



Three questions that patients can ask to improve the quality of information physicians give about treatment options: A cross-over trial

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ABSTRACT

Objective: To test the effect of three questions (what are my options? what are the benefits and harms? and how likely are these?), on information provided by physicians about treatment options.

Methods: We used a cross-over trial using two unannounced standardized patients (SPs) simulating a presentation of mild-moderate depression. One SP was assigned the intervention role (asking the questions), the other the control role. An intervention and control SP visited each physician, order allocated randomly. The study was conducted in family practices in Sydney, Australia, during 2008–09. Data were obtained from consultation audio-recordings. Information about treatment options and patient involvement were analyzed using the Assessing Communication about Evidence and Patient Preferences (ACEPP) tool and the OPTION tool.

Results: Thirty-six SP visits were completed (18 intervention, 18 control). Scores were higher in intervention consultations than controls: ACEPP scores 21.4 vs. 16.6, $p < 0.001$, difference 4.7 (95% CI 2.3–7.0) and OPTION scores 36 vs. 25, $p = 0.001$, difference 11.5 (95% CI 5.1–17.8), indicating greater information provision and behavior supporting patient involvement.

Conclusion: Asking these three questions improved information given by family physicians and increased physician facilitation of patient involvement. **Practice implications.** These questions can drive evidence-based practice, strengthen patient–physician communication, and improve safety and quality.

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1. Introduction

Patients need tailored information from their physicians about treatment and test options, including their risks and benefits and the likelihood of these occurring, to make informed health care decisions, and achieve informed consent. Provision of reliable and accurate information is an important part of high quality, patient-centered care [1], as it helps patients achieve a more active role in decisions about their care [2,3]. Providing information promotes evidence-based practice by bringing relevant evidence into the dialogue between clinician and patient. These strategies can

improve both experiences and outcomes of care [1,4–6], and have been endorsed in patient charters [7].

Healthcare agencies and consumer advocacy organizations have for several decades proposed using patient demand to promote professional behavior change, an approach now supported by clinical evidence [8,9]. For example, one recommends that patients ask questions to enable them to obtain information about and improve the quality and safety of the care they receive [10,11]. Patient-mediated approaches are now supported by some empirical evidence [8,9], but the effect of patients asking questions on the information provided in consultations needs further investigation.

Although randomized trials of question prompt lists (lists of questions for patients to ask) have shown mixed effects on consultations, some show an increase in question asking, particularly about difficult topics like cancer prognosis [12–15]. These trials have been neither specifically designed to support

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evidence-based shared decision-making, nor evaluated in terms of effect on the quality of information provided about treatment and test options for decision-making.

To address this issue we designed a study to test a short set of questions. These questions, developed from a consumer advocacy program Patient First Program, Western Australia, and a consumer health advice book *Smart Health Choices* [10], are designed to prompt physicians to provide information that patients need to make an informed choice between treatment options. The three questions are:

1. What are my options?
2. What are the possible benefits and harms of those options?
3. How likely are the benefits and harms of each option to occur?

These questions aim to elicit the minimum information needed for decision-making under conditions of uncertainty and to help organize the information that physicians give patients. They are based on principles of decision analysis [16], an approach used in other disciplines (such as health economics, engineering and aviation). When combined with an approach that enables patients to integrate this information with their own preferences, they should promote the aims of evidence-based shared decision-making [17], and act as a lever to drive evidence-based practice, if physicians are more likely to find and use evidence if patients ask them.

Our study was designed to test whether these three simple generic questions can increase the amount and quality of information that patients receive from physicians when discussing treatment options. We hypothesized that the intervention questions would (1) increase the amount and quality of information given by physicians when discussing treatment options, and (2) increase physicians' behaviors that support patient involvement.

2. Methods

2.1. Study design

We carried out a cross-over trial with family physicians, each acting as their own control to eliminate between-physician variation, as "proof of principle" test of the effect of the intervention [18].

Each physician was visited by two unannounced standardized patients, actors trained to portray a pre-specified patient presentation with high reliability [19]. One standardized patient delivered the intervention condition, by asking the three questions; the other acted as the control presenting with the same symptoms but not asking the intervention questions.

