Letters

Let’s Talk About the Good, Too

I am responding to two letters in the February 1985 issue, the first of which is Kenneth E. Tae’s letter, “Dealership
Quality Job 1985” (p. 11). I bought a Ford
Explorer in 1982 and have been estab-
lished by the service at my dealership. It
has always performed quality service on
my vehicle. Finished the service on time
or quicker than scheduled, and included
me in the discussions on nonwarranty
repairs. I was even sent a refund check of
$50 one time—two months after the repairs
were made. As in any industry, some places have received the
same service, even most have not.

My second comment is in response to Joseph J. Maher’s letter, “Is the Educational, Community Committing
Fraud?” (p. 12). I don’t know about most
school districts, but the Galena Park
Independent School District in Houston,
TX, led by Don Hooper, is very much in-
volved in total quality management (TQM).
They are very knowledgeable in TQM
techniques, leads many meetings to
discuss its implementation, and is
adequate that his administrative staff
members use the tools, techniques, and
principles in their daily work. I would put him up against most
chief executive officers in American
businesses today.

Let’s remember that there are many
businesses and schools that are prac-
ticing TQM. We must have to search them out and write about them to everyone
will know.

Charlie Magab, Bank United of Texas
FSE, Houston, TX

Charts in Column on Health Care Were Misleading

In the February 1985 Statistics Corner
column, “Another View on How to Measure Health Care Quality” (p. 120) by James C. Benneyan and Frank C.
Kaminsky, a control chart is presented in
Figure 1. It’s not labeled, but I’ll as-
sume it’s an X chart since, on the previ-
ous page, a one-way analysis of vari-
ance is used to test for significant differ-
ences in means (sample averages). It’s
an X chart, it’s not worth looking at
since no corresponding R chart is
down. It’s well known that if the corre-
sponding R chart is not in statistical
control, the X chart does not have valid
control limits. The R chart should always
be viewed first before making any infer-
ences about the corresponding X chart.
In addition, a good practice to follow on
other charts would be to show the con-
limits as dashed lines to distinguish them from the centerline, which is solid. Also, I assume that the authors call the
process out of control because of the
run of nine sample averages below the
centerline. If the limits are correct, there
are no other nonrandom patterns.

Furthermore, the chart in Figure 2 is
even in doubt since the column doesn’t
clearly describe the sample base that
led to a proportion of errors. If the data
are errors per unit of time (e.g., a week),
the errors would have a Poisson distri-
bution and the correct chart to apply
would be a c chart.

In both figures, no original data are
given to correctly check how the charts
were constructed. Using control charts
in nonmanufacturing situations is not easy; hence, they are often applied incor-
rectly. One would hope that all data
would be given so that the readers
could be assured they were looking at a
proper control chart.

Donald S. Ermer, Professor, Department of
Industrial Engineering, University of
Wisconsin-Madison, Madison, WI

Authors’ Reply

Although the primary purpose of our
column was to discuss the applicability and value of statistical process control (SPC) for measuring and improving health care quality, Donald S. Ermer commented on several statistical issues that illustrate some common errors continu-
ously encountered in health care and
many other industries.

In most cases, when using a standard
X chart, an accompanying S or other
dispersion control chart also should be
used. An S or S chart is usually preferred statistically to the R chart that Ermer recommends. In the Pap smear example, our S chart exhibited a state of statistical control (it was omitted from the column for space considerations). Therefore, the X chart shown in Figure 1 of the column is valid and much worth examining. This X chart clearly indicates a dramatic change in laboratory quality. Statistically advanced readers will also note that, based on the theory of runs, detecting this particular process shift depends entirely on the centerline of the X chart and not on a reliability estimate of i.e., an in-control S chart), as Ermer erroneously asserts.

