CLINICAL ETHICS

Interactions of doctors with the pharmaceutical industry

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Objective: To assess the opinions and practice patterns of obstetrician-gynaecologists on acceptance and use of free drug samples and other incentive items from pharmaceutical representatives.
Methods: A questionnaire was mailed in March 2003 to 397 members of the American College of Obstetricians and Gynecologists who participate in the Collaborative Ambulatory Research Network.
Results: The response rate was 55%. Most respondents thought it proper to accept drug samples (92%), an informational lunch (77%), an anatomical model (75%) or a well-paid consultantship (53%) from pharmaceutical representatives. A third (33%) of the respondents thought that their own decision to prescribe a drug would probably be influenced by accepting drug samples. Respondents were more likely to think the average doctor's prescribing would be influenced by acceptance of the items than theirs would be ($p<0.002$). Respondents who distributed drug samples to patients indicated doing so because of patients' financial need (94%) and for their convenience (76%) and less so as a result of knowledge of the efficacy of the sample product (63%). A third (34%) of respondents agreed that interactions with industry should be more strictly regulated.
Conclusion: Obstetrician-gynaecologists largely indicated that they would act in accordance with what they think is proper regarding accepting incentive items from pharmaceutical representatives. Although accepting free drug samples was considered to be appropriate more often than any other item, samples were most commonly judged to be influential on prescribing practices. The widely accepted practice of receiving and distributing free drug samples needs to be examined more carefully.

Interactions between doctors and pharmaceutical companies are prevalent and costly. In 2003, the pharmaceutical industry spent US$25.3 billion on drug promotional activities, including US$16 billion worth of free samples distributed to office-based doctors;[1] the dollar value of providing samples has increased more rapidly than any other type of promotion.[2] In an analysis of the international literature, Wazana[3] found that most doctors typically meet the pharmaceutical representatives four times a month and believe that representatives present accurate drug information; they deny that gifts could influence their behaviour, yet accepting samples was associated with preference for and rapid prescribing of the new drugs.[3] Pharmaceutical companies give doctors gifts, sponsor informational lunches and continuing medical education programmes where their drugs are described and promoted, provide consulting fees and other payments to doctors for services rendered and also fund scientific research.

The possibility that drug companies are exerting too powerful an influence on clinical decision making has led to a recent increase in federal and professional agencies establishing guidelines for appropriate interactions, including the American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).[4] In addition, the International Federation of Pharmaceutical Manufacturers Associations Code underwent a major revision in 1994, and the Association of the British Pharmaceutical Industry, which represents those companies supplying more than 80% of medicines used by the NHS (UK), has a revised code from 1 January 2006.[5 6] The House of Commons Health Committee recently conducted an inquiry into the influence of the pharmaceutical industry on the NHS in response to a perceived lack of oversight such that "a number of practices have developed which act against the public interest".[7]

Our study assesses the opinions of obstetrician-gynaecologists on accepting items of various values from pharmaceutical representatives, whether they would accept such items, whether they thought accepting such items would influence their prescribing practices and how they thought the average doctor would behave in the same situations. We also asked about their practices regarding prescribing drugs and distributing free drug samples to patients, and whether they thought interactions between doctors and industry should be more closely regulated. We hypothesised that doctors viewed accepting smaller incentive items as ethically more appropriate than accepting items of greater value and that they attributed prescribing bias to other doctors more readily than to themselves.[8]

SUBJECTS AND METHODS

In March 2003, questionnaires were mailed to 397 ACOG Fellows and Junior Fellows in Practice who are members of the Collaborative Ambulatory Research Network (CARN). Members of CARN are practising obstetrician-gynaecologists who have volunteered, by submitting a written consent form, to participate in surveys on a range of topics on a regular basis. CARN was established to increase response rates on surveys and thus facilitate the assessment of clinical practice patterns and aid the development of educational materials. Members of CARN represent each of the 10 ACOG districts, and typically have not differed from large random samples of ACOG Fellows and Junior Fellows in Practice on our other survey instruments.[9] On the basis of similar studies conducted by ACOG, where preliminary power analyses indicated that the minimum number of responses needed to ensure significant effect sizes was approximately 100, our

Abbreviations: ACOG, American College of Obstetricians and Gynecologists; AMA, American Medical Association; CARN, Collaborative Ambulatory Research Network; PhRMA, Pharmaceutical Research and Manufacturers of America

sample size was deemed sufficient.[10] All non-respondents received a second mailing of the questionnaire four weeks after the first mailing. Questionnaires returned by 10 June 2003 were included in the study.

