

Original Article

Patient-doctor agreement on recall of clinical trial discussion across cultures

Running title: patient-doctor agreement on trial discussion

J. Bernhard,^{1,2} J. Aldridge,³ P.N. Butow,^{4,5} P. Zoller,¹
R. Brown,⁶ A. Smith,⁵ I. Juraskova⁴

Affiliations

¹ IBCSG Coordinating Center, Bern, Switzerland

² Department of Medical Oncology, Inselspital, Bern University Hospital, Bern, Switzerland

³ IBCSG Statistical Center, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute, Boston, USA

⁴ Centre for Medical Psychology and Evidence-based Decision-making (CeMPED), School of Psychology, University of Sydney, Australia

⁵ Psycho-Oncology Co-operative Research Group (PoCoG), University of Sydney, Australia

⁶ Department of Social and Behavioral Health, School of Medicine, Virginia Commonwealth University, Richmond, USA

Corresponding author

Prof. Jürg Bernhard, IBCSG Coordinating Center, Effingerstrasse 40, 3008 Bern, Switzerland, phone: ++41 31 389 93 91, fax: ++41 31 389 92 39, juerg.bernhard@ibcsg.org

Summary

Purpose: To investigate patient-doctor agreement on clinical trial discussion cross-culturally. **Methods:** In the International Breast Cancer Study Group Trial 33-03 on shared decision-making for early breast cancer in Australian/New Zealand (ANZ) and Swiss/German/Austrian (SGA) centers, doctor and patient characteristics plus doctor stress and burnout were assessed. Within two weeks post-consultation about treatment options, the doctor and patient reported independently, whether a trial was discussed. Odds ratios of agreement for covariables were estimated by generalized estimating equations for each language cohort, with doctor as random effect.

Results: In ANZ, 21 doctors and 339 patients were eligible; in SGA, 41 doctors and 427 patients. In cases where the doctor indicated “no trial discussed,” 82% of both ANZ and SGA patients agreed; if the doctor indicated “trial discussed,” 50% of ANZ and 38% of SGA patients agreed, respectively. Factors associated with higher agreement were: low tumor grade and fewer patients recruited into clinical trials in SGA; public institution, patient born in ANZ (vs. other), higher doctor depersonalization and personal accomplishment in ANZ. **Conclusion:** There is discordance between oncologists and their patients regarding clinical trial discussion, particularly when the doctor indicates a trial was discussed. Factors contributing to this agreement vary by culture. (200 words)

Key words

breast cancer; communication skills training; cross-cultural differences; patient-doctor agreement, shared decision-making

Introduction

Clinical trial discussions are challenging for both patients and doctors. Patient understanding of trial issues is poor.¹ Many patients have negative attitudes to trials, which may potentially compromise informed consent. These attitudes are a key issue to be addressed by doctors.² Both patients and doctors may be concerned about further issues, such as the admission of medical uncertainty or the relocation of the treatment decision from the doctor-patient relationship to computerized random assignment.³ Doctors may be reluctant to present the option of a trial to patients. Albrecht et al. reported on two urban, National Cancer Institute-designated comprehensive cancer centers, where only a minority (20%) of potentially eligible patients was explicitly offered a trial. When offered a trial, most patients (75%) agreed to participate.⁴

In trial discussions, the quality and quantity of communication between the oncologist, patient, and family or companion are important to the patient's decision-making process.⁴ The role of emotions regarding trial participation has rarely been investigated.^{5,6} In elderly cancer patients, the type of nurses' response to their emotions has been shown to impact on information recall.⁷ Whether such factors influence patients' decision-making is not known. One fundamental indication of whether information about trials has been adequately clear is whether there is agreement between the patient and the doctor on whether they discussed a trial at all. Disagreement on trial discussions may compromise informed consent. Further, if we can identify factors associated with such agreement we may be able to identify patient and doctor characteristics indicative of a need for greater care in explaining trials. This information may help tailor training in trial discussion for doctors.

Our objective was to cross-culturally examine agreement between patients with early breast cancer and their doctors regarding whether a trial discussion had taken place in consultations about adjuvant therapy. These consultations were studied within an international randomized controlled trial of a communication skills training to increase the quality of shared decision-making.⁸ We investigated factors related to patients, doctors and the local setting associated with patient-doctor agreement on trial discussion, and the association between patient-doctor agreement and patient

decision outcomes. In a subsample, we explored the association between this agreement and cognitive and emotional aspects of decision-making.