Similarly, the prescriptions error con-


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correct chart to use in this situation rather than Ermer's proposed c chart because we are examining repeated Bernoulli trials (correctly filled vs. incorrectly filled), where the denominator is the total number of prescriptions filled per week. The subgroup size can vary significantly from week to week for many reasons (changes in hospital census, seasons, the number of pharmacists on duty, etc.), resulting in varying control limits. The consequences of using straight control limits in such situations are well known and are easily avoided simply by using the correct chart.

Although the y-axis values in both figures were intentionally omitted to protect our clients, this in no way detracts from the validity and interpretability of these charts. Finally, Ermer is welcome to use dashed lines if this is his preference, although control limits also tend to be easily identifiable as those above and beneath the centerline.

Aside from these statistical misunderstandings, Ermer’s letter unfortunately misses the fundamental point of our column: to encourage readers to consider how health care practitioners can better use SPC. In summary, all health care organizations should use control charts and other quality engineering methods to help study, and improve process quality and to minimize costs, dissatisfaction, and liability. Equally important, these tools should be used correctly. In our experience, improper use of quality methods has been a contributing factor in determining liability in clinical laboratories and in the manufacture of hospital equipment and biomedical devices.

There appears, however, to be considerable misunderstanding and oversimplification of SPC and quality measurements in health care. One disturbing example is the misguided and statistically suspect reliance on standards, outcome metrics, and report cards about which epidemiologist David Birnbaum, in his published response to our column, agreed that “proliferation of administratively simple but misleading report card metrics is a prime example of the worst in today’s practices.” Other common errors include failing to construct histograms of process data; using incorrect control charts; misusing individuals charts; using short-cut control limit formulas; insufficient data, and management by averages; confusing quality with satisfaction; confusing SPC with software; and having a not-applicable-in-your-industry misperception.

Improving health care quality and reducing costs are important national issues. The correct use of SPC and other statistical and quality engineering methods can help in these efforts.

James C. Benneyan and Frank C. Kaminsky

Both Methodologies Are Important in Health Care Quality

I agree wholeheartedly with James C. Benneyan and Frank C. Kaminsky on the applicability of statistical process control (SPC) in health care (“Another View on How to Measure Health Care Quality, February 1995, p. 120). At the same time, epidemiology also has a significant role to play in health care, clinically and operationally.

This is not an either/or issue; both methodologies are useful and necessary to improving health care systems. Both methodologies can benefit significantly from cross-fertilization. Epidemiology is very useful in determining which of the myriad possible variables are important in a given process so that control chart efforts can be economical.

(Cont. on p. 10)

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ly applied. SPC can benefit epidemiology by monitoring process performance over time and identifying special-cause events that epidemiology might miss.

Both methodologies offer important statistical tools that everyone involved in healthcare process improvement should have in his or her tool box.

Bob Luttmann, Boston, MA

ISO 9000 Records Requirements Are Straightforward

Eugenia K. Brummell missed an opportunity to clearly make a point on ISO 9000 records requirements in her article, “Managing Records for ISO 9000 Compliance” (January 1995, p. 73). ISO 9000 is clear of what records must be kept but lets suppliers determine the records’ formatting and content details. Unfortunately, she adds confusion when she writes, “Throughout the standards the concept of implied-records sections indicating that activities be documented, even though the sections do not specify a record requirement.” Please consider a different perspective.

By far the most difficult requirement for most managers is describing how their quality systems work. The second most difficult is how ISO 9000 requirements are met in the context of their quality systems. Stating that the records requirements are implied adds fuel to deniability arguments, such as “The system is in complete and at that level of detail never existed in the organization under study.

ISO 9000 is a dynamic system in which there is direct interaction between elements. In ANSI/ASQC QS9001, for example, the section on quality records is “4.16 Control of Quality Records” and the phrase “(see 4.16)” is used 18 times. Deriving the records requirements can be a straightforward task by reading the ISO 9000 standard carefully.

