Journal of Official Statistics, Vol. 17, No. 1, 2001, pp. 187–206

Practicing What We Preach: The Application of Continuous Improvement in a Preclinical Statistics Department at a Pharmaceutical Company

V. Bill Pikounis[1], *Joseph M. Antonello*[1], *Danielle Moore*[1], *Edith T. Senderak*[2] *and Keith A. Soper*[2]

The Biometrics Research Department at Merck Research Labs supports preclinical and nonclinical phases of drug research and development. Our clients expect us to provide written reports that fully document our statistical evaluations of their data. Studies include toxicity, efficacy, and validation of vaccines and pharmaceuticals. While our primary clients are scientists, the needs of regulatory affairs and quality assurance personnel are also frequently prominent. Principles of Total Quality have been practiced in collecting data for accurate evaluation of the effectiveness of our written reports, and in the implementation of improvements. For the sample of scientists ($N = 24$) surveyed, formal statistical analysis revealed an improvement in clarity at follow-up ($P = 0.008$), even though baseline results for report clarity averaged at or slightly above expectation. Scientists also reported improvement in communications as part of overall service ($P = 0.003$). Response time for producing written reports essentially remained the same, and clients now have raised expectations for timeliness in that regard. The concern for turnaround time points to a closing discussion of long-term prospects for permanent integration of a continuous improvement philosophy into the department.

Key words: Total quality; Merck; written reports.

1. Introduction

The Biometrics Research Department at Merck Research Labs provides statistical support for preclinical and nonclinical phases of drug development. Preclinical refers to all stages of drug discovery and development that take place prior to human testing; nonclinical refers to aspects such as manufacturing or animal-health or agricultural products research. There are a total of 15 statisticians in the department. Ten are located in West Point, Pennsylvania, and five in Rahway, New Jersey, the two largest research sites of Merck and Co. At each site, there are approximately one thousand scientists and engineers conducting research on promising new compounds and therapies.

Our department possesses characteristics of a small open-consulting business within a large company. We largely depend on the motivation of individual researchers to enlist our services. By far, the most common functions we provide in our collaborations with researchers are data analysis and the preparation of written reports to communicate results and interpretations of those analyses.

[1] Biometrics Research Department, P.O. Box 2000, RY70-38, Rahway, NJ 07065-0900, U.S.A. E-mail: v_bill_pikounis@merck.com
[2] Merck Research Laboratories, P.O. Box 4, WP44L-214A, West Point, PA 19846-0000, U.S.A.

With encouragement and input from management and peers, a departmental sub-team was formed to learn and apply concepts of Total Quality to processes and products that occur in the production of our written reports on data analysis. The following presentation chronicles the efforts and accomplishments of this team to identify, study, and increase the quality and efficiency of such processes and products.

2. Defining a Mission

2.1. Names and abbreviations

The phrase ''continuous improvement'' has been firmly established as the common reference label for our department's and organization's efforts. The sub-team for our Biometrics Research (BR) department possesses the abbreviation BR-CI for convenient common reference.

2.2. Training

Experienced facilitators from a corporate division of the company provided education and focus on principles of continuous improvement, particularly over the first few team meetings. Lectures, books, video, and audio materials from Zenger-Miller Inc. (1992) were used. Strategies were also applied from Scholtes (1988). Sharing Hopes and Concerns, developing Ground Rules, and learning techniques of Brainstorming and Nominal Group were all examples of time well-spent up front to enhance the team's capabilities to work productively together and endure the challenges of the long-term nature of the project.

2.3. Mission statement and goals

A clear purpose to guide the team was developed by team members and our management. The mission of the Biometrics Research area team is;

- to increase the usefulness of our written reports for clients and customers,
- to reduce our effort in communicating results without compromising regulatory or internal standards, and
- to demonstrate the value of Continuous Improvement (CI) for enhancing the quality of our products.

In conjunction with our mission statement, the team used criteria of measurability, challenge, attainability, and completion dates to come up with the following set of six major goals:

1. Process map report writing procedures.
2. Evaluate client needs.
3. Develop and communicate implementation strategies.
4. Implement changes.
5. Evaluate and communicate process changes.
6. Become versed in continuous improvement.

Under each of these six major headings, 3–4 sub-heading goals were also identified

to clarify the steps needed to fulfill our mission. Together with management, a rough timetable of five months was sketched for completion of goals 1–4. When it soon became clear that this was an underestimate of the effort involved to effectively achieve these goals, management demonstrated its support by allowing additional time as needed. As it turned out, completion goals 1–4 took twice as much time as originally projected.

3. Identifying the Work Process

We learned the definition of a work process as a series of work steps which results in a particular product or service for the customer. In alignment with our mission, we selected a specific work process to be analyzed. Although we write different types of reports, the Data Analysis type of report is regarded as our major type in terms of time spent, frequency of activity, and the number of departmental members affected. Such reports essentially document in detail the analyses we perform for clients on their data, including statistical methods, results (text, tables, and graphs), interpretations, and summary sections.

Figure 1 displays a detailed mapping of the Data Analysis Report Writing Process.

4. Preparing a Client Survey

Examination of the steps during and after the development of the process mapping (Fig. 1) revealed that, amongst ourselves, we were limited to only being able to assess our efforts in the actual production of written reports. The true quality of our reports, however, could not be accurately determined by any approach solely based on our own perspectives. This simple but important insight led to the obvious question: Why do we not ask our customers what they want? In order to assess the quality of our reports and to determine areas in need of improvement, we surveyed our clients and customers. In addition, measures from a departmental project tracking system were used and are discussed later in Section 7.

