As usual, the truth about the Breast CA Trial misconduct is more complicated than any simplistic verdict. The Office of Research Integrity (or its predecessor) accused the researcher of "fabrication and falsification" but that is their standard language.

One fairly impartial source summarizes the questionable reports this way:

"From a statistical standpoint, though, it is interesting to note the nature of the misrepresentations in the St. Luc data: no randomization assignments were breached and no outcome data were altered--in all but one case, only eligibility data were affected. Furthermore, all assigned treatments were given as specified and all patients were followed per protocol. Re-analysis of data from the affected clinical trials (after removing all St. Luc data, including those cases entered properly) fortunately resulted in no qualitative difference in the scientific conclusions of the tainted studies." [Paul Catalano, "Fraud and the Statistician's Role in Protecting the Integrity of Clinical Research," http://www.biostat.harvard.edu/publications/newsletter/july95/fraud.html ACCESSED: [5/21/2002 2:11:58 PM] ]

Dr. Poisson (the miscreant) justified his actions in these terms:

"I believed I understood the reasons behind the study rules, and I felt that the rules were meant to be understood as guidelines and not necessarily followed blindly. My sole concern at all times was the health of my patients. I firmly believed that a patient who was able to enter into an NSABP trial received the best therapy and follow-up treatment. For me, it was difficult to tell a woman with breast cancer that she was ineligible to receive the best available treatment because she did not meet 1 criterion out of 22, when I knew that this criterion had little or no intrinsic oncologic importance. For example, in the clinical trial assessing the safety of lumpectomy (Protocol B-06), there were six irregularities among 354 cases registered by me, of a total of 2163 patients in the study. All six irregularities related to the authorized length of time after diagnosis during which a patient could be enrolled in the trial -- a period, by the way, that has been increased substantially in the past few years." [NEJM, 330 (1994):1460]

The editors of the New England Journal of Medicine give a slightly different interpretation than I did of the passage just quoted:

"Dr. Poisson maintains that his data fabrication, which for the most part involved relaxing the eligibility criteria, was motivated by his desire to enroll as many women as possible, and he was astonishingly successful. Although St. Luc Hospital was only 1 of 89 institutions contributing data to the lumpectomy trial, Dr. Poisson enrolled 19 percent of the women studied, over twice as many as the next most prolific institution. We believe that this rate of accrual should have caught the attention of the NSABP early on." [NEJM, 330(1994):1448-1450]

And they point out the possible motivation of this as follows:

"Dr. Poisson, no doubt as a result of his high rate of accrual, was the fourth author on the 1985 lumpectomy study, the third on the 1989 follow-up study, and the fourth on the tamoxifen study. In addition to the prestige associated with authorship, Dr. Poisson's institution received funding according to the number of patients enrolled. This funding method may provide too strong a motivation to enroll patients, especially when economies of scale are realized. Dr. Poisson maintains that his desire to enroll as many patients as possible was entirely altruistic, but we have to wonder whether the prestige and enhanced funding for St. Luc Hospital also played a part." [NEJM, 330(1994):1448-1450]

So at least one departure from truthful reporting did not deal directly with eligibility criteria. And the others may not have had quite the lofty motives I ascribed to them (under the spell of the good doctor's altruistic-sounding self-justification).
Setting the Record Straight in the Breast-Cancer Trials

In 1985 the Journal published a paper from the multicenter National Surgical Adjuvant Breast and Bowel Project (NSABP) showing that lumpectomy was as effective as mastectomy in the treatment of early breast cancer. A follow-up paper in 1989 confirmed the finding. It was published in the Journal along with two other papers from the NSABP: one showing that adjuvant chemotherapy was effective for node-negative, estrogen-receptor-negative breast cancer, and the other showing that tamoxifen was effective for node-negative, estrogen-receptor-positive breast cancer. The trials (known as Protocols B-06, B-13, and B-14) were coordinated by Dr. Bernard Fisher of the University of Pittsburgh, senior author of all three papers. They have greatly influenced the way women with breast cancer are treated.

On March 9 of this year we received a telephone call from a reporter, John Crewdson, of the Chicago Tribune, who asked us what we were going to do about the "fraud" uncovered in these studies. That was the first we had heard about any problem with the work, and the ensuing stories in the popular media were the first the American public knew about it. Not surprisingly, many women who had been treated for breast cancer or were facing treatment decisions were alarmed, confused, and angry.

We subsequently learned the following facts: Four years ago, in June 1990, a data manager in the NSABP noticed discrepancies in the data submitted by Dr. Roger Poisson, the principal investigator at St. Luc Hospital in Montreal, 1 of 484 participating institutions. An audit revealed that some of the patient records had been falsified. As a result, in February 1991 the NSABP notified the Food and Drug Administration (FDA), the National Cancer Institute (NCI), which funds the NSABP, and the Office of Scientific Integrity (OSI), the governmental agency...
charged with investigating fraud in research funded by the Public Health Service. These agencies began a formal investigation. During the course of their investigations, the NSABP privately assured officials of the NCI and OSI that the conclusions of the studies were valid even with the St. Luc data excluded. However, it was not until 1993 that the OSI (by then reconfigured as the Office of Research Integrity [ORI]) formally concluded that Dr. Poisson was guilty of scientific misconduct. Brief notices of this conclusion were published in the April 1993 ORI Newsletter, the June 1993 NIH Guide for Grants and Contracts, and the June 1993 Federal Register. The Journal was not notified, however, nor did we receive a reanalysis of the data from Dr. Fisher. When Mr. Crewdson phoned, we were as surprised as anyone else who is not a regular and careful reader of government documents. Since then, other irregularities in the conduct of the NSABP studies have been brought to light, and events have unfolded rapidly. The NCI has undertaken an on-site audit of patient records at a number of participating institutions, and on March 28 Dr. Fisher resigned his position as coordinator of the NSABP. On April 13 Congressman John D. Dingell, chairman of the Subcommittee on Oversight and Investigations of the House of Representatives, held hearings on the adequacy of the response of the National Institutes of Health to the NSABP misconduct.