ISO 9000 does not prescribe exactly how suppliers should work to achieve its requirements; it is not some as a weakness. In the case of quality records, it is clear that quality system management is needed to establish and maintain a comprehensive set of records (and ISO 9000 states exactly which records) that will serve as objective evidence of activities performed or results achieved.” It does not get any clearer than that.

Neil F. McCormack, Quality Systems Lead Auditor, INTEC, Foreside, ME

Reliability Is Integral to TQM

I found Randall Gooden’s article “Reduce the Potential Impact of Product Liability on Your Organization” (January 1995, p. 85) interesting. ASQC has yet to see a big lead in promoting reliability analysis as a core activity to achieve total quality management (TQM) in the commercial sector. Without these front-end analyses, TQM cannot be achieved.

The term “reliability” can be defined by separating it into the prefix and the root word: “reliability,” CSI, can be described as “regarding” or “reducing.” “Reliability” can be described as for which a person or organization is liable. Thus, reliability engineering is the discipline in which an engineer analyzes a design for its effect on performance, maintainability, and safety such that the product does not fail prematurely, obligating the individual or organization to repair the product or pay

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advises. On the contrary, they follow the teachings of people like Peter Drucker and W. Edwards Deming and integrate quality into all processes. Quality professionals (and ISO 9000) have little part to play.

Adams does make a valid point, however, in criticizing the lack of study of quality issues in engineering courses; engineers do need to understand variation and the practical tools of quality and reliability. Quality staff can teach these applications, but only if they understand the engineering context. Knowing how to read a recipe is not enough to create a great meal.

Pat O’Connor

Health Care Quality

Neil West’s letter “VAR Can Decrease Even When Improvements Are Made” (July 1997, p. 6) calls for more articles on the use of quality methods to improve health care processes. A recent article in the Journal of Quality Technology, “Some Perspectives and Challenges for Control Chart Methods” (April 1997, pp. 122-127) by Andrew C. Palm, Robert N. Rodriguez, Fred A. Spring, and Donald J. Wheeler, similarly suggests that health care is an important new area for applying quality engineering methods. Based on my observations as a practitioner and researcher in this area, I strongly agree that greater use of statistical process control and related methods should be made.

Interested readers might like to be aware of several other articles on this subject written during the past decade. Most of them appear in various health care publications, such as Quality Management in Health Care, Journal for Healthcare Quality, Joint Commission Journal on Quality Improvement, and International Journal of Quality in Health Care, to name only a few. Many of these applications also are summarized in a forthcoming series of articles in Infection Control and Hospital Epidemiology.

James C. Benneyan, Northeastern University, Boston, MA

Internal Audits Without Preprepared Checklists

“The More, the Merrier—and the More Effective” by Thomas J. Warling (One Good Idea, August 1997, p. 184) describes an excellent procedure for internal audits. Gujarat Communications & Electronics Ltd. (GCEL), Baroda, India, has been using a similar process since May 1995. GCEL has experienced all the benefits listed by Warling, and I congratulate him for writing such a nice summary of the process and its benefits.

There is one difference, however, between the processes followed by GCEL and Zenith Pumps. At GCEL, there are no preprepared checklists. The checklists are prepared by the auditors themselves before every audit using the following steps:

1. Study the quality manual and procedure manual. Prepare a matrix of applicable procedures. List the points that need to be checked.
2. Study previous audit reports, if any, and identify aspects that were not completely covered in the previous audits or that need special attention. Identify check points.
3. Prioritize the check points and finalize the checklist. Thus, checklists are customized for each audit. This approach has the following advantages:
   - Focus is kept on aspects that need attention today.
   - Auditing is less routine.
   - Areas for improvement can be identified.

It should not be misconstrued, however, that I am against preprepared checklists. In my opinion, the choice depends on the organization’s culture.

B.A. Ramam, India

Clarification

On p. 80 of the 1997 QA/QC Services Directory (August 1997, p. 31), Montgomery Morstad Inc.’s phone and fax numbers should read (608) 588-9172 and fax (608) 588-9174.