KNOWLEDGE MANAGEMENT FOR QUALITY IMPROVEMENT OF SERVICE METHODS - A CASE STUDY OF A LABORATORY INSTRUMENT

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ABSTRACT

Michael K. Nierste

KNOWLEDGE MANAGEMENT FOR QUALITY IMPROVEMENT OF SERVICE METHODS - A CASE STUDY OF A LABORATORY INSTRUMENT

A systematic method can extrapolate tacit knowledge (hidden or subjective knowledge) so that it can become objective and discernable. This process focused on discovering causes of failures by extricating data from medical equipment service software cases closed by telephone by field service personnel. Their responses to observed failures were compared to troubleshooting guides in use by telephone support personnel to find new processes that would increase effectiveness of telephone support staff. We asked “What are indicators of device failure reported in technical support calls?” and then “What factors contribute to user reported device failures identified by callers to technical support?” A series of interviews with veteran personnel were used to validate responses from the “phone closed” cases along with ideas pulled from a review of documentation. Analysis of one hundred seventy three cases yielded over five hundred recommendations to make the telephone support personnel’s responses more accurate, consistent and reliable.

KEYWORDS

Tacit knowledge, objective knowledge, medical equipment, laboratory instrument, troubleshooting, problem, symptom, cause, diagnosis, corrective action, repair, method, service software

CHAPTER ONE: INTRODUCTION

Introduction

This project utilizes a model classified as applied informatics research. "It is work performed to gain the understanding needed to meet a particular need; it is often called problem-oriented research." (Fuller and Messerschmitt et. al., 2000, p. 27) It involves mining of large datasets to uncover hidden phenomena and discovering functional and causal relationships and emergent behaviors across a wide range of phenomena.

This is a qualitative investigative process to explore ideas to increase reliability and decrease service cost. Specifically it is focused on reviewing failures and existing maintenance for the Roche OMNI Blood Gas Analyzer Series and performing an analysis that results in recommendations for improving reliability and avoiding future service costs. Emphasis will be placed on detailed review of the effectiveness of Technical Support Specialist's (TSS) telephone contact by the customer to resolve problems.

This is an exploration in discovering tacit knowledge which is defined in Webster's Dictionary as "expressed or carried without words, implied or indicated but not actually expressed." (Webster's Dictionary, Ninth edition, p. 1007) Tacit knowledge has several variations in meanings as expressed in informatics. Traditionally tacit knowledge is compared to objective knowledge which is also known as articuable, explicit, verbal or declarative knowledge. Polanyi (1966) states that we can know more than we can tell. Emphasizing the aspect of mental models and practical processes Ambrosini and Bowman (2001) argue that tacit knowledge is more of a skill. They refer to previous authors (Kogut and Zander, 1992, Nonaka, 1991) who use the term 'know-how'. This thesis explores the development of capturing tacit knowledge and translating it to objective knowledge.

Tacit knowledge is a resource for any organization. It is a potential resource that can provide a sustainable competitive advantage. The exploration within the organization allows it to keep a dynamic perspective on an ever evolving data base. "Otherwise imitation and innovations in competing firms would erode the firm's competencies." (Ambrosini and Bowman, 2001 p. 822)

Existing skills or know-how are utilized daily by technicians in the field and providing telephone support. It is expressed and shared to varying degrees. It is present in a variety of formats including documentation in the form of service data captured in service tracking software but due to lack of analysis this idle data is not provided as useful feedback to service personnel. We are attempting to create new models from elicited data formed from analysis of existing documentation and through interview of technicians.

The final product demonstrates a heuristic method of systematic analysis that provides practical solutions and improvements for service to a medical instrument. Data are focused to achieve insight into the way that customers report for the analyzers. Final deliverables are limited to documentation regarding the development of this process which also includes new categories of failures and identification of causes. In the long term, these documents led to an updated troubleshooting guide based on the existing OMNI Modular analyzer and a second troubleshooting guide for a new series of models called OMNI S.

The focus is to improve service by conducting an investigation that considers the problem of how technical support can best respond to service requests for the OMNI analyzer. This problem is broken down into two component parts for analysis. The research questions involved are “What are indicators of device failure reported in technical support calls?” and then “What factors contribute to user reported device failures identified by callers to technical support?”

Importance of subject – significance

This specific research question can have implications to (1) larger theoretical constructs, (2) serve as a response to policy issues raised by regulatory bodies, and (3) provide increased efficiencies in practical applications.

1. This research provides a construct by presenting a systematic method for building practical adjustments to existing guidelines for repair based on knowledge within the organization. It will provide a model of how repair processes can be streamlined from a review of recorded data that represents a ‘collective conscious’ experience. Ambrosini and Bowman (2001) describe tacit knowledge within the context of the resource based view of the firm as tacit skills. In other words they see tacit knowledge as a possible resource that can provide a sustainable competitive advantage. The organization must keep a dynamic perspective with new competencies since “otherwise imitation and innovations in competing firms would erode the firm’s

competencies." (Ambrosini and Bowman, 2000, p. 811) Eliciting tacit knowledge is important for corporate survival. "Know how or competence cannot be separated from the person or organization." (Johnson and Lundvall, 2001, p. 15) One way "to mediate this kind of knowledge is to engage in a process of interactive learning with the carrier of the knowledge." (Johnson and Lundvall, 2001, p. 16)

The initial step in this process is codification, which involves a process aiming at making knowledge accessible to a group by classifying failures. Professional communities that develop local coding systems make communication more efficient but exclude outsiders from understanding. The more specific the coding, the more difficult it is to share and the more useable that coding is for a particular design's refinement. The more generalized categories of coding make the phenomena studied easier to share but harder to specify feed back for a particular design. This review will have specific coding for the particular instrument and organization. "Articulation being social communication, presupposes some degree of codification." (Johnson and Lundvall, 2001, p. 3) This study will focus on specific categories with emphasis on instrument improvement but benefit a larger group in as much as it discloses the process as a case study.

2. Increasing scrutiny by the Food and Drug Administration (FDA) now more stringently requires written approved documentation for responses from Technical Support Specialists. This new emphasis on validated methods has stifled sharing previous innovative spontaneous responses and now creates a need for more formalized answers that must go through an internal approval process.

Failures requiring investigation specified by the FDA are escalated through a review process. These specific failures are routinely scrutinized through the quality assurance process at Roche but these cases are filtered, required responses based on policies that designate specific instances and types of failures. This inquiry of tacit knowledge provides an alternative method for investigating performance of the device which addresses the needs to document and validate innovative responses that are conceived in the field. Documenting previously unshared methods ensures compliance by allowing a validation of methods and simultaneously provides a format for sharing those ideas with others in the organization which may be audited by outside regulatory agencies.

3. Some of the increased efficiencies resulting in this review include the following.

Utilizing formalized inquiry of complaints for newer instrument models allows application of troubleshooting procedures from similar models to be applied and increases the efficiency for troubleshooting responses. Revisions to processes address shifting needs resulting from design enhancements including hardware and software changes and simultaneously provide a method of collecting data that will refine the product further.

This review provides a method that can lead to revisions in troubleshooting specific problems and routine preventative maintenance tasks. It will allow adjustment to specific tasks included in specific problems and in preventive maintenance. It was hoped that it would also provide a method to adjust intervals for routine maintenance that have been traditionally applied using risk based intervals. Risk based maintenance intervals are widely adopted by end users who provide in-house maintenance. Likewise, third party service providers incorporate ongoing data review for most efficient utilization of resources. But these intervals are rarely shifted by manufacturers.