At the request of the NCI, Dr. Fisher sent us a reanalysis of the three trials, which we received on March 25, excluding all women enrolled at St. Luc Hospital. Because the audit is still in progress, we elected not to submit this new paper to peer review until the audit was completed and we could be assured by the NCI that all data in the reanalysis were reliable. We expect to publish the reanalysis as soon as we receive such assurances and the paper can be subjected to expedited peer review. Until then, no one can say with certainty that the conclusions of the three trials will stand. However, it is extremely unlikely, given the size of the trials and the large number of participating institutions, that the essential conclusions will be altered. Furthermore, a number of other studies, published after the reports from the NSABP, have come to the same conclusions. There is thus no indication that women with breast cancer have been inappropriately treated on the basis of the NSABP studies.

Despite the fact that women with breast cancer have evidently not been harmed by the misconduct in the NSABP trials, this episode is disturbing. There is no excuse for the four-year delay between the first indication of misconduct in 1990 and the publication of a reanalysis, which we hope will take place in 1994. To be sure, Dr. Poisson was relieved of his position in the NSABP in 1991, but that was not a sufficient response. The Journal's readers and the public at large were left in the dark, and the flawed reports remained uncorrected.

Elsewhere in this issue of the Journal are statements from Dr. Fisher, Dr. Poisson, and representatives of the NCI (the funding agency), the ORI (the official investigative body), the University of Pittsburgh (the institution receiving the primary grant), St. Luc Hospital (where the misconduct occurred), and the University of Montreal (where Dr. Poisson was on the faculty). Readers can decide for themselves whether these parties fulfilled their responsibilities. In our judgment they did not. Each of them had a responsibility to notify us of the fraud more than a year ago, at the conclusion of the investigations. Although the NSABP eliminated 24 of Dr. Poisson's cases from the analysis in a subsequent paper published in the Journal (Protocol B-17), the authors did not tell us why. It is not enough to establish guilt and stop the funding of a guilty researcher; it is also crucial to publish corrections or retractions of fraudulent data. Just as publication is the end result of most research, so should a published correction be the end result of most cases of misconduct.
Dr. Fisher and officials at the NCI and the ORI told us that the reason they did not notify the Journal about the misconduct was that the conclusions of the studies were unaffected. We disagree with that rationale. The reason journals publish data in the first place is to permit readers to judge for themselves whether they agree with the authors' conclusions. Otherwise, we could save space by simply subjecting manuscripts to peer review and then publishing only the conclusions, without any substantiating evidence. Similarly, it is not for the NSABP, the NCI, or the ORI, august bodies though they are, simply to draw conclusions from their reanalysis without making the evidence available.

Over the past decade or so, in the wake of several well-publicized instances of research fraud that were badly handled, many academic institutions and professional associations have developed explicit procedures for responding to allegations of misconduct, as has the federal government. The federal regulations\textsuperscript{27} call for a preliminary inquiry at the institution to determine that allegations are not frivolous, followed by a formal investigation conducted by the institution and the ORI. If misconduct is established, a notice is to be published in the NIH Guide for Grants and Contracts "identifying any publications found in a formal investigation to require correction or retraction." The ORI may also choose to notify other interested parties, including journals, but it is not required to do so. During the investigation itself, only officials with a "need to know" are informed.

These procedures fall short. Immediate notification of relevant journal editors at the end of an investigation should be mandatory, not optional. We are pleased that the NCI and the ORI have changed their procedures to require notification of the journals concerned\textsuperscript{21,22}. Yet, even this is not enough. We believe that journal editors who may have published seriously flawed or fraudulent work should be considered among those with a "need to know" during the formal investigation. Readers can then be alerted that the accuracy of data in a published report is in doubt. Particularly in studies with important clinical implications, this would warn all concerned that there might be a problem and that they should reserve final judgment until the issue is resolved. The Journal published just such a warning, about a study of the impact of silicone breast implants on the subsequent risk of breast cancer, after being notified by the Alberta Cancer Board, the sponsoring institution, that the analysis was seriously flawed and was being redone\textsuperscript{28}.