4.1. Who are our clients and customers?

The mission statement contains the phrase ''clients and customers.'' The terms are not synonymous. Our written reports are not only produced for scientists (researchers) with whom we deal directly, but also for quality assurance and regulatory affairs personnel within Merck who review them prior to inclusion into official filings with domestic and international agencies.

Thus, we felt it best to characterize the scientists who are the primary recipients of our data analysis written reports as clients. The other category of customers includes quality assurance, regulatory affairs, and our own departmental management.

4.2. Presurvey information collection

Only one of our team members possessed any real experience with surveys prior to our undertaking. With input from our facilitator, the team decided to do a pilot survey in order

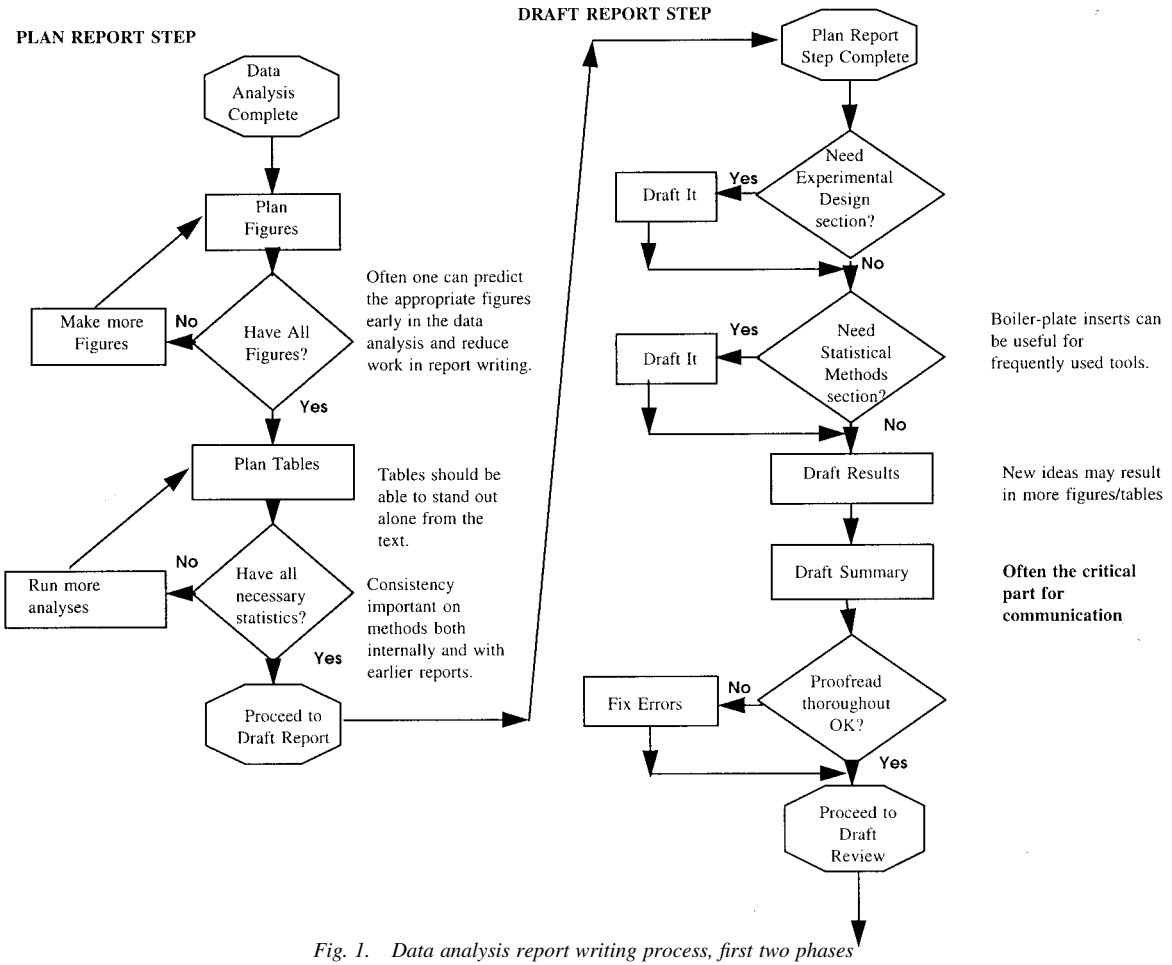
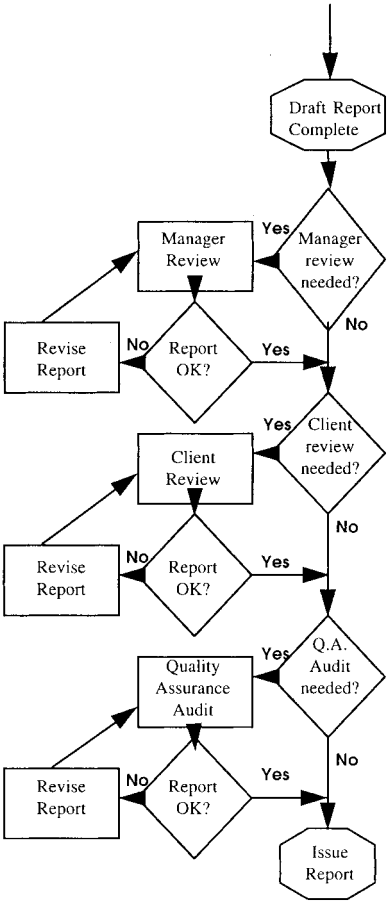


Fig. 1. Data analysis report writing process, first two phases



and/or Peer Review

Q.A. = Quality Assurance Department

If Q.A. finds that the original data were not perfect, all analyses must be revised and the audit repeated. Try to avoid this scenario by asking early if the data is checked and "final."

