RESEARCH ETHICS

Scientific misconduct from the perspective of research coordinators: a national survey

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Objective: To report results from a national survey of coordinators and managers of clinical research studies in the US on their perceptions of and experiences with scientific misconduct.

Methods: Data were collected using the Scientific Misconduct Questionnaire-Revised. Eligible responses were received from 1645 of 5302 (31%) surveys sent to members of the Association of Clinical Research Professionals and to subscribers of *Research Practitioner*, published by the Center for Clinical Research Practice, between February 2004 and January 2005.

Findings: Overall, the perceived frequency of misconduct was low. Differences were noted between workplaces with regard to perceived pressures on investigators and research coordinators, and on the effectiveness of the regulatory environment in reducing misconduct. First-hand experience with an incident of misconduct was reported by 18% of respondents. Those with first-hand knowledge of misconduct were more likely to report working in an academic medical setting, and to report that a typical research coordinator would probably do nothing if aware that a principal investigator or research staff member was involved in an incident of misconduct.

Conclusion: These findings expand the knowledge on scientific misconduct by adding new information from the perspective of research coordinators. The findings provide some data supporting the influence of workplace climate on misconduct and also on the perceived effectiveness of institutional policies to reduce scientific misconduct.

The definition of research misconduct used by the US Department of Health and Human Services Office of Research Integrity (ORI) is ''fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results''.[1] The ORI definitions of fabrication and falsification encompass selective or misrepresentative reporting of study data and manipulation of study subjects to influence results. Other practices have also been identified as deviations from acceptable procedures, such as undisclosed conflicts of interest, safety violations and misuse of funds.[2 3]

A limited number of studies in the past 20 years have provided information on the prevalence of misconduct, although its true extent remains unknown. In the early 1990s, Norwegian investigators reported that 27% of the 119 research project administrators surveyed knew of a case of scientific misconduct, but 42% stated that this knowledge was not publicly known.[4] These findings were corroborated by other concurrent survey research and detailed audits of research practices of individual scientists.[5–9] A higher prevalence was obtained in a 1998 survey of biostatisticians, where a majority of respondents (51%) indicated knowledge of a fraudulent research project within the preceding decade, and in a 2001 survey of newly appointed British medical consultants, where 56% of respondents reported observing misconduct and 11% reported first-hand knowledge of data fabrication.[10 11] More recently, investigators who conducted a survey of published authors of pharmaceutical trials reported that 17% of respondents indicated knowledge of an instance of misrepresentation or fabrication of data; however, a much lower percentage (0.3%) of federally funded US researchers self-reported falsifying data.[12 13]

Many factors have been postulated as contributing to the occurrence of scientific misconduct. The ethical climate of the organisation in which the research takes place is one such factor.[14] Other relevant environmental factors include the amount of oversight, existence of explicit versus implicit rules, penalties and rewards attached to such rules, access to resources and extent of ongoing training. On an individual level, pressures for promotion and tenure, competition among investigators, need for recognition, desire for financial gain, ego, and conflicting personal and professional obligations are cited as factors that may influence certain individuals to engage in misconduct.[2 15 16] The relative importance of these factors on actual occurrences of scientific misconduct remains unclear.

The majority of research on scientific misconduct has focused on the investigators themselves, but actual implementation of research projects is often the responsibility of other personnel. In particular, the role of the research coordinator has developed over the past two decades to meet the increasingly complex demands of the clinical research environment.[17] Typical activities for people in this role include recruitment of subjects, obtaining informed consent, monitoring patient progress, coordination of laboratory and study procedures, and managing trial-related data.[18] As a group, these individuals hold a unique position in managing clinical trials and can be expected to be aware of and even influence the scientific integrity with which the research is conceptualised, and implemented, and the findings disseminated. Yet, little is known about research coordinators' perceptions, attitudes and knowledge about scientific misconduct.

The number of people functioning as research coordinators in the US is not known; however, an estimated 4400 US members of the Association of Clinical Research Professionals (ACRP) identified themselves as research coordinators in 2001 (http://www.acrpnet.org/). Additionally, many research coordinators subscribe to *Research Practitioner*, published by the Center for

Abbreviations: ACRP, Association of Clinical Research Professionals; ORI, Office of Research Integrity; PI, principal investigator; SMQ-R, Scientific Misconduct Questionnaire-Revised

Clinical Research Practice. The purpose of this project was to conduct a national survey of research coordinators in the US to obtain information about their values, beliefs, practices and experiences related to scientific integrity and misconduct.