Can we learn anything from this case about the pitfalls of conducting certain types of large clinical trials? We believe that we can learn several important lessons. First, it is exceedingly difficult to enroll fully informed patients in trials that involve a random chance of receiving a particularly distressing treatment. In the trial of lumpectomy versus mastectomy, clinicians were reluctant to tell women that whether they received a mastectomy would be determined randomly\textsuperscript{29}. Indeed, accrual in that trial was so slow for the first 2 years that the NSABP had to resort to a prerandomization scheme -- an expedient change in design that was criticized in these pages 10 years ago\textsuperscript{30,31}. Dr. Poisson maintains that his data fabrication, which for the most part involved relaxing the eligibility criteria, was motivated by his desire to enroll as many women as possible, and he was astonishingly successful. Although St. Luc Hospital was only 1 of 89 institutions contributing data to the lumpectomy trial, Dr. Poisson enrolled 19 percent of the women studied, over twice as many as the next most prolific institution. We believe that this rate of accrual should have caught the attention of the NSABP early on.

A second lesson to be learned about conducting large clinical trials is the difficulty of maintaining surveillance over widely dispersed, heterogeneous institutions and researchers. Dr. Broder of the NCI assured Congressman Dingell that procedures for surveillance would be more strictly followed\textsuperscript{12}. 
And third, we need to think more about the way we reward researchers in large clinical trials. Dr. Poisson, no doubt as a result of his high rate of accrual, was the fourth author on the 1985 lumpectomy study, the third on the 1989 follow-up study, and the fourth on the tamoxifen study. In addition to the prestige associated with authorship, Dr. Poisson's institution received funding according to the number of patients enrolled. This funding method may provide too strong a motivation to enroll patients, especially when economies of scale are realized. Dr. Poisson maintains that his desire to enroll as many patients as possible was entirely altruistic, but we have to wonder whether the prestige and enhanced funding for St. Luc Hospital also played a part.

All participants in clinical research have a responsibility to protect the integrity of the enterprise. Authors must be honest and must also concern themselves with the honesty of their coauthors; institutions must respond to allegations of misconduct with careful investigations, notifying appropriate authorities when warranted; the ORI must conduct a thorough and speedy investigation and make its findings known; and the funding agency must demand that faulty data be corrected. Journal editors, for their part, should require that any questions about published work be resolved by the appropriate bodies and that they be informed of the outcome. When warranted, editors should publish corrections or retractions promptly. If all participants do not fulfill their responsibilities, we run serious risks. Even if there is no direct harm to patients, the public may become disillusioned with clinical research and indiscriminately skeptical of its results. Such seems to be the unfortunate outcome in this instance.

Marcia Angell, M.D.
Jerome P. Kassirer, M.D.

References


Related Letters:

The NSABP Trials
Levenback C., Bross I. D., Davis N., Heitjan D. F., Altman L. K., Angell M., Kassirer J. P.
Extract | Full Text

Access of Medicaid Recipients to Outpatient Care
Extract | Full Text

Health Care and the Homeless
Mehal W. Z., Blatt S. D., Meguid V., Hibbs J. R., Redlener I.
Extract | Full Text

This article has been cited by other articles:

To the Editor: I am stunned by Dr. Poisson's explanation (May 19 issue) of his behavior in regard to Protocol B-06 of the National Surgical Adjuvant Breast and Bowel Project (NSABP). It is outrageous to suggest that it is permissible for an individual investigator to ignore eligibility criteria. Each investigator has the choice to participate or not to participate in a collaborative study. Once Dr. Poisson made the choice to participate, he was obliged to follow the protocol.

Charles Levenback, M.D.
M.D. Anderson Cancer Center
Houston, TX 77030

References


To the Editor: Your editorial (May 19 issue) seemed to agree with Dr. Fisher's claim that because the fraud had no effect on the findings of the study, there was no harm to public health. From a biostatistical standpoint, what the fraud showed was that the statistical quality control was grossly inadequate in the NSABP studies. Hence, whether or not some fraudulent cases are eliminated post hoc, any findings lack scientific validity.

Irwin D. Bross, Ph.D.
To the Editor: To me, the important point should have been, and should still be, to assure concerned patients that, to date, there has been no reason to believe that their treatment was inappropriate. It is regrettable that this matter has become a political football, with officials of the National Cancer Institute (NCI) attempting to place as much blame as possible on Dr. Fisher because of their obvious intimidation by Congressman Dingell.

The author of a recent editorial in the Lancet expressed the much more reasonable viewpoint that "this affair has been poorly handled" and that "the NCI and media frenzy, much of it directed personally at Fisher, cannot be justified." To the Editor: To me, the important point should have been, and should still be, to assure concerned patients that, to date, there has been no reason to believe that their treatment was inappropriate. It is regrettable that this matter has become a political football, with officials of the National Cancer Institute (NCI) attempting to place as much blame as possible on Dr. Fisher because of their obvious intimidation by Congressman Dingell.

The author of a recent editorial in the Lancet expressed the much more reasonable viewpoint that "this affair has been poorly handled" and that "the NCI and media frenzy, much of it directed personally at Fisher, cannot be justified." The editorialist also pointed out that "Fisher's innovative way of thinking about and organizing breast cancer trials has been copied over and over again by other groups and stands as a testimonial to his foresight and commitment to meeting the challenge of breast cancer."

Norman Davis, M.D.
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References


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References


To the Editor: Several of the letters discussing falsification of data in the NSABP studies stress that the results of Protocol B-06, which found no significant clinical difference between lumpectomy and total mastectomy,1,2 are not altered by the exclusion of the data collected by Dr. Poisson. The results of these reanalyses have persuaded the NCI, the National Institutes of Health, and the Office of Research Integrity that continued reliance on the original findings poses no threat to public health3.