An additional question "What will happen if I do nothing?" was asked by the standardized patient delivering the intervention condition if this option was not offered by the physician. The standardized patients were trained to ensure consistency across all patient-physician encounters to control for patient-physician self-selection and accommodation, and to avoid ethical difficulties that might arise if real patients were employed.

2.1.1. Standardized patient roles

We developed a detailed patient presentation, adapted from one used in a prior study that demonstrated feasibility and high role fidelity [9]. The "patients" pretended to be an otherwise healthy divorced middle-aged female with a prior history of an undiagnosed episode of depression, and current symptoms of worsening mild to moderate depression over the past 1–3 months (see Appendix 1 for details). Presentations for the two roles (one which asked the questions, the other which did not) were identical except for minor differences in biographical information (e.g. name

and gender of children). This clinical presentation was chosen because (i) evidence on the condition and its management is readily available, and (ii) patients express different preferences for treatment, thus requiring shared decision-making. Two professional actors, (middle-aged, white, non-obese women) were trained to portray the roles. The intervention standardized patient asked the three questions; the control standardized patient did not ask the three questions but did ask other questions to portray a similar degree of assertiveness.

2.2. Study setting and participants

Practicing family physicians in Sydney, Australia were identified through the Medical Directory of Australia and Divisions of General Practice (local organizations representing family physicians). Recruitment was by invitations sent directly to recipients from researchers, or through an indirect Division of General Practice mail-out (number and identities of recipients unknown to researchers).

All participating physicians gave written informed consent to be visited by two unannounced standardized patients within a six-month period, without knowing when, and blinded to the specific intention of the study to test the effect of the questions. They were informed that the study was investigating patient-physician communication, and consented to covert audio-recording of these visits. At the end of the study they were debriefed about the detailed study purpose. The University of Sydney Human Research Ethics Committee approved the research protocol.

Family physicians were offered visit reimbursement of A\$100 and could accrue Continuing Medical Education points from the Royal Australian College of General Practice. The trial was registered Australian New Zealand Clinical Trials Registry no. 12609001033235.

2.3. Study procedures

Each standardized patient made one unannounced visit to each of the participating family physicians. The order of the standardized patient visits (intervention vs. control) was allocated randomly. The study coordinator booked appointments for 34 of the 36 visits; 2 visits were not pre-arranged due to a "walk-in" clinic procedure at one practice. Administrative staff within the clinics colluded with the study coordinator to ensure the SP visit was not detected prior to the consultation and to manage the different billing procedures. Australian billing procedures mandated that most family physicians would become aware of the standardized patient visit soon after the consultation or by the end of the day. Accordingly they were asked afterwards to report whether they had detected the standardized patient before, during or after the consultation, and similarly standardized patients recorded whether they believed they had been detected. The consultations were covertly audio-recorded using digital recorders hidden in the purse of the standardized patients, and later transcribed verbatim, and their lengths recorded.

2.4. Study outcomes

We were unable to identify any suitable measures of the quality and content of information about options so we developed the Assessing Communication about Evidence and Patient Preferences (ACEPP) tool as part of this project (see Appendix 2) [20]. There are three domains in the ACEPP tool, covering (1) research evidence or information about the effects of intervention (treatments and tests), (2) patient preferences, and (3) patient clinical and social circumstances. The coding scheme is based on the occurrence and quality (basic or extended discussion) of communication in these

three domains. The three domains are coded using three subscales (subscales I, II and III), respectively. These domains capture the quality and amount of information important to decision-making that is discussed by a physician with a patient when treatment options are being considered and treatment decisions are made. The evidence/information subscale comprises two parts, subscale IA and subscale IB. This reflects the primary purpose of the study, which was to assess the nature and quality of the evidence/information provided by physicians, and therefore we coded this domain in more detail. Subscale IA codes the information given by physicians about options, outcomes and likelihoods of outcomes occurring. Subscale IB codes for other references the physician may make to the quality of evidence/information such as reference to randomized trials, systematic reviews, or guidelines and/or discussion about the importance of the quality of research on which the physician's information is based. Each subscale (IA, IB, II and III) is scored out of 10, giving a total score out of 40.