METHODS

Subjects and sample

This study used a cross-sectional survey design and sampled individuals from across the US in a variety of research settings. The sample consisted of 5302 likely research coordinators selected from the mailing lists of ACRP or Center for Clinical Research Practice, without duplicates. A research coordinator was defined as a respondent indicating responsibility for either enrolment and/or follow-up of subjects in at least one clinical study. This definition was based on job function rather than on job title. Respondents who indicated that they did not have responsibility for either subject enrolment or follow-up were excluded from the analysis. Responses were received from 1785 persons for an overall return rate of 34%. A total of 1645 eligible responses formed the analysis sample, which represented a final return rate of 31%. Data collection occurred from February 2004 to January 2005.

Instrumentation

Data were collected using the Scientific Misconduct Questionnaire-Revised (SMQ-R). This instrument was substantially revised and expanded from the original SMQ, developed by Rankin and Esteves.[16] Development of the instrument and its psychometric properties have been described in detail elsewhere.[19] The SMQ-R has 68 items, divided among 6 sections, including demographic and work setting information and closed-choice Likert-type items about perceptions of institutional factors that influence scientific misconduct, behavioural influences on scientific misconduct and perceived frequency of specific types of scientific misconduct. The Cronbach's α reliability estimates for these three subscales ranged from 0.71 to 0.84. Additional forced-choice items assessed attitudes and beliefs about misconduct, and reporting practices related to scientific misconduct. Respondents who indicated awareness of an actual incident of scientific misconduct were asked to complete 12 additional open-ended questions describing their experiences. Results from these open-ended responses are not included in this report.

Survey procedure

Following procedures developed by Dillman[20] and by Fink[21], questionnaires, cover letters and stamped, self-addressed envelopes were mailed through a contracted third-party mailing service. An identification code assigned by the mailing service allowed second mailings to be sent to non-responders by the same mailing service. All completed questionnaires were returned to the investigators at the university. The anonymous responses were then reviewed to determine eligibility based on job responsibilities.

Data management and analyses

Data were entered into an SPSS V.11.5 database using TeleForm, a scantron-based data-entry system developed by Cardiff (Cardiff, an Autonomy Company, Vista, California, USA). Use of TeleForm eliminates most manual data entry and provides the capability of automatically cleaning and confirming content during data and document capture.

Descriptive analyses were performed on the individual items of the SMQ-R, with frequencies and percentages for categorical and Likert-type response items and means and SD for continuous variables. Chi-square analyses were performed to test hypotheses examining differences in frequency of responses related to factors influencing misconduct and reporting of misconduct based on type of institution and first-hand experience with an actual incident of scientific misconduct.

FINDINGS

Demographic and work setting characteristics

Respondents were predominantly female (95%) and Caucasian (92%). The mean (SD) age of respondents was 46.0 (8.7) years, range of 22–78. The most frequently reported educational background was a baccalaureate degree (43%). Most respondents were registered nurses (64%) and were certified in clinical research (75%).

Almost two-thirds of respondents described their job position as a research coordinator (64%). Various job titles were given in the ''Other'' category, including research associate, manager, supervisor or administrator, as well as site manager or project director. The average length of time in their current position was 7.6 (5.6) years and working in research was 10.3 (6.1) years. The most common work settings reported were academic medical centre (45.4%), private medical practice/health maintenance organisation (25.8%) and freestanding research facility (13.3%). Other settings, in decreasing order of frequency, included non-academic medical centre or community hospital, site management organisation, commercial sponsor and government agency. Commercially sponsored clinical trials were the dominant type of study in which respondents participated.

On average, respondents reported primary responsibility for subject enrolment in 5.2 (7.3) studies per month, and 93% of respondents indicated that they were responsible for enrolment for $\leqslant 10$ studies per month. Respondents reported primary responsibility for subject follow-up for a mean of 7.5 (10.9) studies per month. Almost all respondents (97%) rated their own understanding of rules and procedures related to scientific misconduct as high or very high.

First-hand knowledge of misconduct

Just under one-fifth ($n = 301$, 18.3%) of respondents indicated first-hand knowledge of an actual occurrence of misconduct within the previous year. Respondents identifying their institutional setting as an academic medical centre were more likely to indicate first-hand knowledge of an incident compared with all other settings combined (21.9% vs 15.3%, $\chi^2 = 11.78$, $df = 1$, $p = 0.001$).

Perception of institutional influences on scientific misconduct

With regard to pressures on investigators, workplace investigator competitiveness was rated high or very high by 54.1% of respondents and pressure on investigators to obtain external funding was rated high or very high by 45.8% of respondents. These pressures differed significantly by workplace. Respondents from academic centres were more likely to rate pressure for external funding as high or very high, whereas respondents from private practice/health maintenance organisations, freestanding research facilities or site management organisations were more likely to rate such pressure as very low ($\chi^2 = 409.6$, $df = 12$, $p<0.001$). Also, respondents from academic centres and freestanding research facilities were less likely to rate competitiveness as low or very low, respectively ($\chi^2 = 53.6$, $df = 12$, $p<0.001$).