A successful analysis with recommendations could lead to similar review in other areas using the same device and for other devices. Utilizing the review process could lead to a shared resource for other support personnel leading to long term improvements.

The primary immediate benefits for the company from the research are increased reliability, greater customer satisfaction, improved consistency in performance of the instrument for patients, and decreased service cost. Unless the root cause of high service costs is discovered and reduced, the company that manufacturers the product risks loyalty erosion with customers and loss of profits. Improvements in the customer experience and profitability should follow if effective recommendations are forthcoming. Providing a framework which identifies a best method to perform initial troubleshooting will decrease the time that the equipment is not working.

Coincidental or collateral benefits were also anticipated to be discovered in the form of improved methods used by Technical Support Specialists. For instance, this provides the opportunity to improve troubleshooting responses associated with these newly discovered failures and causes that will aid in developing guides for Technical Support Specialist. FSRs (Field Service Representatives) and Technical Installation

Specialists (TIS) may be able to avoid repeat travel to sites. Recommendations for customer training could be included but will not be emphasized except as outlined as TSS's responses to customers. Newly installed instruments have a higher call in rate according to casual observations and it is suspected that customer training for new installations is a potential root cause so improved responses may reduce call rates for all customers but especially new customers.

These additional recommendations may include changing intervals for particular maintenance tasks, changing troubleshooting methods, possibly revising parts used on the instrument and others. By using summaries of trends noted about maintenance, repairs, and other customer contacts it is hoped that we can specify a variety of future improvements in maintenance approaches. However recommended changes in repair technique and modifications to the instrument are improvements that will remain out of scope of this paper. While observations may be provided and incidental recommendations may be forthcoming they will not be the focus of this thesis. These collateral benefits may be pursued as a follow up project.

Baseline service costs for the analyzer have been established to track long term effectiveness for possible future study but this is outside of the scope of this thesis. If this process is useful, reductions in failures will occur, but the measurements of failure rates are outside of the scope of this paper. Likewise the Mean Time Between Failures and Mean Time Between Service Calls will increase if capturing tacit knowledge is a productive exercise. If measurement of these service processes were to be pursued one additional data set to be gathered includes information to measure the average age of instruments at the start and at the end of the study. This would need to be collected since aging instruments may have greater failures. Those numbers will be available later if needed.

C. Knowledge gap

As noted above the Food and Drug Administration (FDA) has recently increased the emphasis for approved documentation for telephone responses from technical support. This creates a need for more formalized answers that must go through an internal approval process. So there is an immediate need to be addressed. This need can be dealt with in a manner which is outlined in a similar case study published by Bobrow, Cheslow and Whalen's (2002) on Community Knowledge Sharing in Practice: The Eureka Story. This is a case study of how an organization's most valuable asset of intellectual capital is not limited to information contained in official documents but may also evolve to utilize best tactics in problem solving in a corporate setting.

Risk based maintenance intervals widely adopted by end users and third party service providers incorporate ongoing data review for most efficient utilization of resources but these intervals are rarely shifted by the manufacturer. Review of failures could lead to adjustments in specific tasks. Standardization is not present for risk based assessment and few methods are available. The methods that are available emphasize routine maintenance interval adjustment rather than specifically adjusting responses to failures. This updated review may identify variations in processes that occur with subsequent versions of the equipment and specify changes in intervals or adjustments to troubleshooting responses. I hope to identify task based changes that consider the interval but also more importantly focus on specific tasks in the scope of recommended changes. In a sense this paper is expanding the realm of risk based analysis which has always included checking for failures and adjusting maintenance intervals to add a response which focuses on changing responses to specific tasks associated with failures. It minimizes the time equipment is not operating by providing best first responses to failures.

Previous service support analysis processes performed at Roche have considered the service process to begin with the FSR dispatch. This process of service analysis will be different in that it tries to target resolution and cost avoidance before the dispatch occurs. This process will start with first contact by the customer and follow through to dispatch of field personnel to establish root cause of failures. It could be expanded to include data reviewed by design engineering and quality personnel who investigate root causes of failures but those tasks are considered outside the scope of this study..

CHAPTER TWO: BACKGROUND

History and Related Research

These analyzers are desktop size and used as “point of care” devices. They are used primarily by respiratory therapy and laboratory personnel to analyze a variety of parameters which always includes blood gas parameters such as pH (a measure of acidity), pO2 (partial pressure of oxygen) and pCO2 (partial pressure of carbon dioxide) but depending on the configuration may also be used to analyze other parameters. The OMNI Modular includes 9 different model configurations. The OMNI S includes 6 different configurations. These additional parameters include tHb (total hemoglobin) and hemoglobin derivatives, electrolytes including iCa (ionized calcium), Na (sodium), Cl (chloride), K (potassium), SO2 (functional oxygen saturation), bilirubin, Hct (hematocrit) and metabolites which include glucose, lactate and BUN (Blood Urea Nitrogen also commonly known as urea).

Variable risk based maintenance has been outlined and recommended by many. (Kendall, 1993; Donawa, 1995; Brewin D, 2001; Ridgway, 2001; Ridgway, 2003) Routine maintenance intervals performed on equipment have been increasingly based on risk instead of a predefined interval. These varying intervals, generally based on device type, were accepted by JCAHO standards around the mid 1990s. (Joint Commission for the Accreditation of Healthcare Organizations, 2004)

A risk assessment approach has the following key steps although multiple variations are also possible:

- “Construct medical device inventory
- Determine potential failures/degradations of each device
- Rank likelihood of potential failures/degradations occurring based on information available
- Rank potential consequence of each occurrence considering such factors as - patient safety - personnel safety - environmental damage etc.
- Determine acceptability of risk, based on position in a risk matrix
- Assess reduction in risk associated with inspection as compared with current policies for maintenance”. (Electronic and Bio Medical Engineering, 2004)

This research will focus on the second, third and fourth step - Determine potential failures/degradations of each device, ranking likelihood of potential failures and ranking the potential consequences of each occurrence. Decisions about interval changes have been based on professional judgment and it appears that it has resulted in an overall benefit of allowing maintenance efforts to be focused on high risk equipment, reducing costs, and increasing patient safety. Unfortunately, the adjustments to these maintenance intervals have never been validated with statistical method of known significance. Data used to assess are typically a small grouping from the end user facilities about repair rates and a classification for risk to the patient, usage and support needs.

Many questions remain about the validity of risk assessment. Has mean time between failures increased after adjustments to process or intervals? Does reduced frequency of a certain maintenance procedure negatively effect performance? Do instrument failure rates fall when maintenance intervals are adjusted? These and many other questions need to be answered. This paper establishes a baseline of classifications and will verify which types of failures are occurring for a particular instrument by classifying ‘phone close’ failures. Using a single manufacturer with an overview of hundreds of instruments provides the sample size and details needed to perform an original assessment of failure rates. Focus on particular subsets of technician performance (in this case Technical Support Specialist’s responses) requires the availability of data to validate changes enacted that are more readily available from a single manufacturer for a particular device type or model.