I contend that the reanalyses alone do not provide this level of reassurance, because the original conclusions are all negative -- that is, they are findings of statistical nonsignificance. When confronted with a nonsignificant test result, one must ask, "What is the power of the test?" If the power is not substantial (usually 80 percent or more) for clinically important effect sizes, then the nonsignificance may merely reflect an inadequate study design.
This idea is relevant to Protocol B-06. In an analysis of survival, the power depends on the sample size through the number of events. Stablein's reanalysis\(^4\) indicates that in the cohort of women who were eligible for enrollment and accepted therapy, there were 933 treatment failures or deaths; elimination of the data from St. Luc Hospital reduces this total to 776. For a comparison of any two treatment groups, we can assume that there are two-thirds this many events -- a total of 622, and 517 with the St. Luc data deleted. Because this trial intends to show an equivalence, high power is required even when the effects are small -- for example, when the relative hazard of the worse treatment versus the better treatment is 1.25 (roughly a 20 percent decrease in the mean time to an event). By Schoenfeld's method,\(^5\) the chance of detecting such a difference at a 0.05 level of significance is 79.5 percent if all the data are included and 71.8 percent if the data from St. Luc Hospital are excluded. According to the usual standards, this test has barely adequate power if all the data are used and clearly inadequate power if the St. Luc data are excluded.

This is not to say that we should disbelieve the original conclusions drawn from the results of Protocol B-06. Others have corroborated the findings in independent trials, and the admitted pattern of falsification would not be expected to introduce a strong bias one way or the other. Without this information, however, the reanalyses alone do not warrant the level of reassurance that has been drawn from them.

Daniel F. Heitjan, Ph.D.
Pennsylvania State University College of Medicine
Hershey, PA 17033

References


To the Editor: In an analysis of NSABP Protocol B-17, Fisher et al. said they eliminated 24 cases from one hospital because of problems with the quality of the data\(^1\). We now know these were Dr. Poisson's cases at St. Luc Hospital in Montreal, and the Journal appropriately criticized Dr. Fisher for failing to explain the circumstances\(^2\). But why did the Journal itself not demand an explanation from Dr. Fisher before publishing the report?
Lawrence K. Altman, M.D.

*The New York Times*

New York, NY 10036

References


The editors reply:

The letters of Drs. Levenback, Bross, Davis, and Heitjan speak for themselves.

Dr. Altman's question requires a response. In dealing with the manuscript Dr. Altman refers to, we assumed that there were legitimate concerns about the data that would lead prudent investigators to exclude them from the analysis. For example, some of the records might have been accidentally destroyed. We had no reason to suspect misconduct -- which would have immediately raised questions about the integrity of the rest of the work -- and so we did not "demand an explanation."

Marcia Angell, M.D.
Jerome P. Kassirer, M.D.
Dr. Fisher Exonerated of Scientific Misconduct by the Government

Dr. Bernard Fisher was pleased to learn today that he and his colleagues, Dr. C. K. Redmond, former Director of the NSABP Biostatistical Center, and Dr. D. L. Wickerham, former Deputy Director of the NSABP Operations Center, have been cleared of scientific misconduct charges by the Office of Research Integrity (ORI) at the Department of Health and Human Services. He has stated that the investigation should never have taken place. Nonetheless, it took the ORI three years to conclude that Dr. Fisher did not publish falsified data and that his use of data was entirely in keeping with accepted scientific principles.

Dr. Fisher was chairman and principal investigator of the National Surgical Adjuvant Breast and Bowel Project (NSABP) for 27 years. He was responsible for the pioneering research that demonstrated that lumpectomy could replace mastectomy for the treatment of hundreds of thousands of women worldwide. He has also demonstrated that the use of systemic chemotherapy and hormonal therapy following surgery can save the lives of thousands of women with breast cancer. In 1992, he initiated the first study to determine whether tamoxifen can prevent breast cancer in women at high risk for the disease.

In 1991, Dr. Fisher and his staff discovered that an NSABP investigator from St. Luc Hospital in Montreal, Canada, had falsified some patient records so women who were not eligible to participate in the studies could do so. Dr. Fisher immediately notified the NCI, who notified the ORI, which pursued an investigation at St. Luc Hospital. The NSABP conducted numerous reanalyses and shared with the government their findings confirming that the altered data had not affected the published results. The government had concluded in 1992 that there was no "public health" crisis. Furthermore, when the nature and extent of these alterations were known, Dr. Fisher and the NSABP concluded that all data from St. Luc Hospital should be used in their publications.

In 1994, due to pressure from Congressman John Dingell, the National Cancer Institute insisted that the ORI investigate whether Dr. Fisher and his colleagues did anything wrong in publishing results that included data from St. Luc Hospital. Dr. Fisher and his staff had concluded that it was necessary to include in publications all data from St. Luc Hospital. Known as the "intent-to-treat" principle, this scientific methodology is well established. It was this realization that led the ORI to exonerate Dr. Fisher.

