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ASQC Statistics Division

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SPECIAL PUBLICATION **Spring, 1996**

STATISTICAL THINKING

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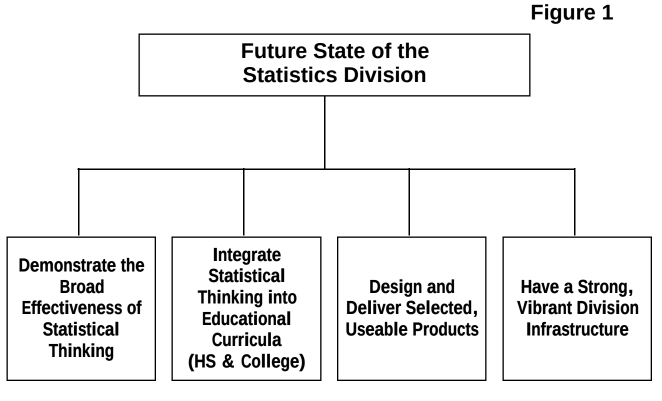
PROLOGUE

In January 1994, the Statistics Division officers, past chairs and committee chairs participated in a long range planning meeting. The purpose of this meeting was to develop a 3 to 5 year plan which would support the mission and vision of the Statistics Division, both in the present and the future. To accomplish this goal, the group defined the elements of the "current reality" and the "future condition".

In defining the "current reality", past and present activities were evaluated from three viewpoints: the Division, the individuals and the society. Next, events, opportunities and trends which would shape the future were discussed. To define the "future condition", the group imagined the most desirable and attainable future for Statistics Division members in the year 2005. Ten major themes were developed that captured the collective vision. These were prioritized and common elements were identified.

Figure 1



The "current reality" and "future conditions" were reviewed to assure that there was a direct link to the Division Vision and Mission. They were then combined to form the tree diagram shown in Figure 1.

A subgroup was formed to further develop the tree diagram. This was accomplished by determining the requirements necessary to attain the long term level depicted in Figure 1. Headers at the tactical plan level of the tree were identified and prioritized. The tactical plans became the short term activities to accomplish the long term plan.

Continued on page 2

STATISTICAL THINKING

Continued from page 1

The top three tactical plans identified during the meeting were selected and added to the existing tactical plans. Time lines were developed for all of the tactical plans to form the Division 5-year plan.

1. Enable broad application of Statistical Thinking.
2. Integrate Statistical Thinking and statistical techniques into educational curricula.
3. Improve Division publications.
4. Understand customer needs process.
5. Drive applications of Statistical Thinking and statistical techniques into broad areas.
6. Continuously improve our overall products and services portfolio.

One of the principles of the Statistics Division is to focus on a few key things. Therefore, the first four tactical plans are underway, while the other two will begin in the next two years.

“Enable broad application of Statistical Thinking” was identified as the key initiative in the long range planning meeting. The tactical plan was developed with the goal of informing Statistics Division members, and others, as to the benefits of applying Statistical Thinking to their work, in order to achieve improved results.

The tactical planning team has been hard at work over the past year. They have developed a definition of Statistical Thinking which is published in the new edition of the **Glossary and Tables for Statistical Quality Control**, ASQC Quality Press, 1996. The Statistics Division session at the 1995 Annual Quality Congress, “Statistical Thinking for Business Improvement” provided insight into how Statistical Thinking can be used.

This publication is a result of the continuing work of the tactical planning team and brings the message from the AQC presentation, as well as additional material to you, our members. We hope you will find this information useful in developing an understanding of Statistical Thinking and how it can be applied to your work.

Nancy Belunis
Statistics Division Chair, 1995-1996

FROM THE AUTHORS

As mentioned in the Prologue, the work of this tactical planning team, enabling the broad application of Statistical Thinking, was sanctioned as a result of the January, 1994 long range planning meeting. The team identified the Statistics Division members as the primary customers, and the business/management community as a secondary customer for initial focus. Based on this charter, the primary accomplishments to date include:
- Sponsoring a session, “Statistical Thinking for Business Improvement” at the 1995 AQC,
- Writing the official definition of Statistical Thinking for the Glossary and Tables for Statistical Quality Control, and
- Issuing this Special Publication of the ASQC Statistics Division.

To provide further value to our members and to the business community, the “canned” presentation given at AQC, which includes the information for slides or transparencies, along with the accompanying text to aid the presenter, is now available. This presentation defines and discusses the philosophy of Statistical Thinking, illustrates the broad application of Statistical Thinking, and demonstrates how to implement Statistical Thinking in an organization.

Each Regional Councilor has a copy of the presentation, and is available to make presentations at Section and other meetings. The names and telephone numbers of the Regional Councilors are listed in the Winter Edition of the Statistics Division Newsletter. In addition, the “canned” presentation is available to each of you in the following formats from the Quality Information Center (QIC) at ASQC Headquarters:
1. Diskette (Powerpoint, Harvard Graphics)
2. Paper Copy

The material is available at a nominal cost to cover materials and handling. Just call (1-800-248-1946) or write QIC to order your copy. The address of QIC is:

611 East Wisconsin Avenue
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Milwaukee, WI 53201-3005

Continued on page 3

Continued from page 2

In the future, we plan to develop a “How To” or other booklet that would include some interactive learning. There is another tactical planning team working on integrating Statistical Thinking into educational curricula. We plan to interact with that team to provide materials and examples for the educational community.

INTRODUCTION

Every day we make decisions. In the business environment, professional decisions secure the financial health of the company. Goals and objectives are developed to identify areas for improvement initiatives. (e.g. decrease inventory costs by 10%, increase production by 1 million pounds, decrease material waste by 20%.) On the personal level, we set goals which improve the quality of our life or the activities we enjoy. (e.g. take 5 strokes off my golf game, eat less fat, exercise at least 5 days a week.) For all the above situations, Statistical Thinking should be used as a means of achieving the desired goal.

Statistical Thinking is the manner in which information is viewed, processed and converted into action steps. It is a philosophy of thinking, not a manner to perform mathematical calculations. Statistical Thinking utilizes the concept that all work consists of a series the interconnected steps which must be completed in order to achieve a desired goal. For success, each step must be investigated to identify areas of opportunity and improvement. The identification and minimization of variation in each of the steps will lead to achievement of the desired goal. Using actual case studies, the benefits of Statistical Thinking will be demonstrated on three levels: operational, managerial and strategic.

In this issue, the philosophy of Statistical Thinking will be addressed. We will first review a case study involving a corporation which has a goal of decreasing the cycle time for bills. The concepts of Statistical Thinking are illustrated, specifically how the corporation separated the process into its sub-process components and worked to identify and eliminate variation in each component.

The definition and the three fundamental principles of Statistical Thinking will then be discussed in detail. Although minimizing variation is the basis for success, it will be shown that variation of individual ideas is equally essential for success. Diversity of thought, opinion and perspective as an operating norm is imperative for identifying variation in each step, and developing action plans to minimize this variation. Team involvement is important in understanding the overall process by identifying the components which comprise the process. Once the overall process is understood, variation can be identified and eliminated.

The applicability of Statistical Thinking in current educational practices will be reviewed. A report from the Center for Quality and Productivity Improvement at the University of Wisconsin-Madison, supports the notion that introductory statistics courses must undergo a redesign in order to meet customer needs. Four critical areas for change outlined in the report are identified and discussed.

Finally, four additional case studies discussing the successful application of Statistical Thinking are presented. These case studies explain, by example, the benefits of utilizing this philosophy: Whether it be personal or professional . . . Whether it be at the operational, managerial or strategic level.

We hope everyone finds value in this special publication. If you are interested in obtaining the 1995 AQC presentation on Statistical Thinking, please contact your regional councilor. Please contact ASQC Quality Information Center for all other requests, (e.g. material, additional copies, etc.).

HISTORICAL PERSPECTIVE OF STATISTICAL THINKING:

The definition of Statistical Thinking includes three fundamental principles;

1. All work is a series of interconnected processes,
2. All processes vary,
3. Understanding and reducing variation are keys to success.

Continued on page 4

STATISTICAL THINKING

Continued from page 3

Key contributors to Statistical Thinking agree that W. Edwards Deming must be recognized as the source of the concept we call 'Statistical Thinking.' Dr. Deming's management theory of Profound Knowledge[1] contains the essence of the 3 principles of Statistical Thinking. There are four parts to the system of Profound Knowledge.

1. Appreciation for a system.
2. Knowledge about variation.
3. Theory of knowledge.
4. Psychology.

The first principle of Statistical Thinking, *'All work is a series of interconnected processes,'* is closely linked to the first part of the system of profound knowledge, '*Appreciation for a system.'* The second and third principles of Statistical Thinking, '*All processes vary'* and *'Understanding and reducing variation are keys to success,'* are closely linked to the second part of the system of profound knowledge, '*Knowledge about variation.'*

"Statistical Thinking is based on Dr. Deming's management theory."

The roots of Dr. Deming's work lie in the work of Walter Shewhart. Shewhart's classic text, **Economic Control of Quality of Manufactured Product** was a major influence on Dr. Deming's thinking. Dr. Deming wrote the dedication for the ASQC's 1980 reprint of Dr. Shewhart's text. In that dedication Dr. Deming wrote, "To Shewhart, quality control meant every activity and every technique that can contribute to better living, in a material sense. . ." "Statistical control . . . requires improvement of the process in every other feasible way." It is from this view of Shewhart's work that Deming went on to develop the 14 points and the Theory of Profound Knowledge.