END: ISSUE REPORT

Fig. 1. (Continued). Data analysis report writing process, third and last phase

to get ideas of the right questions to ask in the full-fledged survey. A total of ten clients and customers were contacted and informed of our CI mission efforts and the purpose of the pilot survey. In a face-to-face interview, we posed the following open-ended questions, asking our interviewees to provide feedback with an emphasis on our written reports, but welcoming them to comment about our general service as well:

- What are your concerns?
- What are your key expectations?
- What are your needs, especially those that are unmet?
- Is there anything superfluous provided in the written reports?

This exercise was definitely worthwhile in several respects. We received guidance on the content for the full-fledged survey. We also discovered that different clients and customers had different expectations, and some of these differences directly conflicted with each other. We decided that face-to-face interviews, though time-consuming, would be the best method for survey data collection. The survey design should include both open-ended questions and choice-oriented questions to get data on qualitative and quantitative scales.

4.3. Sampling frame

A stratified random sample scheme was devised. The two-level stratification consisted of ''key clients'' and ''nonkey clients.'' (Here the term clients includes customers as well.) Key clients were judged as such by each member of the BR-CI area team on the basis of their familiarity with their clients. Guidelines for the judgment included: high visibility in the company (either for the client or the project); the percent of time spent on their projects; and the length, breadth, and depth of the collaborative relationship between the statistician and the client/customer. All key clients were selected to be surveyed. Key clients included our customers in departmental management, quality assurance, and regulatory affairs.

Nonkey clients were subdivided into those who did not receive a report in the past 18 months and those who did. A single client from each subgroup was selected at random for each team member. This design ensured that the survey would include clients who had not consulted with our department recently, possibly because of an unsatisfactory experience.

This scheme produced a target sample size of 34 with over 20 different departments covered. Twenty-nine of these were scientists, three were managers within the statistics department, one was a document quality assurance auditor, and one was a member of our regulatory affairs department. Of the 34 total, 24 were classified as key clients.

5. Baseline Results of Client Survey

The entire interview guide is displayed in the Appendix. A copy of the guide was sent to interviewees ahead of time with a cover letter explaining the purpose of the survey in the context of the department's continuous improvement efforts. A few days after sending out the material, calls were made to schedule an appointment for conducting a face-to-face interview using the guide.

In the course of constructing the interview guide, it was felt that there existed a great opportunity to collect data about our general support beyond written reports even though our mission statement made no direct mention of this. The added interview time to complete this section posed no problems in any of the interview cases for the subject or the interviewer.

5.1. Findings

Responses were received from 29 out of the 34 subjects in the sampling plan. Several subjects specifically indicated their appreciation for our face-to-face survey efforts and what we hoped to accomplish from the exercise. With respect to our written reports, the main observations were:

- All 29 clients/customers said a written report was necessary.
- Nearly all clients considered all sections of written reports as either necessary or useful.
- Content in the sections of Statistical Methods and Results is important and quite satisfactory.

- The Summary section is important but relative to the other sections had the greatest room for improvement. Clients require more clarity and conciseness in the summary section.

Expanding on this last point, Figure 2 displays the average degrees of importance and satisfaction that our respondents felt on specific sections of a written report.

These observations from the data suggest high overall satisfaction with our written reports. The summary and conclusion sections' ratings suggest the most important opportunities for improvement.

Examining the responses directly regarding our queries on general support, we found that:

- Overall quality of service met or exceeded expectations for all 24 scientists (100 percent). Eleven (46 percent) indicated that the level of quality exceeded expectations,

