Financial disclosure and clinical research: what is important to participants?

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ABSTRACT

Objective: To assess what participants in company-sponsored clinical trials wish to know about financial aspects of the study.

Design, setting and participants: Cross-sectional questionnaire administered to 324 participants in six clinical trials conducted at the Royal Melbourne Hospital in 1999–2000 and 2006 for non-acute conditions (asthma, chronic obstructive pulmonary disease, osteoporosis, rheumatoid arthritis, diabetes and influenza vaccine efficacy).

Main outcome measures: Participants' desire for information on study funding, investigators' conflicts of interest, and use of accrued funds.

Results: 259 participants (80%) completed the survey. Participants wanted to be informed about the identity of the project sponsor (148 participants; 57%), whether the investigators owned shares in the company (105; 41%) or received travel grants (83; 32%), how much funding was accrued at study completion (88; 34%), how accrued funds were used (98; 38%), and who approved their use (91; 35%). After adjusting for year of survey and level of education, younger subjects (aged ⩽ 60 years) wished to be informed more often than older participants of who sponsored the project (odds ratio [OR], 2.35 [95% CI, 1.21–4.55]; $P = 0.012$), whether the investigators owned shares in the company (OR, 2.41 [95% CI, 1.27–4.60]; $P = 0.007$) and how much funding was available for other uses (OR, 1.79 [95% CI, 0.94–3.41]; $P = 0.078$).

Conclusion: While most participants indicated that they would take part in clinical research again regardless of whether they received financial information, providing information on the sponsor, the investigators' financial interest in the company, whether accrual of funds is expected, and how these funds will be spent should satisfy the interests of participants in company-sponsored clinical trials.

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In addition to the satisfaction of seeking advances in therapy, it is generally understood that investigators or their departments will receive financial recompense for their involvement in company-sponsored clinical trials. Such payment, albeit highly variable, raises the potential for conflict of interest to affect scientific and ethical behaviour of both sponsors and investigators. This issue has been the subject of frequent debate.[1-4]

Disclosure of financial interest is one measure used by institutional review committees, regulatory authorities and journal editors to ensure the scientific and ethical standards of a study. However, whether financial disclosure is also of importance to clinical trial participants, who are volunteers in the process, has been less often studied.[5-8]

We wished to explore the importance of financial disclosure to participants in company-sponsored clinical trials, to determine what financial information participants desired, and whether this information might influence their involvement in future clinical trials. We hypothesised that younger participants (aged ⩽ 60 years) would be more aware of issues relating to financial conflict of interest than older participants and would be more likely to prefer to be given this information.

METHODS

A questionnaire was developed to explore the information that participants wished to receive on financial aspects of clinical trials. To ensure correct focus and clarity, questions were developed by iterations after review by hospital staff, patients not involved in clinical trials, and clinical trial volunteers. Three areas were covered: (a) funds the department received for conducting a study; (b) whether investigators had a financial conflict of interest (eg, share ownership or receipt of compensation); and (c) how profits were to be spent. Participants were also asked about their motivation for participating in the clinical trial and whether they would participate in future without disclosure of financial arrangements.

Study setting and surveys

The Royal Melbourne Hospital is an adult tertiary teaching hospital of 380 acute medical and surgical beds, with specialty and subspecialty outpatient clinics. Investigators conducting specific outpatient-based clinical trials agreed to send copies of the questionnaire to all participants. Clinical trials for acute, life-threatening or debilitating conditions with inadequate therapy (such as cancer, acute myocardial infarction, or multiple sclerosis) were excluded, because these raised additional issues in regard to patient participation.

A total of 324 questionnaires were posted. In 2001, 225 surveys were sent to participants in pharmaceutical company-sponsored clinical trials undertaken in 1999–2000. Conditions studied in these trials were chronic obstructive pulmonary disease, asthma, diabetes, osteoporosis, and rheumatoid arthritis. In 2007, a further 99 surveys were sent to participants in a study undertaken in 2006 to assess efficacy of influenza vaccine in healthy older adults. Completed questionnaires were returned by prepaid post. Responses were anonymous, with the medical condition of interest identified.

The Melbourne Health Human Research Ethics Committee approved the project.

Statistical analysis

Results are presented as descriptive summary statistics for each survey question. Survey responses were dichotomised into those who responded "Yes" (they wanted information about that issue) and those who responded "No" or "Uncertain". To determine whether there was an association between older age and attitudes toward disclosure of financial information, age was transformed into a dichotomous variable (⩽ 60 years and > 60 years of age).