Many have helped define and advance the concept of Statistical Thinking. A reference list for further information and readings has been compiled and can be found at the end of this publication.

USE OF STATISTICAL THINKING TO IMPROVE BUSINESS PROCESSES
AN EXAMPLE IN STATISTICAL THINKING

Atlas Financial Services, a large corporation, needed to decrease the monthly billing cycle time of customers. Actual billing time was approximately 17 days, although the corporate target for billing was 10 days. Operating to the designated 10 day target was important to both the company and customer. A shorter cycle time for billing would improve the company's cash flow. Customers also desired shorter cycle times. A prompt receipt of billing information improved the customer accounting system by permitting them to close monthly books on a more timely basis.

An assessment of the process revealed that three separate departments were responsible for the billing process. Each department or function worked independently to complete the job. No one understood the process from start to finish, although each department knew their function very well. When problems occurred, there was a great deal of finger pointing:

- "The problem is not in my area."
- "It's over there."
- "If they would clean up their act, the process would perform better."

Atlas Financial Services had no standard operating procedures for the billing process. Each employee performed their function, using the method which worked best for him / her. Although everyone was working to their full potential, "giving 100%", frustrations were high. There was a great deal of "fire-fighting". Heroic efforts, requiring frequent long hours and shifting of priorities, were necessary to keep the process operating.

This case study is an actual account of a problem which occurred in a large corporation. The name has been changed to Atlas Financial Services to maintain the anonymity of the corporation.

Even with all the variation in the billing process, one clear advantage surfaced: A quantitative measure existed to monitor the performance of the process - The total number of days in the billing cycle This measure was important to determine any improvements in the billing process. Without a clear measure of success it would be difficult, if not impossible, to effectively manage and improve the process.

Continued on page 5

Continued from page 4

Three aspects of Statistical Thinking - process and systems thinking, reduction of variation, and use of data to guide decisions - were used to improve the billing process and create a process management system to help hold the gains. A systems map was created for the billing process, while a flowchart was developed for the core process. The systems map identified the responsible functional groups and the activities/information which flowed back and forth between groups. The flowchart was used to construct a production schedule for the monthly billing cycle. This schedule served to:

- Align the organization on the specific activities which must be performed each month.
- Identify the group responsible for completion of a given activity.
- Identify "drop dead dates" for the activity.

Next, critical sub-processes were identified. Cycle time measurements were monitored for each of the critical sub-processes, as well as for the overall process. These measurements assisted in the identification of problem areas.

Cross functional teams were formed to trouble-shoot the process on a daily basis, and to review the performance of the billing process at the end of the cycle. The teams identified problem areas and developed solutions to minimize the variation in these areas. Procedures were created to ensure implementation of the solutions.

Efforts were also initiated to document the process and the procedures used in the corporate billing cycle. This document helped reduce variation in the operational methods used in the process, and became central to training for new employees in how to operate the process.

A process owner was also assigned. The responsibility of the process owner was to care for the health of the process by ensuring that:

- The many aspects of the process management system were used.
- The system remained dynamic, and reflected the changing conditions the process experienced.

"The use of Statistical Thinking significantly improved the operations of the process. Over a 5 month period, the monthly billing cycle time was reduced by almost 50% from 17 days to 9-10 days."

The use of Statistical Thinking significantly improved the operations of the process. Over a 5 month period, the monthly billing cycle time was reduced by almost 50% from 17 days to 9-10 days. This resulted in both satisfied customers and an annual saving of $2.5 million.

Statistical Thinking Definition and Elaboration

The 1996 edition of the **Glossary and Tables for Statistical Quality Control**, published by Quality Press included a definition of Statistical Thinking. The definition is as follows:

Statistical Thinking is a philosophy of learning and action based on the following fundamental principles:

- All work occurs in a system of interconnected processes,
- Variation exists in all processes, and
- Understanding and reducing variation are keys to success.

The implications of this definition require some elaboration. First of all, Statistical Thinking is a **philosophy**. In other words, it is a way of thinking, or a thought process, rather than number crunching or calculations. This is the key difference between Statistical Thinking and statistical techniques. (See Figure 2.)

"Statistical Thinking is a philosophy of learning and action."

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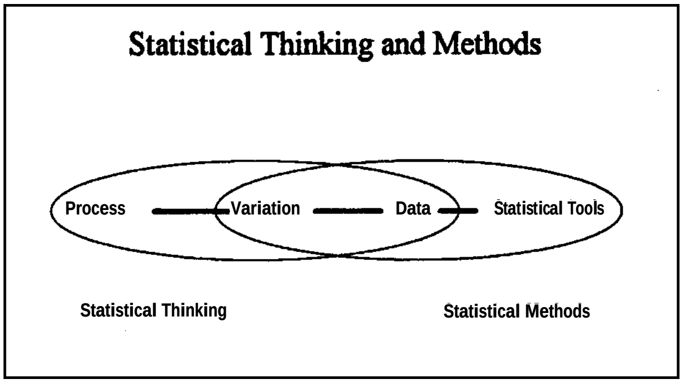

Figure 2

Statistical Thinking is a philosophy of **learning and action**. The emphasis of this philosophy is therefore on how we take in and process information (learning), and how we respond to this information (action). In practice, this results in interpreting situations differently, perhaps through data, and reacting differently than if Statistical Thinking were not being used. In order to specify how the interpretation and response would be different, we need to examine the **fundamental principles** of Statistical Thinking. These principles are fundamental in the sense that the philosophy being applied cannot be Statistical Thinking unless all three are incorporated.

- **All work occurs in a system of interconnected processes.**

"All work" is not limited to employment, but includes working on your golf game, working in your garden, trying to lose weight, developing interpersonal relationships, and so on. Such activities occur through processes which have inputs that are acted upon by the process itself to produce outputs.

For example, when two people enter into a marriage, their attitudes towards each other and beliefs about marriage itself are inputs which will significantly impact the marriage. These attitudes may have been formed early in life from experiences in their own families, or from religious beliefs. These "inputs" are typically impacted gradually as the couple goes through life transitions, such as balancing careers and family responsibilities, adapting to children, "mid-life crisis," and so on. The degree of emotional intimacy in the marriage can increase or decrease depending on the couple's response to these "process transformations." Outputs of the marriage, besides the obvious, can be positive, such as personal fulfillment, companionship, and friendship, or negative, such as spouse abuse or divorce.

"Work, and life, consist of many intertwined, or interdependent processes, which together form a system."

It is also clear that work, and life, consist of many intertwined, or interdependent processes, which together form a system. This last point has been emphasized by Peter Senge and others as "Systems Thinking." In a business, trying to optimize profit by optimizing each function independently, such as minimizing procurement costs, minimizing production costs, maximizing sales, and so on is typically disastrous. This sub-optimal result for the overall system is due to the fact that minimizing procurement costs will often increase manufacturing costs, and decrease sales. In other words, the system as a whole must be optimized because of the interdependencies, or interactions. In our personal lives, it is all too easy for a problem in our careers to impact our family life, and visa versa. None of these processes functions in isolation.

In summary, to apply Statistical Thinking one must be able to view results in light of the process and process inputs which produced the results. It is then obvious that improving results requires improving the process and/or inputs.

- **Variation exists in all processes.**

Variation is a fact of life, and exists in all types of processes. While this appears to be common sense, many business students are taught that actual financial figures should always equal budget, and many science students are taught that mass balances should balance exactly. Unfortunately, many financial and scientific figures are "fudged" in an attempt to achieve these unrealistic objectives.

In our personal lives, we are often surprised when the mail does not arrive at the same time every day, complain when the weather forecast is inaccurate, and become frustrated when our plane does not leave or arrive on time. Helping people grasp this fundamental principle and "unlearn" their deterministic view of the world is the greatest contribution the statistical profession, and only the statistical profession, could provide to society.

- **Understanding and reducing variation are keys to success.**

Traditionally, the statistical profession has emphasized modeling and quantifying variation, rather than reducing it. This is a passive approach which does not directly lead to improvement. Deming, on the other hand, once summarized

Continued on page 7

STATISTICAL THINKING

Continued from page 6

his lifelong message as "reduce variation." In most situations, reducing variation is critical to success. Reducing product variation satisfies customers, while reducing process and input variation reduces product variation, and in business, typically reduces costs. In our personal lives, we generally want our favorite dish prepared just the way we like it, want our planes, buses, and trains on time, and prefer to have relationships on an even keel.

"Reducing product variation satisfies customers, while reducing process and input variation reduces product variation, and in business, typically reduces costs."

It should be noted that sometimes we wish to increase variation. Many businesses value having diversity of thought and perspective; a diversity of thought between team members is important. New product development requires experimentation with new ideas and approaches. In our personal lives, very few people would want to eat the same meals every day ("variety is the spice of life"). Popping popcorn only works because there is variation in the time it takes each kernel to pop. If all the kernels popped at the same time, a virtual explosion would result! In summary, we always want to understand variation, and often want to reduce it. This makes Statistical Thinking proactive.

