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Original Paper

Clinicians' Attitudes to Clinical Trials of Cancer Therapy

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Progress in the assessment and introduction of new treatments is impeded by the failure to recruit eligible patients into clinical trials. Little is known about the attitudes of U.K. cancer specialists towards trial participation, therefore a postal survey was conducted of 553 British clinical, medical and surgical oncologists. A 45-item questionnaire was returned by 357 clinicians (65% response rate). Although 353 (99%) of respondents stated that they were participating in trials, median 3 (range 0–62), 269 (75%) of clinicians were entering fewer than 50% of eligible patients. Differences were seen between professional groups within oncology; medical oncologists placed more emphasis on research than on clinical activities, felt greater pressure to participate in trials and were more likely to value being known by national and international colleagues than did surgeons or clinical oncologists. Surgeons were more likely to rely on clinical experience rather than enter patients into a trial but were more likely to keep patients on study following relapse. The survey identified constraints imposed by the healthcare system which impede trial participation including lack of time, communication difficulties and conflicts between the role of clinician and scientist. Such factors need consideration when trials are designed. Comparison of British data with those from the U.S. clinicians were broadly similar. The few differences found suggest that the more protocol-driven culture of the U.S. might encourage recruitment and a greater commitment to keep patients on trials. © **1997 Elsevier Science Ltd.**

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INTRODUCTION

ALTHOUGH MANY patients are eligible to participate in clinical trials of cancer therapy, accrual remains very low [1]. Recruitment difficulties arise from a complex mixture of barriers, which include the changing system of healthcare delivery in Britain [2]; concern about ethical and medico-legal issues [3]; personality factors in both patients [4] and doctors [5, 6]; prejudicial ideas about experiments in medicine [7]; ignorance amongst the general population about the meaning of randomisation in trials [8–10]; overestimation by patients of likely therapeutic benefits of standard therapy [11] and the inadequate communication skills training of many doctors trying to obtain informed consent [12]. If recruitment is to improve, further research will be needed into methods of removing these barriers and ameliorative interventions designed and implemented.

Doctor-related variables have been cited as the primary reason for poor recruitment of patients [13]. The reluctance of clinicians to enter eligible patients into clinical trials has many causes [5]. These include practice constraints on time and staff, perceived conflicts between the role of clinician and scientist, difficulty in obtaining informed consent and in explaining randomisation, and anxiety that the disclosure of uncertainty might affect the doctor–patient relationship [12, 14].

In the U.S., 1737 physicians within the Eastern Co-operative Oncology Group (ECOG) completed Taylor's Physician Orientation Profile (POP) [6]. Certain items on this questionnaire were grouped into five subscales assessing various attitudes of clinicians towards their clinical and scientific work. These were: primary allegiance, professional activities, decision-making under uncertainty, perceived professional rewards and peer group influence. Scores for each of the five subscales were computed and physicians placed on a continuum ranging from the extremes of pure 'clinician' to pure 'scientist'. The study showed that scores were skewed towards the clinician end of the continuum for each subscale except decision-making under uncertainty. The majority (89%) of the physicians indicated that improving patient

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quality of life was more satisfying than prolonging survival. Physicians overestimated by a factor of six the numbers of patients that they were likely to enter into clinical trials and often used their own idiosyncratic entry criteria as to which patients would be offered trial participation.

British oncologists attending communication skills courses cited the provision of complex information and obtaining patients' informed consent to clinical trials as major areas of difficulty [12]. However, the different attitudes and trial behaviour of clinicians who work with cancer patients in Britain has not been systematically studied. This paper describes results from a survey of 357 oncologists who completed the Physician Orientation Profile used in the ECOG study. The results are compared with those of the U.S. clinicians.

MATERIALS AND METHODS

Sample

301 medical and clinical (radiation) oncologists were identified from a directory of specialities and addresses published by the National Cancer Alliance, U.K. Surgeons with a specialist interest in oncology ($n = 252$) were identified via a regular mailing to approximately 350 members of the British Association of Surgical Oncology (BASO).