Dr. Fisher is relieved that his research has been vindicated and that he and his colleagues have been cleared of scientific misconduct. However, the damage that has been done to them by this baseless investigation has been extensive. Even more important, however, is
the damage that has been done to science, scientists, cancer research, and the breast cancer patients and their families whose fears were so shamelessly inflamed for political purposes. The millions of taxpayer dollars that were spent for this purpose would have been far better spent in the pursuit of a cure for breast cancer.

More information on this subject may be found in the following articles:


Associated Press Wire Service Release, March 4, 1997, Jeffrey Bair article, "Lumpectomy researcher vindicated of data fraud, calls probe a witch hunt."

*Tribune-Review*, March 4, 1997, Roberta Burkhart article, "Fisher cleared of scientific misconduct in notorious breast cancer study."


*Tribune-Review*, March 5, 1997, Ethan Lott article, "Looking for respect: vindicated Fisher continues quest to win back reputation."


*Pittsburgh Post-Gazette*, March 7, 1997, editorial, "End of an ordeal: three long and painful years later, Dr. Fisher is exonerated."


"The Trials of Dr. Bernard Fisher: A European Perspective on an American Episode", *Controlled Clinical*


The Scientist, March 31, 1997, Vol 11, No. 7. Steven Benowitz article, "Observers Say Fisher Case Highlights Flaws In System."


Back to Breast Cancer Updates
Research as a cooperative activity

At a discussion on honesty in science that took place during a Sigma Xi Annual Meeting, one delegate told how, as a graduate or postdoctoral student, he had been working with others in a laboratory with a leading scientist at its head. A new postdoctoral student joined the group. When she arrived, she was told not merely what topic she should work on but also what results she was expected to get. She set to work, did her research conscientiously, and arrived at quite different conclusions from those that had been expected. As the delegate told it, "Her work was never published; she left the lab within a month... and the rest of us drew the obvious conclusions."

It is difficult to think of any situation farther from what scientific research ought to be about, yet there are many other "horror stories" of a similar kind. However honest and conscientious one's own approach to scientific research, others may not be, and their actions can have a damaging, even permanent, effect on your research, career in science, and perhaps life as a whole.

To admit this is not to suggest that we should go through life, or even through graduate and postdoctoral research, with a general suspicion of our colleagues and supervisors. The process of becoming a research scientist, by studying for a research degree and following this with postdoctoral research working with others on the fringes of knowledge, ought to be one of the most stimulating, satisfying and rewarding periods of one's life. Most of us will never forget that experience, nor the help and friendship that we received from our research advisors and from those who had similar hopes for the future as ourselves. To accept that there are some bad apples in every crop should not lead us to avoid eating fruit.

Bad apples there are, however, and bad research situations as well. If you find yourself in an unsatisfactory situation that seems beyond your capacity to change, you may be faced with little alternative but to leave and look for better things elsewhere.

Before that step, what can you reasonably hope to find among those with whom you work? If there is one phrase that sums it up, it is probably esprit de corps, defined in Webster as "the common spirit existing in the members of a
group and inspiring enthusiasm, devotion, and strong regard for the honor of the group." That may seem to be aiming rather high, but it is very evident in the best graduate schools and in many other places as well. Perhaps you wanted to come to this department in this university because it had a reputation for outstanding work. You knew the scientific reputations of the leading figures associated with the research done here, and you wanted to be part of it. Or, another familiar situation: here we are, just a few of us, at what some might regard as an obscure university away from the mainstream of research in my discipline. But there is at least one professor here who knows how to bring out the best in me and the other graduate students, and you can see it happening. It might have happened also at that major research university I could have gone to, but then again it might not. We are a small group that can help one another, and I wouldn't want to be anywhere else right now.

*Esprit de corps* is therefore not dependent on the size or prestige of the institution, though these can help. Nor can it be imposed, though the right sort of leadership for the group is crucial. The spirit—*esprit*—is recognizable in many different research settings. It may in fact be more normal than elusive: scientific research—the discovery of what was previously unknown—is inherently exciting compared to many other activities.

What is apt to destroy or prevent such a general feeling within a group of research scientists is the canker of excessive competition. Competition is part of research and part of the excitement: at any stage in the development of a science there are several problems that seem ripe for solution and it is good to feel that our group may make a significant contribution. At the individual level, competition is inevitable and healthy: "If she can put in those extra hours in the lab in order to get her thesis finished by October, maybe I should be doing the same."

Competition is one thing, but excessive competition between research groups or among individuals within a group is something else. Worse still is when one group or individual steals an advantage by . . . stealing. You are entitled to expect that research data you have collected will be used by you alone, unless you have explicitly agreed to collect the data for someone else, or unless you specifically give someone else the right to use it, in which cases you are entitled to appropriate credit. If you exchange ideas with other scientists, including other students, it should be possible to distinguish between such different actions as the sharing of ideas that can be followed up by anyone, the offering of advice, and discussion of your current work and what you are planning to do next. Stealing research ideas does happen; when it does, the thief is apt to claim that it was not clear that this was something you were actively working on yourself or that it was a definite part of your future research program. Maybe such an assumption was understandable; if it was not, there is probably not much that can be done, except to make known to others that they should be careful in sharing their ideas with the individual or group concerned. But do not assume from the outset that theft of ideas or data is likely to happen; that way lies a view of the world as a conspiracy, implying that one of the
The indifference of many senior people to what their junior colleagues do in the laboratory is more serious.

