Researcher Requests for Inappropriate Analysis and Reporting: A U.S. Survey of Consulting Biostatisticians

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Background: Inappropriate analysis and reporting of biomedical research remain a problem despite advances in statistical methods and efforts to educate researchers.

Objective: To determine the frequency and severity of requests biostatisticians receive from researchers for inappropriate analysis and reporting of data during statistical consultations.

Design: Online survey.

Setting: United States.

Participants: A randomly drawn sample of 522 American Statistical Association members self-identifying as consulting biostatisticians.

Measurements: The Bioethical Issues in Biostatistical Consulting Questionnaire soliciting reports about the frequency and perceived severity of specific requests for inappropriate analysis and reporting.

Results: Of 522 consulting biostatisticians contacted, 390 provided sufficient responses: a completion rate of 74.7%. The 4 most frequently reported inappropriate requests rated as "most severe" by at least 20% of the respondents were, in order of frequency, removing or altering some data records to better support the research hypothesis; interpreting the statistical findings on the basis of expectation, not actual results; not reporting the presence of key missing data that might bias the results; and ignoring violations of assumptions that would change results from positive to negative. These requests were reported most often by younger biostatisticians.

Limitations: The survey provides information on the reported frequency of inappropriate requests but not on how such requests were handled or whether the requests reflected researchers' maleficence or inadequate knowledge about statistical and research methods. In addition, other inappropriate requests may have been made that were not prespecified in the survey.

Conclusion: This survey suggests that researchers frequently make inappropriate requests of their biostatistical consultants regarding the analysis and reporting of their data. Understanding the reasons for these requests and how they are handled requires further study.

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The published literature on research misconduct, including a 2016 Cochrane report, has been evolving slowly, with notable growth during the past decade (1–12). These publications have addressed a wide array of topics, such as the prevalence of and reasons for article retraction (13–17), types of misrepresentation of scientific findings (18), recognition of the complexity of research integrity in community and field research (19–21), and calls for more and better training (22–24). We regard inappropriate analysis and reporting of data as a form of research misconduct if their intent is to mislead those who use the research findings. Whether done intentionally or because of a lack of knowledge, inappropriate analysis and reporting of biomedical research remain a problem, despite advances in statistical methods and efforts to better educate researchers. This study aimed to quantify and describe requests for inappropriate analysis and reporting that biostatisticians receive from investigators during their biostatistical consultations.

METHODS

Survey Instrument

This U.S. national survey used the Bioethical Issues in Biostatistical Consulting (BIBC) Questionnaire, which was developed previously (25) (for the survey instrument, see the **Supplement**). The survey was pretested in a pilot study in which it was administered to a randomly drawn sample of 112 biostatisticians who were members of the American Statistical Association (ASA) (26).

Survey items asked respondents how many times (using a 5-point scale: 0, 1, 2 to 4, 5 to 9, or ≥10) they had received specific requests from investigators for 18 inappropriate analysis and reporting practices during their biostatistical consultations. Respondents also were asked to rate the "bioethical violation severity" of each of the 18 potential inappropriate practices (on a 6-point scale ranging from least [0] to most [5] severe).

Participants

Our goal was to obtain completed surveys from 400 biostatisticians, and we encouraged their response with an ASA endorsement, the offer of a $99 Amazon gift certificate for survey completion, the use of an online data collection system that allowed respondents to remain anonymous, and instructions to report only requests received rather than actual inappropriate behavior.