Questionnaire

The Physician's Orientation Profile was slightly modified retaining wherever possible the wording of the 45 binary-option items in the U.S. version. The questionnaire (Table 1) was sent out to all clinicians (553) on the database together with a pre-paid envelope. Clinicians were also asked to name the trials in which they were participating, the characteristics that made patients either easy or difficult to approach, and were invited to make any other comments that they had about clinical trials. An accompanying letter assured respondents of confidentiality. Basic demographic details were requested such as sex, age and speciality but questionnaires were anonymous. A separate form requesting name and address was included for those clinicians who wished to collaborate on any further research aimed at improving trial recruitment.

RESULTS

Response

357 clinicians from the intended target groups returned completed questionnaires (response rate 65%). 154 of 228 (68%) clinical oncologists and 56 of 73 (77%) medical oncologists responded. Of the 252 practicing surgeons, 143 of this group returned forms (57%). Four replies were received from physicians who did not give their speciality. 298 (84%) respondents were male, 51 (14%) were female and 8 (2%) did not state their sex. The majority of respondents were aged over 45 years. 142 indicated that they wished to collaborate in any further research about clinical trials.

Participation in trials

353 (99%) respondents stated that they were currently involved in clinical trials. Over 200 different clinical trials were mentioned, with participation in a mean of 3.79 (S.D. 4.5, median 3, range 0–62) trials. Medical oncologists were participating in more clinical trials (mean 5.5, S.D. 6.3) than were the clinical oncologists (mean 4.3, S.D. 5.2) or surgeons (mean 2.6, S.D. 1.4). This difference was statistically significant $\chi^2 = 45.65$ $P < 0.00001$: 59% of medical oncologists felt high pressure to participate in randomised clinical trials in comparison with 37% of clinical oncologists and 22% of surgeons. Respondents estimated that they would enter a median of 20 patients into trials in the next 6 months (range 0–600). However, 269 (76%) respondents acknowledged that they were entering fewer than 50% of all eligible patients.

Differences between professional groups

A discriminant function analysis was performed to determine whether or not the different professional groups of oncologists could be separated on the basis of their responses to the questionnaire. Two discriminant functions were calculated with a combined χ^2 (16) of 192 ($P < 0.00001$). After removal of the first function there was still a strong association between the groups and predictors (questionnaire items), χ^2 [7] = 73 ($P < 0.00001$). The first function maximally discriminated medical oncologists from clinical and surgical oncologists. Table 2 indicates the six items which load on to Function 1 using a cut-off > 0.3 which is by convention the lowest cut-off (9% of variance) recommended for this statistical test [15]. Medical oncologists placed a greater emphasis than did surgeons or clinical oncologists on research-related activities as judged by time spent on research, papers published, being the primary investigator on more than one grant and participating in research groups or societies. They also placed more importance on being known by national and international colleagues, rather than local colleagues, than did the other two groups. The second function discriminated surgical oncologists from medical and clinical oncologists (Table 3). Surgeons were more likely than the other two groups to encourage patients to stay on a trial following relapse when the protocol dictated additional treatment the patient did not want. When faced with controversy about treatments, surgeons felt more comfortable relying on their own clinical experience rather than having decisions dictated by a trial protocol. Surgeons were also more likely to feel that doctors in the hospital setting were given more reward for their clinical skills with patients than for their contributions to scientific knowledge. Finally, they were less likely than medical or clinical oncologists to report benefits to their institution as a major reason for trial participation.

Clinician–scientist continuum

Using a method similar to that previously reported [6], 18 of the 45 items were used to compute scores for each oncologist on the five POP subscales. Figure 1 shows the orientation profiles for the different professional groups in Britain. In general, all respondents were more oriented toward the clinician end of the continuum. However, medical oncologists were significantly more oriented towards the researcher–scientist end of the continuum than were surgeons and clinical oncologists as far as professional activities ($\chi^2 = 63.83$ $P < 0.00001$), primary allegiance ($\chi^2 = 14.01$ $P < 0.0009$), perceived rewards ($\chi^2 = 21.91$ $P < 0.00001$) and peer group influences were concerned ($\chi^2 = 35.22$ $P < 0.00001$). Surgeons were significantly more oriented towards the clinician end of the continuum as far as decision-making under uncertainty was concerned ($\chi^2 = 16.93$ $P < 0.0002$).

