligible for inclusion.[23] This included randomised controlled trials (RCT), controlled clinical trials, controlled before and after studies, and interrupted time series studies. Studies that did not meet EPOC design criteria were excluded.

Study screening

Titles and abstracts of all publications returned by the searches were reviewed by one author (AG). As a quality assurance measure, a random 10% of abstracts, and 50% of potentially relevant full-text articles were reviewed independently by a second reviewer (JB). Disagreement between reviewers was resolved through discussion. The number of articles identified, screened, eligible and included were recorded according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[24]

Methodological quality assessment

The EPOC quality criteria and risk of bias (RoB) criteria were used to assess the methodological quality of included studies.[23] For each criterion, 'Low risk' was

assigned if the study met the criterion, ‘High risk’ if it did not, and ‘Unclear’ if there was insufficient information provided. These criteria included whether: 1) allocation sequence was adequately generated; 2) allocation was adequately concealed; 3) baseline outcome measurements were similar in intervention and control groups; 4) baseline characteristics of control and intervention groups were similar; 5) incomplete outcome data were adequately addressed; 6) there was blinded allocation of intervention and control groups; 7) study was adequately protected against contamination; 8) study was free from selective reporting; and 9) study was free from other risks of bias. Each study received a score out of nine (Low risk=1; High risk/Unclear=0). All coding for EPOC quality criteria were carried out by two authors independently (AG and BH) and discrepancies resolved through discussion with a third author (MC). Whether a study employed any process for monitoring delivery of the intervention was also extracted to determine if an intervention was conducted according to protocol.

Data extraction

The following were extracted by two authors independently: year; country; study design; setting; sample characteristics (total number of participants, age [mean, median or categories], percentage male, and diagnosis); details of the intervention and comparator conditions, and number of participants in each group; measures of adherence to the intervention; outcome measures and follow-up time periods; and study results. An emergency treatment decision was defined as a decision made about a medical condition requiring urgent treatment within 48 hours of diagnosis.[25] Studies were coded as emergency/non-emergency based on the diagnosis of the sample included and treatment being discussed. Extraction of study characteristics was carried out by

two authors independently (AG and BH), with discrepancies resolved through discussion with a third author (MC).

Data synthesis

Details and findings of the studies were reported both by intervention category (interventions directed at changing: patient behaviour only; practitioner behaviour only; and both patient and practitioner behaviour), and by outcome. Included studies measured approximately 50 different outcomes, falling into the following categories: decision, information, health, treatment, and communication-related (see Supplementary Material S2 for complete list of outcomes). Given the total number of outcomes, only those pertaining to the patient's perception of a quality decision (decisional conflict, decisional regret, satisfaction with decision) and treatment decision itself were reported. When possible, the effect of each intervention on patient knowledge was also extracted as an indicator of an informed decision.

A narrative approach was used as meta-analysis of all study findings was not possible due to low numbers of studies with suitable data and high heterogeneity in study outcomes. Where sufficient data were reported, intervention effects on relevant outcomes (decisional conflict, decisional regret, satisfaction with decision, and knowledge) were extracted and converted into a standardised mean difference (SMD) and standard error (SE). Results of cluster RCTs were adjusted for design effects when sufficient data were reported.

Results

Search results

The searches resulted in 3,519 potentially relevant abstracts. Manual searching of reference lists of included studies revealed no additional relevant studies. Following removal of duplicates, 2,706 abstracts were retained for relevance screening, 306 of which were assessed for eligibility (Figure 1). In total, 11 intervention studies met the inclusion criteria.

