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

J. Bernhard[1,2*], J. Aldridge[3], P. N. Butow[4,5], P. Zoller[1], R. Brown[6], A. Smith[5] & I. Juraskova[4]

[1]IBCSG Coordinating Center, Bern; [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]School of Psychology, Centre for Medical Psychology and Evidence-based Decision-making (CeMPED); [5]Psycho-Oncology Co-operative Research Group (PoCoG), University of Sydney, Sydney, Australia; [6]Department of Social and Behavioral Health, School of Medicine, Virginia Commonwealth University, Richmond, USA

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Background: The purpose was 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 2 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 a 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 (versus 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 that a trial was discussed. Factors contributing to this agreement vary by culture.
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. [4] 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.

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 the 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

*Correspondence to: Prof J. Bernhard, International Breast Cancer Study Group Coordinating Center, Effingerstrasse 40, 3008 Bern, Switzerland. Tel: +41-31-3899391; Fax: +41-31-3899239; E-mail: juerg.bernhard@ibcsg.org

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 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 the center. The training consisted of a 7-h interactive workshop with 1–2 follow-up telephone calls over 2 months. The elements of this training were evidence-based [9], incorporating presentation of principles [10], a video modeling ideal behavior, 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; and 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 (See Appendix) approved the protocol.

Medical, surgical, radiation and gynecological 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 concurrently enrolled. 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). The local staff identified eligible patients within a flexible time window of ~12 months in each randomization cohort. For each doctor, 5–10 patients were to be enrolled in the pre-randomization cohorts and eight 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 Spielberger [12].

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: (i) decision [13]; (ii) consultation (adapted from Roter [14] and Korsch et al. [15]); and (iii) doctor communication regarding standard treatment options [9] and clinical trials [9]; plus decisional conflict [16]. Patient measures were in English for ANZ and German for SGA centers. Before randomization doctors completed the Maslach Burnout Inventory (three subscales: depersonalization, emotional exhaustion, and personal accomplishment) as used by Ramirez et al. [17] 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 scale [18], the RECC coding system [19], and a rating for doctor blocking and facilitating behavior [20]. 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 end point, patient–doctor agreement, was defined at the patient level. The 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 the 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 (GEEs), with doctor as a random effect. GEEs were 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, the two-sided Fisher's exact test was used to compare categorical variables between patient–doctor agreement groups, and the 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 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 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 the 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, respectively. In patients without missing data, the corresponding proportions were 84% for ANZ and 72% for SGA, respectively.

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 (versus other; $P = 0.0004$) and Australia (versus 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

Table 1. Baseline characteristics for eligible doctors by culture

	Australia/New Zealand *N* (%)	Switzerland/ Germany/Austria *N* (%)
N	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)
Gynecologist	–	26 (63)
Institution		
Public	14 (67)	40 (98)
Private	–	–
Both	7 (33)	–
Previous training in communication skills	11 (52)	10 (24)
Age, median (range)	46 (33, 62)	34 (24, 48)
Previous years of practice, median (range)	19 (2, 37)	6 (1, 24)
Average number of patients per doctor recruited to trials over 6 months, median (range)[a]	10 (3, 50)	15 (3, 200)
Burnout[b]		
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)

[a]Refers to any trial, six Swiss/German/Austrian (SGA) doctors have missing recruitment information.

[b]Nine SGA doctors have missing burnout information.

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

	Australia/New Zealand *N* (%)	Switzerland/Germany/ Austria *N* (%)
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)
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)
Age, median (range)	52 (27, 83)	58 (24, 88)
Tumor size, median (range)	2 (0.1, 40)	2 (0, 12)
Anxiety[a], median (range)	44 (20, 80)	45 (20, 78)

[a]Anxiety was measured pre-consultation. HS, high school.

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 versus 2: $P = 0.002$; grade 1 versus 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 substantial 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).