Review of these records will also check for common errors created by users, some of which may be classified as operator error. “Although adverse drug events have been extensively evaluated by computer-based surveillance, medical device errors have no comparable surveillance techniques.” (Samore, 2004, p. 325) This paper also asks if “computer-based surveillance can reliably identify medical device-related hazards (no known harm to patient) and adverse medical device events (AMDE) are events where patient experienced harm.” (Samore, 2004, p. 325) He compares alternative methods of detection of device related problems. He found that “Few of these events were detected by more than 1 surveillance method, giving an overall incidence of AMDE detected by at least one of these methods of 83.7 per 1000... The positive predictive value of computer flags for detecting device-related hazards and AMDE ranged for 0% to 38%. More intensive surveillance methods yielded higher rate of medical device problems than found with traditional voluntary reporting, with little overlap between methods. Several detection methods had low efficiency in detecting AMDE. The high rate of AMDE suggests that AMDE are an important patient safety issue, but additional research is necessary to identify optimal AMDE detection strategies. (Samore, 2004, p. 326)

In an editorial comment on the Samore article Small (2004) states, "Devices are ubiquitous in the delivery of modern health care. Diagnostics and therapeutics rely on a bewildering, constantly changing array of devices used to monitor and treat patients. Trends in device evolution include increasing complexity and autonomy of operation, device-device interactions, miniaturization, and integration with information technology. Managing risk associated with devices has thus long been a central concern of policy makers, manufacturers, and those providing health care. . . . A growing dependence on devices, their complexity, and their influence on human and task performance therefore place device use at the heart of the patient safety question…Understanding about the epidemiology and roles of devices in medical harms and hazards has lagged behind advances in other areas of safety concerns such as medications". (Small, 2004, p. 367)

Current Practice or Understanding

Some authors have identified degrees of tacitness that range from explicit to deeply ingrained tacit skills. The list below is shown in order of how expressible they are or as they call it from the highest degree of tacitness down to the lowest.

A. Deeply ingrained tacit skills
B. Tacit skills that can be imperfectly articulated
C. Tacit skills that can be articulated
D. Explicit skills. (Ambrosini and Bowman, 2001, p. 816)

The current practice used in remedying failures utilizes all four degrees of tacitness. The middle two, B. Tacit skills that can be imperfectly articulated and C. Tacit skill that can be articulated, may with some extrapolation and study, serve as a source of skills that can be delineated and shared in standardized formats with some work to extract. We will focus on this range of skills. The other two skills listed above A. Deeply ingrained tacit skills, are briefly defined as not expressed or shared and D. Explicit skills, are those that are clearly understood and expressible.

Reference, Instructions for Use, and Service manuals have similar formats for main troubleshooting sections and varying levels of operating and repair instructions are provided in each. These documents are available for review. The troubleshooting chapters of these manuals for the OMNI S and OMNI Modular contain lists of failures that are presented to the user as software codes or error messages on the instrument with varying levels of thoroughness of the response. In these manuals, the failures identified in the trouble shooting guide frequently have in their final step a message directing the customer or service engineer to “call technical support”. Limited documentation has been formally presented that covers the responses to these troubleshooting tips beyond the point that directs the end user to “call technical support”. The more developed OMNI Modular has these failure messages from the analyzer listed and an additional more useful troubleshooting guide based on customer complaints but it has not been updated recently. Some basic troubleshooting guides have been developed in the past to assist with the analysis of problems primarily for the older OMNI Modular analyzer. Failure review has resulted in the engineering evolution from the previous OMNI Modular analyzer to the new version of OMNI S. Many improvements are present but the revisions have created an analyzer that does not have particular solutions to the innovations that make it distinct from the similar previous model for these “call technical support” directed issues.

While one section of the analyzer manual for the OMNI Modular is dedicated to troubleshooting, there are also a wide collection of meeting minutes, emails, and previous troubleshooting guides developed but not considered. A central updated consolidated source is not present nor has an attempt been made to incorporate “lessons learned” from service software log entries, interviews from technicians or from other sources of first hand experience. Unexpected failures occur that cannot be anticipated by engineering and only surface when the instrument is in the field. An updated list of actions for Technical Support Specialist is nonexistent for the OMNI S. For the OMNI S, data are collected but have not been analyzed or not specifically reviewed to update existing documentation to create new material for use by Technical Support Specialists.

Research Questions

This is an investigation that considers the problem of how technical support can best respond to service requests for the OMNI analyzer. This task is broken down into two component parts. The research questions involved are “What are indicators of device failure reported in technical support calls?” and then “What factors contribute to user reported device failures identified by callers to technical support?”

Intended Project

The purpose of this project was to define a process that explores how to uncover hidden knowledge. In particular we focused on how to make service on equipment more efficient by finding what solutions veteran technicians used and then after we discovered those causes of failures and effective responses we captured the problems, causes and resolving processes in detail in writing. This included defining the failures and listing what caused those failures. This process explored the use of both interviews and review of existing unorganized, unclassified information from documented cases in service software and ideas pulled from non-validated informal sources. The final practical goal was to allow future responses for service of these products to be more precise and dependable and provide a foundation for a practical troubleshooting guide. The more generalizable goal was to define and assess the process used to extricate the knowledge from the organization.

CHAPTER THREE: METHODS

Classification of the Method

Applied Research

This project utilized a model classified as applied informatics research. "It is work performed to gain the understanding needed to meet a particular need; it is often called problem-oriented research." (Fuller and Messerschmitt et. al., 2000, p. 27) It involves mining of large datasets to uncover hidden phenomena and discovering functional and causal relationships and emergent behaviors across a wide range of phenomena.

Action Research

This process has also been categorized as action research since it seeks collaboration by the participants (Marshall and Rossman, 1999, p. 5). The role of researcher and participant overlapped. The interview method involved both participation and observation. It is a heuristic method. Participation is unpreventable since the interviewer is also involved first hand in the experience of day to day work. It was necessary for a veteran participant to be involved in the refinement of the data. Observation was also involved during interviews while systematic recording of comments of responses from the Technical Support Specialists presented information about a complex process. The interviewing could be characterized as focused questions. The interviews were conducted multiple times to verify insights and opinions recorded.

A Confirmed and Reviewed Process

The review of documents supplemented and framed the interview observations. The documents were analyzed for content. The analysis of telephone close cases used to classify descriptions in to their initial categories was performed with confirmation from at least one interviewee. When information from documents was included it was used to supplement existing frameworks. Discoveries were included in the list of problems and causes. During the interview, the observations from that information gathering became an integral part of the next step in the process.

A Qualitative Investigative Process

This is a qualitative investigative process to explore ideas to increase reliability and decrease service cost. Specifically it is focused on reviewing failures and existing maintenance for the Roche OMNI Blood Gas Analyzer Series. Emphasis was placed on detailed review of the effectiveness of Technical Support Specialist's (TSS) telephone contact with the customer to resolve problems and comparing them to Field Service Representative's (FSR) methods. They were also compared to a variety written material.

Instrument service diagnosis utilized a detailed case review which relies on free text entries in a notes field that require an informed reader to decipher. Case titles are searchable for key words but text entry involving identification of causes and solutions is not available for review using the older version of service software.

Additional codes are available, including one that is set aside for designating these calls as 'phone close' which indicates that the FSR was able to close the calls by telephone instead of traveling to the site. These calls were targeted in hopes of identifying key processes missed by the TSS who are the primary telephone support personnel

During the process of this study, a new version of Clarify called PRISMA was placed into use to log service data. This is the software used to track service calls, Both systems have read access and were available for review during the study. Both systems have the ability to print text of cases. Data collection is currently pulled using Microsoft Access and there are also reports from the software itself. Some modification to the coding and classification of cases has been altered during this software conversion, but the history remained for all analyzers and the free text entries were not altered at any time.

Design

Introduction

This qualitative "research takes place in the natural setting, employs multiple methods of data collection, is emergent rather than prefigured, is based on the interpretations of the researcher, …and employs a strategy of inquiry" (Creswell, 2002, p. 205). A systematic inquiry was aimed at the question, "How can Technical Support Specialists best respond to service requests for the OMNI analyzer?" This was broken down into two more directly answerable questions for purposes of this research. "What are indicators of device failure reported in technical support calls?" and then "What factors contribute to user reported device failures identified by callers to technical support?"