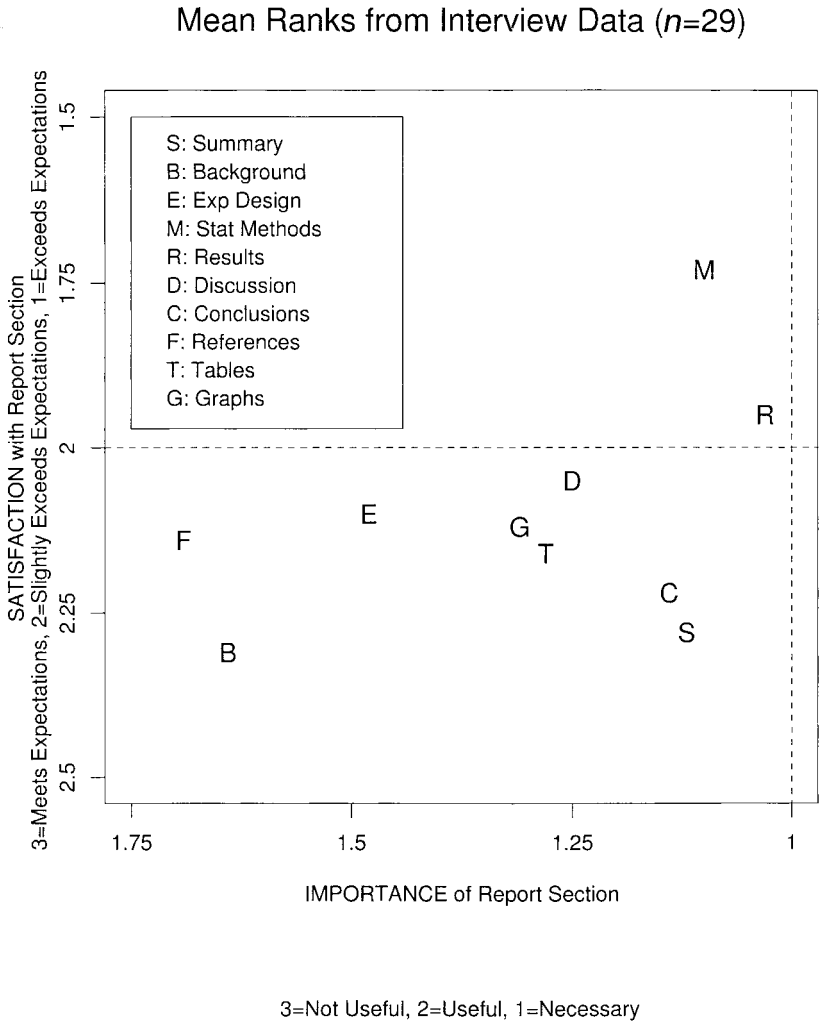


Fig. 2. Scatterplot of average importance and satisfaction for specific sections of a written report

ten (42 percent) indicated that it slightly exceeded expectations, and three (12 percent) indicated that it met expectations;
- Suggestions for improvement of general support included: more involvement in experimental design and statistical education, reduction of turnaround time, and the development of statistical analysis systems to make it easier for researchers to do routine analyses themselves.

The results indicated to us that we have very positive working relationships with our clients and customers, but that we can certainly do better with regard to our written reports and general performance.

5.2. Limiting inferences

The BR-CI team's survey was based on clients from 1/3 of the total number of statisticians in the department. Since at least ten of the clients and customers that were interviewed have received written reports by different statisticians on different occasions, we feel that inferring our results to the entire department is reasonable.

However, it is noted that our results do not address (potential) clients who have never received or read a written report from us. Particularly with respect to interpretations about our general support beyond written reports, it should be kept in mind that we obtained results only from clients who perceive a need for statistical support to some degree and also value the communication of that support in writing.

6. Interventions for Improvement

Diagnosis of the baseline data by the team led to the interventions detailed in the following six recommendations. After receiving department-wide consensus and managerial approval, the interventions were implemented.

6.1. Include a clear, concise summary

Our clients require a summary that:

- Is limited to one page whenever possible.
- Avoids statistical jargon.
- Contains the following elements:
  - Objective of the statistical analysis
  - General perspective such as study design
  - Therapeutic area or drug identification
  - Results, briefly summarized, preferably accompanied with a table or graph
  - Recommendations or conclusions in simple declarative English sentences

Any other elements, such as specific statistical methods, should be only included in rare instances, when they are regarded as critical to the specific report.

6.2. Always provide a written report, though the level of detail can vary

Clients clearly want findings communicated in writing, but the amount of detail required varies greatly. For example, one client may require a complete ''standalone'' document

ready for regulatory review. In another instance (same or different client), only a quick table or graph with a few sentences of explanation is needed.

- Early in the consultation, the statistician and client should determine the level of report required. (Perhaps the client does not even want a report, only a quick analysis with straightforward findings.)
- For the usual case when a client needs a written report, two levels of report are recommended – formal and informal:
  - Formal reports should be as self-contained as possible and include the following elements: summary, objective, design, methods, results, displays, references, and electronic storage. Additionally, it might be useful to have a discussion section with recommendations for strengthening subsequent studies, a background section to complement or expand upon the objective, and a data listing.
  - Informal reports should include the following elements: statistician name, client name, date, findings (e.g., table, figure, statement), and electronic storage.

6.3. Consider alternative methods to achieve gains in efficiency

In tandem with the direct information we received from our client survey, the in-depth examination and mapping of the work process of writing reports led to the following suggestions:

- Define objectives at initial consultation.
- Require that data be complete and valid prior to analysis.
- Encourage clients to provide data in electronic format.
- Get involved in experimental design.
- Capitalize on computer network and desktop applications technologies, such as employing standard text inserts and programs.
- For simple or repetitive tasks, encourage and support clients to perform their own analyses.
- Encourage the writing of a ''joint report'' together with the client.
- Adhere to a standard report format.

None of the client scientists expressed concern about report formatting, although our management preferred that we use a standard format. Skeleton templates easily accessible through the department's computer network were created to increase efficiency and uniformity.

Efficiency could also be gained by having ''statistical methods'' paragraphs that are repetitively used in reports be available on the computer network. These paragraphs could be copied into documents as needed. Computer program listings can likewise be made available. While such programs should work properly and be well-documented, it is understood that any prospective user must always be keenly aware of validation issues.

6.4. Survey clients periodically

As previously noted, clients were generally pleased that we cared enough about the quality of our services and products to do a survey.

- Continue policy of having clients review written reports while still in draft form.
- Formal mechanism of feedback should occur on a regular basis (e.g., every year or two).