There is also a final subscale (subscale IV) which codes summary statements made by the doctor which integrate evidence/information AND patient preferences AND patient circumstances. Although we coded for the presence of such a summary statement if the physician made one, we did not include this coding as a score in the ACEPP tool because we reasoned it would essentially be double-counting, and it would unfairly disadvantage doctors who covered each domain well, but failed to summarize this information at the end of the consultation. We assessed inter-rater reliability of the ACEPP tool as part of the project.

To measure physician facilitation of patient involvement we used the Observing Patient Involvement (OPTION) tool, a 12-item, validated coding system of physician behaviors that facilitate patient involvement. Items are rated on a 0–4 scale and scores are transformed to give a total out of 100 [21,22].

The transcribed consultations were analyzed using ACEPP and OPTION by two trained coders who were not investigators on the study and blinded to the study purpose – specifically that this was an intervention study, nor any information about the intervention. For the OPTION analysis a second coder coded all transcripts independently. Discrepancies were discussed to reach an agreed score.

2.5. Statistical analysis

Demographics and characteristics of the sample were analyzed using descriptive statistics. We constructed random effects models to test the effect of the intervention on the mean Assessing Communication about Evidence and Patient Preferences (ACEPP) and Observing Patient Involvement (OPTION) scores [18] and to assess whether the reported detection of the standardized patient by the family physician had an effect on scores. We analyzed the subscales of the ACEPP scores using the signed rank test, and report these subscales using medians, given the possible non-Normality of these data.

We assessed intra- and inter-rater reliability of the ACEPP tool using intra-class correlation coefficients [23] and Bland-Altman

plots [24]. 13 (36%) of the consultations were dual-coded and 21 (58%) were coded twice by the same rater. Ratings were carried out approximately 10 weeks apart. The intra-class correlation coefficients for intra-rater reliability were 0.77(95% CI 0.38–0.93) (intervention consults) and 0.78 (95% CI 0.30–0.95) (control consultations), and for inter-rater reliability 0.80 (95% CI 0.48–0.94). The Bland-Altman plots showed no association between the difference between ratings and average ratings. There was only one consultation in each of the intra and inter-rater assessments where the ACEPP scores differed by more than 5 (implying a disagreement of 50% in one of the ACEPP components).

Sample size calculations were based on the change in the proportion of consultations at which evidence was discussed. This outcome was chosen, as we had no available data on the ACEPP score to guide the sample size calculations. We calculated that 50 paired consultations (25 intervention and 25 control) would be required in order to detect an increase in the proportion of consultations at which evidence was discussed from 0.15 to 0.45 with 80% power.

3. Results

3.1. Participating family physicians

Nineteen family physicians consented to participate. One was unable to complete the standardized patient visits because of institutional restrictions. The response rate for the direct mail recipients was 13%. Thirteen out of 18 participants were female, years since qualification ranged from 7 to 38 years. All practices were located in urban Sydney. Fourteen of the eighteen physicians worked in small practices, 4 or less physicians.

The intervention standardized patient asked the three questions as indicated. The optional fourth question, “what will happen if I do nothing?” was asked in 15 consultations.

3.2. Assessing effect of questions on outcomes

The score for the quality of the information that physicians gave, measured by the Assessing Communication about Evidence and Patient Preferences tool was higher in consultations where the questions were asked ($p < 0.001$) (Table 1). The ACEPP score was higher by 4.7 (95% CI 2.3–7.0) on average. Among the ACEPP subscales the median scores were higher for the intervention consultations for the “Presentation of evidence related to options” subscale and the “Consideration of patient preferences” subscale but not the “Discussion of other aspects of evidence” subscale and the “Consideration of patient circumstances” subscale.

Scores for physician facilitation of patient involvement measured using the OPTION tool were higher in consultations where the questions were asked ($p = 0.001$). The mean score was higher by 11.5 (95% CI 5.1–17.8) on average.