We recorded the demographic details of doctors and their patient population. Doctors were presented with four scenarios describing hypothetical interactions of doctors with pharmaceutical industry representatives. For each scenario, they were asked five questions on the ethical appropriateness of the interaction and how they would behave in such a situation. Eleven additional questions asked doctors about their professional interactions with the industry and their opinions on direct-to-consumer marketing. These questions were of the fill in the blank, check all that apply and rating scale format. A questionnaire about screening for and personal experiences with depression was included in the same mailing.

The four scenarios are as follows:

1. Doctor A has been offered a lunch meeting with a pharmaceutical representative. The representative provides a buffet lunch for the doctor and staff at the expense of the company. During the lunch, the representative will introduce the company's new drug, hoping that doctor A will prescribe it.
2. Doctor B was recently visited by a pharmaceutical representative, who gave the doctor information about one of the company's new drugs. The representative offered the doctor free samples of the drug, for the purpose of distributing to patients free of charge, hoping that doctor B would prescribe the company's drug.
3. Doctor C was contacted by a pharmaceutical representative who has offered the doctor an anatomical model for the examination room. The model has a monetary value of a little under US$100, and has some patient benefit. It bears the name of one of the company's new drugs, which the representative hopes the doctor will prescribe.
4. Doctor D has had a longstanding relationship with a pharmaceutical representative and has been informed that he or she is a ''high-volume prescriber'' of the company's drug. During a visit, the representative offers the doctor an invitation to sit in as a consultant on a market research meeting. The pay for this is lucrative, although in line with what other companies pay doctors for the same service.

The data were analysed with SPSS V.12.0. Descriptive statistics were computed for the measures used in the analyses, which are reported as mean (standard deviation (SD)). Student's t test was used to compare group mean ages. Differences on categorical measures were assessed using the χ^2 test. Group differences on ordinal measures were assessed using the Mann–Whitney U test. Correlations including an ordinal measure used Spearman's ρ coefficient. Related-sample differences on ordinal measures used Wilcoxon's signed rank test. All analyses were tested for significance using $\alpha = 0.05$.

RESULTS

Demographics

A total of 219 questionnaires were returned. Data were excluded from two respondents who were retired, resulting in a valid response rate of 55% (217/395). The mean age (49.50 (SD 8.48) years) and sex ratio (57.6% men) of respondents closely matched that of non-respondents (49.20 (SD 9.16), 56.7% men) and of corresponding ACOG members overall (47.64, 58.1% men). Table 1 shows respondent demographics. Doctors from 45 of the US states responded (states not included were Hawaii, Maine, New Mexico, North Dakota and Rhode Island), as did doctors from the District of Columbia, Canada and overseas military installations. The respondents to this survey were a subset of ACOG members who make up the CARN. Members of CARN typically do not differ from large random samples of ACOG fellows and junior fellows in practice on our other survey instruments.[9] Although our study may be subject to non-response bias, the findings should be reliable. The typical response rate in these surveys ranges from 35% to 60% and, at 55%, our response rate was at the high end of expected participation.

Table 1 Demographics of responding doctors (n = 217)

Characteristics	
Male:female ratio	57.6:42.4
Mean age* (years)	49.50 (8.48)
Men (n = 125)	51.56 (8.93)
Women (n = 92)	46.70 (6.94)
Mean years since residency†	17.96 (8.52)
Men	20.30 (9.08)
Women	14.75 (6.46)
Patient location (%)	
Urban, non-inner city	31.5
Suburban	29.6
Mid-sized town	20.4
Rural	10.2
Urban, inner city	7.9
Practice type (%)	
Obstetrics-gynaecology partnership or group	44.2
Solo practice	27.0
Multispecialty group	14.9
University full-time faculty and practice	10.7
Health maintenance organisation	3.3

Values are percentages or mean (SD) as appropriate.
*$p<0.001$, men were older than women.
†$p<0.001$, men had been out of residency longer than women.