Setting and Subjects

The setting was at Roche Diagnostics located in Indianapolis, IN which provides service throughout the United States. Although it is widely known by all parties involved in the research process I am informing the readers that I am an employee of Roche Diagnostics, the company that manufactures the instrument being investigated. I believe that I remained objective during the investigation. Some influences that were unanticipated came during the edits of the text inserted from unapproved notes about the analyzer. Since I am so closely intertwined in my daily work activities working on the analyzers and with the Technical Support Specialists I had developed some preconceived notions about how instrument performance could be improved. See notes in the Discussion under Internal Validity about personal bias for an extended discussion.

Four Technical Support Specialists were interviewed. Individual technician names were not used except as acknowledgement for the paper after approval was garnered from the technician. Names associated with raw data changes were not entered but their comments were tracked with a color coding scheme. When two techs made comments in the same line, two colors were used. Each technician had a unique color associated with the comments that were made.

Four Methods for Gathering Information

The methods employed include "four methods for gathering information; (a) participation in the setting, (b) direct observation, (c) in-depth interviewing and (d) analyzing documents and material culture." (Marshall and Rossman, 1999, p. 105) This information gathering method emphasized both the (c) In-depth interviewing and (d) analyzing documents and material culture techniques, which were the primary data sources.

a. Activity on the telephones by primary researcher interacting with customers and Technical Support Specialists (TSS) takes place daily. Incidental anecdotal accounts will have some influence. By 'incidental anecdotal accounts' I mean, comments not captured during an interview or data review but espoused during informal encounters during the day with other technicians or direct conversations with customers when the interviewer was involved on the telephones to resolve issues.

b. Some observations occurred from interactions with technicians during the day in the work setting. These were frequently the result of direct inquiries about problems or indirect observations when working side by side during the period when we were gathering information. Some observations were recorded in section meetings where Technical Support Specialists share ideas.

c. In-depth interviews were performed with TSS with greater than 3 years experience. These technicians have journeyman level experience with instrument repair. See notes on the interview techniques outlined below in the section titled Overview of Specific Interview Methods. They are recruited by invitation to participate by the investigator. There was no staff turnover during the study.

The information below from Ambrosini and Bowman is shown in order to explain the source of the process used and to acknowledge their work which influenced this review method. For a detailed explanation about tacit knowledge see the appendix. They explain tacitness as being presented in different levels and this list is shown from those skills that are hardest to articulate to those that are most explicitly stated.

1. Deeply ingrained tacit skills
2. Tacit skills that can be imperfectly articulated
3. Tacit skills that can be articulated
4. Explicit skills.

Ambrosini and Bowman focus on two types of knowledge when trying to articulate previously concealed information. One is the tacit skill that can be imperfectly articulated and the other is tacit skills that can be articulated.

In order to elicit the skills from the TSS, they suggest a self interview technique called Self-Q which is a non-directive technique. They also recommend semi-structured story telling sessions. These techniques had the advantage of lowering the participant’s resistance to respond since people are not practiced in defending against questions that they ask themselves. The Self-Q technique was modified to allow the interviewees latitude in directing the interviewer to help render vague ideas from the abstract to the concrete. Participants were asked to state what they are – not what they should be doing. The original responses from all interviewees were compiled and used for follow up questioning of TSS. Questions are based on the review of areas of concern noted from data analysis. The interviews were conducted with the goal of identifying best practices that provide successes. They were stopped based on a time limit. The interviewees never reached a saturation point when they could not reveal more indicators of failures or factors contributing to identified indicators. This list of critical skills was targeted from ‘phone close’ cases so that they could then be categorized.

The problems, causes, and known remedies were captured in a step utilizing the troubleshooting guides as initial frameworks. The Service, Operations and Reference manuals have some preexisting concrete knowledge expressed that served as a framework to build on. After verification of the interpretation of the notes, the interviewer and interviewee linked the skills to causes of the failures and formalized the previously unknown procedural knowledge (the ‘how-to skill’ also known as ‘know-how’). This allows the organization to build a link from symptoms to causes and remedies. The goal of the mapping is to find the reasons for the successes. It starts with the success and digs in to find what causes the success until key actions are found.

Since there is limited payback to the organization based on the usefulness of any given skill, an assessment of frequency of the failure was noted during case review. Cases reviewed usually focused on most frequently used skills. For instance, a problem that occurs only once is not likely to return dividends to the institution compared to frequently reported failures but still may be captured based on other factors such as risk to the organization or the potential amount of time that could be saved if the problem reoccurs. Open ended questions involved in the interview were targeted based on potential benefit to the organization. Not all important problems rise to the surface with a simple count of occurrences so latitude in questioning was provided to the interviewer to steer the participants when problems reported as high risk or important by the participants are identified. These corrective actions, when presented in an interview setting were, as much as possible, ranked to ascertain which remedial actions are most likely to resolve problems.

Ambrosini and Bowman suggest that observation and immersion into an organization requires time in the organization so this method was ideal for this investigation. They suggest that there should be a blend of interviewers that are both insiders and outsiders. In this case, only an inside view was presented. The other Technical Support Specialists were used to validate observations of written case history notes when identifying classifications for coding and associated remedies.

d. Analyzing documents and written material provided the majority of the data. This included collecting; minutes from Blood Gas section meetings, telephone log notes from cases, existing troubleshooting guides, customer letters, customer bulletins, tips recorded in emails, Service, Operator and Reference manuals, and multiple reports including inventory and parts usage.

The only source of data for Field Service Representatives cases included reviewing written documentation of case notes from a service software system called Clarify (also known as PRISMA) for a one year period. The in-depth review and analysis focused on ‘phone close’ cases from the Clarify service reporting database. These are cases closed by FSRs after telephone contact with the customers that could be considered invalid dispatches. These dispatched calls, which are later closed by telephone, are also commonly referred to as ‘phone close’ by the field service representatives. They were scrutinized in the analysis to see if these calls provide key information about how call handling could be improved.

PRISMA is the current service tracking software used for incoming service calls to the telephone center and field service work on the analyzers. It is used by Technical Support Specialists (TSS) who provide telephone support and Field Support Representatives (FSR) who repair the instruments to enter information about customer and instrument interactions. TSS capture data during and directly after each telephone call during telephone conversations. Additional data are transcribed by in house staff from telephone reports from the FSR. Some comments are added during audits by reviewing personnel or by quality experts who are involved with escalated equipment complaints. The software contains coding for problem, cause, and resolution but was not used. Details about coding limitations are discussed later in the Conclusion section titled ‘Recommendations for Future Practice’.

These calls were closed for a variety of reasons including; a cancellation by the customer because the problem was resolved by some one on site who persisted and resolved the problem, instruments being removed from service, alternate in-house or third party service strategies being attempted, and others. Review of the cases has found that sometimes FSR have provided alternate methods to repair the instrument by their suggestions on the telephone that TSS could have used. In some of the cases, slight variations in troubleshooting were present when compared to the suggestions made by TSS. These were added to the list of causes and remedies used by the TSS when they were discovered. These cases may be used as models to reduce costs in future similar scenarios. The reason for focusing on these cases is that they are closed by telephone by the FSR and might have been closed by the TSS if similar techniques were used. Analyzing these particular ‘phone close’ cases was thought to be more valuable than analyzing a random set of cases since these have the potential to provide information that could alter the way the TSS classify cases and identify causes. They may yield the highest value in refining technique since they contain results where someone in the field has been able to close the case by telephone.