These effects occurred without any significant difference in consultation length, mean consultation lengths were 26 minutes for control and intervention visits.

Table 1
Effect of the questions on the quality of information about treatment options provided by family physicians.

Measure	Intervention	Control	Difference between means (95% CI)	Median difference	p-Value
Assessing Communication about Evidence and Patient Preferences (mean)	21.4	16.6	4.7 (2.3–7.0)		<0.001
Subscale IA: Evidence: Presentation of evidence related to options (median)	4.4	2.5		1.4	0.001
Subscale IB: Evidence: Discussion of other aspects of evidence (median)	2.0	0.0		0	0.38
Subscale II: Consideration of patient preferences (median)	6.0	4.0		3.0	0.005
Subscale III: Consideration of patient circumstances (median)	10.0	10.0		0	0.38
Observing Patient Involvement (OPTION) ^a (mean)	36	25	11.5 (5.1–17.8)		0.001

^a OPTION scores were transformed to give a score out of 100.

Table 2

Number of consultations where standardized patients were detected as reported as by the physician, and the standardized patient.

	Intervention consultations (n = 18)	Control consultations (n = 18)
According to family physician		
Detected	9	7
Not detected	9	11
According to standardized patient		
Detected	2	0
Not detected	16	18

Table 3

Change in Assessing Communication about Evidence and Patient Preferences (ACEPP) and physician facilitation of patient involvement (OPTION) score, and number of family physicians by detection status^a of standardized patient.

Control SP detected	Intervention SP detected	
	No	Yes
No		
ACEPP change	6	5
OPTION change	16	7
No. of family physicians	7	4
Yes		
ACEPP change	6	2
OPTION change	18	8
No. of family physicians	2	5

^a Detection status as reported by family physicians.

3.3. Detection of standardized patients

Family physicians in the intervention group reported detecting the standardized patients in 9 of the 18 consultations compared to 7 of the 18 of the control consultations. The standardized patients believed they were detected at only 2 of the 36 consultations (Table 2). There was no statistically significant effect of physicians' perceived detection of standardized patient on differences in either the quality of information about treatment options (ACEPP) scores ($p = 0.14$) or patient involvement (OPTION) scores ($p = 0.44$) (Table 3).

4. Discussion and conclusion

4.1. Discussion

This study tested a simple intervention to increase information given by physicians about treatment options and showed that general practitioners gave more information about the benefits and harms of treatment options when prompted by three generic questions asked by patients. Our data also show that the intervention increased family physician consideration of patient preferences about treatment options, thus facilitating patient involvement. These significant and valuable effects were achieved by a minimal intervention without increasing consultation length and suggest that consumer question asking is a potentially powerful intervention for affecting physician behavior.

4.1.1. Limitations

The reliability of our new measure, the Assessing Communication about Evidence and Patient Preferences (ACEPP) tool, to capture the quality of information given by physicians was good, however this is expected in a small sample and in a controlled homogenous group of clinical consultations.

The family physicians in our study detected the unannounced standardized patients more frequently than reported in most unannounced standardized patient studies. In previous studies, detection of unannounced standardized patients ranges from 0 to

70% although most report rates of less than 15% [25]. Reasons may include the short time between visits, and the similar clinical presentation of the study roles. While we acknowledge this higher detection rate, detection of the standardized patients would not be expected to adversely affect our results as participants were blinded to the specific study purpose, so could not have adjusted their behavior in ways that would have positively biased our outcomes. Furthermore, the effect of the questions on consultations was similar whether the standardized patients were detected or not and actually appears to be greater when standardized patients were *not* detected, suggesting we may have underestimated the effect of questions.

Our response rate is similar to other opt-in studies [26], and is comparable to studies recruiting family physicians as participants, with response rates of 2–31% [27–32]. One local study on the effectiveness of strategies to encourage family physicians to access free online evidence-based information reported a 10% response rate [33]. Studies using unannounced standardized patients have either not reported recruitment response rates or have reported recruitment response rates of 50–60% [25,34].