Table 1. Biostatistician-Reported Frequency and Severity Rating of Requests for Inappropriate Analysis and Reporting (*n* = 390)*

Violation Request	Respondents Rating the Item as "Most Severe," %†	Reported Requests During the Past 5 Years, %		
		0	1–9	≥10
Falsify the statistical significance (such as the *P* value) to support a desired result	84	97	2	1
Change data to achieve the desired outcome (such as the prevalence rate of cancer or another disease)	84	93	7	–
Remove or alter some data records (observations) to better support the research hypothesis	80	76	22	2
Interpret the statistical findings on the basis of expectations, not the actual results	68	70	28	2
Do not fully describe the treatment under study because protocol was not exactly followed	62	85	15	–
Do not report the presence of key missing data that could bias the results	68	76	23	1
Ignore violations of assumptions because results may change to negative	64	71	28	1
Modify a measurement scale to achieve some desired results rather than adhering to the original scale as validated	55	79	20	1
Report power on the basis of a post hoc calculation, but make it seem like an a priori statement	54	76	23	2
Request to not properly adjust for multiple testing when "a priori, originally planned secondary outcomes" are shifted to an "a posteriori primary outcome status"	56	80	18	2
Conduct too many post hoc tests, but purposefully do not adjust α levels to make results look more impressive than they really are	54	60	36	4
Remove categories of a variable to report more favorable results	48	68	31	1
Do not mention interim analyses to avoid "too much testing"	50	81	18	1
Report results before data have been cleaned and validated	48	56	39	5
Do not discuss the duration of follow-up because it was inconsistent	45	84	15	1
Stress only the significant findings, but underreport nonsignificant ones	42	45	48	7
Do not report the model statistics (including effect size in ANOVA or R^2 in linear regression) because they seemed too small to indicate any meaningful changes	42	76	23	1
Do not show plot because it did not show as strong an effect as you had hoped	33	58	39	3

ANOVA = analysis of variance.
* Based on findings from questions 1–18 of the Bioethical Issues in Biostatistical Consulting Questionnaire, which asked biostatisticians "to estimate the number of times—during the past 5 years–that you, personally, have been DIRECTLY asked to do this." Data are presented in decreasing order by the percentage of respondents with a perceived severity score of 4 or 5.
† Items were defined as "most severe" if respondents ranked the severity as 4 or 5 on a scale of 0–5.

The ASA's Office of the Executive Director provided the research team with a database of 4000 persons randomly selected from the association's approximately 18 000 registered members. For each member, the database included the membership ID number, name, e-mail address, affiliation, sex, race/ethnicity, birth year, highest degree achieved, employment category, and areas of specialty. The names were removed from the sample, and we retained those whose areas of specialty were listed as statistics, biostatistics, data analysis, or biometrics—that is, we removed those whose areas of specialty were not involved primarily in biostatistical consulting and data analysis and hence were inappropriate for our survey. This process resulted in a final database of 3874 members.

Next, we generated a random number for each ASA record and sorted the numbers of the records included. We used Qualtrics survey software to distribute batches of 50 e-mail invitations at 2-day intervals and e-mailed reminders to nonresponders after 5 days. When we reached our target of 400 completed questionnaires, we ended the survey. These steps were taken to prevent overenrollment, which would have exceeded our budget for the incentives offered to respondents for their participation. By the time 400 responses were received, the Qualtrics e-mail records indicated that 800 e-mails had been distributed and 522 had been received and opened by the respondents.

Statistical Analysis

Statistical analysis of the data included descriptive analyses of the findings from the 18 bioethical violation questions as well as bivariate analyses using Pearson χ^2 tests for the 18 questions by the demographic variables of sex, age group, racial/ethnic group, and research tier of the university with which the respondent was affiliated. The bivariate analyses were performed with SPSS, version 24 (IBM). To determine how well our survey sample represented the overall population of ASA members, we conducted a statistical comparison on 4 demographic variables (sex, race/ethnicity, age, and highest degree achieved) between the sample and the overall ASA membership by using the Bonferroni criterion for multiple comparisons.

Ethical Review

The institutional review boards at the University of Maryland School of Public Health and New York University approved the study with expedited review because of minimal risk to the participants.

Role of the Funding Source

The Office of Research Integrity of the U.S. Department of Health and Human Services funded the study but had no role in the design, conduct, or analysis of the study; manuscript preparation; or decision to submit the manuscript for publication.