Statistical Thinking at Various Organizational Levels

The uniqueness of Statistical Thinking is that it consists of **thought processes**, rather than numerical techniques. These thought processes affect how we take in, process, and react to information. Specifically, they enable us to view "work" within the context of the processes it occurs in, grasp the significance of variation, and value taking the time to understand and reduce variation.

Statistical Thinking takes on different appearances depending on the organizational level where it is applied. See Figure 3.

At the **strategic level**, the focus is on the long-term activities that guide organizational functions. Core processes, most vital to the business, are flow charted. A strategy is mapped out and communicated throughout the organization. Measurement systems are put in place to assess progress. Data from various sources are also used as part of the assessment process, and all are encouraged to experiment to find better ways of doing things.

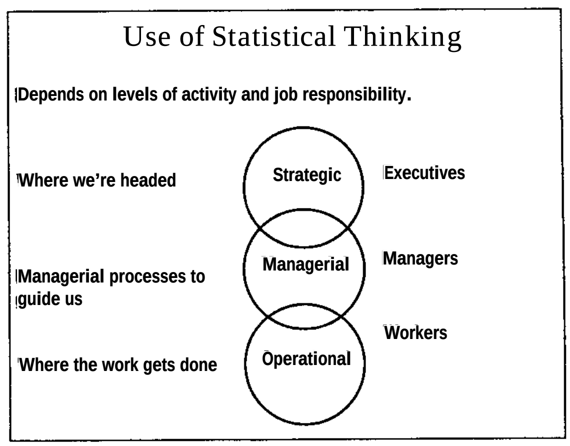

Figure 3

At the **managerial level**, for example, principles of good meeting management are followed so that the variability of output is minimized. Standardized project management systems are put in place, and these systems, together with their results, are reviewed. Process variation is considered when setting goals, and the measurement system itself is viewed as a process. Varying methods of communication are used to help assure that all are informed and involved.

At the **operational level**, the focus is on the day-to-day process and on using data for process improvement. Key measures are identified with time plots displayed. Knowledge of variation and data help to keep the process on track. The focus is always on the process, not on blaming people for process variation.

Statistical Thinking at any level - strategic, managerial or operational - carries over into other level(s), as illustrated in Figure 3. Strategic planning efforts influence managerial efforts which, in turn, influence operational efforts.

A LOOK BACK AT ATLAS FINANCIAL SERVICES

Prior to adopting Statistical Thinking as a standard business practice, Atlas Financial Services required 17 days to bills customers. Although each of the three groups responsible for the process was hard at work delivering against its individual group objectives, the entire process was not meeting the corporate goal of 10 days. When the process failed, each group felt that one, or both, of the other groups failed; but not their own group.

These feelings were a result of each group knowing that their part of the task was completed in a satisfactory time frame. Therefore, "It had to be the other groups." Many of us can relate to this situation. Whether it is Accounting,

Continued on page 8

STATISTICAL THINKING

Continued from page 7

Quality, Production, Assembly or any other group, we have all experienced the "throw it over the fence" syndrome, or the "finger pointing" syndrome. As we learned from the Atlas Financial Services, these syndromes are a direct result of interdepartmental groups working to achieve an end result by using intradepartmental goals.

"Although each of the three groups responsible for the process was hard at work delivering against its individual group objectives, the entire process was not meeting the corporate goal of a 10 days."

With the adoption of the philosophy of Statistical Thinking, Atlas Financial Services was able to review the task of billing customers from a different angle. Only then, did the company realize that no one actually understood the process of customer billing. Yes, each group knew about their specific tasks, but no one knew about the tasks of the other groups, or how the tasks they performed fit into the process of customer billing.

Once the process was identified via a flow chart and systems map, the company was well on its way to breaking the customer billing process into its series of interconnected processes. It was only after this step, that variation in each sub-process was identified and eliminated.

It is important to emphasize the importance of collective thinking during the stages of identifying the process and its interconnected processes or sub-processes. Although the definition states, "Understanding and reducing variation are keys to success", variation is required for opinions, observations, pitfalls, highlights, etc. concerning the process. Members from all responsible groups should be involved in brainstorming sessions.

Once the true process was known, variation could be identified and minimized. Atlas Financial Services might have stopped at this point, thinking the objective had been met. This would have been a great mistake! The company understood that every process is dynamic by nature. Environmental factors (internal and external), company cash flow, head count, etc. are constantly changing. To stop, would have forced this naturally dynamic process to become static. In order to keep the process dynamic, a process owner was assigned. This person actually had the responsibility of keeping the process dynamic.

Within 5 months, the 17 day billing cycle was reduced to 10 days. This represents a significant improvement in only a short period of time. Dependent upon the complexity of the process being reviewed, timing may be longer or shorter in duration. Here are some tips for anyone interested in implementing Statistical Thinking in their company:

TIPS:

- Get upper management buy-in to the philosophy.
- Start small. Pick a process which is not very detailed or involves many groups.
- Designate a core team made up of members of all responsible groups. (Team should not have more than 8-10 members.)
- Include the actual front line workers. This is not an exercise in management developing mandates for workers, it is a means to identify and eliminate variation in a process.
- Go after "low hanging fruit" first, even if it is not a "big ticket item". This will give the team a sense of accomplishment.
- Use the 7 tools to gather data. Remember data **does not** have to be quantitative. Qualitative data is just as important. For example, if we were to look at downtime on a machine, the data collected from down time or maintenance reports may lead to the solution for the problem.
- Use the Plan-Do-Check-Act cycle to ensure the process is dynamic with changing economic climates and company policies.

GETTING STARTED... HOW HARD CAN IT BE?

This is a true account of one company's struggle to incorporate Statistical Thinking into its daily routine. Although the case study makes light of the hurdles faced by Steve and Connie, it demonstrates the importance of acknowledging that understanding and reducing variation are keys to success.

George Botline, VP of Finance for the Stuff Company, informed Clarence E. Olliphant, Stuff's top executive, that the Company was doing well, but that money could be saved by not giving away so much extra product with each package of Stuff. Olliphant, being a man of action, immediately got to Quincy Aspinall, the quality boss, and told him to do something about the fillers.

Continued on page 9

Continued from page 8

Stuff Company makes dry mix consumer goods. The overfill; that is, the amount of Stuff necessary to target the packages above the label declaration to keep in compliance with the law, was outrageously high. Botline was correct in his assessment: too much overfill.

Aspinall put Connie Brown in charge of continuous improvement. Connie, single-handedly, updated the standard operating procedures. Then she sent them out to the production facilities for review and comment. Next, she and Quincy visited the facilities and led group discussions of the standard operating procedures, and they got ideas for improvement of the standard operating procedures. Then they re-wrote the standard operating procedures and sent them out again.

The overfill didn't get better.

Convinced that Steve Hilbert, a statistical consultant, could really write standard operating procedures, Quincy hired him. Steve worked with Connie, and Connie directed him to look at the standard operating procedures they wrote. Steve wanted to see the production facilities instead. Connie explained that it really didn't matter what went on in the production facilities because all the Quality Department could do is adjust the fillers. All other process operations were controlled by Ed Davenport, the Director of Engineering (and golf buddy of Clarence, the CEO). It was best that they stay off Ed's turf.

Steve wanted to see the production facilities anyway, Quincy reluctantly agreed, and Connie and Steve flew off to Butte, Montana for a plant tour. After the appropriate introductions, they donned lab coats and hair nets and went to the production floor.

The first stop was the receiving area. There were stacks of boxes of incoming raw materials. Many were the same item, but from different vendors. Because of space limitations, the ingredients were handled in a last-in-first-out order. Steve and Connie took notes.

The next stop was the blending area. All the ingredients for Stuff were blended together in huge blenders. Steve asked how long a blender batch ran.

“It varies,” said Ben Littleford, the blender foreman.

“No kidding,” said Steve, “Over how wide a range?”

“Could be 20 minutes. Could be 40. Just depends,” said Ben.

“On what?” said Steve, sensing that Ben was becoming impatient.

“On how big the mix is, on how well it blends, on the age of the ingredients - we're stuck with what Receiving sends us, you know - on who is on break, on a whole bunch of things...,” and Ben's voice trailed off as he walked away shaking his head.

Steve and Connie took notes.

They went to the blender discharge area. When the blending was complete, Stuff was dumped into large totes that were staged on a floor above the filling machines. At the appropriate times, when the fillers were starved for product, Tom Workman would open the tote and let the Stuff flow into the fillerbowls. Steve asked Tom how he opens the port at the bottom of the tote.

Tom said, “With this wrench.”

“No kidding,” said Steve, “Does the Stuff flow out fast or slowly?”

“Depends,” said Tom.

“On what?” said Steve.

“On how bad they need the Stuff downstairs, on how well it's blended - we're stuck with what Blending sends us, you know - on how good it flows, on which kind of tote we used, on a whole bunch of things...,” and Tom's voice trailed off as he walked away shaking his head.

Continued on page 10

Continued from page 9

Steve and Connie took notes.

At the filling line, Florence Bartlet was scrambling back and forth from one end to the other. Fill adjustments, it turned out, were only one part of her job. She was also responsible for keeping the carton magazines full, for clearing line jams, for reclaiming slack fill packages, and for several other small details. When she looked like she had a spare moment, Steve asked, "How do you adjust the filler?"