Patients, Doctors and Methods

The International Breast Cancer Study Group (IBCSG) conducted Trial 33-03 in centers in Australia and New Zealand (referred to as ANZ), and Switzerland, Germany and Austria (referred to as SGA), with the doctor as the unit of block randomization after stratification for center. The training consisted of a seven-hour interactive workshop with 1-2 follow-up telephone calls over two months. The elements of this training were evidence-based,⁹ incorporating presentation of principles,¹⁰ a video modelling ideal behaviour and role-play practice focusing on four key concepts: ensuring a shared decision-making framework; structuring information into a sequence or order; ensuring the inclusion of different, specific types of information in a clear manner; considering the disclosure of specific controversial information and avoiding coercive communication.¹⁰ The details are described elsewhere.⁸ The ethics committees of all participating centers (Appendix) approved the protocol.

Medical, surgical, radiation and gynaecological oncologists, involved in the treatment of patients with early breast cancer at major cancer centers or clinics (including private oncologists), and their patients for whom adjuvant therapy for breast cancer was indicated, were eligible. The following additional patient criteria were required: lower age limit of 18 years, adequate knowledge of the local language (English or German), and being mentally and physically capable of participating. Doctor participation was independent of previous or concurrent participation in other types of communication training.

Procedures and measures

After giving informed consent, doctors at participating centers were enrolled concurrently. Following baseline assessment and before the scheduled training workshop, they were randomly assigned to the experimental (training workshop) or control (no training workshop) group. Patients of enrolled doctors were recruited before their doctors were randomized (pre-randomization cohort) and after the workshop, if assigned, or at an equivalent time-point, if not assigned (post-

randomization cohort). Local staff identified eligible patients within a flexible time window of approximately 12 months in each randomization cohort. For each doctor, 5-10 patients were to be enrolled in the pre- and 8 or more in the post-randomization cohorts.

Trial outcomes were selected based on studies that evaluated decision aids designed to facilitate shared decision-making.¹¹ Two weeks before their initial consultation discussing treatment options, patients gave informed consent and completed a baseline questionnaire gathering demographics and self-report measures including state anxiety by Spielberger¹².

Two weeks after the consultation, patients were mailed a questionnaire with a pre-paid, addressed return envelope. In addition to the baseline measures, patients were asked whether a trial discussion had taken place in their consultation, besides other disease and treatment factors. The questionnaire further included measures of satisfaction with: a) decision¹³; b) consultation (adapted from Roter¹⁴ and Korsch et al¹⁵); and c) doctor communication regarding standard treatment options⁹ and clinical trials⁹; plus decisional conflict¹⁶. Patient measures were in English for ANZ and German for SGA centers. Prior to randomization doctors completed the Maslach Burnout Inventory (3 subscales: depersonalization, emotional exhaustion, and personal accomplishment) as used by Ramirez¹⁷ in English.

Further information was obtained within each language cohort. In ANZ centers, cognitive and emotional aspects of shared decision-making were coded in a subsample of audio-taped consultations, using the OPTION scale¹⁸, the RECC coding system¹⁹ and a rating for doctor blocking and facilitating behavior²⁰. In SGA centers, the doctors recorded the duration of each consultation.

Statistical analysis

We investigated factors associated with agreement between patients and their doctors regarding whether or not a trial was discussed. The primary endpoint, patient-doctor agreement, was defined at the patient level. Patients were dichotomized into those who agreed with their doctor about whether a trial had been discussed (agreement) and those who did not agree. Given the explorative nature of

this investigation, we chose a conservative approach to missingness: when either the doctor or the patient reported missing information for trial discussion, the patient was considered not to have agreement with her doctor. When both had missing information for trial discussion, patient-doctor agreement was considered missing, and the patient was excluded from the analysis. For reasons of consistency, we examined the proportion of agreement also in the subgroup of pairs without missing information. All analyses were presented separately by language cohort.