During the rapid growth of the research enterprise in the past three decades, research institutions, universities especially, have slipped into the sloppy habit of substituting for their own judgement of their own achievements the judgement of external assessors as delivered by the appropriate sub-net of the peer-review system.

... a research laboratory jealous of its reputation has to develop less formal, more intimate ways of forming a corporate judgement of the work its people do. The best laboratories and university departments are well-known for their searching mutual questioning.


The greatest benefits of graduate and postdoctoral work — friendly cooperation with other students and senior colleagues — is impossible.

From those who guide your research or for whom you are working as a student or junior in the research lab or other setting, you also have some reasonable expectations. If these expectations are not fulfilled, there may be mechanisms within the university or research institute to improve matters — or at least provide a change of supervisor — but they may well be insufficient to deal with the situation adequately.

You are, for example, entitled to assume that a graduate advisor is there to assist his or her graduate students, not vice versa. How much assistance, formal or informal, you will actually get will vary from one advisor to the next, and you need to remember that a graduate advisor wears other hats as well. But it should be easy to recognize the "advisor" who either regards his graduate students as cheap labor for his own research or who expects unreasonable recompense from the student in return for the assistance that has been provided. One hears, for instance, of students whose graduate work is essentially completed, but who are held back from the next stage of their careers by the need to do more work in the supervisor's lab, so that the research reports can carry the supervisor's name as well as the student's. This is enforced by the need for a
good recommendation from the supervisor before the student can move on. The letter of recommendation becomes an “exit visa.” It is disgusting behavior on the part of the supervisor, but it occasionally happens.

The graduate student is also entitled to the same treatment in respect of written work from laboratory heads or supervisors that the latter would expect from journal editors and referees: the work should not be unduly delayed nor misappropriated. What to the student may seem undue delay may legitimately be seen by the supervisor as a refusal to accept work of an inadequate standard. The supervisor should be prepared to send back substandard work for as long as he or she is prepared to have the student remain in the department. However, if that work is taken and “improved” by the supervisor and published without the student’s knowledge or permission, that is a different matter: call it plagiarism or plain theft.

More generally, and like it or not, any leader of research — head of a laboratory, graduate advisor or whoever — inevitably becomes a role model for those who are beginning scientific research. If such leaders act as though the quantity of papers published is more important than their quality; or if they demand their names on every paper published by the laboratory as some sort of “rent” owed to them for making the facilities available, then others are likely to acquire a view of scientific research which for the conscientious is dispiriting and debilitating and for some seems a license to be equally unscrupulous.

For the student, the best way to avoid such situations is not to get into them in the first place: go to some other graduate school, or change your advisor. Unfortunately this is much easier said than done. The traditional measures of a good graduate school — reputation of the faculty, facilities, published research — may tell you little about whether the school encourages and inspires its graduate students, or whether it uses them as cheap labor and leaves them with a negative view of the whole research enterprise. Nor is it easy to find out from those already there whether the atmosphere is one of esprit de corps or dog-eat-dog. If you find yourself in the latter situation, however, you will detect the symptoms very quickly. If you are in any doubt, some discreet sharing of experience with students in other departments should enable you to decide whether the problem is in your research environment or is in yourself. If the former, then you have probably only three alternatives:

(a) accept the situation and go along with it;
(b) decide that you are too committed to the degree program or the specific research to be able to move; endured the situation and leave as soon as you can;
(c) decide that the situation is unlivable and that, despite the difficulties, you have to go elsewhere.

If it is feasible, (c) is probably the best solution. There are, after all, far more departments and graduate schools where your introduction to scientific research can be exhilarating than those where the attitude is oppressive, unfair or dishonest. Find one.
"Things are very different in my field"

In the previous chapters it has been taken for granted that ethical behavior in one branch of scientific research is true of every other and, for that matter, that plagiarism and other forms of dishonesty in research and publication are as unacceptable in the humanities and social sciences as in the natural sciences.

That is the belief underlying this booklet and it is probably held by the vast majority of scientists. The principles governing the way that research is carried out and reported are the same in geography as in physics, in medicine as in archaeology. Anyone who argues otherwise invites a very critical hearing.

Nevertheless, habits and conventions do vary from one major field to another, sometimes for reasons that seem to be closely linked to the character of the research problems, at other times for no apparent reason other than "this is the way we tend to do things." Two problem areas are discussed in this chapter, because they are of considerable importance in current scientific research in North America: irresponsible authorship and alternative sets of values in biomedical research.

Irresponsible authorship

The tradition of publication in science is similar to that in other branches of knowledge. An individual scientist reports his or her findings and conclusions, whether in the Latin of Newton's Principia, in Darwin's easily read and easily misinterpreted Origin of Species or in the nine thousand words in the Annalen de Physik in 1905 by Einstein that "overturned man's accepted ideas of time and space." The literature of science does have a long tradition of cooperation among two or three authors, who come together because each can contribute specialized knowledge, or because research is often more exciting and rewarding if it is not done entirely alone. What is comparatively new is the practice, in some disciplines, of publishing research reports in which five or even fifty individual scientists claim "authorship" of the same paper. It is particularly evident
in some forms of biomedical research, in high-energy physics and in some branches of geophysics, and is usually explained in terms of the complexity of the research, demanding that many skills are brought together in a carefully-planned program. If the research requires such cooperation, it is argued that those who contributed should be credited with authorship of the report.