Scenarios

Doctors were asked to indicate their level of agreement with five statements for each of the four scenarios (table 2). Most (91.6%) doctors thought it was ethically proper to accept free samples of a new drug from a pharmaceutical representative. Just over half (53.1%) thought it was ethically proper to accept a well-paid consultantship with a company for which the doctor was purportedly a high-volume prescriber of their drugs. Almost all (96.3%) respondents said they would probably accept free samples, and a third (33.4%) said their decision to prescribe a drug would probably be influenced by accepting the samples.

In the case of the lunch, anatomical model and consultantship, but not the drug samples, doctors were significantly more likely to think that the average physician would accept the item than would they (Wilcoxon's signed rank test, all $p \leqslant 0.002$, except samples $p = 0.305$) and that accepting the item would more likely influence the average physician's prescribing than it would influence theirs (Wilcoxon's signed rank test, all $p \leqslant 0.001$). For all four items, we found positive correlations between viewing the acceptance of the item as ethical and reporting that they personally would accept the item (Spearman's ρ ranging from 0.720 to 0.771, all $p<0.001$). All these analyses suggest that doctors think they are less subject to prescribing bias than is the average physician, and that they generally behave in accordance with what they believe is ethical.

In practice

Doctors were asked whether they had samples of two types of drugs, one specifically gynaecological (oral contraceptives)

Table 2 Percentage of doctors responding

	Percentage of doctors				
Is it ethical for the physician to accept the [item]?	Totally proper	Proper	Neither proper nor improper	Improper	Totally improper
Samples	56.0	35.6	8.3	0.0	0.0
Lunch	40.3	36.6	16.2	4.6	2.3
Model	34.3	40.7	18.5	4.2	2.3
Consultantship	23.3	29.8	22.3	16.7	7.9
Imagine that you were in the position of this physician. Would you accept the [item]?	Almost surely	Probably	Not sure	Probably not	Absolutely not
Samples	66.2	30.1	0.5	1.4	1.9
Lunch	40.5	44.7	5.1	6.0	3.7
Model	35.2	38.4	8.3	13.0	5.1
Consultantship	19.9	25.0	13.0	22.7	19.4
If you accepted the [item], would your decision about whether to prescribe the drug be influenced?	Almost surely	Probably	Not sure	Probably not	Absolutely not
Samples	2.8	30.6	10.2	36.1	20.4
Lunch	0.0	7.9	12.0	44.9	35.2
Model	0.5	2.8	8.9	40.7	47.2
Consultantship	5.7	20.5	10.0	36.7	27.1
Do you think the average physician would accept the [item]?	Almost surely	Probably	Not sure	Probably not	Absolutely not
Samples	55.6	44.0	0.4	0.0	0.0
Lunch	40.7	55.6	2.8	0.9	0.0
Model	25.0	57.4	16.2	1.4	0.0
Consultantship	16.7	38.9	33.3	11.1	0.0
If he/she did accept the [item], would his/her decision about whether to prescribe the drug be influenced?	Almost surely	Probably	Not sure	Probably not	Absolutely not
Samples	4.6	33.3	24.1	31.5	6.5
Lunch	0.5	17.2	25.6	50.2	6.5
Model	0.5	11.6	23.7	51.2	13.0
Consultantship	7.9	29.2	25.0	34.3	3.7

and the other not (antidepressants). More than four fifths (83.8%) said they had samples of third-generation oral contraceptives and 88.4% prescribed such drugs. More than three quarters (78.2%) of doctors said they had samples of antidepressants and 91.7% prescribed such drugs. Most (93.1%) doctors reported distributing free samples of drugs (not specifying type) to their patients. They were presented with five reasons for distributing free samples and were asked to indicate all that applied to them. Most of those who distributed samples said they did so because of the patient's financial need (93.5%), the availability of the samples (89.1%) and for the patient's convenience (76.1%). Less than two thirds (62.7%) selected ''knowledge of the efficacy of the sample product'' as a reason for distributing free samples and 59.7% distributed samples to build a good relationship with the patient.

