Family Practice Vol. 21, No. 4 © Oxford University Press 2004, all rights reserved. Printed in Great Britain
Doi: 10.1093/fampra/cmh402, available online at www.fampra.oupjournals.org

Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice

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Edwards A, Elwyn G, Hood K, Atwell C, Robling M, Houston H, Kinnersley P, Russell I and the Study Steering Group. Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice. *Family Practice* 2004; **21:** 347–354.

Background. Shared decision-making (SDM) between professionals and patients is increasingly advocated from ethical principles. Some data are accruing about the effects of such approaches on health or other patient-based outcomes. These effects often vary substantially between studies.

Objective. Our aim was to evaluate the effects of training GPs in SDM, and the use of simple risk communication aids in general practice, on patient-based outcomes.

Methods. A cluster randomized trial with crossover was carried out with the participation of 20 recently qualified GPs in urban and rural general practices in Gwent, South Wales. A total of 747 patients with known atrial fibrillation, prostatism, menorrhagia or menopausal symptoms were invited to a consultation to review their condition or treatments. After baseline, participating doctors were randomized to receive training in (i) SDM skills; or (ii) the use of simple risk communication aids, using simulated patients. The alternative training was then provided for the final study phase. Patients were randomly allocated to a consultation during baseline or intervention 1 (SDM or risk communication aids) or intervention 2 phases. A randomly selected half of the consultations took place in 'research clinics' to evaluate the effects of more time for consultations, compared with usual surgery time. Patient-based outcomes were assessed at exit from consultation and 1 month follow-up. These were: COMRADE instrument (principal measures; subscales of risk communication and confidence in decision), and a range of secondary measures (anxiety, patient enablement, intention to adhere to chosen treatment, satisfaction with decision, support in decision making and SF-12 health status measure). Multilevel modelling was carried out with outcome score as the dependent variable, and follow-up point (i.e. exit or 1 month later for each patient), patient and doctor levels of explanatory variables.

Results. No statistically significant changes in patient-based outcomes due to the training interventions were found: COMRADE risk communication score increased 0.7 [95% confidence interval (CI) −0.92 to 2.32] after risk communication training and 0.9 (95% CI −0.89 to 2.35) after SDM training; and COMRADE satisfaction with communication score increased by 1.0 (95% CI −1.1 to 3.1) after risk communication, and decreased by 0.6 (95% CI 2.7 to −1.5) after SDM training. Patients' confidence in the decision (2.1 increase, 95% CI 0.7–3.5, $P < 0.01$) and expectation to adhere to chosen treatments (0.7 increase, 95% CI 0.04–1.36, $P < 0.05$) were significantly greater among patients seen in the research clinics (when more time was available)

Received 20 May 2003; Revised 20 October 2003; Accepted 10 March 2004.

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compared with usual surgery time. Most outcomes deteriorated between exit and 1 month later. There was no interaction between intervention effects.

Conclusion. Patients can be more involved in treatment decisions, and risks and benefits of treatment options can be explained in more detail, without adversely affecting patient-based outcomes. SDM and risk communication may be advocated from values and ethical principles even without evidence of health gain or improvement in patient-based outcomes, but the resources required to enhance these professional skills must also be taken into consideration. These data also indicate the benefits of extra consultation time.

Keywords. Primary care, randomized trial, risk communication, shared decision making.

Introduction

In the vision of partnership between patients and health care professionals, both parties contribute actively in decisions about treatments or care options,[1] thus moving away from the traditional paternalistic paradigm of decision making. Many of the justifications for this development come from ethical perspectives.[2] There is also some evidence about the benefits of greater patient involvement in decision making.[3] These include improved process measures (such as satisfaction with decisions and lower 'decisional conflict') and perhaps some evidence of improved health (mainly psychological) outcomes.[4]