Characteristics of patients that help or hinder discussion about trials

A total of 249 clinicians recorded 327 different factors that influence the ease of communicating with patients about

Table 1. Differences between U.K. oncologists and ECOG trialists' responses to POP items

	U.K. oncologists	ECOG trialists	Difference between U.K. versus ECOG
q1 Ideally, clinicians are able to increase survival and improve the quality of patients' lives. In cases where only one can be achieved at the cost of the other, I feel more satisfied when I can			
(a) improve patients' quality of life	82%	89%	< 10%
(b) prolong patients' lives	18%	11%	
q2 If a patient refuses to participate in a randomised clinical trial that I suggest, I would:			
(a) treat the patient off the study	99%	99%	< 10%
(b) refer the patient to another clinician	1%	1%	
q3 In general, when I initiate a treatment for cancer, I am:			
(a) optimistic that the treatment will work	95%	91%	< 10%
(b) pessimistic that the treatment will work	5%	9%	
q4 In my hospital the pressure to participate in a randomised clinical trial is relatively:			
(a) low	66%	64%	< 10%
(b) high	34%	36%	
q5 I enter the following amount of my potentially eligible patients into randomised clinical trials:			
(a) under 50%	76%	67%	< 10%
(b) 50% or more	24%	33%	
q6 My primary commitment is to:			
(a) future generations of patients (society)	9%	9%	< 10%
(b) present patients (individuals)	91%	91%	
q7 When faced with a controversial treatment decision, I feel most comfortable when:			
(a) I make the decisions	63%	68%	< 10%
(b) the decisions are made by the trial protocol	37%	32%	
q8 Currently, I am the principal investigator on one or more research grants:			
(a) no	60%	65%	< 10%
(b) yes	40%	35%	
q9 In my hospital, doctors are given more reward for:			
(a) clinical skills with patients	71%	67%	< 10%
(b) contributing to scientific knowledge	29%	33%	
q10 When a patient on a protocol relapses or progresses and the protocol dictates additional treatment that the patient does not want, I:			
(a) encourage the patient to stay on the trial	21%	54%	> 20%
(b) remove the patient from the trial	79%	46%	
q11 In general, patients are referred to me because of my:			
(a) research activities	5%	9%	< 10%
(b) clinical reputation	95%	91%	
q12 I participate more actively in professional organisations that are based on:			
(a) my clinical speciality	79%	79%	< 10%
(b) my research activities	21%	21%	
q13 The time I devote to publications, lectures and research commitments, compared to clinical work, is relatively:			
(a) low	75%	63%	11–20%
(b) high	25%	37%	
q14 The need for detailed monitoring of individual clinicians' activities deters me from participating in randomised clinical trials:			
(a) no	79%	91%	11–20%
(b) yes	21%	9%	
q15 When a potentially eligible patient chooses not to enrol on a trial that I have suggested, I:			
(a) often feel disappointed	53%	58%	< 10%
(b) seldom feel disappointed	47%	42%	

(continued)