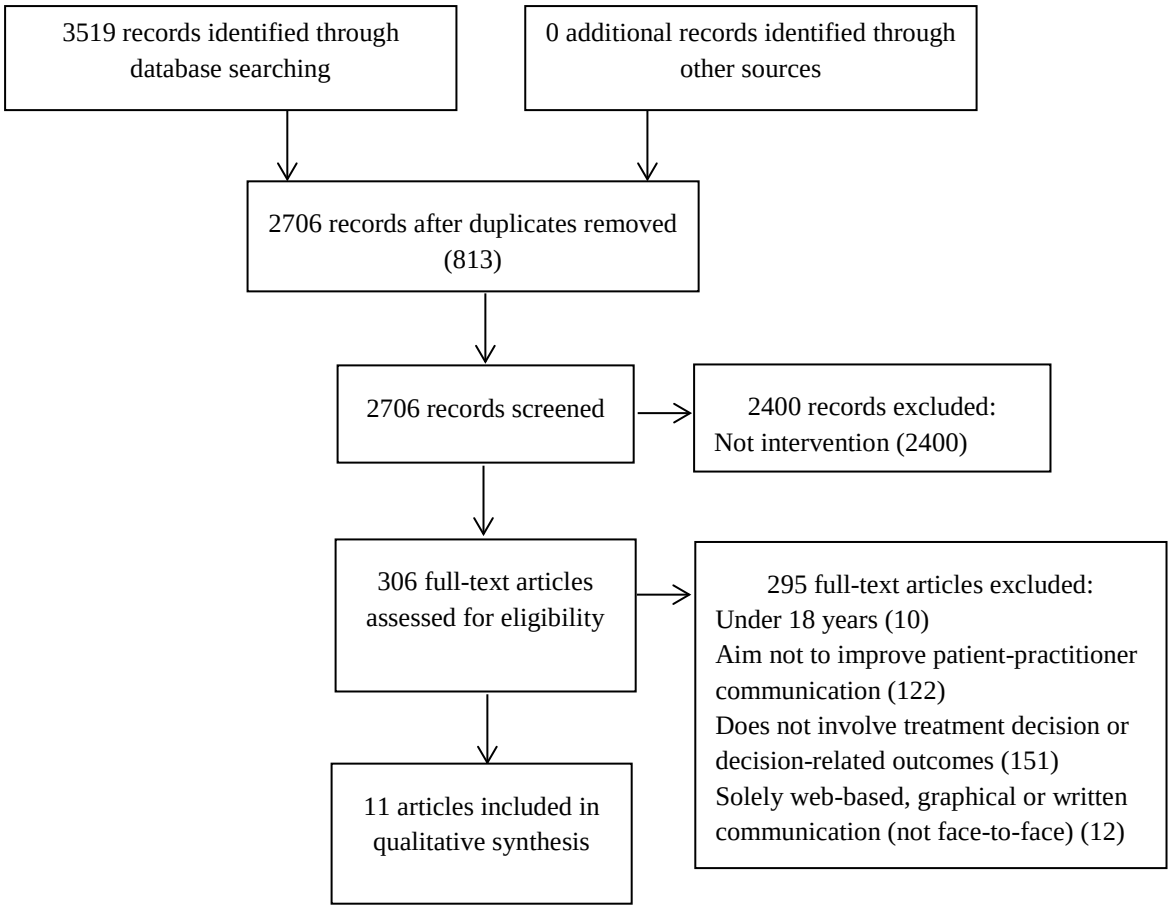

Figure 5.1: Inclusion and exclusion process of literature search findings to determine inclusion in the systematic review, according to PRISMA.

Study characteristics

Seven studies used a RCT to evaluate an intervention,[26-32] while the remaining four used a cluster RCT.[33-36] One cluster RCT included a cross-over in study conditions.[33] Two studies did not have a control group, with an alternate intervention as the comparator,[30, 33] and one study had three arms in which participants could be randomised.[26] Included studies were conducted in Australia,[35] Austria,[35] Canada,[27] Germany,[31, 34, 35] New Zealand,[35] Switzerland,[35] United States (US),[26-30, 32, 36] and Wales.[33] Three interventions were directed at changing patient behaviour,[26-28] five focussed on improving practitioner communication,[29, 30, 33-35] and three used a combined patient-practitioner approach.[31, 32, 36] Sample sizes ranged 85–1,132 for patients and 10-108 for health care providers. Post-intervention outcomes were commonly measured immediately after the intervention, however, follow-ups varied in each study ranging 1 week to 12 months.

Methodological quality of interventions to improve patient-practitioner communication

None of the studies were rated low risk on all nine EPOC RoB criteria (Table 1), with only six studies scoring low risk on 5 or more criteria.[27, 28, 30, 31, 33, 36] The EPOC criteria least likely to be met were: free from risk of other bias (n=3), allocation sequence adequately generated (n=4), contamination (n=3), and baseline outcome measurements similar in intervention and control groups (n=3). Poor consent rates, poor adherence to the interventions, lack of provider randomisation, and biased sampling procedures were other identified risks of bias. A number of studies did not specify the method of patient or provider condition allocation,[26, 27, 29, 32, 34, 35] nor did they include baseline measurements,[28-34] resulting in ratings of unclear. Potential contamination was present in five studies due to patient randomisation or the same healthcare provider interacting

with both intervention and control participants.[26-28, 30, 32] Ten studies met the inclusion criterion for ‘free from selective outcome reporting’, based on the reporting of outcomes described in the study methods.

Table 5.1: Methodological assessment of included intervention studies based on the EPOC assessment criteria.

Author, Year	Allocation sequence	Concealment of allocation	Baseline outcomes	Baseline characteristics	Incomplete data	Knowledge of interventions	Selective reporting	Contamination	Other bias	Total
Fogarty et al. 1999 [29]	?	?	?	X	?	?	✓	✓	X	2/9
Whelan et al. 2003 [27]	?	✓	✓	✓	✓	X	✓	X	X	5/9
Edwards et al. 2004 [33]	✓	✓	?	?	X	✓	✓	✓	X	5/9
Bieber et al. 2008 [31]	✓	✓	?	✓	✓	✓	✓	?	X	6/9
Krones et al. 2008 [34]	?	✓	?	X	✓	X	✓	?	✓	4/9
Mishel et al. 2009 [26]	?	?	✓	X	?	?	✓	X	✓	3/9
Mann et al. 2010 [32]	?	?	?	✓	?	?	✓	X	X	2/9
Saha and Beach 2011 [30]	✓	✓	?	✓	✓	✓	✓	X	✓	7/9
Bernhard et al. 2012 [35]	?	✓	X	✓	?	?	?	?	X	2/9
Fraenkel et al. 2012 [36]	X	✓	✓	X	X	✓	✓	✓	X	5/9
Bozic et al. 2013 [28]	✓	✓	?	?	✓	✓	✓	X	X	5/9

✓: Low risk. X: High risk. ?: Unclear.

Only five studies specified inclusion of a process of monitoring adherence to the intervention,[26, 31, 33, 35, 36] which was done so via use of audiotape for patient-practitioner consultations. Of these studies, only one reported the rate of participant adherence, being 48% and 83% for varying components of the intervention.[36] This criterion was not applicable to two studies that presented videotaped consultations to patients as the intervention.[29, 30]

Effectiveness of interventions to improve patient-practitioner communication according to intervention type

Patient-focussed interventions

Two of the three patient-directed studies demonstrated a positive effect on decision-making outcomes (Table 2). Mishel et al.'s[26] RCT, which only met three of EPOC's RoB criteria, examined treatment decision making for prostate cancer using a three arm RCT. The trial compared: a) usual care with a handout on staying healthy during treatment; b) a patient-directed intervention that included an educational booklet, DVD, phone calls, and question prompt list prior to consultation with the practitioner; and c) a support person condition that, included the patient directed-intervention, as well as separate phone calls to the support person provided during the same time period as patient calls. Compared to controls, patients in either intervention group reported greater improvements in decisional regret at 3 months, and greater knowledge at both 4 weeks and 3 months' follow-up. There was no difference in outcomes between the two intervention arms. Bozic et al.'s[28] RCT, which met five RoB criteria, also tested the impact of an intervention involving an educational booklet, DVD, phone calls, and question prompt list prior to consultation with the practitioner, for patients with hip or knee osteoarthritis. Patients allocated to the intervention were significantly more likely

to report making an informed decision at 6 weeks follow up than were patients allocated to the control; however, no differences were found for treatment choice between the two groups. The third study used an RCT to compare the impact of a decision aid for breast cancer patients administered by a healthcare provider within the medical consultation to usual care.[27] The intervention resulted in improved patient knowledge at 1 week, and improved decisional conflict at 1 week, 3, 6 and 12 months' follow-up, and scored five out of nine on the RoB assessment.