Florence said, "With this knob," said Florence, pointing to a large, graduated knob just below the fillerbowl.

"No kidding," said Steve. "How many clicks do you turn it?"

"When the Stuff is running good, I just turn it a little. When they make a tote change upstairs, I have to turn it a lot and take a sample. Then, if that sample is too light or too heavy I have to turn the knob some more and sample again. I keep doing that until the weight is right. Sometimes it takes all day. I'm stuck with what's in the tote, you know," said Florence.

"What rules do you follow for adjustment?" asked Steve. But, just then, the line stopped and Florence was on it like a cat pouncing on a mouse, pulling twisted packaging material out of the jam, clearing off wasted product, and trying to get the line going again.

It was clear that Florence had no more time for them.

Steve and Connie took notes.

The Plant Manager, Paula Miller, met with Steve and Connie later that same day. She asked Steve if he thought that teaching everybody basic statistics would help reduce product give-away. She went on to say that they had already had some statistics, but nobody used it. For some reason, the training just didn't take hold.

Steve was tempted to say, "No kidding," but he thought better of it. Instead, he told Paula that he didn't think that training in the use of statistical tools would be helpful just yet.

"What do you recommend, then?" asked Paula.

"We have to get everyone to look at the whole manufacturing process," said Steve. "This business of multiple suppliers, of highly variable blending times, of different tote emptying procedures, and of fill adjusting by guess and by golly, has to change. The way things are now, variation in raw materials is made worse by variation in blending, which is made worse by variation in tote dumping, which is made worse by inconsistent fill adjusting. No wonder we're giving Stuff away. If I were you, I'd work to make sure that everyone connected with the process understand that variation must be reduced. And I'd try to get everyone's best ideas about ways to accomplish that reduction." Steve thought that he noticed Connie slink down in her chair a little and bury her face in her notes.

Paula's face reddened. "Steve, you're new with us, aren't you? We have very good people in this organization. Some of our operators have been with us for years. Ben Littleford, Tom Workman and Florence Bartlet know their equipment like the backs of their hands. We couldn't get any better people that these. I'm convinced that they are doing the best job possible, and I'm going to tell Quincy Aspinall that the next time I see him."

"I'm right with you on that, Paula. Better and more experienced people, you could not get. What I'm saying is that you need to help them do their jobs better. Instead of chasing variation around the barn, they need to get control of it. They need to track down the sources of variation and get rid of them. Use fewer suppliers, blend all batches for the same amount of time, use the same kind of totes, and empty them all the same way. When you do that, Florence will experience Stuff with more uniform density, and she won't be driving herself crazy with all those adjustments. The fill variation will decrease, and you'll lower your give-away. Botline and Olliphant will be happy, and so will your customers, because their second experience with Stuff will be more like their first experience with it." Steve noticed that Connie was sitting straight again.

Paula grinned. "I thought you were a statistician," she said. "What does this have to do with statistics?" Connie grinned and looked at Steve.

"Statistics is more than statistical tools, Paula. We're talking about statistical thinking here. Statistical thinking looks

Continued on page 11

Continued from page 10

at the whole process, seeks out the sources of variation and works to minimize them. There is direct benefit to the bottom line when we minimize variation. Not only will you give less Stuff away; your lines will run with fewer interruptions, meaning that you can make more Stuff each hour. I'll bet you'd be delighted with increased productivity."

"But, Steve, it's such a can of worms. Where do we start? How do we know what problems to work on first?"

"I'll bet that Ben doesn't really appreciate the problems that Tom experiences, and that Tom doesn't know what Florence goes through. How about getting them all together to talk to each other about variation in the process. Let them come up with some ideas to reduce variation." Connie could sit in on their meetings occasionally to help out." Connie looked up from her notes. "Once they have some common understanding of how all of the parts of the process work together to influence the Stuff at the end of the line, they can learn about the use of the appropriate statistical tools to help minimize the variation," offered Steve.

"Well, I suppose that has to be better than what we have now," admitted Paula. "Let's give it a try." Connie smiled. So did Steve.

Back at Stuff Headquarters, Connie expressed some concerns about talking with Quincy Aspinall. "We weren't supposed to look at anything but the fillers," warned Connie.

"Could be trouble," said Steve. Then it happened. They were on the way to coffee and ran right into Ed Davenport, Director of Engineering and golfing buddy of Clarence E. Olliphant.

"Hey. Just heard you guys were in Butte. What did you do, win second prize?"

Steve smiled. "Actually, Ed, we found some opportunities for you."

Just then Quincy happened by with an empty coffee cup. "Hi, Ed. Hi, Connie and ... ah, Steve. How was Butte? "

"We were just telling Ed ..." started Connie.

"... Yeah," Ed interrupted, "Paula called me first thing this morning. Quincy, your people caused quite a stir." Connie cringed and Steve started thinking about finding some other clients. "They shined a whole new light on our overpack problems. I sure wish you'd helped us earlier instead of always playing with those fillers. How about getting out to some of the other plants?"

Application of Statistical Thinking to Education

The utilization of Statistical Thinking in the educational process is a topic of both interest and debate. Many authors are skeptical in its applicability, while others work to validate its importance. One recent publication which supports Statistical Thinking in the educational process comes from the Center For Quality and Productivity Improvement at the University of Wisconsin-Madison. The report, **Redesigning the Introductory Statistics Course**, (by Roger Hoerl and Ron Snee), demonstrates how Statistical Thinking has been effectively applied to dramatically improve introductory business statistics education, both in academia and in a business setting. It reviews the radical changes in introductory statistical education which were implemented within the DuPont Company, as well as at the University of Delaware.

"While much of the current reform effort is focused on 'jazzing up' courses with demonstrations and games, course content must also be fundamentally rethought."

The authors' approach was to apply Statistical Thinking concepts to the educational process itself. In doing so, they evaluated the "customers of the process", and their educational needs. Findings, based on this approach, indicated that the typical introductory statistics courses essentially needed to be redesigned from scratch to satisfy the needs of the customers.

When determining course content based on customer needs, Statistical Thinking should be emphasized over statistical methods in an introductory course. While much of the current reform effort is focused on 'jazzing up' courses with demonstrations and games, the authors make a compelling case that the course content must also be fundamentally rethought. The basic introductory curriculum has not changed substantially in over forty years.

Continued on page 12

STATISTICAL THINKING

Continued from page 11

The report outlines four major areas in which radical change is needed, and demonstrates how these changes have been implemented in business and academia:

I Determine the Purpose of the Course

The purpose of the course needs to be given careful thought, explicitly stated, and then used to form the basis of decisions on content and delivery. It is argued that for an introductory course, the primary objectives should be understanding of Statistical Thinking concepts, ability to apply basic tools to improve real business processes, and belief that these concepts and tools will actually help do a better job.

In contrast, it should not attempt to make students experts in all statistical methods, such as regression analysis, ANOVA, experimental design, probability, and hypothesis testing. This latter, obviously unrealistic goal, appears to be commonly sought after, based on the typical curriculum used.

II Emphasize Statistical Thinking vs. Statistical Methods

In order to accomplish these, or other reasonable objectives, the course should emphasize Statistical Thinking over statistical techniques. This implies more time dealing with concepts such as viewing work as a process, the existence of variation, and the frequent need for reducing variation; and less time memorizing numerous formulas for probability calculations and hypothesis testing.

III Reverse the Sequence of Topics

The sequence of topics should be essentially reversed from the typical current day courses. Recent educational and behavioral research is referenced which demonstrates that students learn most effectively when instruction proceeds from:

1. The ‘whole’, or overall approaches to improvement, to ‘parts’, or individual tools;
2. The ’tangible’, or real application, to the ‘abstract’, or theory; and
3. ‘Gross’, or overall conceptual understanding, to ‘fine’, or ability to apply the skills to real problems.

Typical statistical education has generally done the exact opposite, i.e., taught individual tools (parts) and then tried to tie them hurriedly together at the end (whole), taught the theory first (abstract) and then quickly illustrated the calculations with an example (tangible), and emphasized correct calculation of an answer (fine), and hoped students would grasp the concept of why they would want to calculate this answer (gross).

IV Lecture vs. Interactive Learning

The instructional process should significantly reduce the use of the lecture method in favor of experiential learning techniques, such as real team projects, discussions, multimedia presentations, interactive demonstrations, and so on. This area has received considerable attention in the literature, but requires even more radical change.

More detailed advice on how to implement these changes is provided in the technical report. If you are interested in receiving a copy, contact the Center For Quality and Productivity Improvement, University of Wisconsin-Madison, 610 Walnut Street, Madison, Wisconsin, 53705. Ask for Technical Report 130, Redesigning the Introductory Statistics Course, by Hoerl and Snee.

CASE STUDIES WHICH APPLY STATISTICAL THINKING AT VARIOUS ORGANIZATIONAL LEVELS

As mentioned earlier, Statistical Thinking takes on different appearances depending on the organizational level where it applies. Statistical Thinking at any level - strategic, managerial or operational - carries over into another level. Strategic planning efforts influence managerial efforts which, in turn, influence operational efforts.

“Statistical Thinking at any level - strategic, managerial or operational - carries over into another level. Strategic planning efforts influence managerial efforts which, in turn, influence operational efforts.”