RESULTS

Of 400 responses, 10 records were excluded because of a high level of incomplete data. Thus, our final sample of 390 represented a completion rate of 74.7% among members who received and opened our e-mail invitation (that is, the members successfully contacted), whereas the response rate for the survey was 48.8% for the 800 e-mails distributed (that is, regardless of whether the members received or opened the message) (26). Respondents mostly identified as male (64.1% men, 35.9% women); fell into 3 age groups: 23 to 39 (27.9%), 40 to 59 (40.1%), and 60 to 88 years (31.2%); and were predominately white (63.6% white, 23.8% Asian, and 12.6% other). Mean number of years working as a biostatistician was (SD, 13.0). No statistically significant differences were seen in sex, age, race/ethnicity, or highest degree obtained in a comparison between respondents and the 4000 members randomly selected by the ASA.

Table 1 shows the reported severity and frequency of the 18 inappropriate requests in descending order by percentage of respondents who ranked that item as high severity (4 or 5 on a scale of 0 to 5). The proportion of respondents who rated a request as high severity ranged from 84% for requests to falsify statistical significance (such as the *P* value) to support a desired result to 33% for a request to not show a plot because it did not show an effect as strong as the researcher wanted.

Table 2 shows the comparisons of the reported frequency of the top 8 inappropriate requests (rated as high severity with frequent occurrence) by specific questions in the demographic section of the BIBC Questionnaire regarding age, race/ethnicity, and type of research university with which the biostatistician was affiliated. These requests are listed in the table (in an abbreviated format) according to the sequence asked on the BIBC Questionnaire. Of the 8 inappropriate requests, 6 demonstrated statistically significant differences by age, with younger biostatisticians more likely than their older colleagues to report a higher frequency. That 4 of the 8 requests for inappropriate analyses and reporting were statistically reported more often by respondents who identified as Asian or other than those who identified as white may be explained, in part, by age differences. Respondents who reported Asian or other race/ethnicity were younger than white respondents (mean age: Asian, 45.5 years; other, 46.7 years; white, 51.2 years). Among participants who worked in a first-tier research university (that is, one of 115 institutions the Carnegie Classification of Institutions of Higher Education categorized in 2018 as "R1: Doctoral Universities–Highest Research Activity" [27]), only 1 of the 8 requests reported differed in frequency from those made to respondents who did not work at such an institution. As the last row in **Table 2** shows, the percentage of any age, racial/ethnic, or institution-type subgroup that reported receiving any of the 8 highest-severity requests for inappropriate analysis or reporting ranged from 54% to 84%.

Finally, we examined the missing responses for each of the 18 frequency and severity questions. For the 18 frequency items, 11 (mean, 0.6; range, 0 to 3) responses were missing, and for the 18 severity questions, 56 (mean, 3.1; range, 0 to 8) responses were missing. Across all 36 BIBC items with a possible 14 040 responses (36 items × 390 respondents), the 67 missing responses represented only 0.005% of the total.

Table 2. Percentage of Respondents Reporting a Top 8 Violation Request, by Age, Race/Ethnicity, and Affiliation With a First-Tier Research University*

Variable	Respondents Reporting Having Been Asked a Top 8 Violation Request ≥1 Time Over the Past 5 Years, %							
	Age Group			**Race/Ethnicity**			**Type of Research University**	
	23-39 Years (n = 103)	**40-59 Years (n = 151)**	**60-88 Years (n = 115)**	**White (n = 248)**	**Asian (n = 93)**	**Other (n = 22)**	**First Tier (n = 111)**	**Other (n = 85)**
Violation request								
Remove or alter data records	32	29	10†	20	32	32†	23	27
Do not report key missing data	25	25	20	19	34	36†	30	24
Conduct too many post hoc tests without α levels	45	44	29†	38	50	36	53	39†
Modify a measurement scale for some desired results	26	23	13†	15	36	27†	23	24
Interpret findings on the basis of expectation, not actual results	33	33	24	27	37	41	32	38
Ignore violations of assumptions	38	29	18†	25	32	50†	32	36
Misrepresent post hoc calculation as a priori	31	25	16†	19	30	36	33	25
Shift secondary outcomes to be the primary outcome	24	21	10†	16	24	18	24	20
Respondents reporting any of these violations (95% CI), %	79 (71–87)	78 (71–84)	54 (45–63)	65 (59–71)	84 (76–91)	76 (64–88)	78 (70–85)	80 (72–89)