Table 5.2: Characteristics of interventions meeting EPOC methodological study design criteria directed at changing patient behaviour only.

		Intervention Characteristics			
Reference Country Design	**Sample** N; Age; Gender; Diagnosis; Setting	**Intervention**	**Adherence to intervention**	**Outcome measures** **Follow-up**	**Results**
Mishel et al. 2009 [26] USA RCT	*Patients* **N**: 256 **Mean age (SD)**: IA: 62.7 yrs (7.1) IB: 63.3 yrs (7.4) C: 61.3 yrs (7.6) **Males**: 100% **Diagnosis**: Prostate cancer. **Setting**: 2 National Cancer Institute-designated comprehensive cancer centres, 3 community hospitals, and 1 Veterans' Administration medical centre.	*Patients* **IA (n=93):** Patients received a patient-focused, evidence-based booklet on prostate cancer treatment with question prompt sheet; a DVD on communication strategies such as giving information to doctors, asking questions, getting the information you want, and clarifying information; and 4 nurse phone calls to answer questions relating to the booklet, and help patients formulate questions and practice communication skills. **IB (n=89):** Patients received the same intervention as IA, with the addition of their support persons receiving the nurse phone calls. **C (n=74):** Patients received a handout on staying healthy during treatment.	All nurse intervention calls were audio taped and reviewed by the investigators for quality control and maintaining intervention fidelity.	**Measures:** *Patients* (i) Prostate Cancer Knowledge Scale; (ii) Decisional Regret Subscale of the Quality of Life Scale. **Follow-up:** 4 weeks and 3 months.	*Patients* • IA (SMD 0.34, SE 0.16) and IB (SMD 0.34, SE 0.16) reported significantly greater cancer knowledge than C at 4 weeks ($p<0.001$). • IA (SMD 0.24, SE 0.16) and IB (SMD 0.35, SE 0.16) reported significantly greater cancer knowledge than C at 3 months ($p<0.001$). • IA (SMD -0.13, SE 0.16) and IB (SMD -0.20, SE0.16) reported significantly lower decisional regret scores than C ($p<0.05$) at 3 months.
Bozic et al. 2013 [28] USA RCT	*Patients* **N**: 123 **Mean age**: NR **Males**: NR **Diagnosis**: Hip or knee osteoarthritis **Setting**: Two academic medical centres. *Providers*	*Patients* **I (n=61):** Received a DVD and booklet decision aid tool about the natural history and treatment alternatives for osteoarthritis. Subjects then received a telephone consultation from a trained health coach with use of the Situation, Choice, Objectives, People, Evaluation, and Decisions intervention to construct a list of questions to ask the patient's surgeon. Printed copies of the questions were brought to the surgeon consultation. Consultations were audio recorded and sent to patients.	Not specified.	**Measures:** *Patients* (i) Informed decision: treatment decision made at first consultation and scored >50% on the knowledge survey; (ii) Treatment choice.	*Patients* • I had significantly higher rate of reaching informed decision than C (SMD -0.56, SE 0.19, $p<0.05$). • No significant difference between I

	N: Not specified. **Age**: Not specified. **Males**: Not specified.	**C (n=62):** Received existing materials used in surgeon's practice including a map and directions to clinic, and a 1-page informational handout about the signs, symptoms, diagnosis, and treatment options for osteoarthritis.		**Follow-up:** 6 weeks.	and C for treatment choice.
Whelan et al. 2003 [27] Canada/USA RCT	*Patients* **N**: 175 **Mean age**: I: 51 yrs C: 51.8 yrs **Males**: 0% **Diagnosis**: Breast cancer. **Setting**: 4 Cancer Care Ontario Regional Cancer Centres and 2 hospitals. *Providers* **N**: 22 **Median age (range)**: 50 years (40-67) **Males**: 64%	*Patients* **I (n=82):** Received usual medical consultation in addition to a Decision Board presented by a research nurse. The Decision Board presents graphics and written information regarding the patient's treatment choices, outcomes, probability of outcomes, and expected quality of life. Received opportunity to ask oncologist questions after viewing the Decision Board, and a take home version of the board and pamphlet describing breast cancer and treatment options. **C (n=93):** Received regular consultation and a meeting with the primary care nurse to address concerns or information needs, which was consistent with usual care. Received a pamphlet describing breast cancer and treatment options.	Not specified.	**Measures:** *Patients* (i) Patient knowledge questionnaire; (ii) Effective decision making subscale of the DCS; (iii) Treatment decision. **Follow-up:** 1 week; 3, 6 and 12 months.	*Patients* • I had greater mean knowledge than C at 1 week follow-up (SMD 0.62, SE 0.16, $p<0.001$). • I had significantly greater satisfaction with decision making (decisional conflict) than C at 1 week (SMD 0.36, SE 0.15); 3 months (SMD 0.58, SE 0.16); 6 months (SMD 0.79, SE 0.16); and 12 months (SMD 0.08, SE 0.16) ($p<0.05$ at all time points). • No differences in treatment decision between I and C.

