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Appropriateness of Collaborations between Industry and the Medical Profession: Physicians' Perceptions

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Abstract

Background—Physicians' ratings of the appropriateness of collaboration and of receiving payment for collaboration with the pharmaceutical and medical device industries may differ.

Methods—We administered an anonymous, cross-sectional survey to a convenience sample of faculty and post-graduate physicians from all departments within the 11 hospitals affiliated with the Mount Sinai School of Medicine in New York City and New Jersey. We examined 12 collaborations with the pharmaceutical and medical device industries using 4-point Likert scales, ranging from very appropriate to very inappropriate.

Results—Surveys were distributed to physicians within 35 departments at 11 hospitals; 590 surveys were completed by physicians at 9 hospitals, yielding a 67% response rate. Physicians assessment of appropriateness varied among the different collaborations, ranging from nearly all rating developing a drug or device (92%) and designing a drug/device trial (91%) as appropriate to fewer rating preparing a manuscript of a drug/device trial (60%) and recruiting patients for a drug/device trial (65%) as appropriate for physicians not involved in trial design. Physicians consistently rated receiving payment for collaboration as appropriate less often than they rated the collaboration itself as appropriate and ratings varied among the collaborations. For example, 81% rated receiving payment to develop a drug or device as appropriate, whereas 38% rated receiving payment to recruit patients for a drug/device trial when the physician was not involved in trial design as appropriate.

Conclusions—Physicians' broadly perceived most collaboration with the pharmaceutical and medical device industries, and of receiving payment for collaboration, as appropriate.

Keywords

Attitude of Health Personnel; Drug Industry; Biomedical Research

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INTRODUCTION

Patients and the general public are well served when the pharmaceutical and medical device industries work together with physicians and academicians for the common good. Collaborations may generate new knowledge, could lead to the development of new diagnostic and therapeutic products, and can ensure appropriate and rapid dissemination of those products that are effective and safe to save lives and improve quality of life. However, scandals involving industry and the medical profession have led both the public and some within the medical profession to question the value of these collaborations for patients.¹ Instead, these partnerships are perceived as conflicts of interest. In order to establish standards to regulate physician-industry collaborations, a number of organizations have suggested codes of conduct for ethical behavior, including the American Medical Association,² the American Association of Medical Colleges,³ and the U.S. trade organizations for the pharmaceutical and medical device industries: the Pharmaceutical Research and Manufacturers Association and the Advanced Medical Technology Association.^{4, 5}

Absent from many of these codes of conduct is a current understanding of what collaborations practicing physicians in academic and non-academic settings regard as appropriate or inappropriate. Instead, many guidelines highlight the clearly unethical (i.e., ghostwriting manuscripts) and recommend their discontinuation, or alternatively highlight the clearly ethical (i.e., industry-government research funding partnerships of academic investigators) and recommend their continuation. Prior research has documented the epidemiology of physician-industry relationships, finding that 94% of physicians reported some type of relationship with industry, most of which involve receiving food in the workplace or drug samples, while 28% received payments for consulting, giving lectures, or enrolling patients in trials.⁶ However, there has not been sufficient focus on understanding physician-industry collaborations and determining how physicians' perceive the appropriateness of industry collaborations or of receiving payment for these collaborations.

Improving our understanding of how physicians' perceive the appropriateness of collaborations with industry will inform future efforts to establish standards of ethical behavior. Ideally, this information will make such standards more effective by ensuring they are addressing behaviors that are not only clearly ethical or unethical but also by addressing behaviors around which there is uncertainty and ambivalence. Accordingly, our objective was to describe physicians' perceptions of the appropriateness of various collaborations with the pharmaceutical and medical device industries and of receiving payment for collaboration, both overall and to examine whether there are differences in ratings among physicians from different Departments.

METHODS

Survey Distribution

We distributed a cross-sectional survey to physicians at the 11 consortium hospitals of the Mount Sinai School of Medicine in New York City, New York. Consortium institutions include the Mount Sinai Hospital, the primary affiliated academic medical center, as well as community-based and municipal hospitals throughout the New York metropolitan area (including Manhattan, Queens, and Brooklyn counties) and northern New Jersey. The Mount Sinai School of Medicine has a policy which bans or limits marketing-related interactions between physicians and industry and which applies to faculty at all affiliated hospitals. Potential participants included faculty and post-graduate trainees from all

departments of all consortium hospitals as well as 3rd and 4th year medical students on educational rotations within those departments, representing a convenience sample.