Table 1—contd

	U.K. oncologists	ECOG trialists	Difference between U.K. versus ECOG
q16 I devote a lot of time to educating other clinicians about randomised clinical trials:			
(a) no	69%	53%	11–20%
(b) yes	31%	47%	
q17 My income is:			
(a) dependent on my research activities	5%	10%	< 10%
(b) not dependent on my research activities	95%	90%	
q18 Frequent publications are important to my career advancement:			
(a) agree	41%	44%	< 10%
(b) disagree	59%	56%	
q19 When a protocol includes a treatment that is more aggressive than I would usually give to similar non-trial patients:			
(a) I am often reluctant to participate	51%	40%	11–20%
(b) it makes no difference	49%	60%	
q20 I am reluctant to participate in a trial that may randomise the patient to a 'no treatment' group:			
(a) agree	27%	32%	< 10%
(b) disagree	73%	68%	
q21 After being randomised, if a patient refuses the treatment to which he or she has been assigned:			
(a) I accept the patient's decision	87%	42%	> 20%
(b) I make every effort to keep the patient on the trial	13%	58%	
q22 Overall I feel the quality of patient care:			
(a) increases when patient is in a clinical trial	85%	94%	< 10%
(b) decreases when patient is in a clinical trial	15%	6%	
q23 When published data and my clinical experience conflict, I am more likely to rely on:			
(a) my clinical experience	50%	55%	< 10%
(b) published data	50%	45%	
q24 The more frequent obstacle to the successful completion of a clinical trial is:			
(a) clinicians' reluctance to participate	76%	55%	> 20%
(b) patients' reluctance to participate	24%	45%	
q25 If written informed consent were not required, I would approach more patients to enter clinical trials:			
(a) true	36%	15%	> 20%
(b) false	64%	85%	
q26 The opinions of the referring clinician regarding randomised clinical trials affects my decision to approach an eligible patient:			
(a) true	74%	70%	< 10%
(b) false	26%	30%	
q27 The thought of having to spell out all the details of a trial to eligible patients discourages me from approaching them to participate:			
(a) true	41%	23%	11-20%
(b) false	59%	77%	
q28 It is more important for me to be well-known among:			
(a) local colleagues	74%	72%	< 10%
(b) national/international colleagues	26%	28%	
q29 I spend the following amount of my time in research-related activities:			
(a) less than one-third	78%	72%	< 10%
(b) one-third or more	22%	28%	
q30 A major reason for my participation in randomised clinical trials is that it benefits my institution:			
(a) agree	40%	54%	11–20%
(b) disagree	60%	46%	

q31 Overall, participation in a randomised clinical trial is:			
(a) an asset to my reputation	91%	97%	< 10%
(b) a liability to my reputation	9%	3%	
q32 I know the difference between a χ^2 and a *t*-test:			
(a) no	18%	31%	11–20%
(b) yes	82%	69%	
q33 If I could have only one measure, I would assess how successful I was as a physician by:			
(a) my research contributions	15%	16%	< 10%
(b) how I helped individual patients	85%	84%	
q34 When I am personally uncertain as to which treatment is best, I am likely to:			
(a) enter the patient in a randomised clinical trial if one exists	85%	84%	< 10%
(b) personally select a treatment	15%	16%	
q35 When I obtain informed consent:			
(a) I allow patient reaction to influence the content of the information given	63%	34%	> 20%
(b) I do not vary the content of the information given	37%	66%	
q36 If research activities were to enhance my income, I would enter more patients in randomised clinical trials:			
(a) agree	28%	30%	< 10%
(b) disagree	72%	70%	
q37 I am more likely to attend a conference that focuses on:			
(a) clinical issues	75%	73%	< 10%
(b) research issues	25%	27%	
q38 In the past three years, I have authored/co-authored:			
(a) 0 Publications	10%	25%	ND
(b) 1–5 publications	45%	43%	
(c) 6–9 publications	18%	14%	
(d) 10 or more publications	27%	18%	
q39 When informing patients about their prognosis, I find statistics:			
(a) helpful	73%	84%	11–20%
(b) not helpful	26%	16%	
q40 When making critical and controversial decisions I usually:			
(a) seek major input from my patients	93%	92%	< 10%
(b) do not seek major input from my patients	7%	8%	
q41 I think the patient's right to select treatment options is always more important than the advancement of scientific knowledge:			
(a) true	74%	75%	< 10%
(b) false	26%	25%	
q42 If I had to choose, I would say my primary task is:			
(a) caring for individual patients	95%	86%	< 10%
(b) contributing to scientific knowledge	5%	14%	
q43 I would rather be somewhat:			
(a) too involved with my patients	89%	89%	< 10%
(b) too detached from my patients	11%	11%	
q44 When I participate in a randomised clinical trial, it is more likely that I:			
(a) increase my patient population	72%	75%	< 10%
(b) lose patients I might otherwise keep	28%	25%	
q45 When there is controversy in the literature as to which treatment is best:			
(a) I enter the patient in a clinical trial if one exists	84%	85%	< 10%
(b) I personally select a treatment for the patient	16%	15%	

ND, not done.