I: Intervention. C: Control. SD: Standard deviation. N: number of participants. RCT: Randomised controlled trial. DCS: Decisional Conflict Scale. NR: Not reported in manuscript (unable to access supplementary material). SMD: Standardised mean difference. SE: Standard error.

Practitioner-focussed interventions

Two of the five studies that aimed to improve practitioner communication examined the impact of different types of provider communication delivered via video vignettes of a consultation (Table 3).[29, 30] Only one study reported a significant impact on decision-related outcomes.[30] In Fogarty et al.'s[29] RCT, participants with and without cancer were randomised to view one of two hypothetical oncologist-patient consultations in which information about treatment options were presented: a standard condition, and an enhanced compassion condition in which the oncologist displayed greater sympathy and compassion. This study met only two RoB criteria. No differences were found in treatment decisions between groups. Surprisingly, the control group had significantly greater recall of treatment information than the intervention group. Saha and Beach[30] used an RCT to compare two vignettes depicting a cardiologist-patient consultation among patients with coronary artery disease (CAD) or risk factors for CAD, and scored seven out of the nine on EPOC's RoB criteria. In one vignette, the healthcare provider employed a "high" amount of patient-centred communication, and in the other, a "low" amount of patient-centred communication. Patients randomised to the high patient-centred communication vignette reported significantly higher ratings of the likelihood they would undergo treatment, compared to those allocated to the low patient-centred communication vignette.

Table 5.3: Characteristics of interventions meeting EPOC methodological study design criteria directed at changing practitioner behaviour only.

		Intervention Characteristics			
Reference Country Design	**Sample** N; Age; Gender; Diagnosis; Setting	**Intervention**	**Adherence to intervention**	**Outcome measures** **Follow-up**	**Results**
Fogarty et al. 1999 [29] USA RCT	*Patients* Cancer survivors **N**: 123 **Mean age:** I: 52 C:51 **Males**: 0% **Diagnosis**: Breast cancer survivors. No-cancer Sample **N**: 87 **Mean age**: I:48 C:51 **Males**: 0% **Diagnosis**: None **Setting**: 2 local breast cancer support groups.	*Patients* **I (n=63):** Dramatized oncologist-breast cancer patient consultation lasting approximately 18 minutes covering treatment options, treatment risks and benefits, and probabilities of side effects and long term survival. Contained two segments to express support, sympathy, and compassion for the patient's difficult situation. **C (n=60)**: Received a dramatized consultation as in I, without the compassion segments.	N/A.	**Measures:** *Patients* (i) Treatment recall score; (ii) Hypothetical treatment decision. **Follow-up:** N/A.	*Patients* • C had significantly greater recall of treatment information than I ($p<0.05$). • No significant difference between I and C for hypothetical treatment choice.
Saha and Beach 2011 [30] USA RCT	*Patients* **N**: 248 **Mean age (SD)**: IA: 57.8yrs (11.4) IB: 57.8yrs (10.4) **Males**: IA: 40% IB: 42% **Diagnosis**: CAD or risk factors for CAD. **Setting**: Hospital-based, adult primary care clinic in the Western United States.	*Patients* **IA (n=134):** Video-recorded, standardised vignettes depicting a cardiologist recommending bypass surgery. Contained empathetic statements, elicitation and validation of patient concerns, more exploration of patient context/individualised care, more rapport building and partnership statements, more patient education, lay language, positive affect, and high attentiveness/presence of the cardiologist. **IB (n=114):** Video-recorded, standardised vignettes depicting a cardiologist recommending bypass surgery. Contained less exploration of patient context /individualised	N/A.	**Measures:** *Patients* (i) Likelihood of undergoing surgery. **Follow-up:** N/A.	*Patients* • IA patients were significantly more likely to undergo surgery than IB ($p<0.001$).

		care, fewer report building and partnership statements, less patient education, biomedical/complex language, neutral affect, and low attentiveness/presence of the cardiologist. Did not contain empathetic statements, and elicitation and validation of patient concerns.			
Bernhard et al. 2012 [35] Australia and New Zealand (ANZ); and Switzerland, Germany and Austria (SGA) Cluster RCT	*Patients* **N**: 769 **Median age**: *SGA:* C: 58 I: 58 *ANZ:* C: 50.5 I: 53 **Males**: Not reported. **Diagnosis**: Breast cancer. **Setting**: 20 major cancer centres or clinics in ANZ, and SGA. *Providers* **N**: 62 **Age (median)**: *SGA*: C: 33 I: 34 *ANZ*: C: 47 I: 44 **Males**: 42%	*Providers* **I (n=31):** 7-h interactive face-to-face training workshop with 1-2 follow-up telephone calls over 2 months. The evidence-based training incorporated presentation of principles, a video modelling ideal behaviour, role-play practice, and feedback. Training focused on 4 key concepts: ensure a SDM framework; structure information into a sequence or order; ensure the inclusion of different, specific types of information in a clear manner; and consider the disclosure of specific controversial information and avoid coercive communication. **C (n=31):** Received no training workshop.	For each provider, two audio-taped consultations were transcribed and analysed by the research team.	**Measures:** *Patients* (i) Satisfaction with decision; (ii) knowledge; (iii) DCS. **Follow-up:** 2 weeks and 4 months.	*Patients* • Overall, no significant differences between I and C for satisfaction with decision, knowledge, or decisional conflict. • In the ANZ cohort, I reported a significant decrease in decisional conflict post-intervention compared to pre-intervention (SMD 0.11, SE 0.11).
Krones et al. 2008 [34] Germany Cluster RCT	*Patients* **N**: 1132 **Mean age (SD)**: I: M=59.1 yrs (12.3) C: M=58.6 yrs (12.5) **Males**: I: 42% C: 45.5% **Diagnosis**: Risk of CVD. **Setting**: Family practices in Germany. *Providers* **N**: 91	*Providers* **I (n=44):** Attended 2 x 2hr training sessions. The epidemiological background of global CVD risk calculation and the ethics of SDM were discussed. Practical communication strategies and materials for consultations were emphasized. Role playing and feedback from peers was also provided. **C (n=47):** Did not receive any training sessions, but were offered seminars on defined alternative topics that would not interfere with CVD prevention. *Patients*	Not specified.	**Measures:** *Patients* (i) Knowledge relevant to CVD prevention; (ii) Decisional Regret Scale. **Follow-up:** 6 months	*Patients* • I reported less decisional regret at 6 months' follow-up (SMD -0.09, SE 0.07, $p<0.05$) compared to C. • No differences in knowledge between I and C at follow-up (SMD 0.01, SE 0.06).