These and other aspects of Statistical Thinking are illustrated in the following four additional case studies. Please note these are actual accounts, written by the individual(s) who used Statistical Thinking to achieve a desired goal or outcome.

Continued on page 13

Continued from page 12

Excellence Plus (Bob Mitchell)

The city of Hutchinson, MN began its quality improvement journey in 1993 with adoption of its Vision statement. Hutchinson, population 12,000, is located approximately 65 miles west of Minneapolis, MN, and prides itself as home to a number of high-tech companies, Hutchinson Technical College, and many other local industries and businesses.

Excellence Plus is Hutchinson city government's operational plan that focuses on continuous quality improvement. **Excellence Plus** is defined by the following five tenets:

1. Recognize that all work is a process, and all processes have variation.
2. Continuous improvement will become a way of life.
3. Perform beyond expectations; anticipate inarticulate needs; delight the customer.
4. Follow a systematic approach of assembling teams, formalizing a planning process, training team leaders and facilitators, involving citizens, and measuring performance.
5. A never ending journey to position Hutchinson as the global leader in community quality improvement.

Bob became involved in the City Council's quality improvement effort in the spring of 1995 when he was invited to elaborate on the concept of Statistical Thinking and the operational definition of Internal vs. External customers. A series of discussions with the City Directors ensued on the tools of quality improvement, the 7 New Tools of Management & Planning, and a standardized problem solving methodology. At the conclusion, the City Directors began formulating their **Excellence Plus** program for the Hutchinson budget planning process.

Within the budget planning process, several departments of city hall formed teams to begin to:

- Flow chart their key processes,
- Identify their suppliers and customers, and
- Eliminate non-value added steps.

Many of the teams are currently working to define measurements that will monitor their performance and drive the desired behaviors. Training in the use and application of problem solving tools are provided as the need is identified. Process mapping, cause-and-effect, and affinity diagrams are the current focus. Customer satisfaction surveys are conducted to measure progress towards "delighting" the customer. Customer-focused objectives that are measurable, quantifiable, time-bound, and realistic have been established for each city department. Whenever a process is re-engineered, everyone is trained to ensure standardization to minimize variation.

This case study is an example of the power of applying of Statistical Thinking at the strategic level. When the philosophy of Statistical Thinking is applied at the strategic level, the impact for the organization will be the greatest. By working directly with the "top management" of the city, Bob was able to apply the entire philosophy of Statistical Thinking to influence the strategic direction of the entire city. It demonstrates how application at the strategic level can lead to truly innovative solutions in a broad range of issues. The "One Stop Shop" story is a classic example of the importance of understanding the system of interconnected processes. In the HATS facility example, it is hard to imagine the three governments working together to meet their common needs without the application of the same principle and the concept of cooperation between functions (governments) working together to identify the best solution for all. Perhaps the most important message of all lies in the results. By applying Statistical Thinking at the strategic level, results can be dramatic:
Credit eligibility in 15 minutes, instead of 1-1/2 months.
Growth in city government of only 8%, versus population growth of 25%.

One of the most visible success stories in Hutchinson's young quality improvement effort is the Bldg. / Planning / Zoning department's "One Stop Shop" concept. The idea originated in response to surveys taken by the City and the building department which revealed a need to better coordinate various city departments so that developers and contractors could go to one place for all application information and permitting. The City Administrator states, "After flowcharting the current process, identifying improvement opportunities, and ways to implement those improvements, the end result was a value-added concept for permit applicants." The One Stop Shop Team consolidated forms between the Utilities, the Building department and outside contractors (telephone, cable, etc.); formalized communication links; and developed standardized checklists.

Continued on page 14

Continued from page 13

Another early success occurred in the Hutchinson Community Development Corporation office, where the commercial loan application process was greatly simplified and shortened. (30 forms were reduced to just 8.) A user-friendly checklist was created that informs the developer of his/her commercial credit eligibility within 15 minutes - a dramatic reduction from the previous 1-1/2 month process.

The recently completed Hutchinson Areas Transportation Services ('HATS') facility is a good example of inter-departmental (cross-functional) cooperation. The three government entities of the State of Minnesota, McLeod County, and the City of Hutchinson were each planning to build their own garage for road maintenance vehicles. Hutchinson city staff met with representatives of the three government bodies to design a value-added approach that would meet all three's needs at a savings to the tax payer. Today, a model facility serves all three organizations, union and non-union alike, sharing common facilities, equipment, supplies and resources.

Excellent Plus represents many processes and systems by which the City of Hutchinson will reach its vision, including a formalized Planning Process, Continuous Improvement Teams, Citizen Involvement, Human Resource Development and a Process Improvement Council (Steering Team). Still in its infancy, **Excellence Plus** is about developing techniques to support the continuous improvement process; measurements that will drive desired behaviors and recognize Common cause versus Special cause Variation; the design, and interpretation of customer response methods; and, focus on both internal and external customers to enhance stakeholder value.

The Hutchinson community has grown 25% during the last four years, yet the size of the city government, as measured by the number of employee hours, has increased just 8% - a testimonial to the benefits of streamlined work processes and customer focus.

USING STATISTICAL THINKING IN A CUSTOMER COMPLAINT PROCESS

An OEM supplier that was striving to provide value-added quality products to the market realized they needed to become more responsive to their customers. When their customers complained about product or service, this supplier looked for superficial causes of the problem. Too often, reasons were provided rather than corrective action. Each occurrence was treated as a unique and independent event. When corrective action was taken, it focused on solving the individual problem but often did not alter the process to prevent future problems. Quality improvement often consisted of a series of corrective action steps that did not improve the overall quality of the company's processes, and thus could not be used in improving future products.

This case study illustrates Statistical Thinking at the managerial level. It is a good example of the importance of the first principle of Statistical Thinking, "All work is a series of interconnected processes. "The key to progress and improvement was the shared understanding, between the supplier and the customer, of a system of interconnected processes. Once the supplier and customer understood the connections in their shared processes they were able to make rapid improvement in the measure of process success (% Complaints).

After receiving training in Statistical Thinking, this supplier took a whole new approach. They began to focus on the processes used to deliver products and services to their customers; identifying measures, gathering data and improving these processes. The supplier flow charted the major processes, with the goal of determining if all steps were necessary, streamlining the processes where necessary and making permanent changes to improve the output of these processes.

Continued on page 15

Continued from page 14

Customer Complaint Process

The customer complaint process was one of these processes. The supplier decided that they should no longer treat each complaint as an isolated event, instead each complaint should be evaluated to determine if it was:
1. An isolated event (special cause)
2. Generated from a process that needs improvement (common cause)

To better understand the process, it was flow charted. Figure 4 shows a very general flow chart of the manufacturing system and how it related to the complaint process. Inputs were received in the form of product forecasts (to identify future material needs) and customer orders. Then the production process transformation activities were completed; ordering and receiving raw materials, scheduling production, producing the product, and shipping the product to customers. The complaint process provided feedback to the production process.

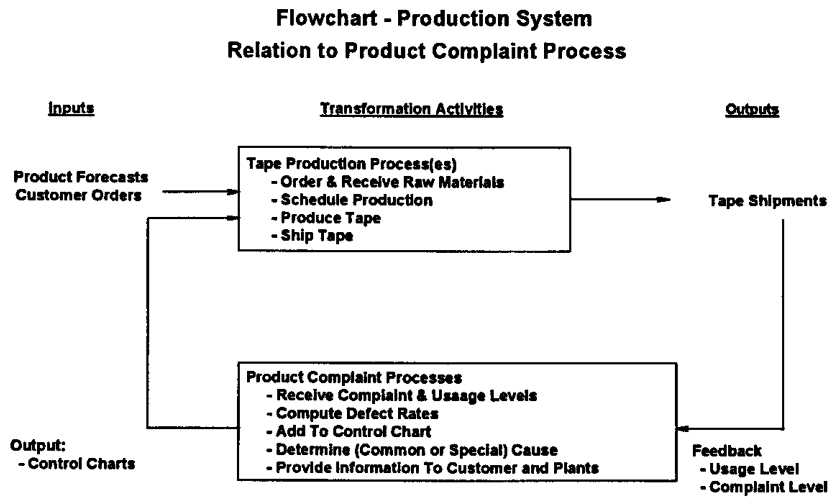

Figure 4

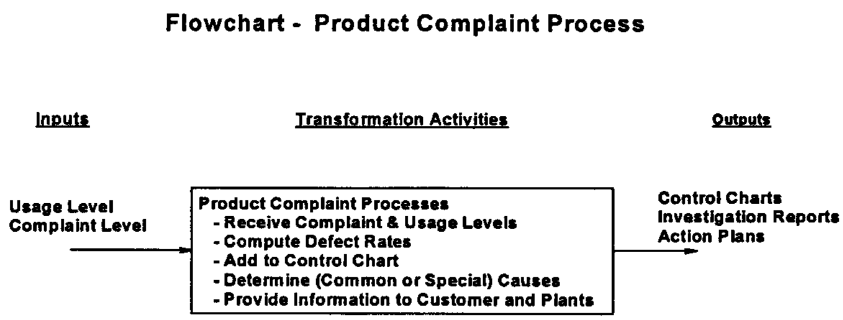

Figure 5

A more detailed flow chart of the complaint process is shown in Figure 5. Previously, customers asked for written documents of corrective action every time a problem occurred. The OEM supplier proposed a new way of dealing with complaints to the customer. The proposal included an ongoing evaluation of the complaint data in a new way.