Most research coordinators rated the effectiveness of their institutional policies and procedures in reducing scientific misconduct as high (49.5%) or very high (37.7%); however, lower ratings were more likely from subjects who indicated first-hand knowledge of an actual occurrence of misconduct

compared with those without such knowledge ($\chi^2 = 116.3$, df = 3, $p<0.001$). In addition, respondents from academic medical centres were less likely to rate the effectiveness of their organisational procedures for reducing misconduct as very high compared with other workplaces combined ($\chi^2 = 20.6$, df = 3, $p<0.001$).

Chances of getting caught were rated as high by 68% of respondents. Severity of penalties if caught was rated as high by 75% of respondents, although 10% thought that the likelihood of disciplinary action against someone reported for misconduct would vary by the person's position (ie, investigator vs staff). Differences were noted among responses for these items based on workplace. Respondents from private medical practice/health maintenance organisation settings were more likely than other workplaces, to rate the chances of getting caught and the severity of penalties as very low ($\chi^2 = 27.1$, df = 12, $p = 0.008$ and $\chi^2 = 49.9$, df = 12, $p<0.001$, respectively).

Behavioural influences on scientific misconduct

The behavioural influences identified by at least 25% of the sample as having a strong influence on misconduct fell into two categories: investigator pressures including needs for funding, recognition and publications, and research coordinator pressures related to workload, including number and intensity of protocols for which the research coordinator was responsible, and insufficient involvement or low interest of the principal investigator (PI). The number of protocols for which the research coordinator was responsible was described as having some influence by 55% of respondents and a strong influence by 25% of respondents.

Perceived prevalence of scientific misconduct

Table 1 lists the perceived prevalence of types of misconduct assessed. The most frequent response in each category was "never". Practices perceived as occurring most often included protocol violations related to subject procedures (43%) or enrolment (36%). Respondents with first-hand knowledge of an incident of misconduct were less likely to report perceived prevalence of protocol violations for procedures or enrolment as "never" ($\chi^2 = 115.0$, df = 3, $p<0.001$ and $\chi^2 = 117.2$, df = 3, $p<0.001$, respectively).

Reporting of scientific misconduct

When asked what a typical research coordinator would do if they were aware that a PI or coinvestigator violated rules for research integrity, 10.4% of respondents indicated that a typical research coordinator would probably do nothing, 37.3% indicated that a typical research coordinator would express disapproval to the PI but not report it, 26.7% indicated that they would ask the investigator to report themselves and report them it they did not, and 25.7% indicated that a typical research coordinator would report the PI to appropriate authorities. Respondents rating organisational effectiveness as high or very high were more likely to indicate that a typical research coordinator would report the incident administratively ($\chi^2 = 54.3$, df = 3, $p<0.001$). Respondents with first-hand experience of misconduct were more likely to indicate that a typical research coordinator would probably do nothing (20.3% vs 8.1%; $\chi^2 = 44.72$, df = 3, $p<0.001$). A majority of respondents (55%) indicated that a typical research coordinator would report an incident of scientific misconduct by research staff to the PI. Again, those with first-hand knowledge of an incident were more likely to indicate that a typical research coordinator would probably do nothing in such a circumstance (13.6% vs 4.2%; $\chi^2 = 41.1$, df = 3, $p<0.001$)

DISCUSSION

This is the first US survey of research coordinators and their perceptions of scientific misconduct. The percentage of registered nurses and their educational backgrounds is consistent with the finding of previous studies of research coordinators.[17 18] No comparative data were available from the professional organisations to assess whether the survey sample was representative of members of the ACRP or of subscribers to *Research Practitioner*.

It is unknown whether the estimated prevalence of misconduct obtained in this study (18%) accurately reflects the true prevalence of misconduct in the settings in which these respondents worked. If it is assumed that the 301 instances of misconduct identified by respondents represented all instances of known misconduct among the 5302 people receiving surveys, then this would represent an overall prevalence of 6%. As a counterargument, the prevalence of reported misconduct for this sample is considerably lower than the prevalence reported in recent surveys of biostatisticians and medical consultants.[10 11] In this study, respondents were asked about misconduct within the past year, whereas in the study by Ranstam *et al*,[10] respondents were asked about occurrences over the preceding decade. The limited time frame for this study may have reduced the number of reported instances, resulting in an underestimate of the true prevalence. Also, definitions of misconduct

Table 1 Perceived prevalence of scientific misconduct

Type of misconduct	n	Frequently (%)	Occasionally (%)	Seldom (%)	Never (%)
Plagiarism	1620	0.2	5.2	27.7	66.9
Falsifying data	1631	0.5	4.0	24.2	71.3
Intentional protocol violations related to subject enrolment	1634	1.2	7.5	26.8	64.5
Intentional protocol violations related to procedures	1636	1.2	9.1	32.5	57.2
Coercion of potential subjects	1634	1.2	4.3	20.7	73.7
Deliberate double billing for study procedures	1623	0.6	2.3	9.1	88.0
Selective dropping of data from "outlier" cases	1628	0.7	3.7	15.3	80.3
Falsification of biosketch, resume, reference list	1633	0.1	1.7	11.9	86.3
Disagreements about authorship	1603	1.5	9.7	28.9	59.8
Pressures from a study sponsor (eg, pharmaceutical company or device company) to engage in unethical practices	1632	0.3	4.0	20.5	75.2

vary among studies, therefore comparisons must be made with care.