Review of documentation for calls not involved with telephone closes could have but did not comprise additional data input to recognize possible symptoms and causes of identified problems. The OMNI S (also known as the cobas b 221) analyzer has fewer cases to review due to fewer instruments in the field so additional telephone close cases from a second year were also used to help create categories of failures.

This research did not consider warehouse or parts in the warehouse or parts stocked in the field called trunk stock levels. Policies, procedures, and work flow processes, were not included.

Overview of Specific Interview Method Used

The following is based in part on a modified Self-Q technique outlined by Michael Bourdon in Cognitive Maps (1983) which was also referred to by Ambrosini and Bowman (2001). Interview questions are focused based on the indicators and causes found during case review. The interview questions varied slightly depending on the need for follow up but the intent and the framework were the same. These questions provide some examples and illustrate the technique used. There are two interviews although in a sense developing the initial indicators and causes could be viewed as a type of interview. The development of the framework of indicators is considered Phase 1, Developing the Initial Data List for Review. Phase 2, Conducting the Interviews, shows how the process is refined to include focusing the questions. This guided the interview process more directly to identifying specific problems and causes. There were two interviews for each TSS.

To illustrate how the data evolved during the interview the following samples accompany this explanation in the table below. Case numbers have been removed from these examples.

Sample A = Excel Spread Sheet tab labeled - Alpha Sort by Fail Desc
Sample B = Excel Spread Sheet tab labeled - Fail Desc with Changed Indicatr
Sample C = Excel Spread Sheet tab labeled - New Desc and New Root Causes

Table 1. Sample Case List Review Used for Interviews

Sect #	OMNI Problem Codes Chapter - page number from Operator Manual	Case #	Date	Model	Description (Root Cause or remedy in parenthesis)
11.2.4	BG not calibrated 11-28	xxx	1/1/2005	OM6	pO2 not calibrated (Had customer clean electrode and run protein)
11.2.4	BG not calibrated 11-28	xxx	3/3/2005	OM3	repo not Ok for O2 and No sample detected for pH - possible block (fixed with Jun and Ref electrode replacement)
11.4.1	Calc 3 11-29	xxx	1/1/2005	OM6	Calc 3 for Calibration (DEFECTIVE REFERENCE/JUNCTION ELECTRODES SOLUTION, CUSTOMER REPLACED ELECTRODES)
11.4.1	Calc 3 11-29	xxx	2/1/2005	OM9	Calc 3 for Na and Ca Measurements (clean salt bridges on bottle compartment and reference bottles)
	COOX LEAKING OR BLOCKED - NEW CATEGORY	xxx	3/23/2005	OM6	tHb cartridge possible clot and leak (customer replaced the THB cartridge)
	Hardware Failure - "Unknown Symptom"	xxx	2/1/2005	OM3	Broken SD cartridge (ORDERED SD CARTRIDGE FOR CUSTOMER INSTALLATION)
	Printer problems	xxx	3/21/2005	OM3	Printer will not advance with print command (RESET ANALYZER)
11.1.46	SD Temp. Error 11-15	xxx	1/1/2005	OM6	SD Temp Error (reboot)
11.1.46	SD Temp. Error 11-15	xxx	3/14/2005	OM1	SD Temp Error (RELOAD SOFTWARE)
	Service Replaceable Part	xxx	3/11/2005	OM6	Reagent Door not closing well (Broken top cover - SHIPPED THE CUSTOMER A NEW TOP COVER)
11.2.12	Software Lockup (analyzer) 11-23	xxx	3/11/2005	OM3	Software lockup/ AQC failure/ Fluidics and cal failure - reboot (Had customer replace SD cartridge, bubble trap and by-pass nipple. No change. Customer now reports FMS volume errors. Had customer replace FMS tubes)
11.2.17	Wrong QC Measurement Values 11-25	xxx	1/1/2005	OM3	All COOX parameters fail except SulfHb (DEFECTIVE THB CARTRIDGE, SOLUTION; INSTRUCTED CUSTOMER TO CHANGE THE CARTRIDGE, CALIBRATE AND RUN QC) Note follow up steps should be included e.g. change electrode AND
11.2.17	Wrong QC Measurement Values 11-25	xxx	1/1/2005	OM1	QC on L1 is high / trending high on PO2 (warranty replacement electrode sent to customer for customer installation. Operational)
11.2.17	Wrong QC Measurement Values 11-25	xxx	2/1/2005	OM3	COOX QC failure (CUVETTES ARE STAINING CAUSING THE RESULTS TO GO HIGH - SOLUTION; INCREASE CLEANING TIME AFTER EVERY 5 SAMPLES)
11.2.17	Wrong QC Measurement Values 11-25	xxx	2/1/2005	OM6	COHB control; recovery (Notes from associated Child case show they troubleshot PO2 QC results Solution; Ordered new PO2 electrode.
11.2.17	Wrong QC Measurement Values 11-25	xxx	2/1/2005	OM6	pH QC low L1 (FLUSH REFERENCE ELECTRODE AND PERFORM SYSTEM CALIBRATION. CUSTOMER RAN QC)
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/1/2005	OM3	AutoQC Sampling Problem (customer had taken care of the problem)
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/5/2005	OM6	PCO2 QC High (CUSTOMER RESOLVED THE ISSUE. THEY RECALIBRATED AND RAN CONTROLS)
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/7/2005	OM3	QC Sampling Problem/ PO2 QC High- dashes for COOX (BAD PERIPUMP TUBING. SOLUTION; HAD CUSTOMER REPLACE PERIPUMP TUBING)
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/16/2005	OM3	NEW QC Lots pO2 high (Root cause was QC not setup as aqueous - sample type was blood)
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/17/2005	OM3	Derivatives are out - Hemolyzer may be defective (DEFECTIVE CUVETTE - SOLUTION; REMOVE AND REINSTALL THE COOX CUVETTE. RAN CALIBRATIONS X2 WITH NO DEFECT NOTED.
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/22/2005	OM6	AQC Sampling Problem/pO2 QC High - (No problem found. Spoke with customer over telephone and problem no longer existed)
11.2.17	Wrong QC Measurement Values 11-25	xxx	3/11/2005	OM6	pO2 recovers high through AQC Module only -(Fix Removed glass from sample line)
	Values added in Red were required to be added to the original troubleshooting guide during initial classification				This will be what the raw data looks like when presented to the technicians at the beginning of the first interview