What, it might be asked, has this to do with scientific honesty? How is multiple authorship related to our taxonomy of trimming, cooking, forging and plagiarism? Nothing in principle, perhaps, but it seems evident that multiple authorship increases the opportunity for each of these to occur, if only because the responsibilities of authorship are diffused or diminished when they are widely shared.

Irresponsible authorship, rather than multiple authorship, is in fact the real problem in such situations. In principle, it is possible for fifteen or fifty scientists to coauthor a single research report, using the term “author” in the full sense of that word. More usually, however, multiple authorship indicates a claim for credit rather than an acceptance of responsibility. Multiple authorship, in other words, can easily become irresponsible authorship simply because it tends to debase the notion of what authorship really means. Too often, someone is named as an author less because of the need to accord appropriate recognition than because a publication list is regarded as the index of a scientist’s worth, and the more the better. How much the “author” actually contributed to the writing of the paper, or even to the actual research on which the paper is based, comes to matter less than the fact that the scientist is listed as an author, preferably as close to the head of the list as possible.

The end of this particular road, as suggested in the opening chapter, may be the Alsabti case in which a publication list was created largely by republishing, under Alsabti’s name, scientific articles by others that had already appeared in other journals. Since Alsabti plagiarized alone, this may seem to be irrelevant to the notion of multiple authorship as irresponsible authorship, but there are several way-stations along the road. They include what Broad and Wade describe as “the gratuitous addition of coauthors by a researcher trying to curry favor.”22 For example, a former graduate student may send his supervisor an article several years later, based on research done long after the graduate studies have been completed, in which the supervisor is surprised — and should be outraged — to find that he is named as a coauthor. Or, as Broad and Wade report,

An editor at one journal, *Blood*, received a call one day from an irate researcher who asked that his name be removed from a manuscript that he had just seen and with whose conclusions he did not agree. His sole contribution had been a few seconds of conversation with the lead author in an elevator.23

It may seem paradoxical that authors are multiplied in this way by scientists who are well aware — perhaps to the point of paranoia — that the length of one’s own publication list may be measured against those of others. That para-
dox is neatly, and even more dishonestly, resolved by those scientists who agree with one another that each will add the other’s name to a paper, with or without any contribution to the work, in the knowledge that the other will return the “favor.”

The scientist who complained that a conversation in an elevator had been used as a pretext for listing him as an author presumably subscribed to the responsible view of authorship. Quite apart from his minute contribution, he did not agree with what the paper said and wanted no share of either credit or responsibility. That view ought to be both understandable and undeniable. As multiple authorship has proliferated, however, many have come to the comfortable belief that their appearance as authors does not indicate responsibility for the paper as a whole, but only for their specific contribution to it. This attitude has gradually spread to cover even cases of limited coauthorship. As the editor of the *New England Journal of Medicine* commented after the withdrawal of a paper in which John Darsee had been one of only two authors, and another in which he was one of three,

... the two formal retraction notices, as well as Darsee’s supporting letter ... seem to suggest that his coauthors at Emory had no responsibility at all for what happened, simply because they are honest and had no hand in the manipulation of the data. I cannot agree, and neither will most other editors.21

Other editors do share Relman’s views, and are endeavoring to establish rules that would have seemed unnecessary a few decades ago. For example, the *Journal of Animal Science* adopted in 1984 a new policy in regard to submission of manuscripts:

All authors regardless of whether senior or coauthor must provide a signed affidavit assuring that they have read the manuscript prior to submission and (or) are fully aware of its content and that no substantial portion of the research has been published or is being submitted for publication elsewhere.

In an attempt to clarify responsibilities in multiauthor papers, one Sigma Xi member recently suggested that articles in *American Scientist* (and presumably other journals as well) should include a brief section on “Attributions”: “For example, in a paper by Smith, Jones and Brown, the Attributions section might read ‘Smith took the data, Jones analyzed it, and Brown fed the animals.’” This would certainly help to identify the contributions made by multiple authors, and might be worthwhile for that alone. Whether the section would do much to solve the problems liable to arise from irresponsible authorship is more doubtful. It seems to define the limits of responsibility so narrowly that, in effect, Brown would be able to say “Don’t blame me if there is anything wrong with the data”; Smith could argue that his data were accurate even if the use made of them was faulty; and Jones could claim that it was not his responsibility to verify that the data were collected under the right conditions.

Some of us may also be inclined to ask whether, if Brown’s contribution to
How much responsibility do authors have for the accuracy of the clinical-laboratory data they describe? . . .

. . . they were not familiar enough with the technique to have been aware that their colleague had given them a factitious tracing . . . . When authors discuss and advocate the clinical use of a diagnostic procedure, and when they publish illustrations of its application in specific patients, I think they ought to know something about the procedure itself, not simply how to interpret the results. . . .