These figures should be interpreted with caution since the nature of the misconduct was not specified on the questionnaire and not all reported instances may have fit the ORI definition of falsification, fabrication or plagiarism.[1] The finding that more respondents with first-hand knowledge of an incident were from academic medical centres should also be interpreted with caution. It is possible that the actual prevalence of misconduct is higher in these settings; however, the observed difference may also have been a result of differences in workplace organisational structure or climate. Respondents from academic settings may have been more likely to become aware that an incident had occurred or may have been more willing to report first-hand knowledge of an incident. Information obtained on job function was limited to subject enrolment and follow-up. Subjects probably differed with regard to their scope of responsibilities, which may have affected their perceptions of misconduct and knowledge of occurrences.

The findings in this study support the commonly held assumption that there are differences between workplaces with regard to the perceived pressures on investigators and research coordinators and on the regulatory environment of these different clinical research settings. Contextual factors such as financial rewards and workloads seem to play some discriminating role. The environmental factors described in this study provide a general overview of the perceptions of research coordinators, but do not fully address the specific concepts of an ethical climate in the workplace, such as situational influences at the group and organisational levels.[14] The findings also provide some data that support the perceived effectiveness of institutional policies to reduce scientific misconduct.

One disturbing finding was that respondents who reported an experience with scientific misconduct were more likely to indicate that they thought a typical research coordinator would probably do nothing if aware of an incident. Preliminary, ongoing analysis of the responses from the qualitative portion of this survey suggests that the experiences surrounding the scientific misconduct incident were often negative and that, on some occasions, administrative reporting of such instances resulted in significant negative professional consequences for the reporter. First-hand experience with an incident also seems to influence perceptions of the prevalence of misconduct.

The study results reported here are subject to a number of limitations. First, the response rate was 31%. This is slightly higher than the 24–30% recently reported in a similar study with nurses about the ethical challenges they face in practice,[22] but lower than return rates from surveys of biostatisticians (37%) and of early- and mid-career scientists (43% and 52%, respectively).[10 13] Given the sensitive nature of the information requested, particularly with regard to describing actual occurrences of misconduct, this response rate could be viewed as higher than expected. Owing to the anonymous nature of the survey, a second mailing to non-responders was the only intervention used to improve the response rate.

A second limitation related to sample selection. This survey focused on perceptions of scientific misconduct among research coordinators who were members of a single professional organisation or subscribers to a single professional journal. The resulting sample included a large number of respondents who were certified and whose self-rated knowledge of scientific misconduct was high, hence, this sample may not be representative of all research coordinators. Further, research coordinators are only one category of personnel working in the arena of clinical research studies, and these results may have limited the generalisability beyond this target population.

Study results presented in part in:

(1) Broome M, Habermann B, Pryor E, *et al*. Scientific misconduct (SM): Perceptions of research coordinators. Poster presented at the *Southern Nursing Research Society, 19th Annual Conference*, Atlanta, Georgia, USA, February 2005.

(2) Broome M, Habermann B, Pryor E. Scientific misconduct: Role of the research coordinator. Paper presented at the *Midwest Nursing Research Society, 29th Annual Conference*, Cincinnati, OH, USA, April 2005.

(3) Pryor E, Habermann B, Broome M, et al. Scientific misconduct: perceptions of research coordinators participating in a national survey. Poster presented at the *Association of Clinical Research Professionals 2006 Global Conference and Exhibition*, Phoenix, AZ, USA, May 2006.

CONCLUSIONS

These findings expand the knowledge on scientific misconduct by adding new information from the perspective of research coordinators. Further work is needed to determine the impact of workplace climate on the prevalence of misconduct. This investigation also provides some information to guide development of interventions to foster a research environment where the highest standards of research integrity are maintained. To do otherwise is to undermine the confidence of the public and healthcare practitioners in the process that underlies our current system of healthcare.

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CORRECTION

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The second authors name in the paper titled, The concept of brain death did not evolve to benefit organ transplants (*J Med Ethics* 2007;**33**:197–200). The correct author listing is Calixto Machado, Julius Kerein, Yazmina Ferrer, Liana Portela, Maria de la C García, José M Manero. The journal apologises for this error.