Sample A

Sect #	OMNI Problem Codes Chapter – page number from Operator Manual	Case #	Date	Model	Description (Root Cause or remedy in parenthesis)
11.2.4	BG not calibrated 11-28	xxx	1/10/2005	OM6	pO2 not calibrated (Had customer clean electrode and run protein)
11.2.4	BG not calibrated 11-28	xxx	3/3/2005	OM3	repo not Ok for O2 and No sample detected for pH - possible block (fixed with Jun and Ref electrode replacement)
11.4.1	BG not Calibrated - Calc 3 11-29	xxx	1/1/2005	OM6	Calc 3 for Calibration (DEFECTIVE REFERENCE/JUNCTION ELECTRODES SOLUTION, CUSTOMER REPLACED ELECTRODES)
11.4.1	ISE not calibrated Calc 3 11-29	xxx	2/1/2005	OM9	Calc 3 for Na and Ca Measurements (clean salt bridges on bottle compartment and reference bottles)
	COOX LEAKING OR BLOCKED -	xxx	3/23/2005	OM6	tHb cartridge possible clot and leak (customer replaced the THB cartridge)
	SD Cartridge - Hardware Failure - Unknown Symptom	xxx	2/1/2005	OM3	Broken SD cartridge (ORDERED SD CARTRIDGE FOR CUSTOMER INSTALLATION)
	Printer problems	xxx	3/21/2005	OM3	Printer will not advance with print command (RESET ANALYZER)
11.1.46	SD Temp. Error 11-15	xxx	1/1/2005	OM6	SD Temp Error (reboot)
11.1.46	SD Temp. Error 11-15	xxx	3/14/2005	OM1	SD Temp Error (RELOAD SOFTWARE)
	Reagent Door not closing - Service Replaceable Part	xxx	3/11/2005	OM6	Reagent Door not closing well (Broken top cover - SHIPPED THE CUSTOMER A NEW TOP COVER)
11.2.12	Software Lockup (analyzer) 11-23	xxx	3/11/2005	OM3	Software lockup/ AQC failure/ Fluidics and cal failure - reboot (Had customer replace SD cartridge, bubble trap and by-pass nipple. No change. Customer now reports FMS volume errors. Had customer replace FMS tubes)
11.2.17	QC Measurement AQC Sampling Error 11-25	xxx	3/1/2005	OM3	AutoQC Sampling Problem (customer had taken care of the problem)
11.2.17	QC Measurement Values BG 11-25	xxx	1/1/2005	OM1	QC on L1 is high / trending high on PO2 (warranty replacement electrode sent to customer for customer installation. Operational)
11.2.17	QC Measurement Values BG 11-25	xxx	2/1/2005	OM6	pH QC low L1 (FLUSH REFERENCE ELECTRODE AND PERFORM SYSTEM CALIBRATION. CUSTOMER RAN QC)
11.2.17	QC Measurement Values BG 11-25	xxx	3/5/2005	OM6	PCO2 QC High (CUSTOMER RESOLVED THE ISSUE. THEY RECALIBRATED AND RAN CONTROLS)
11.2.17	QC Measurement Values BG 11-25	xxx	3/7/2005	OM3	QC Sampling Problem/ PO2 QC High- dashes for COOX (BAD PERIPUMP TUBING. SOLUTION, HAD CUSTOMER REPLACE PERIPUMP TUBING)
11.2.17	QC Measurement Values BG 11-25	xxx	3/16/2005	OM3	NEW QC Lots pO2 high (Root cause was QC not setup as aqueous - sample type was blood)
11.2.17	QC Measurement Values BG 11-25	xxx	3/20/2005	OM6	AQC Sampling Problem/pO2 QC High - (No problem found. Spoke with customer over telephone and problem no longer existed)
11.2.17	QC Measurement Values BG 11-25	xxx	3/31/2005	OM6	pO2 recovers high through AQC Module only -(Fix Removed glass from sample line)
11.2.17	QC Measurement Values COOX 11-25	xxx	1/1/2005	OM3	All COOX parameters fail except SulfHb (DEFECTIVE THB CARTRIDGE, SOLUTION, INSTRUCTED CUSTOMER TO CHANGE THE CARTRIDGE, CALIBRATE AND RUN QC) Note follow up steps should be included e.g.
11.2.17	QC Measurement Values COOX 11-25	xxx	2/1/2005	OM3	COOX QC failure (CUVETTES ARE STAINING CAUSING THE RESULTS TO GO HIGH - SOLUTION; INCREASE CLEANING TIME AFTER EVERY 5 SAMPLES)
11.2.17	QC Measurement Values COOX 11-25	xxx	2/1/2005	OM6	COHB control, recovery (Notes from associated Child case show they troubleshot PO2 QC results Solution, Ordered new PO2 electrode
11.2.17	QC Measurement Values COOX 11-25	xxx	3/17/2005	OM3	Derivatives are out - Hemolyzer may be defective (DEFECTIVE CUVETTE - SOLUTION; REMOVE AND REINSTALL THE COOX CUVETTE. RAN CALIBRATIONS X2 WITH NO DEFECT NOTED
	unknown symptom - This comment to be added for illustration purposes???				
	Values changed in Red required modification. These examples represent category refinements provided by the technicians.				These indicators are not all rearranged into alphabetical order on this list for continuity of showing the changes but would be sorted and listed alphabetically as demonstrated in the QC Measurement indicators
	Please also note that this documentation is an example of what the data will look like after the first interview is completed				

Sample B

Sect #	OMNI Problem Codes Chapter – page number from Operator Manual	Case #	Date	Model	Description (Root Cause or remedy in parenthesis)
11.2.4	BG not calibrated 11-20	xxx	1/10/2006	OM6	pO2 not calibrated (Had customer clean electrode and run protein)
11.2.4	BG not calibrated 11-20	xxx	3/2/2005	OM3	repro not Ok for O2 and No sample detected for pH - possible block (fixed with Jun and Ref electrode replacement)
11.4.1	BG not Calibrated - Calc 3 11-29	xxx	1/1/2005	OM6	Calc 3 for Calibration (DEFECTIVE REFERENCE/JUNCTION ELECTRODES SOLUTION; CUSTOMER REPLACED ELECTRODES.)
11.4.1	ISE not calibrated Calc 3 11-29	xxx	2/1/2005	OM9	Calc 3 for Na and Ca Measurements (clean salt bridges in bottle compartment and reference bottles)
	COOX LEAKING OR BLOCKED -	xxx	3/22/2005	OM6	tHb cartridge possible clot and leak (customer replaced the THB cartridge)
	SD Cartridge - Hardware Failure - Unknown Symptom	xxx	2/1/2005	OM3	Broken SD cartridge (ORDERED SD CARTRIDGE FOR CUSTOMER INSTALLATION)
	Printer problems	xxx	3/21/2005	OM3	Printer will not advance with print command (RESET ANALYZER)
11.1.46	SD Temp. Error 11-15	xxx	1/1/2005	OM6	SD Temp Error (reboot)
11.1.46	SD Temp. Error 11-15	xxx	3/14/2005	OM1	SD Temp Error (RELOAD SOFTWARE)
	Reagent Door not closing - Service Replaceable Part	xxx	3/11/2005	OM6	Reagent Door not closing well (Broken top cover - SHIPPED THE CUSTOMER A NEW TOP COVER)
11.2.12	Software Lockup (analyzer) 11-23	xxx	3/31/2005	OM3	Software lockup/ AQC failure/ Fluidics and cal failure - reboot (Had customer replace SD cartridge, bubble trap and by-pass nipple. No change. Customer now reports FMS volume errors. Had customer replace FMS tubes)
11.2.17	QC Measurement AQC Sampling Error 11-25	xxx	3/1/2005	OM3	AutoQC Sampling Problem (customer had taken care of the problem)
11.2.17	QC Measurement Values BG 11-25	xxx	1/1/2005	OM 1	QC on L1 is high / trending high on PO2 (warranty replacement electrode sent to customer for customer installation. Operational)
11.2.17	QC Measurement Values BG 11-25	xxx	2/1/2005	OM6	pH QC low L1 (FLUSH REFERENCE ELECTRODE AND PERFORM SYSTEM CALIBRATION. CUSTOMER RAN QC)
11.2.17	QC Measurement Values BG 11-25	xxx	3/5/2006	OM6	PCO2 QC High (CUSTOMER RESOLVED THE ISSUE. THEY RECALIBRATED AND RAN CONTROLS)
11.2.17	QC Measurement Values BG 11-25	xxx	3/7/2006	OM3	QC Sampling Problem/ PO2 QC High- dashes for COOX (BAD PERIPUMP TUBING. SOLUTION; HAD CUSTOMER REPLACE PERIPUMP TUBING)
11.2.17	QC Measurement Values BG 11-25	xxx	3/16/2005	OM3	NEW QC Lots pO2 high (Root cause was QC not setup as aqueous - sample type was blood)
11.2.17	QC Measurement Values BG 11-25	xxx	3/20/2005	OM6	AQC Sampling Problems/pO2 QC High - (No problem found. Spoke with customer over telephone and problem no longer existed)
11.2.17	QC Measurement Values BG 11-25	xxx	3/31/2005	OM6	pO2 recovers high through AQC Module only -(Fix Removed glass from sample line)
11.2.17	QC Measurement Values COOX 11-25	xxx	1/1/2005	OM3	All COOX parameters fail except SulfHb (DEFECTIVE THB CARTRIDGE, SOLUTION; INSTRUCTED CUSTOMER TO CHANGE THB CARTRIDGE, CALIBRATE AND RUN QC) Note follow up steps should be included e.g
11.2.17	QC Measurement Values COOX 11-25	xxx	2/1/2005	OM3	COOX QC failure (CUVETTES ARE STAINING CAUSING THE RESULTS TO GO HIGH - SOLUTION; INCREASE CLEANING TIME AFTER EVERY 5 SAMPLES)
11.2.17	QC Measurement Values COOX 11-25	xxx	2/1/2005	OM6	COHB control, recovery (Notes from associated Child case show they troubleshot PO2 QC results Solution, Ordered new PO2 electrode
11.2.17	QC Measurement Values COOX 11-25	xxx	3/17/2006	OM3	Derivatives are out - Hemolyzer may be defective (DEFECTIVE CUVETTE - SOLUTION; REMOVE AND REINSTALL THE COOX CUVETTE. RAN CALIBRATIONS X2 WITH NO DEFECT NOTED
	unknown symptom - This comment to be added for illustration purposes???				

