

FACILITATING CONTINUOUS IMPROVEMENT WITH SAS/ASSIST™ SOFTWARE
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ABSTRACT

This paper describes the evolution of an application using SAS/ASSIST software to empower the end-user. The application facilitated a change from a top-down, task-oriented management style to a continuous improvement (CI) team approach. Having organized a multi-disciplinary team consisting of a researcher, data abstractors, an application developer, and a statistical consultant, it became apparent that the disciplines did not share a common language or culture and that team members needed to understand how each task contributed to the whole. SAS/ASSIST provided the tools to accomplish these goals.

We will discuss, from the perspective of each discipline and, at each stage of the project, how SAS/ASSIST was used to facilitate the CI approach. We will also discuss problems that arose and important technical and cultural considerations when developing end-user applications. By instructing each participant to use SAS/ASSIST, we were able to communicate needs more precisely and obtain results more efficiently. As each person became more knowledgeable about the entire scope of the project, there was a shared sense of responsibility and ownership. We believe the quality of both the research and the activity was enhanced by combining SAS/ASSIST with the CI approach.

INTRODUCTION

In this paper, we discuss the advantages of SAS/ASSIST as a tool for facilitating the Continuous Improvement (CI) approach to academic research in a clinical setting. The research environment was the Department of Health Sciences Research at the Mayo Clinic. The hallmark of this department is population-based epidemiologic and health services research, conducted under the auspices of the Rochester Epidemiology Project (REP)¹. The REP has been described as a natural laboratory for studying the occurrence of disease in human populations. This is the result of a unique set of circumstances: 1) Rochester, MN, is relatively geographically isolated from other large population centers; therefore, residents of the community receive essentially all of their medical care from a few local providers. 2) Each of the providers employs a unit record system whereby all medical information for each individual is accumulated in a single dossier. 3) The medical records have been maintained and are available for review in approved studies. 4) The records are easily retrievable due to the establishment of provider-linked indices of the diagnoses and procedures for each resident.

Our specific research objective was to employ the rich resources of the REP to investigate temporal trends in morbidity, mortality, and use of medical services among Rochester residents with a diagnosis of diabetes mellitus. A detailed proposal was submitted to and funded by the National Institute on Aging (AG08729); we are currently in the fourth year of the project.

THE TRADITIONAL APPROACH

The Rochester Epidemiology Project has been very productive with large-scale epidemiologic studies of the sort that we proposed, yielding over 700 publications in the past 29 years. The success is attributable in part to a strong tradition of inter-disciplinary collaboration within and across departments. The disciplines involved typically include an investigator, data collectors (nurse abstractors), a data analyst (a bachelor degree statistician), and a doctoral level statistician. Traditionally, projects are viewed as a series of discrete stages: Proposal development, data collection, data entry, data editing, data analysis, interpretation of results and preparation of manuscripts. The individuals are involved with the project at different stages, depending on their particular expertise. Interaction among individuals is typically limited to two

disciplines at any one time.

The investigator defines the specific aims of the project and consults with the statistician to determine which data elements to collect. The investigator then meets with the data analyst to design the data collection tool. Until recently, this was a paper abstract form. The nurse abstractors are charged with abstracting information and recording it onto the paper abstract. At the end of data collection, the results are entered into a computerized file. The data are subjected to numerous edits by the data analyst, who then gives a listing of questionable and missing entries to the nurse abstractors. Corrections are recorded on the printout and sent back for data entry. The data analyst performs preliminary statistical analyses on the corrected data. After reviewing a hard copy printout of the results, the statistician and investigator consult with the data analyst. Corrections are made and sophisticated statistical analyses are then performed.

THE CONTINUOUS IMPROVEMENT APPROACH

Several changes, both internal and external to the research environment, and important differences between our project and previous studies caused us to question the applicability of the traditional approach for our specific needs. External to the research environment, there was a growing interest in a "systematic team-oriented approach to problem solving"²⁻⁵. The approach has been operationalized in a variety of ways: Total Quality Management (TQM), Total Quality Control (TQC), Continuous Quality Improvement (CQI), etc. An amalgam of the philosophies and strategies common to each is referred to here as Continuous Improvement (CI)⁶. CI differs in important respects from the traditional approach described above. With CI, the focus shifts from discrete stages or micro-processes to continuous improvement of the macro-process. CI requires a change from top-down management style to a "self-directed team approach". The teams are "problem-focused" rather than task focused, and membership is "cross-functional" rather than task specific. Two basic tenets of CI are that 1) the best person to say how to get the job done is the person doing the job, and 2) quality is enhanced when responsibility for the process is shared by all team members and all members are empowered to contribute to the process⁶.