Multivariable logistic regression was used to analyse which factors influenced participants' preferences for financial information; age (as a dichotomous variable), year that the survey was completed (2001 or 2007),

1 Characteristics of the 259 respondents

Participant characteristic	No. (%)*
Medical condition	
COPD	38 (15%)
Asthma	33 (14%)
Rheumatoid arthritis	10 (4%)
Osteoporosis	8 (3%)
Diabetes	82 (32%)
Influenza vaccine study	88 (34%)
Male	134 (52%)
Aged > 60 years	188 (73%)
Age in years, median (range)	
All participants	70 (21–93)
COPD trial	73 (50–82)
Asthma trial	48 (21–69)
Rheumatoid arthritis trial	61 (53–77)
Osteoporosis trial	68 (53–76)
Diabetes trial	64 (32–79)
Influenza vaccine study	75 (65–93)
Highest level of education	
Primary school	12 (5%)
Secondary school	145 (56%)
Undergraduate degree	76 (29%)
Postgraduate degree	26 (10%)
Region of birth	
Australia	196 (76%)
United Kingdom	32 (12%)
Europe	21 (8%)
Asia	6 (2%)
Africa	4 (2%)
Employment status	
Home duties	50 (19%)
Employed	69 (27%)
Between jobs	3 (1%)
Student	1 (0.4%)
Retired	97 (38%)
Pension/sickness benefit	39 (15%)

COPD = chronic obstructive pulmonary disease.
* Figures are number (%) of respondents, except for ages, which are median (range). ◆

2 Clinical trial participants' preferences for disclosure of information that might constitute a financial conflict of interest, by age group

Financial information preference	Age ⩽ 60 years (*n* = 71)	Age > 60 years (*n* = 188)	Odds ratio* (95% CI)	*P*
How much funding was available for other uses at study completion	44%	30%	1.79 (0.94–3.41)	0.078
Which company sponsored the study	70%	53%	2.35 (1.21–4.55)	0.012
Whether investigators own shares in the company	55%	35%	2.41 (1.27–4.60)	0.007
Whether investigators receive a salary	35%	23%	1.77 (0.88–3.57)	0.108
Whether investigators receive funding to attend overseas scientific meetings	36%	30%	1.23 (0.64–2.38)	ns

* Multivariable logistic regression was used to adjust reported odds ratios for level of education and year that the survey was completed (2001 v 2007). ns = not significant. ◆

and level of education were included in the model. Significant predictors were defined as having a *P* value < 0.05 and lower bound of the 95% confidence interval > 1.00.

Survey data were processed and analysed using Stata, version 8.2 (StataCorp, College Station, Tex, USA).

RESULTS

Two hundred and fifty-nine participants (80%) completed the survey; 134 (52%) were male, the median age was 70 years (range, 21–93 years), and 71 (27%) were aged ⩽ 60 years. Participant demographics are shown in Box 1.

Funding and financial management

Of the 259 responding participants, 91 (35%) wished to know how much the hospital or department received for the clinical trial, and 65–81 (25%–31%) wished to know how much funding was spent on administration, such as running costs, ethics committees, and staff salaries. Eighty-eight participants (34%) wanted to be informed of how much funding had accrued for other uses at study completion; 98 (38%) wanted to know how these accrued funds were used and 91 (35%) wanted to know who approved their use. Younger participants (aged ⩽ 60 years) were 78% more likely to want this information than older participants (odds ratio [OR], 1.78 [95% CI, 1.01–3.13]; *P* = 0.044).

Disclosure of financial interests

Of the 259 respondents, 148 (57%) preferred to know who the project sponsor was, 105 (41%) wanted to know whether the investigators owned shares in the sponsoring company, 69 (27%) wanted to know whether the investigators received a salary from the sponsor, and 83 (32%) wanted to know whether the investigators received overseas travel grants as a result of undertaking the clinical trial. The logistic regression analysis demonstrated no significant differences in preferences between participants with medical conditions surveyed in 2001 and the healthy volunteers in the influenza vaccine trial surveyed in 2007.

After adjusting for year of survey, we found that younger subjects more commonly wished to be informed of who sponsored the project (Box 2), as did those with a higher level of education (OR, 1.62 [95% CI, 1.12–2.30]; *P* = 0.007). Younger subjects were also more often interested than older subjects in whether the investigators owned shares in the company and how much funding was available for other uses (Box 2).

Use of funds

Participants' preferences on how accrued funds should be used (more than one response was permitted) were: medical research in general, 192 (74%); research into their condition, 130 (50%); staff education, 106 (41%); general hospital use, 88 (34%); staff attendance at conferences, 80 (31%); and staff salaries, 54 (21%). Twenty-six participants (10%) thought that study participants should receive some compensation for taking part in the clinical trial. Only a small minority thought that accrued funds should be available for personal use by investigators (26; 10%) or participants (3; 1%). Fifteen (6%) thought that accrued funds should be donated to charity.