To distribute surveys, we first contacted a department representative at consortium hospitals to ask permission to distribute surveys. Representatives included department chairmen, residency program directors, or department administrators. We then used one of two methods to distribute surveys, depending upon the department size. For small departments, we distributed the survey to potential participants through department administrators. Administrators pre-specified the required number of surveys based on the number of potential departmental participants, distributed the survey one time internally and then collected and returned anonymous surveys. The number of distributed surveys was used to calculate response rates. For larger departments, a research assistant attended one Grand Rounds presentation for each Department, where surveys were distributed to all potential participants in attendance at the beginning of the lecture and collected at the end. Again, the number of distributed surveys was used to calculate response rates. All potential participants were informed of the voluntary nature of the study and that their responses were strictly anonymous.

We administered all surveys anonymously, but subjects who completed the survey were eligible to submit their name and email address using a separate form for the opportunity to receive one of two \$100 gift cards. All surveys were distributed and collected between June 1 and September 1, 2008. Gift cards were awarded to two randomly selected respondents in September 2008. The survey required approximately 10-15 minutes to complete and was approved by the institutional review board of the Mount Sinai School of Medicine.

Survey Design

The survey assessed demographic characteristics, including standard questions about sex, race/ethnicity, hospital and department affiliation, level of training, and time since graduation, and a question about past collaborations with the device or pharmaceutical industry. The survey had been piloted for readability but not validated. To assess the appropriateness of collaborations between physicians and industry, we reviewed the literature and incorporated key questions and themes from prior studies⁷⁻¹⁰ and then created new questions to examine additional areas of interest. We used 4-point Likert scales to examine physician ratings of the appropriateness of 12 collaborations between physicians and either the pharmaceutical or device industry, related to product development, product testing (including clinical trials), dissemination of findings (including manuscripts and educational lectures), and advisory board participation, using the following responses: “very appropriate”, “appropriate”, “inappropriate” and “very inappropriate”. Subsequent questions examined physician ratings of the appropriateness of receiving remuneration for each of the previous 12 collaborations.

Data Analysis

We used descriptive statistics to report physician ratings of the appropriateness of collaborations between physicians and the pharmaceutical/device industries, as well as the appropriateness of receiving remuneration for these collaborations, collapsing the “very appropriate” and “appropriate” response categories as “appropriate”. We then used Chi-square tests to test for differences in these physician ratings, comparing physicians by academic department. For the purposes of analysis, we categorized physicians’ Departments into the following specialty groups: internal/general/family medicine, internal medicine subspecialty, pediatrics, psychiatry, general surgery/surgical subspecialty/OB/GYN, or other. Analyses were performed using SAS 9.1 (SAS Institute, Inc., Cary, NC). All

statistical tests were 2-tailed and used a type I error rate of 0.004 to account for multiple comparisons.

RESULTS

We attempted to contact 61 departments at 11 hospitals within the Mount Sinai consortium to arrange for distribution of surveys to potential physician participants. Thirty-five agreed to allow survey distribution, 9 agreed to allow survey distribution but were unable to coordinate distribution during the study period, 3 declined, and 14 did not respond to our inquiry. The 35 participating departments from 9 hospitals represented academic, community and municipal centers in Manhattan, Queens, Brooklyn and New Jersey.

We received 590 completed surveys, a response rate of 67% among our convenience sample. Respondents were 59% male, 54% self-identified as white, 39% were attending physicians and 56% were in post-graduate training (residency or fellowship) (Table 1). Respondents represented many academic departments; 24% were within internal/general/family medicine and 24% were within general surgery/surgical subspecialty/OB/GYN. Fifty four percent of respondents were familiar with their institution's policy on industry interactions and 25% had collaborated with industry.

Appropriateness of Collaborations

Physicians assessment of appropriateness varied among the different collaborations (Table 2), ranging from nearly all rating collaborating to develop a drug or device (92%) and collaborating to design a drug/device trial (91%) as appropriate to fewer rating collaborating to prepare a manuscript of a drug/device trial (60%) and collaborating to recruit patients for a drug/device trial (65%) as appropriate for physicians not involved in trial design.