The lesson seems clear: Authors should be familiar with the laboratory tests they write about; otherwise, they risk embarrassing themselves and misinforming their readers. . . .


due to limited to feeding the laboratory animals, that contribution really merits coauthorship. Occasionally multiple authorship is justified on the grounds that “I had to have my samples tested (or my animals fed) by so-and-so, and he wouldn’t have done it if I had not been prepared to make him a coauthor of this paper.” This attitude may be entirely legitimate if the colleague has an unusual expertise required by the nature of the research problem. Sometimes, however, it may be an excuse for laziness on the part of a principal researcher who cannot be bothered to master all the techniques appropriate to that type of research. At worst it may be a form of academic blackmail.

If Brown does indeed deserve to be a coauthor, then this should be on the basis suggested by Broad and Wade:

Two principles might be established. First, all people named as authors should have made a defensibly major contribution to the work reported. Any minor contribution should be explicitly acknowledged in the text of the article. Second, all authors of a paper should be prepared to take responsibility for its contents in precisely the same measure as they stand to take credit. 25

These principles are intended for all branches of science: there are no “local
rules" that exempt particular disciplines.

A word is necessary about the meaning of being "prepared to take responsibility" for the contents of a paper. Taking credit is straightforward: we include the paper in our list of publications and expect other scientists, scientific employers and grant-making bodies to give us due credit. Responsibility is normally a more private matter. Even if parts of the research are subsequently found to be based on carelessness or fraud, other scientists may be unwilling to censure you severely, if it appears that one of your coauthors was the source of the errors or dishonesty.

The generosity, or the pusillanimity, of other scientists does not however allow you to evade responsibility. If the paper contains fraudulent statements, or mistakes caused by the carelessness or self-deception of others, it should not have been published and you should not have attached your name and scientific reputation to it as a coauthor. In short, the time to take responsibility for a paper is not after its errors have been exposed but before it is published. Whatever view of the matter is taken by other coauthors, it is up to you to ensure that the manuscript is free of error or bias. This may involve learning more about some areas of expertise than you might otherwise need to know, but this is seldom as difficult as it sounds. You should, for example, not have to become a mathematician to understand the analysis contained in a particular research paper. If understanding every word and symbol is really beyond you, then you should have those sections you cannot understand checked by someone who is not a coauthor but whose knowledge and judgment you trust. Errors (or even dishonesty) can still slip through such checks, but the vast majority are caught by such responsible authorship.

Authorship, then, should mean the same thing in any branch of science. If the trend in a particular system is towards multi-authored papers, this cannot justify irresponsible authorship of the type described in this chapter.

Alternative sets of values in biomedical research

A second area of concern is limited to biomedical research rather than evident in other branches of science. Because of the vast scale of biomedical research today, and the large numbers of disciplines and scientists involved, it is nevertheless of great significance. The problem can best be stated by quoting from one recent study.

... there are significant differences between the values of scientists whose professional training was in a particular field of science and those who have entered research after training in medicine. In particular, the central value in what might be called the "ethos of modern medicine" is to benefit patients rather than to produce scientific knowledge. ...

It is our sense — primarily experiential and impressionistic in nature — that honesty in research work as a fundamental moral rule is valued more strongly among
scientists than among physicians . . . physicians tend to evaluate research in terms of harm or benefit to patients rather than in terms of adherence to the rigorous norms of scientific investigation . . . .

When discussing the actual or possible occurrence of fraud in research, physicians seem less distressed morally than do scientists. With respect to what is often termed "massaging data" — as distinct from what apparently is the more negatively viewed occurrence of outright data fabrication — the physician reactions that we have heard (and that others have reported to us they have heard) indicate a pattern of indifference: "So what? It happens all the time . . . ."

The ethos of modern science with respect to the integrity of data may also be weaker among nonphysician researchers who work in clinical settings than it is among basic or laboratory-based researchers, probably because the former absorb the prevailing norms of their physician colleagues. 26

If this is reasonably accurate, the physician's attitude to research may be understandable, even if it cannot be condoned. The physician may be wary of the motives behind the research interest of the scientist. The latter may be slightly less concerned with doing everything possible to save the life or improve the health of an individual patient than the physician, and slightly more interested in the reason why the patient does or does not recover. The physician may therefore try to protect his or her patients from someone who may be inclined to view the patient primarily as an element in a scientific sample. If this means that tests are not conducted with the rigor that the scientist would like, so be it. However, the physician's refusal to become obsessed with absolute scientific accuracy may also be due to an inability — shared with a much wider public — to understand why the scientist treats data as sacrosanct. This does not mean that the scientist's attitude is wrong, any more than the physician's concern for patient welfare is unjustified.

The problem is not that one set of professional mores has to be chosen over another, but rather that the choice may take place if we are not careful. Scientific research in a clinical setting requires both the physicians' and the scientists' guiding principles. In Swazey and Scher's words,

Adopting the position of a clinical researcher makes a physician subject to the standards of the scientific community in addition to those of the medical community. Indeed, since it is primarily practicing physicians who will be using the results of clinical research, the medical community itself relies upon the physician-investigator's conducting research in accordance with the highest scientific standards. 27

The danger is that this will not happen; it is all-too-easy for the "nonphysician researchers in clinical settings" to forget or minimize the standards of accuracy they have learned as scientists and to adopt "the prevailing norms of their physician colleagues." If the head of the clinical research team sets the right example, such slippage is unlikely, but role models do not always behave as they should.