Decision support is often provided in the form of 'decision aids' or 'shared decision making (SDM) programmes',[3] i.e. packages that provide information about the pros and cons of different treatment or care options in various ways. However, packages are often not used or recommended by professionals.[5] Professionals consistently cite a lack of time as a barrier to using decision aid packages.[6] There are likely also to be issues in terms of skill acquisition for successful involvement of patients in decision making.[7] The competences of sharing decisions have been proposed[8,9] (see Box 1). These are stages that professionals may use in their discussions with patients (not necessarily in sequence), but this is an area that is not covered in most communication skill training programmes.[10]

The competences listed in Box 1 show that there is a specific stage of portraying information about the risks and benefits of different options, otherwise termed 'risk communication'.[11] Whilst part of the process of involving patients, there is evidence that the concepts of SDM and risk communication are not inseparable. Patients frequently desire information about treatment options more than they desire involvement in the decision making itself.[12] This suggests that patients at least distinguish between the two concepts.

We undertook a cluster randomized trial, designed to evaluate the effects of SDM skills and the use of simple risk communication aids, separately and then in combination. The focus was on general practice consultations, reviewing treatments for established conditions, a context in which effects of risk communication interventions are likely to be greatest.[11] This latter focus was selected because many of the treatment decisions chosen for study were of high prevalence but relatively low incidence, making sample acquisition difficult if only new treatment decisions had been addressed. In view of the barriers cited above, the study also evaluated the effects of having more protected time in which to hold such consultations. This paper reports the patient-based outcomes, and the accompanying paper reports the effects on *processes* in the consultations.[13]

Box 1 *The competences of shared decision making*

Problem definition—clear specification of the problem that requires a decision.

Portray equipoise—that professionals may not have a clear preference about which treatment option is the best in the context.

Portray options—one or more treatment options and the option of no treatment if relevant.

Provide information in preferred format—identify patients' preferences if they are to be useful to the decision-making process.

Check understanding—of the range of options and information provided about them.

Explore ideas, concerns and expectations about the clinical condition, possible treatment options and outcomes.

Checking role preference— that patients accept the process and identify their decision-making role preference.

Decision making—involving the patient to the extent they desire to be involved.

Deferment if necessary—reviewing treatment needs and preferences after time for further consideration, including with friends or family members, if the patient requires.

Review arrangements—a specified time period to review the decision.

Methods

Subjects and setting

These and other methodological aspects are described in detail in the accompanying paper.[13] Twenty-one GPs from separate practices in Gwent, South Wales were recruited, though one dropped out after the baseline

phase of the study. Eligibility required them to have been in practice between 1 and 10 years, to have sufficient practice computerization for identification of relevant patients, and to be audio-taped in routine surgery consultations before the study. Patients were identified from practice registers with one of four conditions: non-valvular atrial fibrillation; prostatism; menorrhagia; and menopause-related problems, and were invited to attend a consultation for review of their condition or treatment(s). Patients were recruited to the study by mailing information and consent forms from the practices. The Gwent Local Research Ethics Committee approved the study.

Design and interventions

A randomized trial design with crossover was chosen to evaluate the two interventions (Fig. S1 available at *Family Practice* Online). Randomization was by cluster, i.e. by doctor. Within each cluster, patients were also allocated randomly to consult with the doctor at one of three time points in the study (baseline, first intervention phase or combined intervention phase). Randomization was conducted by the trial statistician (KH) using a random number generator, and implemented (still concealed) by the research officer (CA). A further randomization allocated patients to attend either in usual surgery time or in a 'research clinic'. This was characterized as 'protected time', with fewer interruptions and more time for each consultation (up to 15 min each), which were also audio-taped. The interventions for doctors comprised training workshops with simulated patients to acquire skills in either SDM skills or the use of the risk communication materials devised for the study.[14,15]

Outcomes

The patient-based outcomes used in the evaluation were selected on the basis of empirical evidence from consumers about the most important outcomes from SDM and risk communication.[16] They were as follows:

(i) COMRADE instrument (the principal measure)[17]
    risk communication subscale
    patient's confidence in the decision subscale
(ii) Anxiety (short form of Spielberger[18])
(iii) Enablement[19]
(iv) Health status (SF-12[20])
    mental subscale
    physical subscale
(v) Satisfaction with the decision made (single item)
(vi) Intention to adhere to chosen treatment (single item)
(vii) Patient's perceived support in decision (single item)

These therefore comprised a range of cognitive, affective and health outcome measures to capture a range of potentially important domains.[21,22]

All outcomes were assessed after the study consultation and 1 month later. The first questionnaire was given to the patient at the time and either completed before leaving or returned by post. The second questionnaire was administered by post, with a reminder if necessary after 2 weeks, and a second mailing after 4 weeks.