We found differences in ratings of the appropriateness of 4 of the 12 collaborations among physicians from different Departments: collaborating to develop a drug or device, provide educational lectures, and prepare a manuscript and recruit patients for a drug/device trial for physicians not involved in trial design. Physicians within general surgery/surgical subspecialty/OB/GYN were more likely to rate collaborations as appropriate (Table 2), whereas physicians within pediatrics were less likely.

Appropriateness of Remuneration for Collaborations

Physicians consistently rated receiving payment for collaboration as appropriate less often than they rated the collaboration itself as appropriate and ratings varied among the collaborations (Table 3). For example, 81% rated receiving payment for collaborating to develop a drug or device and 73% rated receiving payment for collaborating to design a drug/device trial as appropriate, whereas 40% rated receiving payment for collaborating to prepare a manuscript of a drug/device trial and 38% rated receiving payment for collaborating to recruit patients for a drug/device trial when the physician was not involved in trial design as appropriate.

We found differences in ratings of the appropriateness of receiving payment for only 1 of the 12 collaborations between physicians within different Departments: receiving payment for collaborating to develop a drug or device. Again, in general, physicians within general surgery/surgical subspecialty/OB/GYN were more likely to rate receiving payment for collaborations as appropriate (Table 3), whereas physicians within pediatrics were less likely, although these differences were not statistically significant.

DISCUSSION

We found a great deal of consensus among physicians with respect to the appropriateness of much collaboration between physicians and the pharmaceutical and medical device industries. More than 75% of physicians rated as appropriate collaborations such as serving on an advisory board and both recruiting patients for a drug/device trial and preparing a manuscript describing a drug/device trial so long as the physician was involved in the trial design. Surprisingly, nearly as many physicians rated the last collaboration as appropriate even when the physician was not involved in the trial design, an activity that may conflict with the authorship standards of the World Association of Medical Editors¹¹ and is generally discouraged for being unethical. Similarly, the high ratings of appropriateness by physicians of other activities, such as editing a review manuscript drafted by the company and serving on a clinical trial Data Safety and Monitoring Board when a company representative is present, may also conflict with other professional standards.¹¹⁻¹³

There was less consensus among physicians with respect to the appropriateness of receiving payments for collaboration between physicians and the pharmaceutical and medical device industries. While approximately three-quarters of physicians rated as appropriate receiving payment for collaborating to develop a drug or device, approximately half rated as appropriate receiving payment for collaborations such as providing educational lectures (beyond room and board) and recruiting patients or preparing a manuscript for a drug/device trial so long as the physician was involved in the trial design. Fewer than half of physicians rated as appropriate receiving payment for recruiting patients or preparing a manuscript for a drug/device trial when the physician was not involved in the trial design.

Although physicians' perceptions of the appropriateness of various collaborations with the pharmaceutical and medical device industries and of receiving payment for collaboration varied, there were few consistent differences across specialties as to whether collaborations were considered appropriate. More physicians within general surgery/surgical subspecialty/OB/GYN tended to rate collaborations as appropriate and fewer physicians within pediatrics tended to rate collaborations as appropriate, although many of these differences were not statistically significant. Physicians within other Departments, such as internal/general/family medicine, internal medicine subspecialty, and psychiatry, all tended to rate collaborations as appropriate at similar rates. Perhaps these ratings of appropriateness reflect the more complex relationships of surgeons with industry, particularly representatives from the device industry. Surgeons rely on industry representatives to learn about and to receive training to use new devices, often with industry representatives present in the operating room, such that collaborations may often appear to be a necessity for professional development.

Whereas the public seems to have grown increasingly concerned about the financial relationships between industry and the medical profession, we found that the majority of physicians rate as appropriate receiving payment for nearly all collaborations surveyed, including providing educational lectures and recruiting patients for clinical trials, both of which are often considered part of the duty of the profession (i.e., advancing education and scientific knowledge) and for which there probably should not be remuneration. For the profession to restore and maintain its public standing, physicians should prioritize improving the public perception of industry collaborations by ensuring they are transparent and focused on improving patient care, particularly in the face of declining trust in the profession.¹⁴ Clearly, much collaboration is focused on and leads to improved care for patients. However, high ratings of appropriateness by physicians of activities that conflict with professional standards speaks to a disconnection between those experts writing said standards and the practicing physicians in academic and non-academic settings who are expected to adhere to them. To this end, the medical profession and industry trade organizations should offer

explicit guidance on the appropriateness of different scientific and editorial collaborations. Adherence to this guidance should be a professional obligation, encouraged by state medical societies and Department leaders. To ensure its rapid uptake, coordinated education and professional development activities can be employed to improve physician knowledge, closing the “appropriateness” gaps between expert guidance and practicing physicians and establishing standards of behavior that ensure public confidence in the medical profession is not further eroded by perceived conflicts of interest.