7. Assessing the Interventions

To assess the effect of the interventions, three investigations were conducted: (1) a resurvey of clients, (2) an analysis of report tracking data, and (3) a survey of Biometrics Research departmental members.

7.1. Client follow-up survey

All clients who were initially surveyed were resurveyed six months after the interventions were implemented. Clients who had received or reviewed a written report following implementation of the interventions were asked to complete the entire resurvey; other clients were asked to complete only a portion of the resurvey. The resurvey contained questions which allowed for expanded responses, and measures which allowed for direct comparisons to original survey responses. A copy of the client resurvey is provided in the Appendix.

Despite our best efforts to achieve 100 percent follow-up, two scientists from the original 24 (9 percent) chose not to respond to the resurvey, citing time pressure. Thirteen scientists received a written report during the six-month follow-up period and so could comment on whether our written reports had changed. Table 1 includes preintervention and change results from follow-up for **Report Clarity**. Some clients chose to give intermediate scores, e.g., 1.5, so the change from preintervention to postintervention could range anywhere from -4 to $+4$ in steps of 0.5. Change was defined as postintervention score MINUS preintervention score, so negative changes indicate improvement.

The original scores for scientists not in the follow-up group were generally equal to or slightly better than those in the follow-up group, suggesting that scientists participating in the follow-up survey were representative of the entire study sample.

Formal statistical analysis was restricted to the scientists, the only group with sufficient sample size. One-sided P-values based on the exact permutation distribution of the Wilcoxon signed rank test were used. Results for the nonscientists are also listed in Table 1.

The pretest results averaged above expectations (mean 2.4), but an improvement in clarity was still detected at follow-up ($P = 0.008$). Interestingly, though, clients did not report consistent improvement in the report summary, one of the target areas of our intervention ($P = 0.203$). Many of the written comments supported the notion of improved clarity in the reports, but not in the summary section per se.

Similar tabulations and analyses were conducted for the areas of **Performance/ Communication**, **Promptness**, and **Timeliness**. Scientists indicated improvement in communication ($P = 0.003$), which is perhaps not surprising since we did a face-to-face survey and then took action to respond to client concerns. Written comments were generally favorable, including nearly unanimous approval for regular surveys. Section 7.3 below contains discussion pertinent to the timeliness and promptness findings.

Table 1. Written reports overall – clarity (negative change scores indicate improvement)

Preintervention survey results	
Scale	Number of scientists
1 = Exceeds expectations	4
(1.5)	2
2 = Slightly exceeds	6
(2.5)	1
3 = Meets expectations	8
4 = Slightly falls short	2
5 = Falls short	1
Total number	24

Overall Mean = 2.4.
Mean of two follow-up nonrespondents = 2.

Change at follow-up survey		
Category	Post – Pre	Number of scientists
Better	−3.0	1
	−2.0	1
	−1.0	3
	(−0.5)	2
No change	0.0	6
Worse	1.0	0
	2.0	0

$P = 0.008$ by one-sided Wilcoxon signed rank test.

Results for nonscientists			
Client type/ID	Pretest	Follow-up	Change
BR manager 1	3	3	0
BR manager 2	3	2	−1
BR manager 3	3	2	−1
Quality assurance	3	3	0
Regulatory affairs	3	2	−1

7.2. Items marked as problematic

At pretest, there were a total of 20 out of 162 possible items (12 percent) from 9 clients marked as not meeting expectations (score 3.5 or worse). Eighteen of these 20 items were marked as meeting expectations or better at follow-up.

One exception was a scientist who felt the conclusion section of reports remained slightly below expectations on follow-up. Interestingly this client marked the summary page as ''meets expectations'' on both baseline and follow-up surveys. The other exception was a Biometrics manager who felt timeliness of general performance was slightly below expectations at both baseline and follow-up. None of the follow-up surveys had any items scored below expectations but there were 16 items from seven clients scored

4, ''slightly below expectations.'' Lower marks on report promptness and general performance timeliness came from two Biometrics managers and two scientists. Two other scientists indicated dissatisfaction with various sections of the written reports, while the Regulatory Affairs client specifically cited the report Background and Discussion sections.

We believe it is important to respond to every item not meeting expectations. The issue of timeliness (work load) is a complex problem that Area Team individuals each address with their own clients, but it was not the focus of this area team.

7.3. Report tracking data

For each written report requested, three dates are entered into an electronic database. The database is used to record the request and track the project's status. The **received date** is the day all materials to start the project are received and work can begin; the **initiate date** is the actual day statistical work is initiated on the project; and the **draft date** is the day the draft report is circulated for client review. Using information from the report tracking database, the following two measures were considered: (1) the time from project received to project draft; and (2) the number of projects per month having a drafted or completed written report. To assess the impact of the interventions, preintervention results were compared to postintervention results for each measure.

Figure 3 is a scatterplot of the elapsed turnaround time. Note that the *y*-axis tick marks are in the natural log scale, and that the monthly values are jittered (Chambers, Cleveland, Kleiner, and Tukey 1983) to alleviate overlap.

Each data point falls into the month in which the project was started. Since there are uncompleted projects at any given time, and some of these projects take several months to generate a written report, we decided to use only projects that possessed a time elapsed value of 60 days or less. (For example, some elapsed time data in August was not actually observed until October. The final possible draft date was October 30, i.e., 60 days from August 31.)