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

Patient(below)/doctor (right)	Missing	Trial not discussed	Trial discussed	Total
Australian/New Zealand				
Missing	–	26	7	33
Trial not discussed	3	219	27	249
Trial discussed	1	22	34	57
Total	4	267	68	339[a]
Swiss/German/Austrian				
Missing	–	24	8	32
Trial not discussed	4	225	84	313
Trial discussed	2	24	56	82
Total	6	273	148	427[b]

[a]Excludes one patient with both doctor and patient assessments missing.
[b]Excludes two patients with both doctor and patient assessments missing.

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 in the 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 the 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

Table 4. Odds ratios for patient–doctor agreement versus disagreement. Generalized estimated equations by language cohort for eligible doctors and their assessable patients[a]

Cohort	Variable[a]	Odds ratio	Standard error	Lower confidence limit	Upper confidence limit	*P*-value
ANZ	Public only versus private/public institute	3.67	1.17	1.96	6.86	<.0001
	Born in Australia versus other	1.58	0.43	0.92	2.68	0.09
	Born in New Zealand versus other	3.01	0.94	1.64	5.56	0.0004
	Doctor burnout, depersonalization[b]	1.03	0.01	1.01	1.05	0.01
	Doctor burnout, personal accomplishment[b]	1.04	0.01	1.02	1.06	<.0001
SGA	Tumor grade 1 versus 2	2.98	1.06	1.48	5.99	0.002
	Tumor grade 1 versus 3	3.65	1.18	1.94	6.88	<.0001
	Average number of patients per doctor recruited to trials over 6 months: ≤5 patients versus >5 patients	2.01	0.64	1.08	3.76	0.03

The ANZ cohort includes 21 doctors and 339 patients. The SGA cohort includes 41 doctors and 427 patients.
SGA, Swiss/German/Austrian; ANZ, Australian/New Zealand.
[a]Accounting for the randomization group and pre- or post-randomization cohort.
[b]For doctor burnout variables, depersonalization and personal accomplishment, higher scores correspond to higher degrees of depersonalization and personal accomplishment, respectively. 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).

Table 5. Odds ratios for patient–doctor agreement versus not, generalized estimated equations for assessable ANZ audio-taped consultation participants only, five separate models[a]

Model[a]	Variable in model[a]	Odds ratio	Standard error	Lower confidence limit	Upper confidence limit	*P*-value
OPTION	Observing patient involvement scale[b]	0.95	0.037	0.88	1.02	0.17
RECC (part a)	Total number of emotional cues and concerns[c]	0.83	0.079	0.69	1.00	0.04
RECC (part b)	Average level of empathy expressed across all cues[c]	0.26	0.206	0.05	1.23	0.09
Blocking	Blocking behavior					
	High versus low	3.41	3.081	0.58	20.03	0.17
	High versus medium	1.36	1.097	0.28	6.60	0.70
	Medium versus low	2.50	2.028	0.51	12.26	0.26
Facilitating	Facilitating behavior					
	High versus low	1.66	1.580	0.26	10.72	0.59
	High versus medium	0.75	0.492	0.20	2.72	0.66
	Medium versus low	2.23	1.670	0.51	9.68	0.29

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

ANZ, Australian/New Zealand.

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

[b]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].

[c]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].

behavior exhibiting competent shared decision-making (OPTION) nor blocking or facilitating behavior was associated with patient–doctor agreement.

In the SGA cohort, the association between the duration of the consultation and the patient–doctor agreement was explored. The median duration was 40 min ($N = 415$, range: 15–125). There was moderate variation among Austrian, Germany, and Swiss centers with a median (range) of 30 (15–90), 35 (15–125), and 60 (30–100) min, respectively. There was no association between the 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]. The factor of fewer 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 doctors' gender, age, or the years of professional experience, and patients' 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 the 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. [25] 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. We feel that these conditions are similarly important 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 an 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 lung [27] 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. [29] pointed recently to the omissions of important information, such as prognosis. 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 that 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.

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disclosure

The authors have declared no conflicts of interest.

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appendix: 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. Lüesse, 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