Our study had several important limitations. First, we examined a convenience sample of physicians. We attempted to minimize selection bias by surveying all faculty attendees of grand rounds or all faculty in smaller departments and we achieved a 67% response rate. However, by recruiting participants at departmental grand rounds, we may have underestimated physician ratings of appropriateness of collaborations between physicians and industry because we may have been more likely to survey more academically oriented physicians, who may be more aware of the influence of industry. Second, the Mount Sinai School of Medicine has a policy which bans or limits marketing-related interactions between physicians and industry and which applies to faculty at all affiliated hospitals, making our estimates of appropriateness more conservative and perhaps less generalizable to the greater physician population in private clinical practice. Third, despite it being administered anonymously, our survey may have been susceptible to response bias, where respondents favor socially desirable responses, which would again likely lead to underestimates of physician ratings of appropriateness of collaborations between physicians and industry. Finally, our use of a Likert-scale rating system, as opposed to open-ended survey responses, prohibits a more nuanced understanding of what are clearly complex collaborations between the medical profession and the pharmaceutical and medical device industries.

In conclusion, our study is among the first to describe physicians’ perceptions of the appropriateness of various collaborations with the pharmaceutical and medical device industries and of receiving payment for collaboration, both overall and among physicians from different Departments. This information should be used to inform currently recommended standards of conduct, improving their effectiveness by ensuring they are addressing behaviors that are not only clearly ethical or unethical but also by addressing behaviors around which there is uncertainty and ambivalence.

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Table 1Respondent Characteristics (n=590).^a

Sex	
Male	351 (59)
Female	239 (41)
Race/Ethnicity	
White	320 (54)
Asian	154 (26)
African-American	32 (5)
Other	84 (14)
Academic Department ^b	
Internal/Family/General Medicine	131 (24)
Internal Medicine Subspecialty	58 (10)
Pediatrics	54 (10)
General Surgery, Surgical Subspecialty or OB/GYN	131 (24)
Psychiatry	53 (10)
Other	126 (23)
Training level	
Medical Student	37 (6)
Intern, Resident or Fellow	319 (56)
Attending	230 (39)
Mean time since graduation, ^b y (range)	12.8 (1 to 67)
Practiced medicine for 20 years or more ^c	126 (56)
Affiliated with an Academic Medical Center (Mount Sinai School of Medicine) ^c	111 (50)
Familiar with Institution's guidelines about pharmaceutical/device industry interactions	313 (54)
Worked collaboratively in past with pharmaceutical/device industry	145 (25)

^aValues expressed as number (percentage) unless otherwise noted. Percentages may not sum to 100 because of rounding.

^bAmong physicians who have graduated from medical school (excludes medical students).

^cAmong physician no longer in post-graduate medical training (attendings only).

Table 2

Percentage that rate the following collaborations between physicians and the pharmaceutical/device industry as “Very Appropriate” or “Appropriate”, stratified by Academic Department, training level, and familiarity with institution’s guidelines for interactions between physicians and the pharmaceutical/device industries.

	Overall Sample, No. (%)	Academic Department, No. (%)					P value
		IM/GP/EM	IM Subsp.	Peds.	Surg./ OBGyn	Psych.	
						Other	
Develop/Design drug/device	531 (92)	132 (94)	56 (92)	45 (83)	129 (97)	47 (84)	0.009
Develop/Design clinical trial to test drug/device safety/efficacy	523 (91)	124 (89)	53 (89)	53 (87)	126 (95)	48 (87)	0.23
Recruit patients for clinical trial to test drug/device (MD involved in trial design)	455 (79)	103 (75)	50 (83)	40 (74)	114 (86)	42 (76)	0.22
Recruit patients for clinical trial to test drug/device (MD not involved in trial design)	369 (65)	83 (60)	40 (67)	31 (57)	103 (79)	28 (52)	0.003
Prepare manuscript of clinical trial of drug/device (MD involved in trial design)	481 (84)	113 (83)	53 (87)	43 (80)	111 (85)	48 (87)	0.87
Prepare manuscript of clinical trial of drug/device (MD not involved in trial design)	339 (60)	78 (57)	33 (55)	22 (42)	94 (72)	29 (55)	0.003
Prepare review manuscript (MD drafts original)	497 (88)	120 (88)	50 (86)	42 (81)	120 (92)	49 (91)	0.44
Edit review manuscript (Drug/Device Co. drafts original)	440 (78)	108 (79)	41 (72)	38 (73)	108 (84)	41 (75)	0.41
Serve on clinical trial DSMB (No Drug/Device Co. Reps. present)	476 (84)	115 (84)	50 (86)	39 (72)	117 (90)	42 (76)	0.03
Serve on clinical trial DSMB (Drug/Device Co. Reps. present)	482 (86)	118 (86)	51 (89)	39 (72)	114 (88)	46 (84)	0.08