The ''Before-Intervention Period'' covered January through April, while the ''After-Intervention'' Period ran from May through August. The LOWESS curve (Cleveland 1979) superimposed on the plot indicates that the time elapsed measure is essentially unchanged. Further evidence of the similarity of the time periods is given in Table 2 and Figure 4. The number of projects with written reports ''drafted'' is just the number of recorded elapsed times for a given month.

At follow-up, the client survey results on promptness and timeliness showed lower scores by seven scientists and all three Biometrics managers. Taken with the results from the tracking data base, we feel these results do not reflect that reports are taking longer than before. Written comments in the pretest survey suggested that expecta-

Table 2. Number of written reports by month

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
29	20	54	31	30	40	27	26
TOTAL: 134				TOTAL: 123			

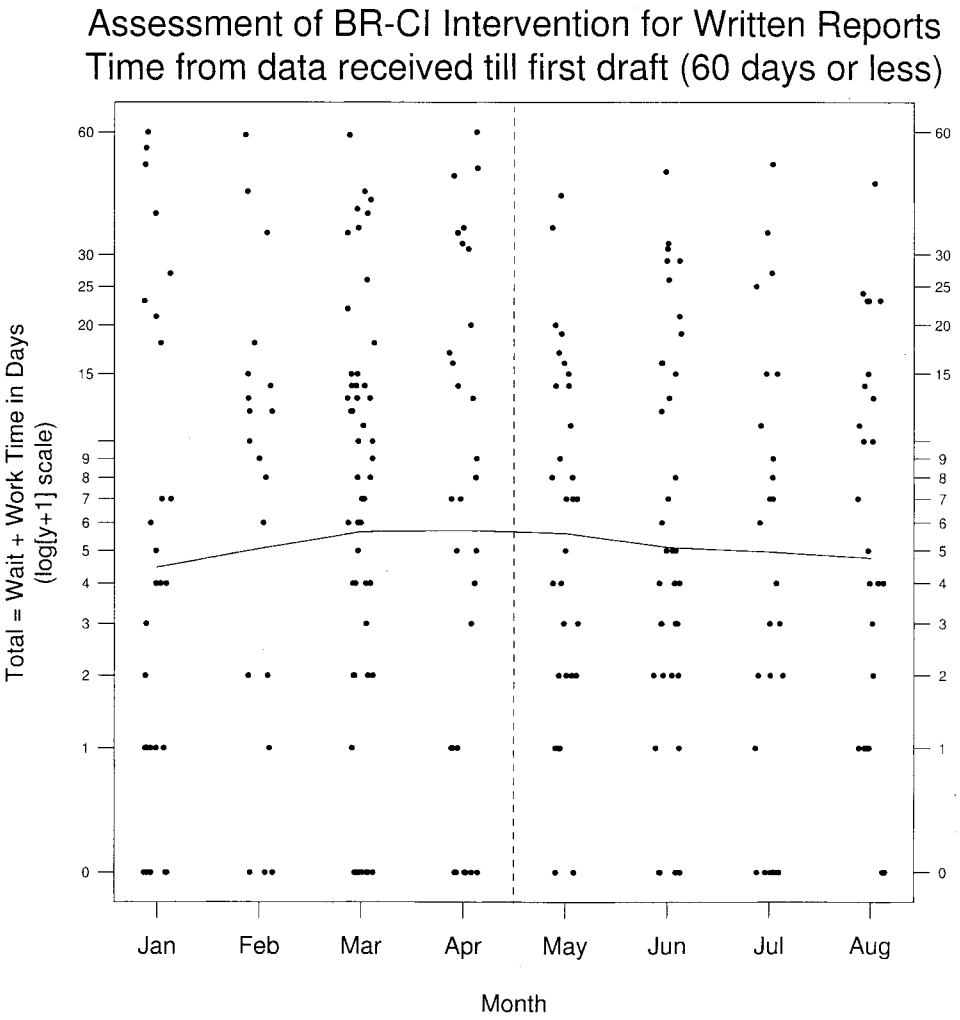


Fig. 3. Scatterplot of time elapsed to generate a written report. The dotted line indicates the division of before and after intervention periods of four months each

tions on timeliness were low. One interpretation of lowered scores on these items in the follow-up survey is that the Continuous Improvement paradigm has raised expectations. Client concerns about report clarity were addressed during follow-up, and now clients are ready to see their concerns about timeliness addressed as well.

7.4. Statistician survey

Because the area team represented only about 1/3 of the department, the success of the continuous improvement effort relies on the support of nonteam members. To gauge the level of support within the department, all members of Biometrics Research were asked to complete a survey. While the survey was anonymous, individuals identified themselves as either managers, statisticians on the area team, or statisticians not on the area team.