Baseline characteristics of doctors and patients were reported. Trial discussion responses were cross-tabulated by patients and their doctors. Odds ratios of patient-doctor agreement for selected covariables were estimated by generalized estimated equations (GEE), with doctor as a random effect. GEE was used to account for the clustering of patients within doctor and to ensure that the variability of parameter estimates and testing accounted for this effect. To determine which of the doctor and patient characteristics were to be considered in the models, two-sided Fisher's exact test was used to compare categorical variables between patient-doctor agreement groups, and two-sided Wilcoxon Rank-Sum test was used to compare continuous variables between these groups. Both the Fisher's exact test and the Wilcoxon Rank-Sum test assume independence of patients. Results from the Fisher's exact tests and Wilcoxon Rank-Sum tests were considered, and doctor and patient characteristics that differed between patient-doctor agreement groups were included in the initial model. Stepwise selection was used to determine the best GEE fit model. Odds ratios, standard errors, and 95% Confidence Intervals (CIs) of the covariates are reported. No alpha-adjustments were made because we intend our findings to be hypothesis-generating and therefore descriptive only, and p-values should be regarded as such.

Results

Sample description and patient characteristics

For the present analysis, 769 patients from 62 doctors were eligible. For three patients, both doctor and patient data regarding discussion of a trial were missing, leaving 766 patients. Ten patients had missing doctor assessments, and 65 patients had missing patient assessments. The doctors documented that a trial was available

in 68 patients (20%) from the ANZ cohort and in 150 (35%) from SGA cohort, respectively.

The baseline characteristics of eligible doctors are shown in Table 1. They were balanced between randomization arms. With a few exceptions, the baseline characteristics of eligible patients of these doctors were also balanced between randomization arms (Table 2, randomization arms not shown).

Patient-Doctor Agreement

The patient-doctor agreement on trial discussion is summarized in Table 3. These numbers do not account for the effect of multiple patients per doctor. The overall proportion of concordant responses regarding whether or not a clinical trial was discussed was 75% for ANZ and 66% for SGA. In patients without missing data, the corresponding proportions were 84% for ANZ and 72% for SGA.

In cases where the doctor indicated “trial not discussed,” 82% of both ANZ and SGA patients agreed. In those cases where the doctor indicated “trial discussed,” the agreement was lower, with 50% and 38% of ANZ and SGA patients agreeing, respectively. These findings were consistent in patients without missing data.

Predictors for patient-doctor agreement

The predictors for patient-doctor agreement in our GEE model are summarized in Table 4. In the ANZ cohort, treatment in a public institution was associated with better agreement ($P < 0.0001$). Patients born in New Zealand (vs. other; $P = 0.0004$) and Australia (vs. other; $P = 0.09$) showed better agreement. Doctors who indicated more personal accomplishment had better agreement ($P < 0.0001$). Those who indicated more depersonalization showed a marginal although statistically significant association with better agreement ($P = 0.01$).

In the SGA cohort, a lower tumor grade was associated with better agreement (grade 1 vs 2: $p = 0.002$; grade 1 vs 3: $P < 0.0001$). Those doctors who recruited less patients into clinical trials had better agreement with their patients ($P = 0.03$). When looking at percentages of patients, more patients with positive hormone receptor status, less positive lymph nodes, and less anxiety had better agreement, and patients' country

of birth and education were associated with agreement; however, these effects were no longer significant when accounting for multiple patients per doctor.

The remaining patient and doctor characteristics (Tables 1 and 2) were not associated with patient-doctor agreement in either cohort. In particular, there was no indication that agreement was influenced by the randomized communication intervention. The negative effect of a higher number of patients recruited into clinical trials by the participating doctors was not driven by those doctors recruiting no patients to clinical trials or by the number of patients the doctors enrolled into the present trial. A separate investigation of predictors according to agreement on “trial discussed” and “not discussed” showed little variation and was consistent overall (data not shown).

Patient-doctor agreement and patient decision outcomes

The association between patient-doctor agreement and patient decision outcomes (i.e., decisional conflict, satisfaction with decision, satisfaction with consultation, satisfaction with doctor communication overall and regarding a clinical trial) was investigated. Whether patients agreed or not with their doctors on trial discussion was not associated with patient decision outcomes in the ANZ or SGA cohort (data not shown).

Further explorative analyses

In the ANZ cohort, we explored cognitive and emotional aspects of shared decision-making based on blind interview ratings. Quantitative and qualitative data were available from 70 audio-taped consultations. After removing cases with incomplete transcripts (due to recording problems), or insufficient patient data (due to non-return of questionnaires), a total of 55 consultations from 20 doctors were assessable. No differences in demographics or patient outcomes were found between the 55 complete cases and the 12 cases with incomplete data.