* Top 8 violation requests are survey items that >50% of respondents reported as being "high severity" and that were requested of ≥20% of respondents ≥1 time over the past 5 years.
† Indicates a statistically significant difference across groups (*P* < 0.050).

DISCUSSION

This U.S. national survey of consulting biostatisticians suggests that requests by researchers for inappropriate analysis and reporting occur frequently. Of note, however, the 2 request types rated as highest severity (falsification of statistical significance and changing the data to achieve the desired outcome) were reported as the least frequently requested. Nonetheless, the frequency of inappropriate requests and the rating of many as high severity by respondents indicate a need to better educate researchers about the inappropriateness of such requests, which may represent poor-quality science at best and research misconduct at worst. The reasonably high survey response rate and the low rate of missing items bound the possible bias from nonresponse.

Before the pilot study of our survey (28), the only published report we could identify that quantified researcher requests for inappropriate analysis and reporting was a 1998 international survey of biostatisticians who were members of the International Society for Clinical Biostatistics (29). Although the response rate was only 37%, the authors felt that " . . . the high proportion of respondents knowing about fraudulent projects [51%] provided the primary motivation for [publishing their] report" (29). In general, surveys of lapses in actual research practices have had low response rates, possibly because respondents are reluctant to incriminate themselves or their colleagues. Despite assurances of respondent anonymity, a survey of all biomedical researchers in China (30), an online survey of self-identified neuropsychologists in Spain (31), a survey of university and industry researchers in Belgium (32), a survey of participants at a meeting of the World Congress on Research Integrity (33), and several others all reported low response rates, ranging from 4.5% to 48%, with most below 20% (34–36). A survey of doctoral students in Norway and Sweden that asked about their perceptions of research misconduct had a response rate of 65% (37).

A strength of our study was the support of the ASA leadership, which facilitated a high response rate from a national sample of consulting biostatisticians, who in many ways serve as "eyewitnesses" to research conduct. Another factor that probably contributed to the good response was that the questionnaire asked about reported requests rather than actual actions based on these requests, eliminating the possibility of self-incrimination.

Several limitations of the study deserve mention. The first is that we asked the biostatisticians only what they were asked to do but did not collect data from them regarding their response to inappropriate requests. The second limitation, then, is that our survey provides information on the reported frequency of inappropriate requests but not on how such requests were handled. Third, our survey provides no data on whether the request reflected researchers' maleficence or inadequate knowledge about statistical and research methods. Finally, we did not obtain any data as to whether the respondents received inappropriate requests that were not prespecified in the survey. Although an accurate accounting of the biostatisticians' conduct in responding to the requests for inappropriate analysis and reporting specified in our survey would have been ideal, that type of self-incriminating data also would probably be difficult—if not impossible—to obtain.

The findings from this U.S. national study, which has served to describe both the frequency and perceived severity of requests for inappropriate analysis and reporting by researchers during biostatistical consultation should be both an impetus and a guide to carefully develop future education and training for biomedical researchers. These educational modules should be targeted at university-based clinical research training programs and their directors for mandated presentation to biomedical researchers in training, as well as to researchers currently employed in both industry and academia. Further, these findings should be used to encourage research universities and companies to develop or improve institutional efforts to reduce workplace- and publication-related stress to alleviate the pressure that may be contributing to these inappropriate requests.

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