Internal to the research environment, there were a number of changes that supported the adoption of the CI approach. Increasing demands on data analysts and statisticians were resulting in project delays. It was recognized that empowering investigators to conduct routine analyses of their data would provide the statistical consulting staff with time for more sophisticated analyses. There was also a general computerization of the institution, leading to increased opportunities for on-line data entry and electronic data transfer. Whereas, in the past, the REP was primarily a paper-based data resource, there were now numerous opportunities to obtain the necessary data electronically. The utility of the traditional mode of data collection (i.e. manually abstracting information from the medical record onto paper abstracts) was diminished by these new opportunities and resources.

The wealth of data from a variety of sources created challenges as well as opportunities. The traditional team membership lacked expertise in accessing and managing the multiple and varied electronic data sources. The addition of a new individual, an analyst/programmer, helped to resolve this problem. But it was also necessary to adopt a shift in attitude. Given the relative lack of familiarity with these data sources and the large number of unknowns that they brought to the project, we recognized the advantages of the CI approach, with its emphasis on process relative to the traditional focus on separate well-defined stages.

Our project also involved applying current criteria and definitions to data collected in an earlier study. Questions regarding data quality, completeness and consistency arose with both the new electronic sources and the historical data. Faced with these challenges, the advantages of CI's team approach to problem solving were particularly apparent. The investigator had established the criteria and definitions applied in the proposal; the nurse abstractors and the data

analyst participated in the earlier study and were familiar with the criteria and definitions employed; and the analyst/programmer was aware of limitations of the electronic data sources. The quality of the final data was dependent on each member contributing their knowledge and participating in decisions about the relative reliability, validity, and consistency of the various data sources for each piece of information to be obtained.

The identity of our team members also differed from other studies. In contrast to the traditional clinician investigator, the principal investigator on this study was a social scientist, with experience in computerized databases and routine data analysis. Clinical expertise for this project was provided, not only by physician co-investigators, but also by the nurse abstractors, who on this project were RNs. The CI "cross-functional" definition of team membership was able to take advantage of this experience and training.

Although the benefits of CI for our project were apparent, there were serious impediments to its application. Despite some overlap of roles, expertise was still very task specific and our understanding was incomplete. There was little appreciation for the consequences of each micro process (e.g. design of the data collection tool) on another (e.g. data analysis) and on the project as a whole. Two additional tenets of CI are that 1) local goals (i.e. micro processes) should never get in the way of improving the macro process and 2) problems arise because persons are unaware that their actions are doing damage⁶. In order to accomplish our research objective, it was essential that we identify a common language. This language would increase communication across disciplines and enhance our appreciation of the contribution of each phase of the process to the whole.

THE ADVANTAGES OF SAS/ASSIST AS A TOOL FOR APPLYING CI

There are a number of reasons that SAS/ASSIST was selected as the most appropriate tool to meet our needs⁷. These include the analyst/programmer's expertise with this package and the fact that it is compatible with the existing SAS™ environment. We required a package that could handle multiple and varied data sources. SAS/ASSIST can interface with other clinical databases while providing a common user interface. Although a large amount of data was available from electronic sources, much of the clinical information on each patient still needed to be abstracted from the hard copy medical record. The common user interface enabled us to display multiple values for the same piece of information in separate fields, thus affording the opportunity to visually compare data from the various sources with the medical record during the abstracting process. SAS/ASSIST is capable of data transfers to and from other database systems and operates on multiple hardware platforms. This portability was a distinct advantage because we needed to collect data at a number of remote sites with different operating platforms.

Several features of SAS/ASSIST proved especially important for our transition to the CI approach:

- 1) SAS/ASSIST is menu-driven. The ease of application helped minimize start-up time and prevented both new and experienced users from becoming discouraged.

- 2) The flexibility of SAS/ASSIST empowers the user. Team members became familiar with the vocabulary (SAS terms, ASSIST terms, GUI terms, and data management terms) and the grammar (SAS operators, where clauses). Because they had access to the many SAS products through SAS/ASSIST (text editing, screen building, dataset creation, etc.), members were empowered to use the language to communicate meaning. Rather than submitting requests in English to the data analyst (and risking misinterpretation), the investigator and abstractors could write and test code to meet their specifications. Tested code could then be submitted to the data analyst and analyst/programmer for application enhancement. Nurse abstractors, after collaborating with other team members, were able to design and prototype their own data entry screens and on-line data edits. Using SAS/FSP™, the investigator and other team members were able to access, manage, analyze, and present data throughout each phase of the project.