Values changed in Red required modification - These examples represent category refinements provided by the technicians. These indicators are not all rearranged into alphabetical order on this list for continuity of observing the changes but would be sorted and listed alphabetically as demonstrated in the QC Measurement indicators.
Please also note that this documentation is an example of what the data will look like after the first interview is completed.

Sample C

Phase 1 Developing the Initial Data List for Review

To summarize briefly the steps to prepare the initial data list for review include

1. Pull the case data from service software from 'phone close' cases

2. Review data, categorize failures, and verify content with veteran technician and interviewer

3. List summary of failures and root causes and actions from data review in spread sheet with newly created categories highlighted.

Outcome of Phase 1 - A summary of 'phone close' cases. (See Table 1 Sample A)

'Phone close' cases yielded a high value in refining technique since they contain results where some one in the field has been able to close the case by telephone. Several undocumented solutions emerged to be captured and thus moved from the realm of tacit knowledge to documentation.

Data review of existing telephone close cases generated a list of indicators of failures (also called problems or symptoms) identified by customers and the associated cause identified on each case. These problems are categorized according to existing troubleshooting guide checklists indicators and when necessary new categories were created. The initial categories created were verified by the researcher and another TSS to check that the correct problem is pulled and the correct root cause is identified from each case. See the categorized Sample data which is pulled from the first three months of data for the OMNI Modular in Sample A in Table 1.

Phase 2 Developing the list - Conducting the Interviews

What was done in interview 1?

Interviews were conducted by telephone or in person but face to face interviews were preferred and used when they could be arranged. To initiate the interview process the following statement was used.

> This is the first of two interviews. The focus is on troubleshooting the OMNI Modular and OMNI S (cobas b 221) analyzers. Since you are an expert on the devices, I would like you to explore how technical support can best respond to service requests. This task is broken down into two component parts. They are "What are the indicators of device failure reported in technical support calls?" and then "What factors contribute to user reported device failures identified by callers to technical support?"
>
> I adjusted a list of failures originally pulled from telephone close cases. It may help to think about what questions you ask customers to discover what causes the failures that are reported to us. We will review these problems if you view them as important and focus on them.
>
> You are encouraged to use any documents available and to draw on your experiences to provide these suggestions. Written material may include meeting minutes, telephone log notes from cases, existing troubleshooting guides, customer letters, customer bulletins, tips recorded in emails, Service, Operator and Reference manuals, and any other source you can think of to use.
>
> Previous interviewee's notes were summarized and available to you for this interview when available. Follow up questions may be asked to further determine what causes the success until key actions are identified. For instance I may ask "How do you discover causes regarding this indicator?"

The second interview will verify the concepts identified in the first interview. It will check that I have recorded the indicators and causes identified by you and other techs and make refinements as needed.

Your responses will remain anonymous and your privacy will be respected and protected.

First Interview

1. Summarized case review data is submitted for editing and refining to TSS. (See Table 1 Sample A).

   Questions asked include

   a. "What are the best classifications that we can use to identify the indicators of the failures?"
   b. Exploratory follow up questions were asked such as; "What are the most important aspects we should focus on?" "Would you expand on that idea?", "Should that be added to this category as well?", "Tell me more about this category.", "Is there a better way to capture that idea?", "Is there anything that can be added?", "Do you have any notes in manuals or stand alone documents that would be helpful?", "Any old emails you'd like to share?" (When the indicator classification is complete the result appeared similar to Table 1 Sample B.)
   c. "Please verify that the root causes that you see listed from the cases are likely causes of the failures. Modify these causes as needed by clarifying, adding or removing causes. (See Table 1 Sample B which was the approximate starting point for this part of the discussion and Sample C which was similar to the desired end point.) Some of the same follow up questions as noted in step 1b were asked but some were added such as "Please describe the root cause regarding this failure more succinctly?" and "Please repeat that again so I can write it down."

2. Summary data were sent to the technician to confirm proposed changes along with the original data (See Table 1 Sample A or B which represent the original

data set or the original data set with comments from previous interview and Sample C which represents the data after the interview). Data are collected in the interview by marking up the consolidated list of problems and causes in the spread sheet

3. Additional first round interviews were conducted. Original summarized case review data are presented along with results of the most recent interview from the other tech(s) (See Table 1 Sample A and C). Steps 1 and 2 were repeated for the next technician(s) until all four technicians had been interviewed.

Second Interview

1. Summary data with changes from final first round interviews was sent to technicians to start the second round. (See Table 1 Sample C for an example of changes from the technician's first round of interviews.) The amended list from the first round of interviews is reviewed for correction again. The same questions were asked and data were recorded in much the same way as it was done in the first interview round but the starting point used the summary data from all four first round interviews. Data are once again collected in the interview by marking up the consolidated list of problems and causes in the spread sheet.

2. A summary of changes made in the second round of interviews from that TSS is sent to them to confirm discussed changes along with the summary data obtained after the first round of interviews for comparison. (See Table 1 Sample C which will have evolved to another document with more changes but still be similar).For the final interviews review of revised trouble shooting documents were included.

3. Additional second round interviews are conducted. Original summarized case review data are presented along with results of the most recent interview from other tech(s) (See Table 1 Sample C).

4. Repeat steps 1 and 2 for each technician until all technicians have been interviewed.

This completed the interviews.

The outcome of the first and second round of interviews is a list of the indicators of device failure reported in technical support calls and a list of factors that contribute to the failures reported by users. The outcome lists the previously tacit knowledge presented in a shareable understandable format.

CHAPTER FOUR: DATA ANALYSIS AND RESULTS EVALUATION

Introduction

In order to facilitate current understanding, a review of data submitted by Technical Support Specialists (TSS) and Field Service Representatives (FSR) was conducted. The data were categorized according to the problem reported. The intent of this project focused on enhancing a framework for the practical guides for use by TSS. The focus is the classification of documented failures, capturing failures not previously classified and discovery of new causes for all failures.