In addition to complaints, the supplier asked customers to also supply actual product usage data, so defect rates could be calculated and control charted. (Note: Education of customers in Statistical Thinking was needed before they would agree to the new way of handling complaints.) The other transformation activities included:

- Computing defect rates,
- Charting the data,
- Analyzing the charts to determine the type of cause, and
- Providing information to the customer in the form of charts, reports and action plans.

Continued on page 16

STATISTICAL THINKING

Continued from page 15

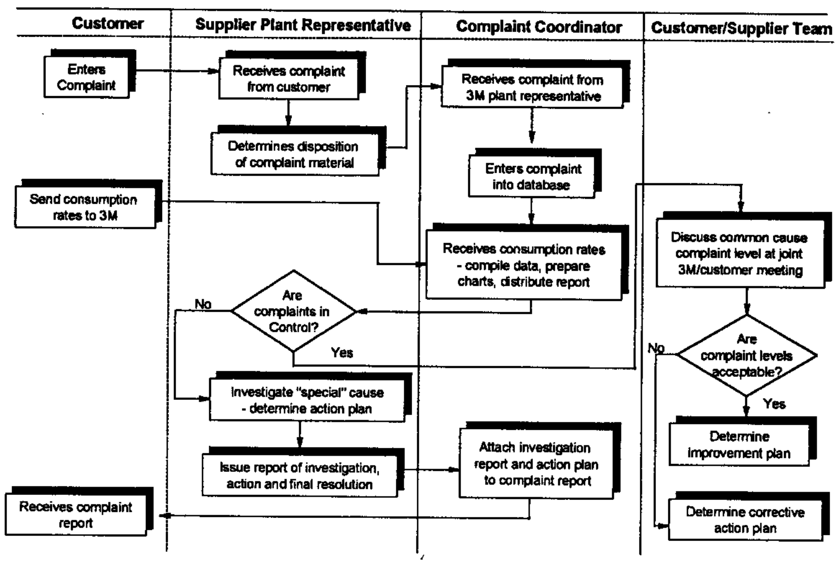

Figure 6

Figure 6 shows the responsibilities of each person in the process in a deployment flow chart. The customer / supplier team reviews the complaint control charts on a monthly basis. If special causes occur, the supplier is expected to develop a corrective action plan to identify the cause and eliminate it. If the process is operating at an unacceptable level of complaints, the team jointly decides if the supplier should take action to improve the process, prioritizing this improvement project along with all other currently active joint projects.

% Rejects Decrease

An example of how the complaint process helped achieve a new, improved level of quality is illustrated in Figure 7. The control chart tracks one of the quality characteristics for one customer. The 0.023% reject level (the performance level of the process prior to September, 1991) is quite a low level, but it was a level that that was not satisfactory for the customer. Improvement of the process was desired, but had not been accomplished.

Then in October, 1991 a special cause was experienced. The supplier immediately began to investigate to determine the cause of this unique event. The search led to the raw materials used by the OEM supplier. The raw material supplier had used the wrong material resulting in the increased complaint level. Of course, the problem was easily corrected, but the conversation with the raw material supplier led to a discussion for an additional improvement in the raw material.

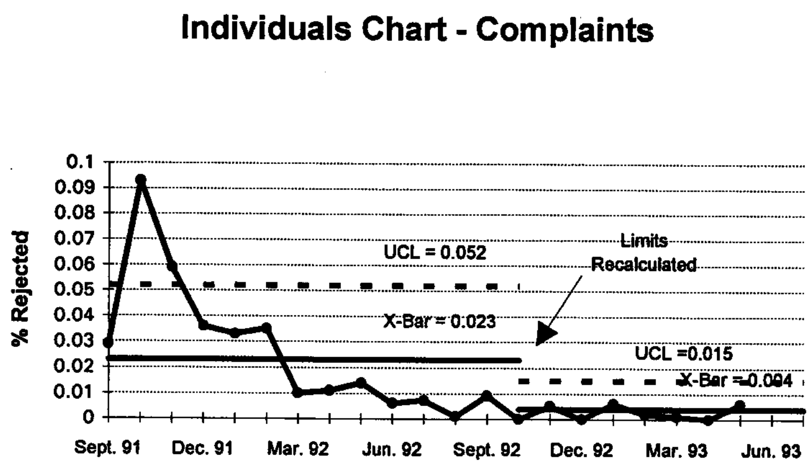

Figure 7

The raw material supplier and the OEM supplier conducted a series of designed experiments which identified the preferred composition for the raw material. The improved raw material was used to make new product which was sampled to the customer. The results were positive and the change was made for standard production. The results began to show up on the control chart in March, 1992, and the complaint level settled in at 0.0004%. This level was much more acceptable to the customer, and it was sustainable because a fundamental improvement had been made to the process.

STATISTICAL THINKING IN THE BOARDROOM

Statistical Thinking is a philosophy of **THOUGHT** AND **ACTION** that will enable you to analyze your business and make better decisions on what actions you need to take to improve faster than your competition. (See Figure 8 for an illustration of the role of Statistical Thinking in your decision making process.)

Continued on page 17

STATISTICAL THINKING

Continued from page 16

Statistical Thinking enables you to analyze processes and the information flowing from processes, using simple process analysis tools and control charts, and from these simple tools develop insight and make decisions. This will lead to better, more effective actions resulting in improved results.

Let's look at an example of how you can use Statistical Thinking.

The following is a typical line from a monthly report:

Product "X"			
	Jan.-94	Jan.-95	% Change
Sales Dollars	2,264	1,768	-21.9%

Figure 9

This result can cause a spirited discussion about what happened. "How can we accept this big drop?!" People can be sent off with the task of finding out what was wrong with the 1995 sales! Even worse, the manager responsible for the product could lose his job.

How can Statistical Thinking help?

Let's start by plotting monthly sales on a control chart. Figure 10 is a chart of monthly sales from January, 1994 to January, 1995. This chart presents a very different picture of the two months. January, 1995 is almost an average month for sales and the system is quite stable over the 13 month period.

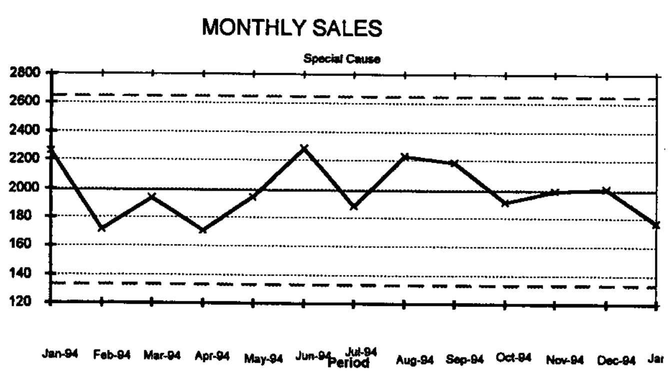

Figure 10

Does the number of selling days make a difference?

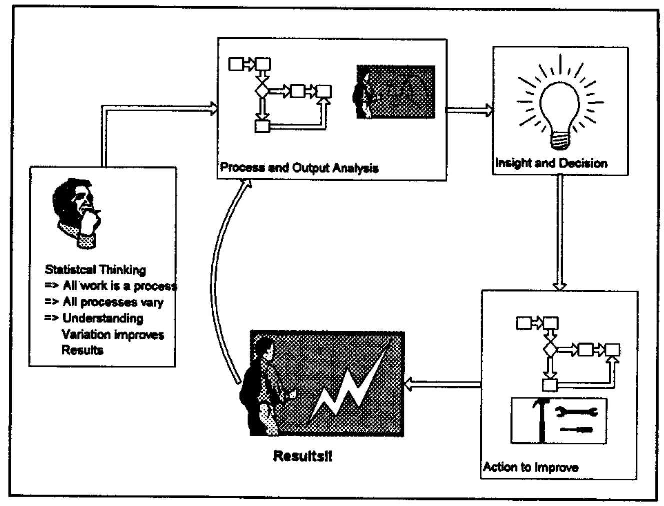

Figure 8

This case study demonstrates how the top management of a business can use Statistical Thinking in the analysis of key business measurements. The case study highlights two advantages Statistical Thinking brings to the analysis of a key business measurement.

The first principle demonstrated is that of understanding the context of your data. It is impossible to look at two-point comparisons in a monthly or quarterly report and know if it is "this period" or the "last period" that could be the problem. In fact, without the chart, you don't know if the 21.9% drop in sales indicates a real change in the process.

The second principle demonstrated is that of understanding the system in which you operate. Without understanding that there are a different number of selling days in some months, you can miss signals that something unusual has happened, like the unusually high daily sales in January, 1994. Also notice that it isn't only problems that are discovered. In this case, an opportunity was lost to identify the cause of unusually high sales. (This is certainly a good thing to know!).