Motivation for participation

Participants could nominate more than one reason for study participation. Of the 171 participants with a chronic condition, 144 (84%) were primarily motivated by the desire to contribute to research into their specific condition or to help those with the same condition in the future. Participants

involved in the vaccination study were healthy community-based volunteers, and most (71/88) were motivated to contribute to medical research in general. Although about 80% of participants overall took part in clinical trials for altruistic reasons, 88 (34%) volunteered in order to have closer monitoring of their condition.

Future participation in clinical trials

Although 52 of the 259 respondents (20%) were specifically interested in the financial aspects of their clinical trials, and 69–105 (27%–41%) wished to be informed about issues that might constitute a financial conflict of interest, 228 (88%) stated that they would participate in a clinical trial in the future even if they had no such information. A handful of participants commented that other matters would also be of interest, including reassurance regarding the scientific integrity of the research, and reassurance that the investigators had the intellectual right to publish the results without the interpretation of the research findings being biased by industry sponsors. A few participants commented that they would like information about publication of research results when these became available.

DISCUSSION

Our findings suggest that about a third of subjects wished to have information on financial aspects of clinical trials. This proportion was relatively independent of the condition being studied, and we did not observe significant differences between the two time periods analysed. Our results indicate that younger participants had a greater preference for financial information than older participants. Importantly, participants wished to see accrued funds used for medical research in general or into their condition, or for staff education, but not for personal use by either patients or investigators.

A number of factors may limit the generalisability of our findings: our clinical trial participants were all English-speaking (to fulfil informed consent criteria) and tended to be around retirement age. In addition, clinical trials for malignancies or specific severe conditions with otherwise inadequate therapy were excluded.

Nevertheless, our findings are in broad agreement with those of an American study, which found that 64%–87% of potential trial participants with a wide variety of medical conditions would prefer to have disclosure of financial conflict of interest.[7] In contrast, another study in the United States found that only 20% of subjects wished to receive this information;[8] however, these subjects all suffered from malignancies and both their motivation to participate in clinical trials and their focus on financial disclosure may have been different from participants with other illnesses.

Participation motivated by lack of availability of medication or other treatment options, or for financial reasons, was not a significant factor in this survey. We excluded clinical trials for life-threatening or severely disabling conditions with limited therapeutic choices, where participants' immediate health concerns might take priority over interest in the conduct of the clinical trial. Most internationally available medications for the conditions studied were readily available to patients under the Australian health care system. While financial rewards may improve patient adherence with therapy,[9] they were not a basis for participation in these studies because, under the hospital's guidelines, participants were either not paid at all or received only nominal payments for transport or parking expenses. The third of respondents who volunteered so they could receive close monitoring of their condition suggests that self-interest is a significant factor in clinical trial participation,[10] possibly reflected in the preference for accrued funds to be spent on research into their own condition.

Younger adults with higher levels of education tended to be more interested in issues related to financial management of trials and potential conflicts of interest. This may reflect their level of education, their focus on financial issues in general, or their greater awareness of issues relating to conflict of interest or research integrity. On the other hand, older, predominantly retired adults may have been more able to donate their time to medical research and more willing to delegate responsibility for research integrity to bodies such as institutional ethics committees. We did not observe a substantial change in attitudes between the two periods when the surveys were conducted, but younger adults were not represented in the 2007 data. A larger study with more equal age distribution is needed to explore differences in attitudes between different generations.

While 88% of our respondents indicated that they would take part in clinical research again regardless of whether they had information on financial aspects of the trial, our findings suggest that providing information on the sponsor, the investigators' financial interest in the company or the product, whether accrual of funds (after expenses) is expected, and how these funds will be spent should satisfy the interests of Australian participants in company-sponsored clinical trials.

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COMPETING INTERESTS

Abe Rubinfeld has received honoraria for professional lectures from GlaxoSmithKline (GSK), AstraZeneca, Pfizer and Boehringer Ingelheim, and has participated in clinical trials conducted on behalf of GSK, AstraZeneca, Roche, ALTANA Pharma, Merck Sharp & Dohme and Bristol-Myers Squibb. No outside interests were involved in the conduct of this project or writing of this paper. This study was funded by the Respiratory Medicine Special Purposes Fund, Royal Melbourne Hospital, which has been accrued from participation in various company-sponsored clinical trials.

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