Table 2. Stepwise discriminant function. Items which loaded above 0.3 are listed. Function 1. Medical versus clinical + surgical oncologists

	Medical	Clinical	Surgical
q29 I spend the following amount of my time in research-related activities:			
(a) less than one-third	30%	88%	85%
(b) one-third or more	70%	12%	15%
q13 The time I devote to publications, lectures and research commitments, compared to clinical work is relatively:			
(a) low	37.5%	88%	77%
(b) high	62.5%	12%	23%
q38 In the past 3 years, I have authored–coauthored:			
(a) 0 publications			
(b) 1–5 publications	16%	66%	58.5%
(c) 6–9 publications	84%	34%	41.5%
(d) 10 or more publications			
q8 Currently, I am the principal investigator on one or more research grants:			
(a) no	20%	66%	69%
(b) yes	80%	34%	31%
q12 I participate more actively in professional organisations that are based on:			
(a) my clinical speciality	46%	82%	88%
(b) my research activities	54%	18%	12%
q28 It is more important for me to be well-known among:			
(a) local colleagues	55%	81%	74%
(b) national/international colleagues	45%	19%	26%

Table 3. Function 2. Surgeons significantly different to clinical and medical oncologists on the following items

	Surgical	Clinical	Medical
q9 In my hospital setting, doctors are given more reward for:			
(a) clinical skills with patients	84%	62%	63%
(b) contributing to scientific knowledge	16%	38%	37%
q10 When a patient on a protocol relapses or progresses and the protocol dictates additional treatment that the patient does not want, I:			
(a) encourage the patient to stay on the trial	34%	15%	5%
(b) remove the patient from the trial	66%	85%	95%
q30 A major reason for my participation in randomised clinical trials is that it benefits my institution:			
(a) agree	29%	48%	46%
(b) disagree	71%	52%	54%
q45 When there is controversy in the literature as to which treatment is best:			
(a) I enter the patient in a clinical trial if one exists	76%	90%	91%
(b) I personally select a treatment for the patient	24%	10%	9%

clinical trials. These factors were divided into 11 thematic categories to assist analysis and are shown in Figure 2. Categories concerned with social class, age and perceived intelligence level are subdivided to reflect the diversity of responses. Intelligence level was the most frequently mentioned category of characteristics, considered by 83 (33%) of the clinicians who commented as helpful when communicating about trials. Generally, patients perceived as being of high intelligence and/or having a greater understanding were seen as easier to approach, although a minority of clinicians stated that patients with poorer understanding were easier. 108 clinicians did not cite any characteristics that make trial discussion easier.

264 clinicians mentioned 366 patient characteristics which they felt impeded their communication about trials (Figure 3). Intelligence level and disease stage or site with poor prognosis were the two most frequently cited categories (24% clinicians commented). 93 clinicians did not report any specific patient characteristics which gave rise to difficulties.

Additional comments

129 (36%) respondents wrote 159 additional comments, 105 of which reflected their differing attitudes to trial recruitment. Almost 60% commented on the lack of time or resources preventing them from trial involvement e.g. 'Why is it that potential trial patients always materialise when the clinic is running late and a patient's charter audit is in progress?!!' Some respondents revealed different perspectives about the value of trials e.g. 'Trials tend to clash with the responsibility to do one's best for the individual patient in the consulting room at that time.' 'Trials are good for clinicians as it keeps them on their toes and may even help their patients.' Other respondents made comments concerning the difficulties of obtaining informed consent e.g. 'Informed consent is something I believe in but it is difficult to achieve.' 'Dishonesty in this area makes life easier but it is wrong. Patients are worried about informed consent and some prefer the doctor to make the decision presenting moral dilemmas.' Concern was expressed by some doctors about potential professional repercussions of trial involvement e.g. 'I have an