3) SAS/ASSIST applications are compatible with CI's emphasis on process. The CI strategy for improving process invokes "structured problem-solving". Graphical and other techniques are used to specify each component and phase of the process and identify opportunities to decrease cost and increase quality. We were able to involve all team members in this strategy in large part due to SAS/ASSIST. The ability to query during the data collection phase of our project afforded the nurse abstractors the opportunity to identify missing or illogical entries and correct their own errors. The data management and data analysis applications allowed us to identify and diagnose problems of data reliability and validity. With the data edit application, we were able to add, change, delete, or update values and variables throughout the project with minimal cost and effort.

An important tenet of CI is that any change in the process should result in added value. Using the quality control application of SAS/ASSIST we were able to generate estimates of the relative costs and benefits of alternative strategies. The following example illustrates this capability. Our project involved collecting data offsite on 1200 cases. In order to retrieve the records, offsite personnel required a list of cases identified by patient name and offsite number. They required a hardcopy list on a standardized form. A problem solving team, consisting of the investigator, nurse abstractors, and analyst/programmer, met to identify alternative strategies and determine the most efficient method. With the aid of brainstorming techniques and Ishikawa diagramming (available in SAS/QC™), each phase of the task was delineated. The time needed to accomplish each phase was estimated, based on measurement and experience. The traditional approach, using paper abstracts, would have required 34.7 hours of abstractor time to retrieve and record identifiers, sort abstracts, and hand write and copy the lists. By contrast, because our project was managed in SAS/ASSIST, the time required to accomplish the same task, including programming time, was 13 hours. The exercise revealed that the task of hand writing and copying required 6.4 hours; by writing a program to print the labels, the total time needed to identify 1200 numbers, sort the cases and generate a listing on the required forms was reduced from 13 to 7.4 hours. Because a majority of the research projects done in this department involve collecting data offsite, the potential savings resulting from this program are considerable.

CAVEATS AND CONCLUSIONS

SAS/ASSIST is similar to other tools in that it requires training and is subject to misuse. Misuse of SAS/ASSIST could result in disastrous consequences for a research project. With the traditional approach there was potential for miscommunication (e.g. between the nurse abstractors and data entry person or between the investigator and data analyst). By empowering individuals to use SAS/ASSIST, the risk of miscommunication was reduced because SAS/ASSIST alleviates errors with syntax. However, ASSIST does not prevent problems with accuracy. There is a danger that individuals with little formal training in database management, programming, and analysis may lack the necessary expertise and awareness to assure validity of results. We believe that these difficulties can be minimized when SAS/ASSIST is combined with CI. CI empowers team members to engage in self-directed activity by increasing communication and understanding among the multi-disciplinary membership, not by diminishing the involvement of any one discipline. While the function of certain individuals on our project changed from performance of the specific task to consultation or instruction, the involvement of all team members in the research process actually increased rather than decreased.

The extent to which increased involvement reflects the fact that this is the first experience with SAS/ASSIST for some members of the team is unclear. Our decision to use SAS for data entry instead of paper abstracts was influenced largely by the flexibility that SAS/ASSIST afforded the end user. The decision was consistent with the CI aphorism that, "Usefulness is more important than ease of use"⁸. Although a significant amount of time was spent in instruction and

on-the-job training to assure proficiency in SAS/ASSIST, the knowledge gained is transferrable to future research projects and other activities. We also believe that the additional start-up time will be recovered in this last year of our project. This is because much of the data editing and exploratory analysis has occurred simultaneous with data collection. With the traditional approach, it was necessary to complete the data collection stage before entry, editing and analysis could begin.

Our experience of combining SAS/ASSIST with the CI approach has been very positive. As the team members became more fluent in the common language, new roles began to emerge and self-directed work groups were able to function. We were able to apply structured problem-solving techniques, and were rewarded with knowledge of new ways to improve the process. Because all team members could recognize problems and identify solutions, both responsibility for the project and pride in accomplishment were shared.

TRADEMARKS

SAS, SAS/ASSIST, SAS/FSP, and SAS/QC are registered trademarks or trademark of SAS Institute, Inc. in the USA and other countries.

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