Sample size requirements

It is difficult to identify which of the above outcomes should be regarded as the most important and thus the primary measure.[23] Sample size calculations were based on providing 80% power (5% significance levels) to detect a change of 20 percentage points in either direction from a baseline of 50% for binary variables. This would require 125 in each comparison group, and represents a conservative estimate of power for continuous variables or for changes from higher or lower initial levels of binary variables.[24] Intra-cluster correlation (ICC) was likely in a study of doctor–patient communication. No relevant data about likely ICCs were available before this trial, but an ICC of 0.03 was allowed for in sample size calculations. After inflation for this ICC and some allowance for loss of patients from follow-up, the sample size requirements were 240 in each phase, 960 for the whole trial. Each doctor would consult with 48 patients: 12 in baseline, 24 in either the risk communication only or SDM only phase, and 12 in the final combined phase (see Fig. S1). [13] (Subsequently no intra-class correlation of patient-based outcomes was identified, so these samples provided allowance for lower sample recruitment, but maintained the power of the design.)

We sought a pool of 60 patients to achieve 48 patients per doctor accepting their appointments for the study. As consent rates (to a single mailed invitation) were just below 50%, 130 patients were identified from each practice register for approach.

Data processing and analysis

Scores on 11 items of COMRADE were reversed so that high scores indicated better outcomes. Scales were calculated as in the original scale development stages, using mean substitutions for up to five missing items.[17]

Analysis compared the baseline and single (SDM or risk communication) and combined intervention phases. With clusters of patients attending 20 doctors in the study, multilevel modelling was appropriate for all patient-based outcomes. Highly skewed variables such as enablement and anxiety were analysed after transformation to a (log) normal distribution. MLWin software was used.[25,26] Explanatory variables were entered as fixed effects in regression models for each of the nine outcomes, with the outcome score or rating as the dependent variable. The improvement of fit from allowing the effect to be random was also assessed. Using a reduction in the log likelihood of fit, a three-level

model was fitted with follow-up (i.e. exit questionnaire or 1 month later for each patient) at level 1, patient characteristics at level 2 and GP characteristics at level 3 to the data. The models assessed the extent to which variability in outcome could be explained by patient variables (age and condition), GP variables (age, gender and membership of the Royal College of General Practitioners) and the interventions (risk communication, SDM, both, the order received, and whether the consultation took place in normal or protected clinic time). This sequence *order* effect was entered as the last explanatory variable. Interactions between the two types of training and between research clinic and follow-up with the training were tested.