	Overall Sample, No. (%)	Academic Department, No. (%)					P value
		IM/GP/FM	IM Subsp.	Peds.	Surg./ OBGyn	Psych.	
Provide educational lectures	413 (73)	95 (71)	42 (70)	31 (57)	112 (86)	32 (58)	<0.001
Serve on advisory boards	455 (81)	111 (83)	50 (85)	38 (72)	113 (87)	41 (75)	0.11

Note: IM=Internal Medicine; GP=General Practice; FM=Family Medicine; Subsp.=Subspecialty; Peds=Pediatrics; Surg.=Surgery; OBGyn=Obstetrics & Gynecology; Psych.=Psychiatry; Reps.=Representatives.

Table 3

Percentage that rate the following payments for collaborations between physicians and the pharmaceutical/device industry as “Very Appropriate” or “Appropriate”, stratified by Academic Department, training level, and familiarity with institution’s guidelines for interactions between physicians and the pharmaceutical/device industries.

	Overall Sample, No. (%)	Academic Department, No. (%)					P value
		IM/GP/EM	IM Subsp.	Peds.	Surg./OBGyn	Psych.	Other
Develop/Design drug/device	468 (81)	116 (83)	49 (83)	39 (72)	122 (92)	42 (75)	100 (75)
Develop/Design clinical trial to test drug/device safety/efficacy	419 (73)	100 (71)	44 (75)	35 (65)	106 (80)	40 (73)	94 (71)
Recruit patients for clinical trial to test drug/device (MD involved in trial design)	288 (50)	68 (49)	33 (55)	27 (50)	67 (50)	31 (65)	62 (47)
Recruit patients for clinical trial to test drug/device (MD not involved in trial design)	218 (38)	53 (38)	23 (38)	17 (31)	65 (49)	13 (24)	47 (36)
Prepare manuscript of clinical trial of drug/device (MD involved in trial design)	323 (57)	83 (60)	34 (60)	30 (57)	62 (47)	37 (67)	77 (59)
Prepare manuscript of clinical trial of drug/device (MD not involved in trial design)	224 (40)	59 (43)	25 (42)	13 (25)	52 (40)	18 (33)	57 (44)
Prepare review manuscript (MD drafts original)	337 (60)	91 (67)	32 (54)	28 (53)	70 (54)	35 (64)	81 (61)
Edit review manuscript (Drug/Device Co. drafts original)	324 (57)	87 (64)	28 (47)	29 (55)	68 (52)	31 (56)	81 (61)
Serve on clinical trial DSMB (No Drug/Device Co. Reps. present)	348 (62)	87 (64)	35 (60)	29 (54)	84 (65)	33 (60)	80 (61)
Serve on clinical trial DSMB (Drug/Device Co. Reps. present)	358 (63)	87 (64)	39 (67)	29 (54)	87 (67)	35 (64)	81 (62)

	Overall Sample, No. (%)	Academic Department, No. (%)					P value
		IM/GP/FM	IM Subsp.	Peds.	Surg./ OBGyn	Psych.	Other
Provide educational lectures (beyond room and board)	311 (55)	76 (57)	31 (52)	24 (45)	84 (65)	22 (40)	74 (57)
Serve on advisory boards	383 (68)	97 (72)	42 (71)	28 (53)	97 (75)	32 (58)	87 (66)
							0.03
							0.03

Note: IM=Internal Medicine; GP=General Practice; FM=Family Medicine; Subsp.=Subspecialty; Peds.=Pediatrics; Surg.=Surgery; OBGyn=Obstetrics & Gynecology; Psych.=Psychiatry; Reps.=Representatives.