A higher total number of emotional cues and concerns in the consultation (initiated either by the patient or doctor) was associated with less patient-doctor agreement ($P=0.04$; Table 5). A higher average level of the doctors' empathy in response to all cues and concerns showed a tendency in the same direction, with less empathy

being associated with better agreement ($P=0.09$). Of note, neither the doctors' level of behavior exhibiting competent shared decision making (OPTION) nor blocking or facilitating behavior were associated with patient-doctor agreement.

In the SGA cohort, the association between the duration of the consultation and patient-doctor agreement was explored. The median duration was 40 minutes ($N=415$, range: 15-125). There was moderate variation among Austrian, German and Swiss centers with a median (range) of 30 (15-90), 35 (15-125), and 60 (30-100) minutes, respectively. There was no association between duration of consultation and agreement.

Discussion

Two weeks after their consultation, a moderate percentage of doctors and their patients with early breast cancer were in agreement on whether or not they had discussed a clinical trial. Agreement includes the components of both "discussed" and "not discussed". The agreement between doctors and patients was good on "trial not discussed" but poor on "trial discussed". Thus, if a trial was introduced into the discussion as a real option, the recollection of this discussion clearly diverged between patients and their doctors. This observation was consistent between the ANZ and the SGA cohorts. It is suggestive of a selective patient perception that clinical trials are not discussed. Many patients may have perceived a trial as less important in this particular situation. Based on this assumption, we would expect an impact of patient-doctor agreement on actual decision-making.

Factors predicting patient-doctor agreement were not consistent between the ANZ and the SGA cohorts. In SGA, poorer prognostic factors and in particular a high tumor grade were associated with poorer agreement, perhaps because these factors made the trial discussion more demanding. It is possible that patients struggling with the bad news of a poor prognosis may have heard, understood and recalled less of the consultation.²¹ Less patients recruited into clinical trials by the doctor was also associated with better agreement in SGA only. Enrolling patients on a routine basis does not imply an increase in agreement. The reason for this unexpected finding was not determined by those doctors recruiting no patients into trials and, therefore, remains unclear.

The doctors' perceived personal accomplishment was associated with better agreement in ANZ only, as was treatment in a public institution and being born in the country of recruitment. It is possible that doctors who explain trials more clearly achieve not only greater agreement with their patients but also feel a greater sense of personal accomplishment. Patients not born in the country of recruitment, perhaps struggling with cultural and language differences, may find it harder to understand what their doctor is saying, including information about clinical trials.²² The differences between ANZ and SGA in factors associated with agreement point to the critical impact of cultural factors and the local setting, whereas doctor gender, age or the years of professional experience, and patient age were not related to agreement in either cohort.

In the ANZ cohort we explored the doctors' shared decision-making behavior and its association with agreement. It is important to note that this analysis was restricted to a selected and underpowered subsample for investigating multiple predictors by our GEE model. The less emotional cues and psychosocial concerns were emitted in the consultation, the higher the agreement on trial discussion. Doctors' empathy, a key communication skill, appeared to be rather hindering for this particular outcome. It is possible that with greater emotion present, patients were less able to focus on the discussion and recall what was said later. The patients who emitted more cues and concerns, and subsequently received more empathy, were more distressed. This has been shown to limit information recall.²³ Cognitive and emotional aspects of shared decision-making have different effects on various patient outcomes, as previously suggested in this subsample.²⁴

Agreement on trial discussions is likely to be higher if information provision is clearer. Clarity is enabled by short information units provided in a clear and explicit structure. Interestingly, since the duration of the consultation was not associated with agreement in the SGA cohort, simply talking longer does not appear to result in greater clarity and therefore greater agreement.

Our communication training did not affect patient-doctor agreement. A more targeted and intensive training is needed to ensure that clinicians are able to tailor their

consultations to their patients' information needs about treatment options and clinical trials. Elwyn et al have summarized the main conditions for shared decision-making to become part of mainstream clinical practice: ready access to evidence-based information about treatment options; guidance on how to weigh up the pros and cons of different options; and a supportive clinical culture that facilitates patient engagement.²⁵ We feel that these conditions are similarly significant for trial discussions. The impact of these conditions may be moderated by selected patient and doctor characteristics as suggested by our findings. As discussed elsewhere, we propose interventions more specifically adapted to local needs with individual follow-up based on real-time supervision of the doctors' communication with their patients.⁸ Skills uptake may be improved by practicing trial discussions related to a specific trial currently recruiting in the center.