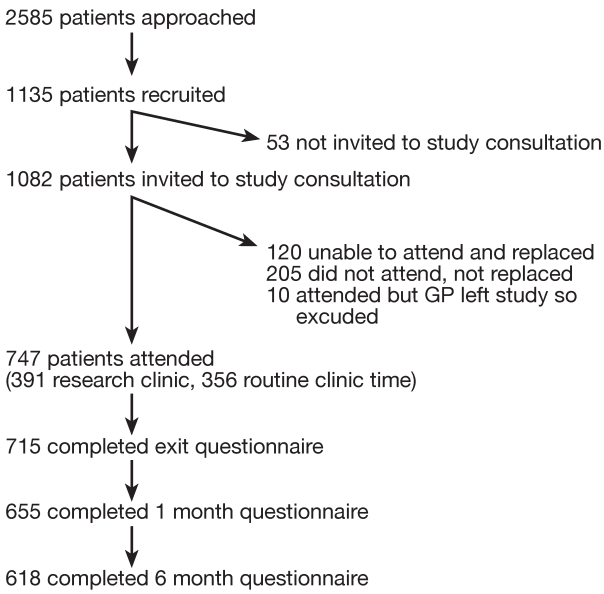

FIGURE 1 *Flowchart of patient progress through the study*

Results

Twenty-one out of 49 practices (42.8%) had a GP who agreed to participate, could have a surgery session audio-taped, and had sufficient practice computerization for patient identification. One doctor dropped out after the baseline phase. The remaining participating practitioners, 12 men and eight women, had an average age of 38 years. There was no difference between these characteristics and those of the eligible sample frame (101 practitioners with average age of 41 years, 62% male). Eighty percent of the participating clinicians had membership of the Royal College of General Practitioners, compared with 54% in the sample approached.

A total of 2585 patients were approached in the participating practices, and 1135 (43.9%) provided their consent to take part in the trial. The flow chart for patient progress through the study is shown in Figure 1. Patients were selected randomly to be sent appointments for the study, requiring 960 scheduled appointments, stratifying to maintain balance of study conditions. In reality, there were fewer available patients with atrial fibrillation, and the other groups made up the required numbers. If patients indicated that they could not attend despite prior consent, then further patients were selected randomly for invitation, again stratifying for study conditions. In the event, more patients with menorrhagia and menopausal symptoms could not or did not attend. The shortfall in patient numbers with menopausal symptoms was made up by replacement from others available, but this was not possible for patients with menorrhagia.

In all, 1082 patients were invited to study appointments, of whom 120 indicated they could not attend the scheduled date and 205 did not attend the study consultation. This left 757 study consultations attended. One doctor left the study after the baseline phase (10 consultations), leaving 747 patients for the main analysis of patient-based outcomes. The mean age of patients recruited and attending in each condition category was as follows: prostatic symptoms 63 years, atrial fibrillation 65 years, menorrhagia 45 years and hormone replacement therapy (HRT) 56 years. Further details regarding the numbers attending, the patients' ages, clinical condition and gender in each study phase (baseline, risk communication only, SDM only, and combined intervention phases), and questionnaire response rates are shown in Table 1. These did not show statistically significant differences between study groups.

Response rates and analysis of bias from non-attendance or non-response

The response rates for the patient questionnaires are also shown in Table 1. There were no data available on non-consenting patients to assess whether there were differences in characteristics from those consenting to participate. There were statistically significant differences in mean age between the 335 non-attenders and 747 attenders for the study (mean 54 versus 59 years; $P < 0.05$); there were more women among the non-attenders (81.7 versus 58.2%; $P < 0.01$); related to this, the proportions of the four conditions varied, with fewer patients with prostatism (19.0%) and atrial fibrillation (17.3%) and more with menorrhagia (25.8%) and menopausal symptoms (40.0%) among non-attenders than attenders ($P < 0.05$).

In analysing possible bias from non-response to questionnaires, no statistical tests were performed on the exit questionnaire because of the very high response rate. For the 1 month questionnaire, there were no statistically significant differences for age or condition type between the 655 responders and 92 non-responders.

Table 1 *Characteristics of patients in the different study phases*

	Baseline phase	RC only	SDM only	Combined intervention	Totals
No. of patients attending (% of total available)	201 (84%)	208 (87%)	152 (63%)	186 (78%)	747 (79%)
Mean age of attenders (SD)	59 (11.5)	59 (10.9)	58 (11.4)	59 (11.1)	59 (11.2)
% of male patients	39	39	41	44	41
Condition (*n*)					
Prostatism	52 (26%)	55 (26%)	43 (28%)	57 (31%)	205 (27%)
Atrial fibrillation	41 (20%)	39 (19%)	30 (20%)	37 (20%)	147 (20%)
Menorrhagia	42 (21%)	35 (17%)	30 (20%)	32 (17%)	136 (18%)
Menopausal symptoms	76 (38%)	79 (41%)	49 (32%)	60 (32%)	259 (35%)
No. of patients completing exit questionnaire (% of attenders)	197 (98%)	197 (95%)	146 (96%)	175 (94%)	715 (96%)
No. of patients completing 1 month questionnaire (% of attenders)	186 (92%)	169 (81%)	136 (90%)	164 (88%)	655 (88%)

Patient-based outcomes

Table 2 shows the effects on patient-based outcomes attributable to the risk communication and SDM interventions (columns 3 and 4), the effect of the research clinics with more time for consultations (column 5) and statistically significant co-variates from the multilevel models (column 6).