Continued on page 18

Continued from page 17

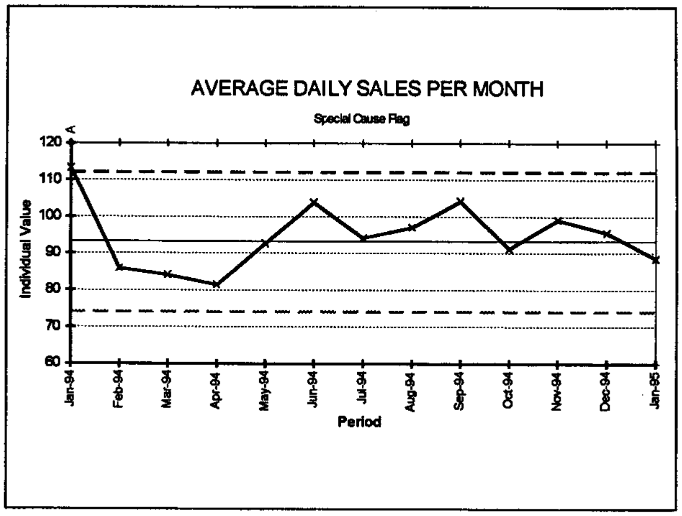

Figure 11

But someone mentioned that there are a different number of selling days in a month. Maybe January, 1995 is really soft if you factor in the number of selling days. Figure 11 is a control chart of the average daily sales per month for the same time period. (January, 1994 to January, 1995)

What a different tale this chart tells! January, 1995 is, again, very close to an average performing month. The actual time of interest here is January, 1994. The chart signals that January, 1994 was unusually high for average daily sales.

What happened last year to result in such high sales? Of course, if the chart had been in place last year that question could have been asked. Now, a year latter, it's harder to find the cause.

STATISTICAL THINKING - A PERSONAL APPLICATION (TOM POHLEN)

I was introduced to Statistical Thinking in October, 1988 when I attended Heero Hacquebord's course on "Statistical Thinking for Leaders". I went into the course thinking that I already knew everything I needed to know about SPC. I came out of the course with a whole new perspective on statistics, looking upon SPC and other statistical applications more as a way of thinking about processes so we can learn how to improve them. I also found that I could never again be satisfied with looking at numbers without graphical analysis.

I immediately began to think of all sorts of ways to apply this new knowledge at work and at home. One of my first applications was to control chart my weight, and I have been doing so ever since. My enthusiasm, however wasn't shared by my wife, Carolyn. She had been an insulin-dependent diabetic since Nov., 1976. I could see an obvious application of control charts to her blood glucose, which she was testing daily. No matter what my argument was, she wasn't interested.

What could be more important than a person's health. Here we see Statistical Thinking applied to ease someones pain. This "operational level" case study powerfully demonstrates the broad applicability of Statistical Thinking. It is an example of the third principle of Statistical Thinking, "Understanding and reducing variation are keys to success." Understanding the variation in the process was a vital step toward making progress. Once Tom and Carolyn had a better understanding of the variation in the process, they were able to apply techniques to reduce that variation. The results were heartwarming, ". . . I can tell you for sure I know it worked because I feel a lot better now than I did before we started!" Can there be any better reason for applying Statistical Thinking in every part of our lives?!

Continued on page 19

Continued from page 18

Then in June, 1994 something changed. Somewhere between being tired of pricking her finger up to four times a day to get blood, having laser surgery in Nov.,'93 to repair eye damage caused by diabetes, and having been sick so frequently during the winter of '93/'94, she finally said she was ready to be my guinea pig for applying Statistical Thinking.

The Objectives

We started out with a few simple objectives. For Carolyn it was to reduce the pain and inconvenience of diabetes, in particular, to regain her health and reduce the blood testing to no more than once a day. My objective was to get her what she wanted. To do so I knew that we had to understand her "process" variation, gain control of it, and reduce that variation. It seemed like a simple problem; after all it should be just like a production process! It wasn't!

"My objective was to get her what she wanted."

The "Process"

Carolyn is a "brittle' diabetic, due to the fact that she has little or no insulin production. In June 1994, her swings in blood glucose levels were high. The normal non-diabetic has blood glucose of 70-120 milligrams/deciliter. It was not uncommon for Carolyn to vary from over 300 mg/dl to under 70 mg/dl (usually accompanied by an insulin reaction) in a very short time, sometimes within 24 hours. I ran a regression analysis to try to determine the effect of insulin on her blood glucose and re-learned the futility of analyzing "production" records for correlations. The analysis indicated that "increasing insulin increased blood glucose", an obvious error! What was actually happening was that we had to increase insulin because blood glucose was up.

The Goal

"We dug into books and magazines and learned much about diabetes, including some of the mechanisms and key causes of blood glucose variation (food types, exercise, illness, infections, emotional stress...)"

Our main goal early in the project was to reduce glucose variation with an emphasis on reducing the overcontrol that was occurring. This was not a simple task because with diabetes there is no choice but to eat (usually sugar) when blood glucose drops and there is very little choice but to take extra insulin when blood glucose gets high (> 250 mg/dl). There was no doubt that we were dealing with a truly "chaotic" process. This indicated that we needed to try to find a control condition for Carolyn's diabetes that would make her "process" more robust (insensitive to sources of variation.)

Understanding Variation

In June '94 before we could really get going with our efforts to control her diabetes, Carolyn had a bout with high blood glucose that we could not contain and she ended up in intensive care. She came out of the hospital June 26th still not very healthy. She continued to have high blood glucose problems and by August was back in intensive care.

This second failure was a big let-down, but we recommitted ourselves and decided it had to be done and it could be done. Carolyn long ago had learned that she had to take control of her own sickness and learn as much as she could about it. We dug into books and magazines and learned much about diabetes, including some of the mechanisms and key causes of blood glucose variation (food types, exercise, illness, infections, emotional stress...) A key book (reference #4) identified a very important fact: "The effect of any insulin on BG (blood glucose) usually diminishes as BG rises." This indicates blood glucose has a non-linear response to insulin, a characteristic of a chaotic process.

After Carolyn came out of the hospital August 24, 1994, we began to make progress. Around this time we shared our data with Carolyn's physician, Dr. John Zenk, doctor of internal medicine. He was pleased to see our active interest in controlling Carolyn's blood glucose and was particularly satisfied with our charting of her numbers. As we gained better control, Carolyn had more low blood glucose reactions, a very undesirable complication. Low glucose tends to cause severe headaches and the potential to go into an unconscious state. The latter never happened but the potential of some brain cell damage is very undesirable. Her reactions tended to occur when sleeping in the early morning.

Continued on page 20

Continued from page 19

To deal with this we developed a theoretical quadratic model of how her insulin levels would build-up during a normal day. She was taking multiple shots/day of two kinds of insulin, Ultralente (long-acting, typically over 24 hrs.) and Regular (short-acting, typically over 3-6 hours, taken to handle the immediate effect of meals). Of her total insulin about 65-75% was Ultralente (initially 36 total units of insulin.) Our graphical model indicated we could improve the overall uniformity of insulin if she delayed her last shot of Ultralente till about 8 p.m. rather than taking it at 6 p.m. with dinner. To coincide with the change we also delayed our dinner time. The result was a reduction in problems with early morning insulin reactions.

"The theory that seemed to fit best was that the blood glucose level is really trying to be at some average level based on all the competing factors (insulin level, stress, illness/health, food intake,...)"

Finding Solutions

Knowing that we could not eliminate the causes of high blood glucose, we realized we needed to develop an adequate control strategy to bring high blood glucose down when it occurred. In the spirit of Statistical Thinking our first action in case of an out-of-control signal was to ask "why?" and investigate. Then based on that investigation, if an increase in insulin was called for, we needed an adjustment plan. The theory that seemed to fit best was that the blood glucose level is really trying to be at some average level based on all the competing factors (insulin level, stress, illness/health, food intake,...)

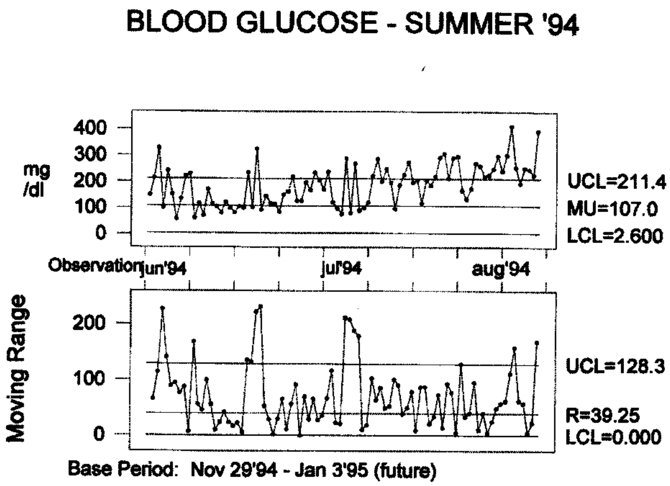

Figure 12

Due to the dynamics of the situation all these factors were simultaneously either rising or falling in amount. At any moment in time no single value of either the insulin dose or blood glucose level really has meaning. Thus, it was decided to use 24-48 hour averages of each of these two key parameters for determining the amount of change to make in the insulin doses to bring down high blood glucose. An initial crude formula was developed that worked well in dealing with high blood glucose levels in Nov. '94 and Feb. '94.

In Jan. '94 a more fundamental theory was developed using the concept that the effect of insulin on blood glucose is non-linear. This was combined with an approach to apply differential equations further theorizing that the problem was similar to a population growth model. The final theory adopted the idea that the derivative of blood glucose with respect to insulin dose was an exponential function of blood glucose.