Our sample had more female than male family physicians although the Australian family physician population is approximately 33% female [35]. This may reflect greater female interest in communication issues, as our sample is likely to be those interested in patient–physician communication. As participants were blinded to the study purpose it is plausible that the intervention effect could be also expected in consultations with other physicians. However, we acknowledge it is possible that family physicians who declined to participate in the study would be less inclined than our participants to respond positively to patients who ask questions.

4.1.2. Comparison with other studies

Our findings extend those of a study designed to assess the effect of patients' explicit requests for medication based on direct to consumer advertising for anti-depressants [36]. That study found that an explicit request for medication for depression improved depression care. Both studies indicate that consumers asking targeted questions can positively and substantially influence physician behavior. In contrast to specific treatment-related requests described by Young et al. [36], our study used a generic intervention that might be applicable across clinical conditions, and demonstrated positive effects on information provision and patient involvement, also within the context of depression care as an exemplar of the intervention's use.

Our study appears to fill an important gap in promoting evidence-based shared decision-making. Previous interventions have focused on either patients or clinicians. Butow et al.'s study [37] showed that endorsement by physicians of patient question-asking increased the effect of their consultation preparation package; whereas our study supports the possibility of the patient being a powerful agent of physician behavior change. Systematic reviews suggest that decision support interventions for patients such as question prompt lists, coaching [15,38], and decision aids [39] increase question asking, knowledge, patient involvement and informed choice. However, these tools have not been widely adopted, do not exist for all health problems or clinical situations, can take considerable time and resources to develop, and require regular updating as new evidence becomes available. One study testing a consultation preparation package for consumers that included a question prompt list and pamphlets on patients' rights and responsibilities and how treatment decisions are made did *not* increase information requested by patients or given by oncologists about evidence to support treatment options [37].

Results of previous studies evaluating interventions designed to increase uptake of evidence-based practice have been

disappointing [40]. Studies evaluating physician training in shared decision-making show positive effects on patient involvement [30]. One of these showed similar significant changes in the OPTION score in consultations after training [32]. While a successful and important part of physician training, these training programs are resource intensive. Our brief intervention not only prompts physicians to increase patient involvement, but directly and within any consultation in which patients ask these questions. It is worth exploring further because of potential advantages in terms of cost-effectiveness, generalisability to numerous clinical conditions and sustainability.

4.2. Conclusion

We have demonstrated powerful effects of three simple questions on physicians' communication about information related to treatment options and on physicians' encouragement of patient involvement in decisions. Patients received higher quality information about therapeutic options and their benefits and harms without increasing consultation length. The promotion of question asking by patients is potentially simple, inexpensive and sustainable. By promoting a patient-centered approach and shared decision-making, these simple questions may also work as a lever to drive evidence-based practice, helping physicians to make better decisions with patients, strengthen patient-physician communication, and improve safety and quality of care.

4.3. Implications for practice and future research

These three questions appear to have potentially important effects on clinical consultations, particularly given the minimal nature of the intervention. We do however not know how readily ordinary patients would learn and ask the questions in routine healthcare situations. Thus a proportionate investment in developing tools and supports to prompt patients to ask the questions may be warranted.

Role of the funding sources

The design, conduct, data collection, analysis and interpretation of the results were performed independently of the funders. The funders played no role in the review or approval of this manuscript.

Conflicts of interest

All authors declare they have had; no financial support other than their employer; no financial relationships with commercial entities that might have an interest in the submitted work in the previous 3 years; no financial relationships that may be relevant to the submitted work; and no non-financial interests that may be relevant to the submitted work.

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Appendix 1. The standardized patient roles

We developed a detailed clinical role and two psycho-social biographies for the study.