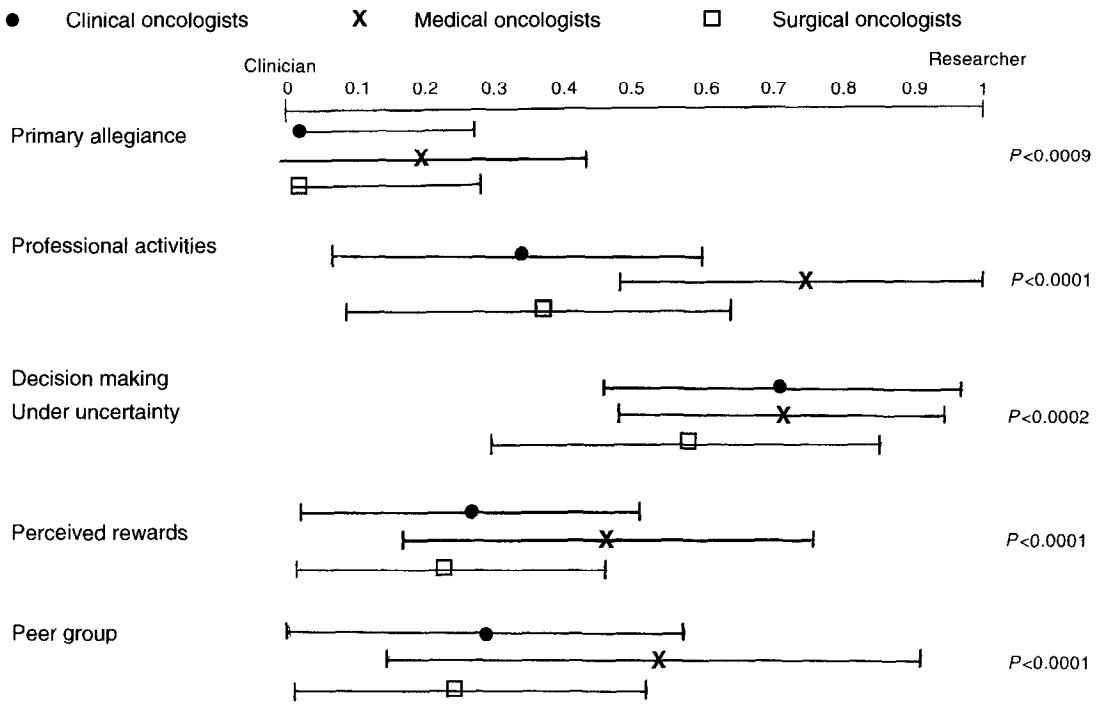

Figure 1. Oncologists' mean scores on the POP subscales.

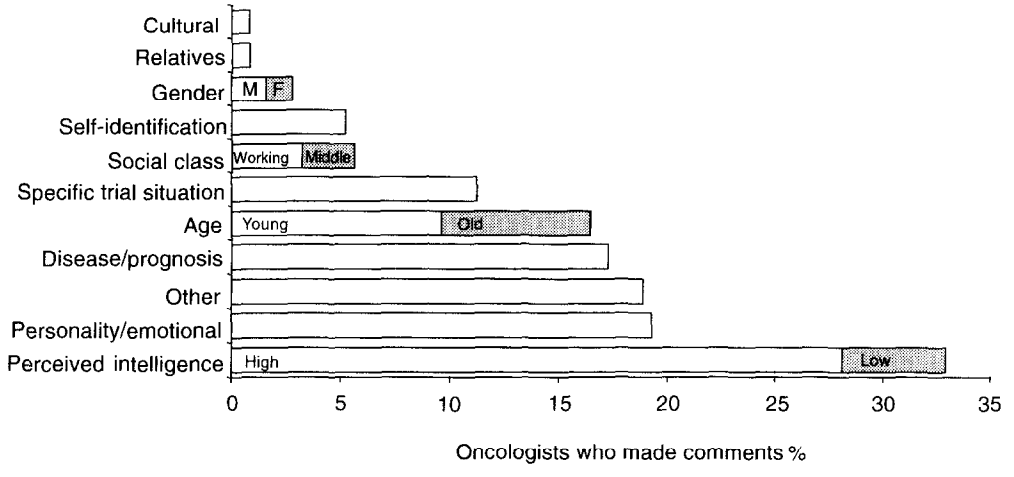

Figure 2. Patient characteristics which respondents cited as helping communication about trials (number of oncologists who made comments = 249).

underlying anxiety that a patient will make a formal complaint about me on the grounds that I am experimenting on them.'