Overall, our findings confirm that there is substantial discordance between oncologists and their breast cancer patients on treatment information conveyed and received.²⁶ Similar findings were reported in lung²⁷ and other cancer patients. Our study shows that this is true for clinical trial discussions also.²⁸

Several limitations have to be considered. Although the question on trial discussion has obvious face validity, it would need to be defined more exactly for a further investigation. For the particular setting of phase I trial discussions, Jenkins et al pointed recently to the omissions of important information, such as prognosis.²⁹ Audio recording as independent reference material, and thus a comprehensive analysis of concordance,^{27,30} was not feasible for our total sample. We have no information on whether patients received study information (handout with trial description, web-link, consent form), which may impact on patients' recollection of trial discussions. Finally, whether the doctors were more reluctant to clearly address the option of a trial because they felt monitored on their communication cannot be excluded.

In conclusion, there is discordance between oncologists and their patients regarding clinical trial discussion, particularly when the doctor indicates a trial was discussed. In contrast to well established international standards of clinical trial methodology, the discussion about trials is also related to the local setting and to cultural factors. These

issues are relevant for communication skills training and have not received sufficient attention in studies on decision-making in oncology. (3000 words)

Acknowledgments

This trial was a collaborative effort between the Centre for Medical Psychology and Evidence-based Decision-making, School of Psychology, University of Sydney, and the International Breast Cancer Study Group (IBCSG). It needed considerable logistic efforts.

We would like to thank the physicians who participated in the trial, the patients who took the time to complete the questionnaires, the data managers and local coordinators in the participating centers (see Appendix), and Peter Zoller, Cornelia Zuberbühler, Monika Dzidowska, Gwynneth Wong, Gina Bark and Anna-Lena Lopez for central trial coordination.

This study was orally presented at the International Psycho-Oncology Society (IPOS) World Congress, October 16–20, 2011, Antalya, Turkey.

Funding

We would like to thank the National Breast Cancer Foundation of Australia (no grant number), Oncosuisse/Swiss Cancer League (OCS – 01165-09-2001/KLS – 01648-02-2005), Deutsche Krebshilfe (106668) and IBCSG for funding this trial. The IBCSG Statistical Center (J.A.) is partially funded through a grant from the US National Cancer Institute (CA-75362)

Disclosure

The authors have declared no conflicts of interest.

References

1. Olver IN, Buchanan L, Laidlaw C, et al: The adequacy of consent forms for informing patients entering oncological clinical trials. *Ann Oncol* 6:867-70, 1995
2. Fleissig A, Jenkins V, Fallowfield L: Results of an intervention study to improve communication about randomised clinical trials of cancer therapy. *Eur J Cancer* 37:322-31, 2001
3. Jenkins V, Fallowfield L: Reasons for accepting or declining to participate in randomized clinical trials for cancer therapy. *Br J Cancer* 82:1783-8, 2000
4. Albrecht TL, Eggle SS, Gleason ME, et al: Influence of clinical communication on patients' decision making on participation in clinical trials. *J Clin Oncol* 26:2666-73, 2008
5. Todd AM, Laird BJ, Boyle D, et al: A systematic review examining the literature on attitudes of patients with advanced cancer toward research. *J Pain Symptom Manage* 37:1078-85, 2009
6. Luschin G, Habersack M, Gerlich IA: Reasons for and against participation in studies of medicinal therapies for women with breast cancer: a debate. *BMC Med Res Methodol* 12:25, 2012
7. Jansen J, van Weert JC, de Groot J, et al: Emotional and informational patient cues: the impact of nurses' responses on recall. *Patient Educ Couns* 79:218-24, 2010
8. Bernhard J, Butow P, Aldridge J, et al: Communication about standard treatment options and clinical trials: can we teach doctors new skills to improve patient outcomes? *Psycho-Oncology* Published online: DOI: 10.1002/pon.2044, 2011
9. Brown RF, Butow PN, Boyle F, et al: Seeking informed consent to cancer clinical trials; evaluating the efficacy of doctor communication skills training. *Psychooncology* 16:507-16, 2007
10. Brown RF, Butow PN, Butt DG, et al: Developing ethical strategies to assist oncologists in seeking informed consent to cancer clinical trials. *Soc Sci Med* 58:379-90, 2004
11. O'Connor AM, Stacey D, Entwistle V, et al: Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*:CD001431, 2003
12. Spielberger CD: *Manual for the State-Trait Anxiety Inventory STAI (Form Y)*. Palo Alto, CA, Consulting Psychologists Press, 1983
13. Holmes-Rovner M, Kroll J, Schmitt N, et al: Patient satisfaction with health care decisions: the satisfaction with decision scale. *Med Decis Making* 16:58-64, 1996
14. Roter D: Patient participation in the patient-provider interaction: the effects of patient question asking on the quality of interaction, satisfaction and compliance. *Health Educ Monogr* 5:281-315, 1977
15. Korsch BM, Gozzi EK, Francis V: Gaps in doctor-patient communication. 1. Doctor-patient interaction and patient satisfaction. *Pediatrics* 42:855-871, 1968
16. O'Connor AM: Validation of a decisional conflict scale. *Med Decis Making* 15:25-30, 1995
17. Ramirez AJ, Graham J, Richards MA, et al: Mental health of hospital consultants: the effects of stress and satisfaction at work. *Lancet* 347:724-8, 1996
18. Elwyn G, Hutchings H, Edwards A, et al: The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. *Health Expect* 8:34-42, 2005