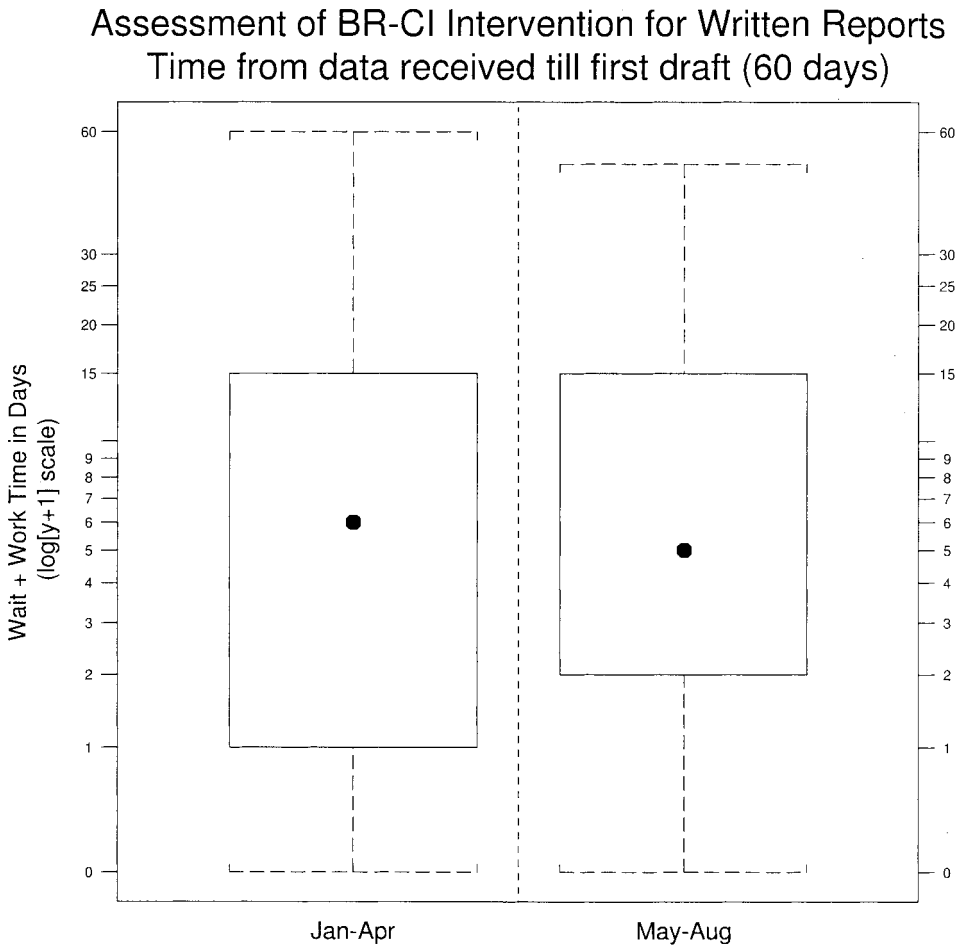


Fig. 4. Similarity before and after interventions of time elapsed to generate a written report. The dotted line indicates the division of before and after intervention periods of four months each

All individuals responded: two managers, five area team (AT) statisticians, and eight non-AT statisticians. (A change in management after the client follow-up survey accounts for the decrease from 3 to 2 in that group.) The majority of AT and non-AT statisticians indicated that the CI effort has influenced them to: (1) improve the written report summary page; (2) improve the clarity of the overall report; and (3) provide better service. Both AT and non-AT statisticians were divided over whether the CI effort has influenced them to improve their efficiency (5 yes, 6 no, and 2 no improvement needed). See Table 3 below for a listing of the actual data responses. Statistician and manager comments regarding the continuous improvement effort were positive overall, noting improvements in the summary page and emphasizing the utility of the client survey.

8. Discussion

Prior to formulating a specific mission statement at launch, the team drew up an extensive list of hopes and concerns. Looking back specifically at these, we observed that we indeed

Table 3. Statistician survey results on interventions

During the past year, has the continuous improvement influenced you to			
Improve the summary page?			
Group	Yes	No	No improvement needed
Manager	2	0	0
Area team	4	0	1
Non-area team	6	1	1
Total	12	1	2
Improve clarity of the overall report?			
Group	Yes	No	No improvement needed
Manager	1	1	0
Area team	4	0	1
Non-area team	6	2	0
Total	11	3	1
Improve your efficiency?			
Group	Yes	No	No improvement needed
Manager	1	1	0
Area team	2	2	1
Non-area team	3	4	1
Total	6	7	2
Provide better service?			
Group	Yes	No	No improvement needed
Manager	2	0	0
Area team	3	1	1
Non-area team	5	1	2
Total	10	2	3

(1) developed better relations among department members between and across sites; (2) worked on concrete, practical problems; (3) found alternative ways of documenting our work; (4) learned the dynamics of teamwork; (5) experienced creative synergy; (6) communicated securely and freely; and (7) determined that clients cared about our efforts.

Direct management support was clearly established for the project. We felt that the three stated points of the mission of the Biometrics Research area team (see Section 2.3) had been fulfilled. We learned that we are doing well, but that we can do better. After consensus by all department members, a second team has been launched to deal with the response concerns of our services. The second team is focused on a long-term vision to provide education and computer systems to better enable scientists to explore and analyze their data themselves.

Whether the resources required under a continuous improvement paradigm is worth the effort, though, remains an open question for our own department and other colleague groups in the organization. Peers and management in other departments around the

company continue to view the continuous improvement paradigm with a considerable degree of skepticism for their specific work processes. On a brighter side, two teams from other departments in our organization have formed and worked on problems under the continuous improvement framework. Portions of our interview guides (see Appendix) have served as useful templates for their projects.