The role was that of middle-aged female with symptoms of mild to moderate depression. She had no chronic physical or psychological problems. She worked part time, was divorced and had had one previous undiagnosed episode over 20 years ago. She had been feeling down for the last 1–3 months, but had felt worse in the last two weeks. She portrayed lack of interest and involvement in usual activities, low energy, reduced appetite and poor sleep. She did not portray or report confusion, agitation, or suicidal thoughts. This clinical presentation was chosen to due to (i) evidence on the condition and its management being available and which clinicians are likely to be familiar with, and (ii) patient preferences vary, thus providing scope for exploration of preferences, and variation in decisions achieved by shared decision-making from patient to patient.

The two psycho-social biographies were Susan Parker and Patricia Sully. While remaining faithful to the clinical role, these biographies differed in their details. For example, they had slightly different occupations, the names, ages, gender of their children were different, their social histories were slightly different. Two professional actors (middle aged, white, non-obese women) were trained to portray these women and were able to do so convincingly and reliably. They were trained to portray a very similar degree of severity of depression. The intervention SP (Susan Parker) asked the consumer questions; the control SP (Patricia Sully) did not ask the intervention questions but did ask other questions to portray a similar degree of assertiveness.

Appendix 2. The Assessing Communication about Evidence and Patient Preferences (ACEPP) tool

The framework of the Haynes model describes evidence-based decision-making as the integration of clinical expertise, patients' clinical state and circumstances, patients' preferences and action, and research evidence [41]. The role of communication is flagged as a challenging and vital element both in determining preferences and presenting information.

Step 4 of EBM, 'Applying the evidence', provides the framework for the ACEPP Tool. We have expanded and developed step 4 and interpret the demonstration of evidence-based decision-making as integration and communication of the three elements of EBM [17]. The ACEPP tool is designed primarily to measure the manner and extent to which clinicians communicate the evidence behind their recommendations for treatments or tests.

The ACEPP tool coding scheme captures the explicit integration of evidence with clinical expertise and patient preferences and values, in making a practice decision or change. The coding scheme is based on the occurrence and quality (basic or extended discussion) of communication in three domains: (I) research evidence about the effects of intervention (treatments and tests),

(II) patient preferences, and (III) patient clinical and social circumstances. These domains capture the quality and amount of information important to decision-making discussed by a physician with a patient when treatment options are being considered and treatment decisions are made.

DOMAIN I is about how evidence is communicated. This domain is divided into 2 parts.

- IA focuses on presentation of evidence related to options.
- IB focuses on communication about other aspects of evidence overall in the consultation.

DOMAIN II is about consideration of patient preferences

DOMAIN III is about consideration of patient's circumstances

SCORING. The ACEPP Coding scheme scores the 3 domains using 5 subscales.

SUBSCALE IA. Presentation of evidence related to options. Maximum score 8

This subscale codes discussion of treatment and test options, the possible outcomes (clear description of both benefits and adverse effects) and the probability of these benefits and adverse effects occurring, with distinction drawn between effectiveness described in words or numerically as event rates, relative risk reduction or absolute risk reduction.

SUBSCALE IB. Discussion of other aspects of evidence in consultation. Maximum score 5

This subscale codes references to evidence-based guidelines and discussion of the quality of any cited evidence. This includes reference to clinical practice guidelines, the quality of research evidence (systematic reviews and trials being better quality than observational studies), and the importance of research evidence as a basis for decision-making.

SUBSCALE II. Patient preferences. Maximum score 5

This subscale codes discussion of patient's expressed preferences regarding tests or treatment being considered.

SUBSCALE III. Clinical/Patient Circumstances. Maximum score 2

This subscale codes discussion or reference to clinical or social circumstances of the patient in the consultation and related to tests or treatments being considered.

The ACEPP Total is calculated by summing the individual components of subscales I–III.

Each subscale (IA, IB, II, III) is reported as a proportion (e.g. 5/8 for IA, 3/5 for IB, 1/5 for II and 1/2 for III). These proportions are then summed, with each subscale re-scaled to give a value out of 10, rather than 1, giving an ACEPP total score out of 40. SUBSCALE IV. Integration. Maximum score 3

This final subscale captures statements made by the clinician which integrate evidence/information AND patient preferences AND patient circumstances. Subscale IV, Integration is not included in the total ACEPP as this subscale summarizes information captured in subscales I–III.

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