19. Butow PN, Brown RF, Cogar S, et al: Oncologists' reactions to cancer patients' verbal cues. *Psychooncology* 11:47-58, 2002
20. Butow P, Cockburn J, Girgis A, et al: Increasing oncologists' skills in eliciting and responding to emotional cues: evaluation of a communication skills training program. *Psychooncology* 17:209-18, 2008
21. Jansen J, Butow PN, van Weert JC, et al: Does age really matter? Recall of information presented to newly referred patients with cancer. *J Clin Oncol* 26:5450-7, 2008
22. Butow PN, Sze M, Dugal-Beri P, et al: From inside the bubble: migrants' perceptions of communication with the cancer team. *Support Care Cancer* 19:281-90
23. Kessels RP: Patients' memory for medical information. *J R Soc Med* 96:219-22, 2003
24. Smith A, Juraskova I, Butow P, et al: Sharing vs. caring-The relative impact of sharing decisions versus managing emotions on patient outcomes. *Patient Educ Couns*
25. Elwyn G, Laitner S, Coulter A, et al: Implementing shared decision making in the NHS. *Bmj* 341:c5146
26. Brown RF, Hill C, Burant CJ, et al: Satisfaction of early breast cancer patients with discussions during initial oncology consultations with a medical oncologist. *Psychooncology* 18:42-9, 2009
27. Gabrijel S, Grize L, Helfenstein E, et al: Receiving the diagnosis of lung cancer: patient recall of information and satisfaction with physician communication. *J Clin Oncol* 26:297-302, 2008
28. Albrecht TL, Egly SS, Gleeson MEJ, et al: Influence of clinical communication on patients' decision making on participation in clinical trials. *Journal of Clinical Oncology* 26:2666 - 2673, 2008
29. Jenkins V, Solis-Trapala I, Langridge C, et al: What oncologists believe they said and what patients believe they heard: an analysis of phase I trial discussions. *J Clin Oncol* 29:61-8
30. Albrecht TL, Penner LA, Cline RJ, et al: Studying the process of clinical communication: issues of context, concepts, and research directions. *J Health Commun* 14 Suppl 1:47-56, 2009

Table 1:**Baseline characteristics for eligible doctors by culture**

	Australia/New Zealand		Switzerland/Germany/Austria	
	<i>N</i>	%	<i>N</i>	%
<i>N</i>	21	100	41	100
Gender				
Male	11	52	15	37
Female	10	48	26	63
Specialty				
Medical Oncology	12	57	11	27
Radiology	6	29	-	-
Surgeon	3	14	4	10
Gynaecologist	-	-	26	63
Institution				
Public	14	67	40	98
Private	-	-	-	-
Both	7	33	-	-
Previous training in communication skills	11	52	10	24
	med	(range)	med	(range)
Age, median (range)	46	(33, 62)	34	(24, 48)
Previous years of practice, median (range)	19	(2, 37)	6	(1, 24)
Ave. number of patients per doctor recruited to trials over 6 months, median (range)*	10	(3, 50)	15	(3, 200)
Burnout**				
Depression	21.3	(0, 55.3)	21.3	(0, 76.5)
Emotional Exhaustion	28.9	(5.8, 62.1)	23.8	(7.2, 65)
Personal Accomplishment	76	(40, 84)	68	(36, 84)