	Age: I: 41% >50 yrs C: 47% >50 yrs **Males**: I: 61.4% C: 55.3%	**I (n=550):** A six step decision aid counselling structure was provided to patients by their physician. This included an invitation to participate in SDM, the provision of patient risk of CVD and prognosis, and discussion of treatment options and their possible outcomes. **C (n=582):** Not specified.			
Edwards et al. 2004 [33] Wales Cluster RCT with cross-over	*Patients* **N**: 747 **Mean age (SD)**: Baseline – 59 yrs (11.5) IA – 59 yrs (10.9) IB – 58 yrs (11.4) Combined – 59 yrs (11.2) **Males**: Baseline – 39% IA – 39% IB – 41% Combined – 44% **Diagnosis**: Atrial fibrillation, prostatism, menorrhagia or menopausal symptoms. **Setting**: 20 rural and urban general practices. *Providers* **N**: 20 **Mean age**: 38 yrs **Males**: 60%	*Providers* **IA (n=11):** Attended 2 training workshops with skill development processes undertaken by using treatment outcome data presentations via various formats, discussions and participation and feedback in 2-3 pre-prepared consultations with simulated patients to acquire skills in risk communication and use of risk communication aids. **IB (n=9):** Attended 2 training workshops with skill development processes undertaken by using presentations, discussions and participation and feedback in pre-prepared consultations with simulated patients to acquire skills in SDM. **Combined I:** After phase 1 of the study period, providers in each group received training for the other intervention arm (i.e. IA received IB and vice versa). *Patients* **Baseline (n=201):** Appointments with providers pre-intervention. **IA (n=208):** Appointments with providers assigned to the IA group first. **IB (n=152):** Appointments with providers assigned to the IB group first. **Combined I (n=186):** Appointments with providers after they had received training from both IA and IB.	Random selection of consultations in research clinics were audiotaped for OPTION outcome measure.	**Measures:** *Patients* (i) Satisfaction with the decision made. **Follow-up:** 1 month; 6 months	*Patients* • No significant effects of IA or IB on satisfaction with the decision.

I: Intervention. C: Control. SD: Standard deviation. N: number of participants. RCT: Randomised controlled trial. SDM: Shared decision making. RC: Risk Communication. CVD: Cardiovascular disease. ANZ: Australia and New Zealand. SGA: Switzerland, Germany and Austria. DCS: Decisional Conflict Scale. CAD: Coronary Artery Disease. SMD: Standardised mean difference. SE: Standard error.

The remaining three studies that tested interventions aimed at improving provider communication skills were cluster RCTs. Two of these studies examined the impact of provider communications skills training on breast cancer patient outcomes[35] and patients at risk of cardiovascular disease (CVD).[34] Krones et al.[34] demonstrated that patients seeing healthcare providers who had undergone training reported lower decisional regret compared to patients seeing providers who had not received training, at 6 months' follow-up. In contrast, Bernhard et al.[35] reported no intervention effect for patient satisfaction with the decision, and decisional conflict at 4 months' follow-up. Neither Bernhard et al.[35] nor Krones et al.[34] demonstrated an impact on patients' knowledge, and met only two and four of the RoB criteria, respectively.

The third study, which met five RoB criteria, compared two different intervention conditions amongst patients with atrial fibrillation, prostatism, menorrhagia or menopausal symptoms, by using a cross-over cluster RCT.[33] Intervention conditions consisted of a shared decision making (SDM) workshop, and a risk communication (RC) workshop. In phase 1 of the study, healthcare providers were randomised to either SDM or RC workshops. Following completion of phase 1, providers then received training in the alternate workshop to which they were randomised (cross-over phase). Within each cluster, participating patients were also randomised to one of three time points: baseline, phase 1, or cross-over phase. Patient outcomes were measured immediately following the consultation and at 1 month, and 6 months' follow-up. No intervention effects on patients' satisfaction with the treatment decision were reported.

Patient-practitioner interventions

All three studies that aimed to improve both patient and provider communication included a patient-directed informational decision aid, two of which also included provider training in communication via examples and role-plays.[31, 32] The third study used printouts of patient risk information and treatment options, and prompts for intervention providers to discuss treatment options[36] (Table 4). Comparator conditions varied amongst the studies. Bieber et al.'s[31] RCT was conducted in two outpatient clinics. All healthcare providers at one clinic received communication training, while providers at the second clinic did not. Healthcare providers in both clinics were provided with a computer-based decision aid for patients with fibromyalgia syndrome. Patients were randomised to one of the two clinics: 1) computer-based decision aid alone, and 2) computer-based decision aid plus communication skills training for providers. No differences were found between groups for patient decisional conflict or satisfaction with the decision. This study scored six on the RoB assessment.

Table 5.4: Characteristics of interventions meeting EPOC methodological study design criteria directed at changing both patient and practitioner behaviour.