No statistically significant effects of the risk communication or SDM interventions were seen on the whole range of patient-based outcomes. In particular, the main effects of the trial interventions were that COMRADE risk communication scores increased 0.7 [95% confidence interval (CI) −0.92 to 2.32] for risk communication training; 0.9 (95% CI −0.89 to 2.35) after SDM training. COMRADE satisfaction with communication scores increased by 1.0 (95% CI −1.1 to 3.1) after risk communication, and decreased by 0.6 (95% CI 2.7 to −1.5) after SDM training.

However, significant effects of the research clinic (i.e. mainly the provision of more time) did lead to improvement in two of the outcomes [confidence in decision (2.1 increase, 95% CI 0.7–3.5, $P < 0.01$) and expectation to adhere to chosen treatments (0.7 increase, 95% CI 0.04–1.36, $P < 0.05$)]. Anxiety scores approached statistical significance for the risk communication intervention, as did expectation to adhere to chosen treatment for both interventions. In other outcomes, changes were arguably in the expected direction (such as increased COMRADE scores for risk communication and confidence, and feeling supported or overall satisfaction) after the risk communication intervention, though this pattern was not consistent. Furthermore, the analysis of ICC (see below) suggests higher power to detect changes than originally intended, so inferences drawn from such 'trends' in the data must be made with caution. Essentially, these data show no changes in patient-based outcome measures due to the interventions, but did show some improvement associated with the research clinic context for consultations.

Some other co-variates were identified. Regarding specific patient groups, women discussing HRT felt less supported in their decision making than patients in the other three condition categories; women with menorrhagia and patients with atrial fibrillation felt less 'enabled' to cope with their condition than patients in the other two categories.

Seven out of the nine models showed deterioration of outcome measures with 'follow-up' (i.e. from exit questionnaire to 1 month later). The two exceptions were anxiety and the SF-12 mental subscale. This may suggest that there was benefit for patients from attending study consultations in all the phases (even without the interventions or research clinic setting), which deteriorated as time went on, and this was detected by the outcome instruments at 1 month later.

Two statistically significant interactions were identified: between the SDM intervention and time elapsed from exit questionnaire to 1 month later. The deterioration in the confidence subscale of COMRADE and expectation to adhere to chosen treatments were greater in the patients who had seen a doctor trained in SDM. This may be the expected direction of effect (if any is detected) as the training encourages doctors to recognize elements of uncertainty in treatment choices. There were no interactions between risk communication and SDM interventions, or between either of these interventions and the research clinic setting (versus usual surgery time).

TABLE 2 *Results of modelling for patient-based outcomes*

Outcome	*n*	RC effect	SDM effect	Research clinic (more time)	Statistically significant co-variates
COMRADE confidence	1284	0.7 (0.81)	0.9 (0.81)	**2.1 (0.70)**	Follow-up: −1.7 (0.75)
COMRADE communication	1284	1.0 (1.05)	−0.6 (1.05)	1.8 (1.05)	Follow-up: −3.8 (0.67)
SF-12 physical[a]	990	−1.0 (0.96)	−0.5 (0.97)	−0.5 (0.96)	Patient age: −0.2 (0.05) Further education: 2.3 (1.02) Age left school: 3.5 (1.19) Condition-AF: −5.3 (1.34) Follow-up: −1.1 (0.36)
SF-12 mental[a]	1059	1.1 (0.78)	−0.3 (0.79)	0.3 (0.77)	Patient age: 0.2 (0.04) Further education: 2.8 (0.85)
Enablement (ln)	1268	0.0 (0.06)	0.0 (0.06)	0.0 (0.06)	Condition-AF: −0.2 (0.09) Condition-Men: −0.3 (0.09) Condition-HRT: −0.2 (0.08) Follow-up: −0.1 (0.03)
Anxiety (ln)[b]	1504	−0.04 (0.02)	−0.01 (0.02)	−0.04 (0.02)	Patient age: −0.003 (0.001) Further education: −0.05 (0.02) Age left school: −0.07 (0.03)
Support (binary)	1274	0.3 (0.26)	0.2 (0.26)	0.2 (0.26)	Condition-HRT: −0.9 (0.33) Follow-up: −0.4 (0.13)
Satisfaction (binary)	1286	0.5 (0.33)	0.1 (0.33)	0.5 (0.33)	Follow-up: −1.3 (0.13)
Expectation to adhere (binary)	1169	0.6 (0.35)	0.6 (0.36)	**0.7 (0.33)**	Patient age: 0.04 (0.02) Follow-up: −0.0 (0.22)