Regarding relationships with the industry, almost two thirds (65.6%) of doctors were familiar with the guidelines developed by ACOG, a third (33.0%) with those developed by the AMA and a quarter (25.6%) with those given by the PhRMA.[11–13] Those who said they were familiar with guidelines given by the ACOG were more likely to agree that they would probably or almost surely accept the consultantship (51.8% *v* 32.5%; $U = 4017.5$; $p = 0.005$), but not the samples ($p = 0.919$), lunch ($p = 0.451$) or model ($p = 0.824$).

Doctors were asked to indicate their level of agreement with the statement that ''Interactions between industry and physicians, particularly in the form of gifts, should be more strictly regulated''. Two fifths (39.9%) disagreed, a third (33.6%) agreed and 26.5% were neutral. We found negative correlations between responses to this statement and to the scenario statements regarding appropriateness of accepting an item and likelihood of personally accepting the item (all $p<0.001$). In other words, those in greater agreement that interactions should be more strictly regulated were less likely to agree that accepting gifts was proper and were less likely to agree that they would accept them. We found no association between familiarity with guidelines given by the ACOG and agreement that interactions should be regulated ($U = 4777$; $p = 0.579$).

Four fifths (80.4%) of doctors said their primary work institution did not have financial interests in drug or medical equipment companies and 18.2% did not know. Almost one in five (18.8%) reported that they personally had a financial interest in such a company. Having financial interests was not associated with guideline familiarity ($U = 3429$; $p = 0.915$) nor with the statement that interactions should be more strictly regulated ($U = 3239.5$, $p = 0.634$).

DISCUSSION

In our study of the opinions of obstetrician-gynaecologists on accepting incentive items from pharmaceutical company representatives, we found that most respondents thought it was ethically proper to accept items ranging from drug samples to a lucrative consultantship, and that accepting such items would probably not influence their prescribing. Acceptance of drug samples was judged to be ethical by almost all respondents and acceptance of a lucrative consultantship by just over a half. Respondents seem to believe that the average doctor is more likely to accept most

items and is more likely to be influenced in his or her prescribing practices by accepting an item than they are. Most doctors distributed free drug samples, and are more likely to do so based on a patient's financial need or sample availability than on knowledge of the effectiveness of the sample product. Only one third of the doctors thought interactions with industry should be more strictly regulated. Two thirds of the doctors were familiar with guidelines given by the ACOG for relationships with industry—a level of familiarity in line with self reports of familiarity with other recent ACOG guidelines.[11 14 15]

Our findings from a sample of obstetrician-gynaecologists are in line with findings from studies on other groups of doctors. In a study of a random sample of US doctors, 9 in 10 had free drug samples available.[16] In two other studies, over half the respondents thought that drug samples would influence their prescribing.[17 18] As in our study, other studies have also found that prescribing bias in response to pharmaceutical incentives is thought to be more likely in other doctors than in themselves.[19 20] Avoiding cost to patients was also the reason most commonly selected for dispensing free drug samples in general medicine and by family doctors.[21] Another study also reported that two thirds of doctors were familiar with at least one guideline on the interactions of doctors and pharmaceutical companies.[18]

Of the incentive items presented in our study scenarios, free drug samples elicited the least ethically consistent responses. Most respondents said they would accept free drug samples and that accepting was ethically appropriate; however, a third said accepting the items would probably influence their prescribing. This pattern of responses suggests that prescribing bias is acknowledged and accepted by several doctors. Patients may make a similar exception for drug samples. In a study of the attitudes of patients regarding gifts to doctors from the pharmaceutical industry, few patients disapproved of free drug samples; further, the belief that various gifts influenced prescribing behaviour was associated with the level of disapproval for that gift, but not so for drug samples.[22] By contrast, although most of our respondents would accept the lunch, very few thought their prescribing would be influenced by doing so, a more consistent response pattern. Similarly, over a quarter of the doctors thought accepting consultantship would influence their prescribing, but respondents were much less likely to say they would accept the consultantship than they would the other incentive items.