Comparison of British with U.S. data

Comparisons between the British and the U.S. ECOG trialists' responses to the questionnaire were made. Differences between responses are shown in Table 1 in terms of less than a 10% difference, 11–20% difference and > 20% difference. There was less than a 10% difference between British and U.S. responses on 31 (69%) of the items and an 11–20% difference on 8 (18%) of the items. Only 5 items, 10, 21, 24, 25 and 35, showed a greater than 20% difference. British clinicians were more likely than those in the U.S. to allow patient reaction to influence the content of information given when obtaining informed consent (q 35, 63% versus 34%) and to accept the decision of a patient who refused their assigned treatment following randomisation (q 21, 87% versus 42%). More of the British than U.S. clinicians (q 24, 76% versus 55%) felt that the most frequent obstacle to the successful completion of a clinical trial was reluctance by clinicians, rather than patients, to participate. 36% of British clinicians compared to 15% of U.S. clinicians acknowledged that they would approach more patients about trials if written informed consent were not required (q 25). U.S. clinicians were much more likely than their British counterparts (q 10, 54% versus 21%) to encourage a patient to stay on trial if a patient who had relapsed did not want the additional treatment dictated by the protocol.

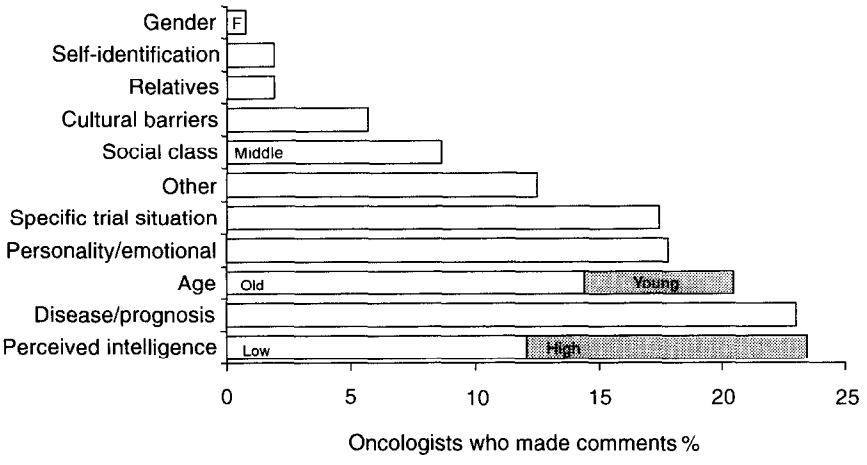

Figure 3. Patient characteristics which hinder communication about trials (number of oncologists who made comments = 264).

British and U.S. mean scores on the five subscales of the clinician/scientist continuum were both skewed toward a more clinical than scientist orientation.

DISCUSSION

This survey is the first systematic attempt to examine the attitudes of British clinicians to clinical trials in cancer. Response rate to an unsolicited postal questionnaire was good permitting reasonable confidence in the findings. That 142 (40%) wish to be involved in any future research on ways to improve recruitment to clinical trials reveals the extent of the problems and conflicts that many clinicians experience when attempting at the same time to help individual patients and to contribute to scientific knowledge.

Several authors have drawn attention to the fact that patients who are entered into clinical trials may not be truly representative of eligible patients [6, 16]. Previous research has shown that clinicians operate their own idiosyncratic selection of patients [6]. In the study reported here a wide range of factors that influence the willingness of doctors to approach eligible patients about trials were identified. These factors are complex and unpredictable, for example, perceived intelligence of patients was seen as the most important factor influencing the relative ease or difficulty of approaching patients about trials. However, some clinicians obviously find the prospect of challenge and questioning by more intelligent patients about a trial difficult, while others find giving complex information about a trial and describing the concept of randomisation in simple terms too daunting to deal with alongside the demands of a busy clinic. A related finding was that clinicians perceived middle class patients to be more difficult to approach, whereas working class patients generally were described as easier. Middle class patients are usually more confident about asking probing questions during the consultation and often take up more of the clinician's time.

Additional comments were made by 129 respondents and revealed a wide range of issues and concerns including different perspectives held about the value of trials, difficulties of obtaining informed consent, concerns about professional repercussions and time pressures within the clinic. These factors need to be addressed if doctors are to feel comfortable about trial participation.