		Intervention Characteristics			
Reference Country Design	**Sample** N; Age; Gender; Diagnosis; Setting	**Intervention**	**Adherence to intervention**	**Outcome measures** **Follow-up**	**Results**
Bieber et al. 2008 [31] Germany RCT	*Patients* **N**: 85 **Mean age (SD)**: I: 49.5 yrs (11.3) C: 50.4 yrs (8.8) **Males**: I: 6.8% C: 9.8% **Diagnosis**: FMS **Setting**: 2 University rheumatologic outpatient clinics. *Providers* **N**: 10 **Mean age (SD)**: I: 30.8 yrs (2.3) C: 30.6 yrs (3.5) **Males**: I: 50% C:50%	*Patients* **I (n=44):** Computer-based visualized information package regarding FMS symptoms, treatment options, and prognosis, and consultation with physician trained in SDM communication. **C (n=41):** Computer-based visualized information package and consultation with physician not trained in SDM communication. *Providers* **I (n=4):** 12 x 1.5 hr training sessions for physicians focussed on patient-centred communication and interaction skills to enable SDM. Training included interactive talks, role plays and instructional videos. **C (n=6):** Usual care.	Provider adherence to protocol ensured through audiotape recording of consultations.	**Measures:** *Patients* (i) SWD; (ii) DCS. **Follow-up:** N/A.	*Patients* • No statistically significant difference between I and C for SWD (SMD 0.35, SE 0.22). • No statistically significant difference between I and C for DCS (SMD 0.07, SE 0.22).
Mann et al. 2010 [32] USA RCT	*Patients* **N**: 150 **Mean age (SD)**: I: 58 yrs (12) C: 58 yrs (SD=11) **Males**: I: 26% C: 25% **Diagnosis**: Diabetes. **Setting**: Primary care. *Providers* **N**: 108 **Age**: Not reported. **Males**: Not reported.	*Patients* **I (n=80):** Received the Statin Choice decision aid tool. Included a provider led discussion during their consultation of their tailored risks and benefits from using and not using a statin. Four steps were used including: discussion of heart attack risk factors, and patient's risk over next 10 years; review of risks of taking statin; and discussion of choices for next steps. **C (n=70):** Received printed materials from the American Diabetes Association on how to reduce cholesterol through diet. *Providers* All providers trained with a standard process using a video example and role-playing.	Not specified.	**Measures:** *Patients* (i) Knowledge of statins; (ii) DCS. **Follow-up:** 3 and 6 months (statin adherence only).	*Patients* • No difference in knowledge or overall DCS scores, at either follow-up between I and C.

Fraenkel et al. 2012 [36] USA Cluster RCT	*Patients* **N**: 135 **Age**: I: 58% were 75+ yrs C: 54% were 75+ yrs **Males**: I: 99% C: 98% **Diagnosis**: NVAF. **Setting**: Primary care clinics within the Veterans Affairs Connecticut Healthcare System. *Providers* **N**: Not reported. **Age**: Not reported. **Males**: Not reported.	*Patients* **I (n=69):** A computer-based decisional aid tool administered by a research nurse. The tool included education on the connection between NVAF and stroke, treatment options, and why treatment for NVAF involves choice. Participants were provided with individualised information regarding their risk of stroke and bleeding; discussed which option they thought was best for them and why; and provided with a printout of this information. **C (n=66):** Not reported. *Providers* **I:** Clinicians were provided with the patient's information printout and a prompt card to invite the patient to discuss treatment options. **C:** Not reported.	Consultations were audiotaped and trained coders assessed whether the prompt and printout was used during the encounter, and whether discussion on risks took place. The physician prompt was used in 83% of intervention encounters and participant printout was used in 48%.	**Measures:** *Patients* (i) DCS (Informed and Values clarity subscales); (ii) Knowledge of treatment options and adverse events. **Follow-up:** N/A.	*Patients* • I had significantly lower scores than C on informed (SMD -0.22, SE 0.17, p=0.01) and clarity (SMD -0.31, SE 0.17, p<0.001) subscales of the DCS. • I had significantly higher knowledge of medications (SMD 0.69, SE 0.4, p=0.001), risk of bleeding (SMD -0.24, SE 0.17, p=0.004) and risk of stroke (SMD -0.27, SE 0.17, p=0.002) compared to C. No significant difference in knowledge of side effects between I and C (SMD 0.35, SE 0.4, p=0.07).

I: Intervention. C: Control. SD: Standard deviation. N: number of participants. RCT: Randomised controlled trial. SDM: Shared decision making. FMS: Fibromyalgia syndrome. NVAF: Non-valvular atrial fibrillation. SWD: Satisfaction with Decision Scale. DCS: Decisional Conflict Scale. SMD: Standardised mean difference. SE: Standard error.

Mann et al.[32] used an RCT to examine whether use of a computer-based decision aid in addition to physician communication skills training resulted in improved outcomes, compared to physician communication skills alone, for patients with diabetes. No significant differences in knowledge or patient ratings of decisional conflict were found between the intervention and control groups. This study met only two RoB criteria.

Fraenkel et al.'s[36] cluster RCT, which met five RoB criteria, consisted of a patient-directed informational decision aid along with printouts and prompts for intervention providers treating patients with non-valvular atrial fibrillation. The comparator condition was not clearly described. Patients attending consultations with intervention providers reported significantly lower scores on the informed and values clarity subscales on the decisional conflict scale, and were more likely to correctly name treatment options and risk estimates, when compared to control patients. These findings indicate greater knowledge.

Effectiveness of interventions to improve patient-practitioner communication according to outcome

Five of the eight studies that measured patient knowledge reported significant differences between intervention and control groups[26-29, 36] (Table 5). One patient focussed,[27] and one[36] of three patient-practitioner focussed studies produced a significant effect on decisional conflict. Of the two studies that measured decisional regret, both reported positive findings.[26, 34] Three studies examined patient satisfaction with the treatment decision,[31, 33, 35] none of which reported results in favour of the intervention. Two patient[27, 28] and two provider-focussed[29, 30] studies examined the

treatment decision by patients, with only one provider study reporting a significant effect of the intervention.[30]

Table 5.5: Effectiveness of interventions to improve patient-practitioner communication according to outcome measured (significant finding/number of studies measuring outcome).