*refers to any trial, 6 SGA doctors have missing recruitment information

**9 SGA doctors have missing burnout information

Table 2:
Patient baseline characteristics by culture, for assessable patients

	Australia/New Zealand		Switzerland/Germany/ Austria	
	<i>N</i>	%	<i>N</i>	%
N	339	100	427	100
Stage of Tumor				
Missing	8	2	10	2
Localized (node negative)	196	58	267	63
Advanced (node positive)	135	40	150	35
Number of Nodes				
Missing	8	2	10	2
0	196	58	267	63
1-3	85	25	73	17
4-10	27	8	44	10
>10	8	2	12	3
Unknown	15	4	21	5
Grade of tumor				
Missing	16	5	11	3
1	68	20	58	14
2	142	42	184	43
3	113	33	174	41
Hormone receptor status				
Missing	-	-	-	-
Negative	77	23	78	18
Positive	218	64	328	77
Unclear at time of consultation	39	12	15	4
Country of birth				
Missing	-	-	14	3
Australia	161	47	-	-
New Zealand	78	23	-	-
Switzerland	-	-	90	21
Germany	-	-	165	39
Austria	-	-	105	25
Other	99	29	52	12
Language				
Missing	-	-	5	1
English	307	91	3	1
German	-	-	380	89
French	-	-	3	1
Italian	-	-	7	2
Other	31	9	29	7

	Australia/New Zealand		Switzerland/Germany/ Austria	
	<i>N</i>	%	<i>N</i>	%
Medical Training	73	22	66	15
Education				
Missing	9	3	16	4
Did not graduate HS or equivalent	109	32	165	39
HS diploma or equivalent	135	40	182	43
University degree	57	17	59	14
Graduate degree	29	9	5	1
	med	(range)	med	(range)
Age, median (range)	52	(27, 83)	58	(24, 88)
Tumor size, median (range)	2	(0.1, 40)	2	(0, 12)
Anxiety**, median (range)	44	(20, 80)	45	(20, 78)

**Anxiety was measured pre-consultation

Table 3:
Cross tabulations of patient-doctor agreement information on trial being discussed by language cohort, for all patients

ANZ	Patient(below)\ Doctor (right)	Missing	Trial not discussed	Trial discussed	Total
	Missing	-	26	7	33
	Trial not discussed	3	219	27	249
	Trial discussed	1	22	34	57
	Total	4	267	68	339**
SGA	Patient(below)\ Doctor (right)	Missing	Trial not discussed	Trial discussed	Total
	Missing	-	24	8	32
	Trial not discussed	4	225	84	313
	Trial discussed	2	24	56	82
	Total	6	273	148	427*

*Excludes 2 patients with both doctor and patient assessments missing

**Excludes 1 patient with both doctor and patient assessments missing

Table 4:
Odds ratios for patient-doctor agreement vs disagreement. Generalized
Estimated Equations by language cohort for eligible doctors and their
assessable patients*

Cohort	Variable*	Odds Ratio	Standard Error	Lower Confidence Limit	Upper Confidence Limit	P-value
ANZ	Public only vs. Private/Public institute	3.67	1.17	1.96	6.86	<.0001
	Born in Australia vs. Other	1.58	0.43	0.92	2.68	0.09
	Born in New Zealand vs. Other	3.01	0.94	1.64	5.56	0.0004
	Doctor burnout, depersonalization [†]	1.03	0.01	1.01	1.05	0.01
	Doctor burnout, personal accomplishment [†]	1.04	0.01	1.02	1.06	<.0001
SGA	Tumor Grade 1 vs. 2	2.98	1.06	1.48	5.99	0.002
	Tumor Grade 1 vs. 3	3.65	1.18	1.94	6.88	<.0001
	Ave. num. of patients per doctor recruited to trials over 6 months: ≤5pts vs. >5pt	2.01	0.64	1.08	3.76	0.03

* Accounting for randomization group and pre- or post-randomization cohort

[†] For Doctor burnout variables, depersonalization and personal accomplishment, higher scores correspond to higher degrees of experienced burnout. Thus, an odds ratio >1 indicates that the odds of agreement increase when the average response score increases by one unit [Doctor depersonalization range: 0 – 102; Doctor personal accomplishment range: 0 – 84].