All results for effects of risk communication, SDM and research clinic interventions on the nine patient-based outcomes are presented (regression coefficients and SEs in parentheses), even though only two (highlighted in bold type) are statistically significant; only statistically significant interactions and co-variates are presented (follow-up identifies differences between scores at exit and at 1 month later).
Two interactions were statistically significant: SDM training by follow-up for the COMRADE confidence outcome [scores lower by 1.8 at follow-up (SE = 0.89) than in RC training] and also SDM by follow-up for expectation to adhere to treatment [scores 0.8 lower for SDM than RC at follow-up (SE = 0.29)].
The patient-based outcome data were analysed for evidence of intra-cluster correlation. For this doctor-level intervention, the coefficients were found to be zero for all the outcomes, thus the power to detect changes in outcomes was greater than in the original protocol.
[a] Fewer questionnaires available as calculation requires 100% complete data.
[b] More questionnaires available as includes assessment at 6 months after study consultation.

Discussion

Principal findings

This study found no improvement or deterioration in patient-based outcomes following skills-based interventions to UK GPs regarding SDM and risk communication. However, improvements in patients' confidence in decisions and expectation to adhere to their chosen treatments were evident with the provision of more time and a 'protected' environment (without interruptions, etc.) for consultations. Consistent with other literature,[27,28] most of the patient outcomes assessed here deteriorated with follow-up after the consultation, suggesting a general but short-lived benefit arising from these consultations. Given these changes, clinically significant changes in the patient-based outcomes appear unlikely following the risk communication and SDM training interventions to doctors. Even with the wide confidence intervals on these patient-based outcomes, including a possible positive effect, the power of the study appears likely to rule out a failure to identify a benefit of these interventions. These findings should be taken together with the evidence of substantial changes in the *processes* of consultations associated with these interventions.[13]

Strengths and weaknesses of the study

This study was explanatory in design.[29] It chose a group of doctors who were more likely to be familiar with the training methods used, and evaluated the interventions in two settings—'usual' practice and protected research clinics. The interventions used operational definitions for SDM and equipoise in order to (i) test whether it was possible to teach doctors to implement the former and (ii) give the best chance for patients to genuinely get involved, if they wanted to do so. There are clearly other contexts where SDM could take place, such as incident not prevalent conditions, but the issue here was to control the context for test purposes. As the interventions might influence clinical practice and patient outcomes more for incident conditions, the effects estimated here might be conservative. Bias was evident in the differences in patient characteristics between attenders and non-attenders and responders to

questionnaires versus non-responders. Patient satisfaction in the baseline phase was high, but even at these levels the outcome instruments had reasonable discriminant ability. Overall, the study had greater power to detect differences than in the original protocol, owing to the (almost) zero ICCs identified for patient-level data. This finding requires corroboration in further studies, as ICCs have been found elsewhere in primary care,[30,31] but may be important for future trials which may not require such large numbers.