Successful Results

The use of the equation was successful in dealing with high blood glucose levels that occurred in May '95, June '95, July '95, Aug. '95, Dec. '95. We learned that in applying the equation it was important to continue to keep the relative doses of Ultralente and Regular at about the same ratio (about 65-75% Ultralente.) Usually, more than one iteration of the formula was needed to counteract high blood glucose due to the dynamic nature of each situation. Using the equation in cases of low blood sugar tended not to be as effective since these instances usually were accompanied by insulin reactions which generally required large doses of extra sugar to regain blood glucose levels.

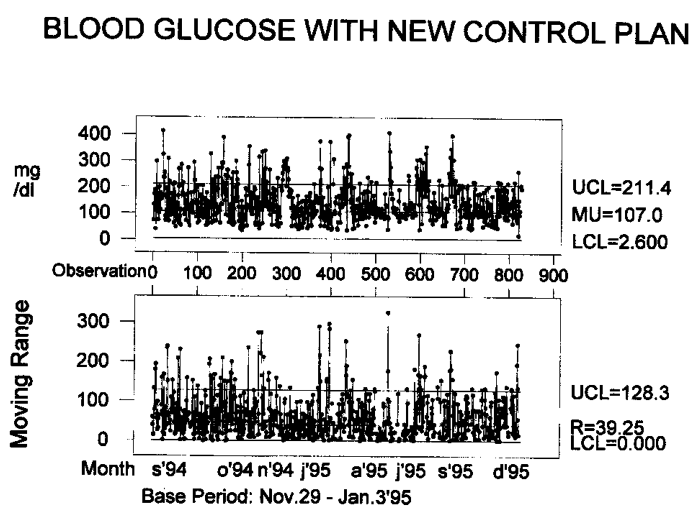

Figure 13

The control charts (Figures 12 and 13) show the results of Carolyn's blood glucose between the visits to the hospital June-Aug., '94 and after Aug. '94. The limits shown are based on one of the best periods of control from Nov. 29, 1994 through Jan 3, 1995. ($\bar{X}$ = 107 mg/dl; $\hat{\sigma}$ = 34.8 mg/dl).

Continued on page 21

Continued from page 20

The early data were taken usually as three to four readings per day. Beginning Jan '95 most data were taken once/day in the morning except during periods of high blood glucose, when more readings were taken. In general, analysis of the days with multiple readings failed to show any specific pattern in blood glucose levels throughout the day; thus, the data are graphed all together.

Benefits

There is clearly still plenty of room for improvement in controlling the complex process of Carolyn's blood glucose. However, we have already obtained many benefits, most of which we believe can be directly attributed to our use of Statistical Thinking with control charts:

1. We met our objective of safely getting down to one blood glucose test per day. This was accomplished because we successfully reduced the variation in her "process" making it possible to "see" and predict within limits what was actually going on with her blood glucose.

2. We learned much about the causes of Carolyn's high blood glucose (different foods, exercise, illness, infections, and especially emotional stress.)

3. Carolyn is taking less insulin now than when we started in June '94 and she also has lower blood glucose (current insulin = 26 units; June '94 = 36 units.) My theory is that her body has now gotten used to lower blood glucose and is now more robust against fluctuations. In fact, Carolyn used to feel jittery when she was at near normal blood glucose levels; she no longer feels that way.

4. Carolyn was sick less often during the winters of 1994-1995 and 1995-present, compared to '93-94. (Winter '94-95: sick four times. 1995-present: sick two times. Winter '93-94: No hard data but memory recalls a frequency of an illness every one-three weeks.) In addition Carolyn has been much more energetic. High blood glucose tended to make her lethargic, whereas with lower blood glucose she clearly has had more energy.

5. A successful control strategy was developed for appropriately correcting high blood glucose with minimal over-control.

6. The time between insulin reactions has improved, that is, the time between these reactions increased when compared to where it was when we first started to control the blood glucose. (Figure 14, Note: log of time-between-reactions was used due to the highly skewed nature of the time data.)

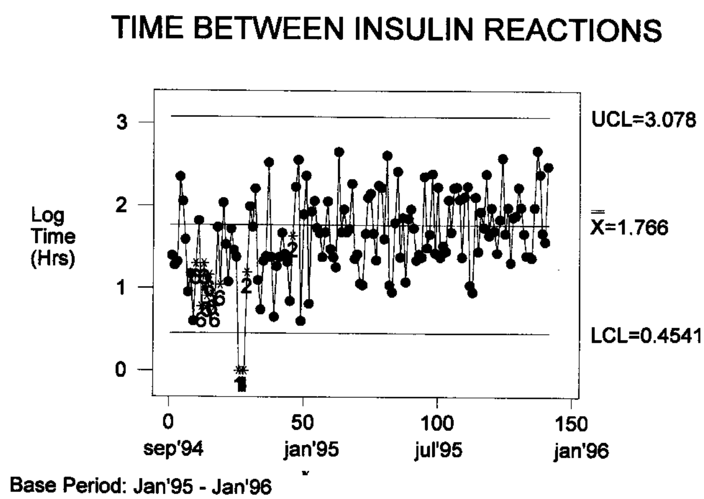

Figure 14

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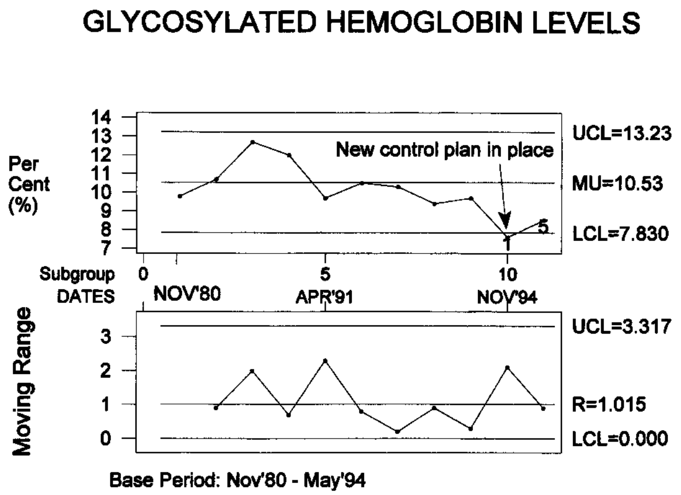

Figure 15

7. Carolyn has had a significant drop in her Glycosylated Hemoglobin (GH) levels since we started this program. (Figure 15). This test is an estimate of the long-term average blood glucose over approximately the last two months prior to performing the test. It is an indicator of future complications due to diabetes. Recent studies have indicated that people with GH levels below 8.1 percent have significantly lower risk of kidney disease.

8. Carolyn was anticipating having a second laser surgery on her eye in Nov. '94; however, the eye exam in November indicated no need to have the surgery.

9. We have also developed some additional ideas for further improvement of our control of Carolyn's diabetes. One thought to reduce the chance of insulin reactions in the night is to have Carolyn take a small amount of food (a sugar tablet) in the early morning (e.g. 2 or 3 am.) Of course, that idea is not very popular with the subject and has been rejected at this time.

Lessons Learned

Beyond the tangible benefits of the control plan for Carolyn's health, we have also learned or reaffirmed some additional valuable lessons regarding Statistical Thinking and science. These include:

1. A process has no regard for the "specifications"; it just does what it is capable of doing. There is no better evidence than this case of diabetes. The insulin regulatory system controls blood glucose to within +/- 25 mg/dl. The best we've been able to get Carolyn's variation is +/- 104 mg/dl. Tampering only increased the variation.

2. Statistical Thinking should be used to help us develop theories as well as to test them. To do so we should remember to use all of our scientific/mathematical background to try to explain the patterns in data.

3. Chaos is alive and well and living in diabetes. Recognition of the presence of conditions in some systems that can result in chaos can help us be conscious of the importance of working to create robust processes which are less sensitive to sources of variation.

4. The real value of control charts and Statistical Thinking is to help us learn about our processes. It is a serious fallacy to avoid introducing control charts to a process due to lack of adequate knowledge of how to control it. Failure to introduce the charts essentially guaranties that one will continue to be ignorant of how to control the process.

5. The human body is a marvelous creation that is extremely robust.

Continued on page 23

Continued from page 22

While I was preparing this case study my wife pretty well summed up our results when she said "I don't know what the data say about whether or not my diabetes improved, but I can tell you for sure I know it worked because I feel a lot better now than I did before we started!" As my friend, Ken Kotnour, once said in quoting Dr. Deming: " the customer doesn't always know what they need, but they will treasure it if you give it to them."

"I don't know what the data say about whether or not my diabetes improved, but I can tell you for sure I know it worked because I feel a lot better now than I did before we started!"

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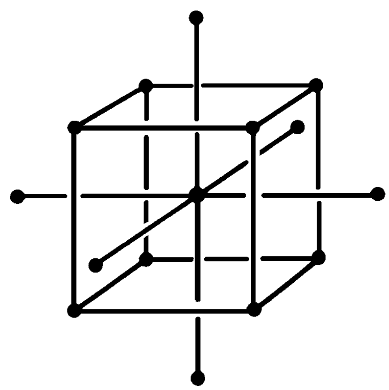

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