Note: The ANZ cohort includes 21 doctors and 339 patients. The SGA cohort includes 41 doctors and 427 patients.

Table 5:
Odds ratios for patient-doctor agreement vs. not, Generalized Estimated Equations for assessable ANZ audio-taped consultation participants only, five separate models*

Model*	Variable in Model*	Odds Ratio	Standard Error	Lower Confidence Limit	Upper Confidence Limit	P-value
OPTION	Observing Patient Involvement scale [†]	0.95	0.037	0.88	1.02	0.17
RECC (a)	Total number of Emotional cues and concerns ^{††}	0.83	0.079	0.69	1.00	0.04
RECC (b)	Ave. level of empathy expressed across all cues ^{††}	0.26	0.206	0.05	1.23	0.09
Blocking	Blocking Behavior					
	High vs. Low	3.41	3.081	0.58	20.03	0.17
	High vs. Med	1.36	1.097	0.28	6.60	0.70
	Med vs. Low	2.50	2.028	0.51	12.26	0.26
Facilitating	Facilitating Behavior					
	High vs. Low	1.66	1.580	0.26	10.72	0.59
	High vs. Med	0.75	0.492	0.20	2.72	0.66
	Med vs. Low	2.23	1.670	0.51	9.68	0.29

*Each model accounts for randomization group and pre- or post-randomization cohort and doctor as a random effect

[†] For the variable, OPTION, higher scores correspond to a higher level of behavior exhibiting the competencies of share decision making; thus, an odds ratio <1 indicates that the odds of agreement decrease when the average response score increases by one unit [OPTION scale: 0 - 100]

^{††} For the variables, RECC (a), and RECC (b), higher scores correspond to a higher level of empathy provision to cues/concerns; thus, an odds ratio <1 indicates that the odds of agreement decrease when the average response score increases by one unit [RECC scale: 0-3]

Note: The ANZ audio-taped consultation cohort includes 20 doctors and 55 patients.

APPENDIX OF PARTICIPATING CENTERS, DOCTORS AND LOCAL COORDINATORS

Australia

St Vincents Hospital, Melbourne: R. Snyder, W. Burns, A. Dowling, Nadia Ranieri

Maroondah Hospital, Maroondah: J. Chirgwin, Suzanne Giddings

Royal Prince Alfred Hospital, Sydney: S. Pendlebury, J. Beith, A. Hamilton, Gina Bark

Sir Charles Gairdner Hospital, Perth: C. Saunders, L. Jackson, N. Spry, F. Cameron, M. Taylor, R. Chee, Anna Davies, Philippa Kelly

Flinders Medical Center, Adelaide: B. Koczwara, Alison Richards

Westmead Hospital Sydney: V. Ahern, P. Harnett, Mary Cooper

Nepean Cancer Care Center, Penrith: N. Wilcken, Penny Murie

New Zealand

Auckland Hospital, Auckland: P. Thompson, V. Harvey, Joline Ong

Waikato Hospital, Hamilton: I. Campbell, Jenni Scarlet

Dunedin Hospital, Dunedin: D. Perez, Alison Wylie

Switzerland

Kantonsspital St. Gallen: B. Thürlimann, A. Casty, M. Hoefliger, A. Müller

Inselspital Bern: S. Aebi, M. Rabaglio, C. Baumann

Germany

Universitätsklinik Frankfurt: M. Liszka, S. Loibl, K. Schmidt, V. Gies, H. Trümper

Frauenklinik Technische Universität München: K. Miska, U. Euler, D. Paepke, K. Gauger, A. Baumgärtner

Universitätsfrauenklinik Kiel: C. Crohns, I. Meinhold-Heerlein, A. Ulrich, S. Grebe, J. Haller, A. Lüsse, J. Dürkop

Krankenhaus München Schwabing: Andrea Schulte, Alexandra von Holle, Sabine Schmid

Universitätsklinikum Jena: O. Camara, J. Hermann, A. Egbe, A. Kavallaris, H.

Winzer, B. Härtwig, S. Krauspe

Austria

Wilhelminenspital Wien: H. Lass, T. Scholl, M. Brunbauer M. Riegler-Keil

Allgemeines Krankenhaus Wien: C. Singer, Y. Yücel, D. Gschwantler-Kaulich, A. Fink-Retter, D. Bikas, M. Tea

Landeskrankenhaus Feldkirch: M. Knauer, R. Köberle-Wührer, P. Elke