The direction of effects anticipated

One concern at the outset was that the interventions, when implemented in clinical practice, might cause adverse outcomes. Sharing decisions may have disturbed some patients if they had previously perceived that there were clearly preferred treatments for their condition. The consequent uncertainty could have manifested as lower 'confidence in decisions' and lesser 'expectation to adhere to chosen treatment'. Similarly, when doctors discussed the benefits and particularly risks of certain treatment options, this could have caused higher anxiety levels, but significant adverse effects of the interventions appeared absent.

The context for implementation of shared decision making

Separate from the interventions, the benefits of longer consultations were supported. Co-intervention effects were possible here, as patients were exposed to more input from the research team in this setting (giving questionnaires, some selected for interviews, etc.). Even so, positive outcomes from the longer consultation setting were evident. Longer average consultation duration is associated with quality across a broad spectrum of measures, and more than just patient involvement,[32,33] and these data suggest that this extends also to SDM. Fundamental re-structuring of the way general practice-based primary care is delivered may be required, for example having fewer patients on doctors' practice lists, or modifications in demand/provision. If these are not possible, then SDM and risk communication approaches may be restricted to highly selected consultations.

As there was no evidence of major adverse effects on patients, one can advocate SDM from values and ethical principles.[2] Few developments however are worthwhile and to be implemented regardless of research evidence about effects, and cost-effectiveness of interventions to achieve them, and SDM is no exception. Debate is required about its priority, both in relation to other training interventions for communication skills and for broader health care interventions. A number of constituencies must contribute to this policy debate. Those most immediately involved are patients, patient or consumer advocate groups, health service managers, health policy makers and funders, and clinicians. Other groups who should also contribute to this debate include ethicists, economists and educationalists. People need to decide when they desire the SDM model of care and when the conventional evidence-based health care approach may be more desirable to achieve known benefits of interventions.

Implications for professional development and research

If the debate described above concludes that SDM approaches are still desirable, then the data from this study show that it is feasible for post-graduate doctors to acquire these skills and to use the risk information 'tools' in practice. There has been relatively little attention to the decision-making stages of consultations in traditional communication skills training.[10] The intervention was based on workshop models, with small group, experiential work-based learning.[14,15] This model is intensive to deliver but effective. From the individual GP's perspective, the time commitment involved in participating in the workshops is not unmanageable and doctors can acquire competence in this aspect of communication skills. Research is required to examine the sustainability of this competence. Future research should also assess the degree of performance in routine practice once doctors have acquired the competence. The effects of training, measured with patients over a series of consultations, should be evaluated to better reflect the real life implementation of decision-making approaches.

Performance usually fails to match competence for many skills.[34,35] This may reflect time constraints, as above, and perceived low patient expectations for involvement by doctors. Greater patient involvement is likely to come about if patients express greater desires and expectations for it.[7] Individual patients may generate this stimulus for patient involvement, but a key role in delivering policy initiatives in SDM may come from patient and consumer advocacy groups.[7] This may make SDM a reality for patients.

Acknowledgements

AE and GE designed and managed the study and were responsible for the interventions. CA was the principal research officer on the study. KH was the principal statistician. MR managed the trial data. IR also designed the trial and evaluation. In addition, the members of the trial steering group were as follows: Hazel Thornton (Independent advocate for quality in Health Care, Colchester, UK), David Cohen, Mirella Longo, Ruth Davis, Sue Thomas, Laurie Mosely, Donna Mead (all at School of Care Sciences, University of Glamorgan) and Roisin Pill. (Department of General Practice, University of Wales College of Medicine). For their contributions to the study and the drafting of this paper, joint authorship

is attributed to all. AE and GE are the guarantors of the study.

We thank the GPs and patients for their participation in the trial; Jill Bourne and Cathy Lisle for the ratings, Christine Farrell and Carolyn Davies at the Department of Health for their advice in the conduct of the study, Michel Wensing and Richard Grol for their work on the OPTION instrument, and Sheila Morris and Claire Darmanin for considerable secretarial work on the project. The authors also thank Clare Wilkinson, Richard Gwyn, Simon Williams and Lindsay Prior for their assistance and guidance at various stages. Funding for this study was provided by the Department of Health, Health in Partnership Programme.

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