Intervention type	Number of interventions	Patient Outcomes				
		Decisional conflict	Decisional regret	Satisfaction with decision	Treatment decision	Knowledge
Patient [26-28]	**3**	1/1	1/1	0	0/2	3/3
Practitioner [29, 30, 33-35]	**5**	0/1	1/1	0/2	1/2	1/3
Patient-practitioner [31, 32, 36]	**3**	1/3	0	0/1	0	1/2

NB: a significant result at any follow-up time point within a study is reported here as a significant finding.

Types of treatment decisions examined in included studies

The disease of interest and subsequent treatment decisions varied amongst studies. Non-emergency treatment decisions were examined for cancer,[26, 27, 29, 35] heart disease,[30, 36] diabetes,[32] osteoarthritis,[28] CVD,[34] fibromyalgia syndrome,[31] and a mix of atrial fibrillation, prostatism, menorrhagia and menopausal symptoms.[33] None of the studies examined patient-practitioner communication involving treatment decision making under emergency conditions.

Discussion and Conclusions

To the authors' knowledge, this is the first review to examine the methodological quality and effectiveness of interventions in improving patient-practitioner communication when making treatment decisions. Eleven intervention studies met inclusion criteria. None of these studies examined treatment decision making in emergency situations. The limited number of intervention studies identified may reflect challenges inherent in conducting experimental research in this field.

Methodological quality of intervention studies examining patient-practitioner communication when making treatment decisions

None of the studies were low risk on all EPOC RoB criteria, with three studies being rated low risk on just two out of a possible nine criteria.[29, 32, 35] It is difficult to ascertain whether these scores are due to poor reporting or methodological weakness as these studies all had unclear ratings for five EPOC criteria. Caution is warranted when interpreting findings of these studies.

Six of the 11 studies received a rating of unclear regarding whether the allocation sequence was adequately generated. Numerous studies stated the sequence of participant allocation to condition was randomly generated; however, their method of doing so was not reported. Similarly, six studies did not clearly report whether baseline outcomes were similar between groups. Due to the nature of the review topic and outcomes (for example, decisional conflict), numerous studies[28, 30-34] did not include a baseline assessment prior to intervention implementation. The applicability of this criterion should be taken into consideration when evaluating interventions in which measurement of outcomes is only appropriate post-intervention.

Other biases identified within studies included healthcare providers not being blind to patient allocation;[27, 28, 31] and the same healthcare provider interacting with both intervention and control patients.[27, 28] In one study, all physicians administering both the intervention and control received communication training.[32] Unsurprisingly, this study did not report a significant effect on patient outcomes as contamination has the potential to reduce the effect size of an intervention due to inadvertent provision of intervention components to control participants.[23]

Few studies included a process of monitoring adherence to the intervention by patients or providers,[26, 31, 33, 35, 36] with only one study reporting the rate of adherence.[36] Without validation of participants' adherence to the protocol, it is not certain if and/or how the intervention was executed. Participant behaviour and adherence should be measured in order to accurately attribute study outcomes to the intervention and draw valid conclusions. Considerations are needed regarding reactivity (i.e. individuals altering their behaviour due to monitoring) and the measurement of differences in intervention execution both within and between clinicians and patients.

The lack of methodological rigour identified across studies may be indicative of difficulties in conducting intervention trials examining the impact of communication and decision making strategies. Nevertheless, there is a need for high-level evidence to guide development of recommendations about best-practice patient-practitioner communication.

Effectiveness of interventions to improve patient-practitioner communication when making treatment decisions

Decisional conflict: Both Whelan et al.'s[27] patient focussed decision aid and Fraenkel et al.'s[36] patient-directed decision aid with printouts and prompts for intervention providers, reported significant differences in intervention and control patient ratings on (effective decision making, and informed and values clarity) subscales of the decisional conflict scale. This provides some evidence that patient-directed, and patient–practitioner directed interventions might have potential for improving communication involving decision making. Use of a cluster RCT by Fraenkel et al.[36] compared to an RCT employed both Bieber et al.[31] and Mann et al.[32] may account for conflicting

findings between the three patient-practitioner directed interventions, as contamination between intervention and control participants may have occurred in Bieber et al.[31] and Mann et al.[32]. Since neither of these studies reported the rate of intervention fidelity, this interpretation cannot be verified.

Decisional regret: Two studies provided evidence that communication skills training interventions involving treatment decisions can reduce decisional regret.[26, 34] Mishel et al.'s[26] training was conducted with patients, while Krones et al.'s[34] training was directed at practitioners. These studies targeted different disease groups, cancer and CVD. These findings suggest communication skills training for either patients or practitioner may be effective in reducing decisional regret among various disease groups.

Satisfaction with the decision: None of the studies examining satisfaction with the decision reported a positive outcome.[31, 33, 35] All three of these studies provided communication training workshops to healthcare providers, suggesting this type of strategy has no effect on this outcome. Given that only two of these interventions included a process of monitoring adherence to the intervention[31, 33] and neither reported the rate of adherence, delivery of the intervention according to protocol cannot be guaranteed. The inevitable variability among healthcare providers in skill development, and application of these skills with each patient and in different clinical environments may contribute to this finding. Previous research suggests skills taught in provider training courses are not maintained in clinical practice.[37]

Treatment decision: Patient-directed interventions did not appear to influence treatment choice. The findings for provider-directed interventions, however, were mixed. Fogarty

et al.[29] reported no intervention effect on patients' treatment decision, while Saha and Beach[30] reported participants in the "high compassion" condition were more likely to undergo treatment when compared to the "low compassion" condition. Further comparison between these studies is limited due to differing treatment decisions (cancer and CAD). Never-the-less these findings highlight use of communication strategies that influence treatment decisions should be considered with caution. The impact of communication strategies on treatment decisions should not be examined in isolation from measures of quality of the decision making process, particularly for those decisions which may be irreversible or hold long-term consequences. To determine a strategy's effectiveness in improving patient-practitioner communication for decision making overall, we need to know if a communication strategy is also likely to produce a significant difference in the quality of the decision, as determined by measurement of outcomes such as satisfaction with the decision, and knowledge.