There were quite marked differences in attitude between the various professional groups who work in cancer medicine. Medical oncologists were more oriented toward the scientist–researcher end of the continuum. In Britain, medical oncology is a relatively small speciality. These clinicians tend to have appointments in teaching hospitals and cancer institutes where research activity is an explicit expectation. Many of the surgeons and clinical oncologists in the study on the other hand worked in large district general hospitals where more emphasis and resources may be placed on clinical involvement with patients than on research. The influence that the type of institution in which a doctor works and their speciality needs consideration by those involved with trial design, especially when predicting the likely accrual rates. There was a non-significant trend for surgeons to be less enthusiastic about trials with a no treatment arm.

The comparison between U.S. and British data showed a striking concordance so only the five items showing >20% difference are worthy of comment. The differences in attitudes of U.S. clinicians who appear to try harder to keep patients on trials than their British counterparts could be a reflection of the fact that in the U.S., clinicians work within a more protocol-driven culture and have more statutary obligations about informed consent issues to prevent litigation whether or not a patient is in a trial. Differences in the financial incentives available for trial participation may also influence recruitment and willingness to encourage patients to remain on a trial. However, it is also possible that some of these differences could be attributed to the different sample populations surveyed. (In the U.S. survey, 59% were medical oncologists, 14% clinical oncologists, 14% surgeons and 13% stated more than one speciality.) Membership of ECOG implies regular participation in clinical trials, whereas the British sample represent a wide spectrum of oncologists who were not necessarily active trial participants. In fact, 353 (99%) of respondents claimed to be participating in trials. However, it is interesting to note that 62% of the ECOG sample failed to enter a single patient into trials for which they were registered in the 12 months following the survey. The clinicians themselves had predicted that they would enter a mean of 9.5 patients during that period.

There were some apparent conflicts experienced by doctors between helping individual patients and helping with the progress of scientific knowledge. Taylor and associates suggested that clinicians could be placed on a continuum between clinician and researcher. Respondents in both the

U.S. and Britain were more oriented toward the clinician end of the continuum with their primary allegiance being toward current patients rather than future generations. Most felt that more reward was to be gained from their clinical skills than that found in making contributions to scientific knowledge. There was some discrepancy in answers to those items in the questionnaire dealing with decision-making under uncertainty. Overall 60% of British oncologists said that they preferred to make the decision if faced with controversial treatment decisions and only 54% would rely on published data rather than clinical experience when faced with conflict about treatment decisions. However, when treatment controversies existed in the literature, 87% claimed that they would enter the patient into a trial if one existed. These data suggest a three-stage process of dealing with uncertainty about treatment. Clinical experience appears to take priority in decision-making; where this is lacking doctors then tend to look to published data for guidance. Finally, if the literature does not yield a satisfactory solution, doctors appear more confident about entering a patient into a trial.

There are large numbers of eligible patients who are clearly not being entered into trials, 269 (76%) of the British sample acknowledged that they enter fewer than 50% of their eligible patients. Factors such as a lack of time and resources contribute to this with too many patients being seen by too few doctors in busy clinics within hospitals where trial activity is not valued. However, this is not the only barrier with 271 (76%) doctors acknowledging that the more frequent obstacle to successful completion of a trial was a reluctance of clinicians to participate in trials rather than reluctance by patients. Doctors were able to identify the characteristics that made certain patients more difficult to approach than others. This, together with the fact that senior doctors in cancer medicine recognise that issues surrounding informed consent and complex information giving are their primary communication problem area, demonstrates the need for better communication skills training. We also need research to design and evaluate interventions and innovative approaches aimed at helping doctors and patients when trials are discussed.

The drive towards more multinational trials and large collaborative groups may well assist trial recruitment and permit quicker answers to important questions, but those charged with trial design and protocol development need to take account of the overoptimistic assessments made by clinicians about likely accrual of patients. Furthermore, the clinical environment and encouragement offered by different hospitals in which doctors are based exerts an important influence. Worries about throughput and cost containment can diminish the likelihood of participation by even the most enthusiastic clinician.

Finally there does seem to be a need to educate the public about the meaning of randomisation and potential advantages of trial participation before patients are in the situation of coping with the news that they have cancer [17, 18].

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