What makes the distribution of free drug samples so acceptable despite evidence of their influence on prescribing practices? Is it their ubiquity? Is it the seemingly insignificant value of each sample? Perhaps the perceived need for patients to have inexpensive and immediate access to drugs outweighs the concern that samples influence which drug doctors prescribe. As incentives go, samples provide the most direct benefit to the patient and the least tangible benefit to the doctor. Among our respondents, most distribute free samples on the basis of the patient's financial need. In an accompanying survey, when asked what the best way to treat possibly depressed hypothetical patients would be, we found that respondents who had samples of antidepressants available were far more likely to indicate treatment with antidepressants than were those who did not have samples available.[23] This suggests an association between sample availability and increased prescribing. Alternative explanations are possible—for example, doctors who are more likely to prescribe may be more likely to keep samples available. Or doctors who distribute free samples of drugs to their patients may have in their practice only samples of the drugs that they prescribed anyway because the product had been approved by their institution or practice group. Other data, however, suggest otherwise. Fewer than two thirds of our respondents indicated that they distributed free samples on the basis of the knowledge of the drug's effectiveness. Further, sample availability may lead to increased prescribing of the sample drug once the free drug has run out,[24] even if the sample differs from the doctor's preferred drug.[21] This can lead to increased costs for the patient because samples are typically of new, more expensive products, not the less expensive generic or older products.[25]

The belief that accepting other types of incentive items, such as an informational lunch meeting or an anatomical model, would not influence prescribing is in line with other findings.[3] It seems that accepting such items may influence prescribing, although research in the social sciences indicates that such bias is unintentional and unconscious.[3 8]

Concerns about the influence of pharmaceutical companies on clinical practices are not limited to the US; despite differences in healthcare structures, the UK seems to be struggling with similar issues. The House of Commons Health Committee recently conducted an inquiry into the pharmaceutical industry's excessive influence:

> The consequences of lax oversight is that the industry's influence has expanded and a number of practices have developed which act against the public interest. The industry affects every level of healthcare provision …[7]

The recent ''How to dance with porcupines: rules and guidelines on doctors' relations with drug companies,'' from the UK, points to the complex and potentially dangerous relationships between drug companies and medical practitioners.[26] As in the US, a study on UK general practitioners found that most respondents realised that marketing techniques could influence their prescribing, but were generally confident that they would not succumb to such pressure.[27] Another study on UK general practitioners found that almost all met pharmaceutical representatives, and that the most frequently used source of information for evaluating drugs was the pharmaceutical industry, despite general practitioners questioning the industry's objectivity.[28] Also, those who had more frequent contact with pharmaceutical representatives were more prone to behaviours leading to unnecessary prescribing.[29] A similar survey of attitudes of European doctors on accepting incentive items and prescribing bias may be quite interesting.

The possibility that pharmaceutical companies are providing doctors with gifts that exert a powerful influence on clinical decision making has led government, pharmaceutical and professional agencies to update their guidelines or recommendations for appropriate interactions, both in the US and in other countries. The ACOG, the AMA, the PhRMA and the Association of the British Pharmaceutical Industry have all recently revised their codes.[6 11–13] The AMA guidelines on gifts to doctors have been adapted by both the ACOG and the PhRMA and state, in part:

> Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples.[12]

The Association of the British Pharmaceutical Industry code similarly limits gifts and hospitality. Regarding the provision of samples, the AMA code does not consider the

possibility that the ubiquitous free drug samples may influence prescribing. The PhRMA's Code on interactions with industry mentions drug samples only in passing.[13] The ACOG adds that ''Physicians have an obligation to go beyond the information provided through advertising or other marketing strategies in selecting the best product for care of the patient.''[11] The ACOG also goes a step further, warning that prescribing practices can be influenced by gifts in a way that doctors may be unaware of, and that the enormous value of the free samples distributed by pharmaceutical companies is likely to have an effect on practices unrelated to drug merits.[11]

We found, as have others, that most doctors do not think that accepting incentive items from industry influenced their prescribing; regarding drug samples, even those who do think that their prescribing is being influenced think that accepting samples is ethical. Some (including the authors of this paper) suggested that the only way to exclude bias is to do away with incentive items entirely, because bias remains even when people are taught about bias.[8] Some studies, however, suggest that educational interventions may be effective in changing attitudes or behaviours towards interactions.[30 31] We found that most doctors do not think that interactions between doctors and industry should be more strictly regulated. The generally held view that accepting modest incentive items such as drug samples is appropriate and primarily of benefit to the patient needs to be reconsidered, both by doctors and policy makers, and continues to require more attention in guidelines as well as early on in medical education programmes.

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