Knowledge: There is evidence to suggest communication interventions may have an effect on knowledge among individuals making decisions about cancer treatment.[26, 27, 29] Both patient-directed interventions were effective,[27, 28] while only one[36] of two patient-practitioner intervention studies found significant findings in favour of the intervention. Interestingly, one practitioner-directed intervention produced a significant finding for knowledge; however, the control condition produced higher knowledge scores than the intervention.[29]

Types of treatment decisions examined in included studies

No studies examined patient-practitioner communication involving treatment decision making for emergencies. Given heterogeneity in treatment decisions made in healthcare,

as well as additional challenges faced by patients, family members and practitioners when communicating treatment information under emergency conditions, the lack of experimental research conducted to guide clinicians is concerning. Testing communication strategies via use of hypothetical emergency scenarios may be a potential starting point for the generation of evidence. This approach allows for the testing of strategy efficacy prior to implementation in clinical practice, and therefore reduces the potential of adverse events.

Implications

While the current evidence-base for patient-practitioner communication involving treatment decisions is insufficient to inform clinical practice, this review highlights important areas of focus for future research. There is a gap in the evidence-base for reporting of interventions according to guidelines and standards (e.g. Consolidated Standards of Reporting Trials)[38] as evidenced by the number of studies receiving ratings of "Unclear" in the EPOC RoB assessment. Improved reporting of research methodology is needed to adequately assess bias, determine effectiveness, and replicate interventions to build a stronger evidence-base. Future research should consider incorporating measures of patient and provider adherence to the intervention to ensure execution of the intervention in accordance with protocols. Adherence may be monitored via use of audio or direct observations. However, such techniques may be susceptible to the Hawthorne effect,[39] that is, a change in behaviour in response to the awareness of being observed.

Studies were heterogeneous in terms of intervention strategies, target of intervention (patient, practitioner, or both), and disease type (cancer, fibromyalgia syndrome,

diabetes, osteoarthritis). No studies examined patient-practitioner communication in emergency treatment decision making. While a diverse range (decision, information, health, treatment, and communication-related) and large number (approximately 50) of outcomes were assessed in each study, only those relating to an informed (knowledge) and quality (decision regret, decisional conflict, satisfaction with decision) decision (treatment decision) were extracted. However, even when the same outcomes were assessed across studies (e.g. satisfaction with the decision), there was little consistency in the measures used. This heterogeneity limits the ability to draw conclusions regarding effectiveness of interventions. This raises two questions: 1) what constitutes effective patient-practitioner communication; and 2) how should this be measured? Consensus surrounding these issues is needed to identify the most important outcomes for measuring quality decision making. As patient preferences for consultation and decision making involvement vary,[40] this adds to the complexity in determining what constitutes effective patient-practitioner communication involving treatment decisions. There is some evidence to suggest patient-directed interventions, involving DVDs, information booklets and decision aids within the health provider consultation may be effective in improving patient knowledge. Exploration of these strategies in methodologically rigorous interventions is recommended.

Regardless of the participant focus, strategies employed, and disease or treatment options, it is clear that with few methodologically rigorous interventions identified for inclusion, additional studies evaluating the effectiveness of patient-practitioner communication interventions are required for both emergency and non-emergency treatment decision making.

Limitations

Search terms employed for the review may not have identified all relevant interventions. However, this is unlikely given the large number of articles identified. A university librarian reviewed the search strategy to ensure all relevant terms were used. Studies employing designs that do not meet EPOC design criteria, such as cohort studies, were not included. While these designs cannot provide evidence of the effectiveness of communication strategies, they may yield important findings regarding patient preferences for communication and decision making that were not incorporated into this review. Finally, the level of agreement between reviewers was not recorded when screening potentially relevant articles.

Conclusions

Few studies examined the effect of communication styles on patient outcomes for decision making. Despite the challenges of making a decision about treatment, there is little high-level evidence to inform the development of intervention trials, and recommendations about best-practice communication involving decision making. Given treatment decisions may have long-lasting adverse effects, and be required in emergency situations, it is imperative to develop an evidence-base to inform communication about treatment options. While it is acknowledged difficulties exist in conducting intervention research in this area, strategies to overcome these barriers need to be explored. There is some evidence to suggest patient-directed interventions may be effective in improving knowledge, however given the heterogeneity of studies, the overall effectiveness of these interventions on decision-related outcomes is unclear.

Acknowledgements: Dr Jamie Bryant is supported by an Australian Research Council Post-Doctoral Industry Fellowship. Dr Mariko Carey is supported by a National Health and Medical Research Council Translating Research into Practice Fellowship. We would like to acknowledge Dr Christopher Oldmeadow for his assistance with data analysis.

Conflicts of interest: None.

Authorship Contribution: AG, MC, JB, and RSF contributed to the conception and design of the review. AG conducted the literature search and screening of articles for inclusion. AG and BH performed the methodological quality assessments and data extraction. AG, MC, JB, and RSF contributed to the interpretation findings. AG drafted the manuscript with help from MC and JB. All authors contributed to the critical revision of the manuscript. All authors have given final approval of the version to be submitted.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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