Statisticians join other professionals in widespread praise of the great work accomplished by W. Edwards Deming, and most perhaps feel some degree of pride that Deming was often recognized as a statistician. His teachings of Total Quality emphasize people and management principles as well as technical aspects. Statisticians who collaborate with scientists on applied research problems need to recognize the vital importance of both aspects, not just the technical side. By experiencing the processes of formulating questions to research and then performing a study to help answer those questions, we can gain insight and understanding into the difficult nature and pitfalls of carrying out the scientific method in reality. Such experience should strengthen our influence with clients in their using statistical methodology to achieve their research goals. The efforts and accomplishments of this article are an example of practicing what we preach.

Appendix

A. Biometrics Research Continuous Improvement Team INITIAL survey

INTERVIEW QUESTIONS:

I. *On Written Reports*

1. The following represents a breakdown of sections usually included in Biometrics Research written reports. Please rate with respect to importance and satisfaction.

	Importance	Satisfaction
	1. – necessary	1. – exceeds expectations
	2. – useful but not required	2. – slightly exceeds expectations
	3. – not useful	3. – meets expectations
		4. – slightly falls short
		5. – falls short
SUMMARY	_____	_____
BACKGROUND	_____	_____
EXPERIMENTAL DESIGN	_____	_____
STATISTICAL METHODS	_____	_____
RESULTS	_____	_____
DISCUSSION	_____	_____

CONCLUSIONS	_____	_____
REFERENCES	_____	_____
TABLES	_____	_____
GRAPHS	_____	_____

2. What are your expectations of our written reports?
3. How well do our written reports meet your expectations?
4. Please rate our reports with respect to the following items using the given scale:

1	2	3	4	5
exceeds expectations	slightly exceeds expectations	meets expectations	slightly falls short	falls short of expectations

a) Promptness _____

b) Clarity _____

c) Comprehensiveness _____

d) Utility _____

5. How can we improve our written reports?
6. Is a Biometrics Research written report necessary for your purposes?
   Yes or No
   a) What do you use it for?
   b) What do your management and peers require in the summary section?
   c) What value do you feel would be lost if we did not provide written reports?
7. What is the best way to measure your satisfaction on an ongoing basis?

II. *On General Performance*

1. What are your expectations of our overall statistical support?
2. How well does our support meet your expectations?

In particular, please rate our overall support with respect to the following items using the given scale.

1	2	3	4	5
exceeds expectations	slightly exceeds expectations	meets expectations	slightly falls short	falls short of expectations

a) Qualify _____

b) Timeliness _____

c) Usefulness _____

d) Communication _____

3. How can we improve our overall statistical support?

B. Biometrics Research Continuous Improvement Team Resurvey

INTERVIEW QUESTIONS:

I. On Written Reports

Have you received or reviewed a Biometrics Research written report since May 1, 1994? _____ Yes _____ No. If yes, please answer items 1 to 4 with respect to written reports issued since May 1, 1994. If no, please proceed to Section II.

1. The following represents a breakdown of sections usually included in Biometrics Research written reports. Please rate with respect to satisfaction using the given scale.

1	2	3	4	5
exceeds expectations	slightly exceeds expectations	meets expectations	slightly falls short	falls short of expectations
SUMMARY	_____	_____		
BACKGROUND	_____	_____		
EXPERIMENTAL DESIGN	_____	_____		
STATISTICAL METHODS	_____	_____		
RESULTS	_____	_____		
DISCUSSION	_____	_____		
CONCLUSIONS	_____	_____		
REFERENCES	_____	_____		
TABLES	_____	_____		
GRAPHS	_____	_____		

2. Have you noticed a change in our written reports? Please comment.
3. Have you noticed a change in our summary page? Please comment.
4. Please rate our written reports with respect to the following items using the given scale.

1	2	3	4	5
exceeds expectations	slightly exceeds expectations	meets expectations	slightly falls short	falls short of expectations

a) Promptness _____

b) Clarity _____

c) Comprehensiveness _____

d) Utility _____

II. *On General Performance*

Have you had any type of business interaction with Biometrics Research since May 1, 1994?

_____Yes _____ No. If yes, please answer items 5 and 6. If no, please proceed to Section III.

5. Please rate our overall support since May 1, 1994 with respect to the following items using the given scale.

1	2	3	4	5
exceeds expectations	slightly exceeds expectations	meets expectations	slightly falls short	falls short of expectations

a) Quality _____

b) Timeliness _____

c) Usefulness _____

d) Communication _____

6. Do you have any comments or suggestions regarding our overall statistical support?

III. *On Interventions*

7. Do you think the interventions presented in the cover letter are beneficial? Please comment.

IV. *On Survey*

8. This survey has given us a second opportunity to discuss our work together. Would you support repeating this exercise in 1 or 2 years? _____ Yes _____ No

If yes, what has been useful about it from your perspective?

9. References

Chambers, J.M., Cleveland, W.S., Kleiner, B., and Tukey, P.A. (1983). Graphical Methods for Data Analysis. Monterey, California: Wadsworth.

Cleveland, W.S. (1979). Robust Locally Weighted Regression and Smoothing Scatterplots. Journal of the American Statistical Association, 74, 829–836.

Scholtes, P.R. (1988). The Team Handbook. Madison, Wisconsin: Joiner Associates.

Tukey, J.W. (1977). Exploratory Data Analysis. Reading, Massachusetts: Addison-Wesley.

Zenger-Miller, Inc. (1992). Launching and Refueling Your Team: Tools and Techniques. San Jose, CA: Zenger-Miller.

Received September 1997
Revised September 2000