Identifying causes of failures or perhaps more correctly the suspected causes were performed. Initially framed by the existing methods of addressing problems in troubleshooting guides, new improved responses and techniques were created. These solutions are focused to enhance TSS responses during the initial customer interaction and focus on tasks that can be performed by the customers with assistance by telephone.

The eventual outcome as a result of the investigation was modifications to that list of causes and failures which led to a change in practices associated with TSS skills. Improving the documentation was an almost inevitable conclusion and actually the final target of this process.

We analyzed the results from asking the two research questions, “What are indicators of device failure reported in technical support calls?” and “What factors contribute to user reported device failures identified by callers to technical support?” This entails a specialized analytic approach called content analysis.

The six phases of analyzing the data and results are “1. Organizing the Data, 2. Generating Categories, Themes and Patterns, 3. Coding the Data, 4. Testing the Emergent Understandings, 5. Searching for Alternative Explanations, and 6. Writing the Report.” (Marshall and Rossman, 1999. p. 152)

1. Organizing the Data

Review of 173 cases from the service record database associated with ‘phone close’ calls was performed. These are the reviewed data from the PRISMA service software database. The indicators of device failure reported in Technical Support calls were classified initially by placement into a spread sheet listing the problems. Problems were sorted by case titles when possible but additional underlying problems resolved or noted within a call or case were also used for classifying data after discussion and review. They were placed into categories from existing documentation or into new categories when they were determined to be outside the existing classifications. Suspected causes were identified on each line beside the problem when possible. Troubleshooting categories were refined as needed to classify these problems.

This initial classification was performed by me (the interviewer) and a veteran Technical Support Specialist volunteer by examining printouts of the cases and listing case numbers, date of incident, model number, problem code, and a summary of the problem. Whenever possible, those categories for failures and causes that match existing troubleshooting categories were used. When they were not matched they were added to the guide as noted in phase 2 Generating Categories, Themes and Patterns, 3. Coding the Data, and 4. Testing the Emergent Understandings. As much as possible data fell into classifications based on problem descriptions in existing troubleshooting outlined in manuals or other documents. Changes occurred when these classifications had to be expanded or when previously undiscovered root causes were ascertained.

Interview data were confirmed by reviewing written summaries presented to the interviewees after the first and second interviews and also clarified in discussions during the interviews. Datum from the first interview is presented linearly as it is recorded and in the same manner it was presented temporally in a continuous flow of conversation. I recorded notes from the conversation as they were presented with no additional organization provided for verification. The interviews were used to organize the data and that organization was also presented and verified. The first interview collects questions and comments about how device failures are reported and what they are. Likewise, causes that contribute to user reported device failures identified by callers to technical support were also recorded. The second interview was used to verify the concepts identified in the first interview.

Samples

Detailed data showing total ‘phone close’ calls by month and by analyzer are available in a spreadsheet were downloaded from the PRISMA database and saved in an Excel spreadsheet for analysis. There were a total of 173 total cases for the OMNI Modular for 2005 and the OMNI S for 2005 and 2006.

2. Generating Categories, Themes and Patterns

Creating additional categories and identifying new causes of failures was required in order to classify problems and causes in both the interviews and in the analysis of data from the computerized database. These additional categories were created and evaluated while observing techniques in use when compared with existing recommended methods. This step of generating categories captured central themes and concepts that are sometimes overlapping and intermingled. The Operator Manual for the OMNI Modular was used since it had the most usable categories for classifications and was the most recently revised. All steps in that document were available to be performed by the operator. The OMNI S (cobas b 221) Service Manual had the richest details and highest level of granularity along with the greatest number of categories so it was selected for the OMNI S. Using these two manuals as a starting point ensures that multiple categories that are known were covered. This list of problem codes from these two manuals were the initial source of error codes that were used to classify indicators of device failure and factors that contribute to user reported device failures. Noting patterns and finding emerging meanings uses both those existing and additional categories that are created by participants during processing. These were added to form a list generated through analysis by the participants.

Different types of tacit knowledge are classified in a coding scheme using the categories of know-*what, know- why and know-how* (Johnson and Lundvall, 2001) which correspond with *problem, cause and remedy* codes that are currently classified by the service software in use at Roche. Unfortunately these codes or categories in the software from Roche are created at a global level and are based on generalizations from failures involving other equipment. Ideally these categories should be available for extricating trends in precise equipment failure but are limited due to the lack of specificity for the analyzers. These categories noted in the software will not be considered because they are arbitrarily assigned by technicians trying to make best matches to inexact classification categories. Text entries by the technicians were considered instead. We are focusing on the specific problems for a model in order to provide concise categories of failures and root causes that are particular to those failures.

Interviews created categories of failures framed around the classifications of the initial indicators provided. Data were grouped and then prioritized as high risk, frequently occurring or important for some other reason. The concepts were ranked for investigation while considering potential consequence of each occurrence including factors such as patient safety, personnel safety or other consequences. This was not a formal algorithm but ranking was performed based on the individual interviewee's input. Priority was frequently given to indicators that are not currently covered by existing documentation. In other words, when tacit knowledge is starting to show, those indicators that are imperfectly articulated or articulated and not incorporated into written documentation merited an extended exploration as we pushed them to the realm of explicit skills.

Troubleshooting categories were revised for easier access. Some new categories were added. For instance Power Fail is a new category. It contains information about commonly asked questions such as Uninterruptible Power Supplies (UPS). This category grew to include other power outages on the instruments. It was difficult to classify since it is often reported as Screen blank, No Touch Screen, Power Supply, etc. Sometimes these categories were renamed but addressed the same problems.

In the interview, linking the indicators, causes and remedies was explored. Causes and remedies were organized within a category of an initial failure indicator. These include indicator categories found during interviews and from the review of telephone close cases. The indicators, causes and remedies that have been identified and prioritized were further explored so that categories could be generated. An exploration of the failures and causes allowed further specific coding. Data were presented utilizing the newly created categories when they were formed.

Meeting minutes were a rich source of troubleshooting tips. These troubleshooting tips came from discussions in regularly scheduled section meeting minutes that had occurred for the two years, 2005 and 2006. Incorporation required a formatting switch from free text notes to a troubleshooting guide format. The metamorphosis to a standardized format required change of style but not content.

Another example of a rich source of information discovered comes in the form of retired documents. A previous collection of published notes were not adopted into the list of approved documents when Roche purchased the company that manufactured the analyzers. These legacy documents were widely known by the technicians who migrated from the company during acquisition.

The largest category included in trended data that was not previously documented or supported by troubleshooting guide was for QC materials measurements failing to test within range.

Ideas Translate During Processing

Sometimes cause or root cause is not known. Over the years practical experience sometimes creates solutions without understanding of what causes the problem. For instance when electrode replacement is necessary, a variety of underlying root causes may be causing deterioration of the membrane or any number of other causes. The root cause is never known. For that reason 'root' cause is rarely used in this analysis. Likewise there are multiple instances in documents that do not specifically discuss the cause. From a practical standpoint it is enough to know what the corrective action is and so many times the cause is not listed separately.

Text entries by the technicians were considered instead of specific codes. Extracting specific problems from free text notes required interpretation. This interpretation was confirmed in interviews so that categories of failures and causes could be classified. Identification and creation of additional categories of new indicators of device failure and new causes of those failures occurred much as expected.

Instances Where No Discovery Was Made

a. In some instances the causes or remedies applied by Field Service Representatives (FSR) were an exact match to those performed by Technical Support Specialists (TSS) but performing the remedy one more time fixed the problem. For example several errors showed symptom 11.1.51 in the OMNI Modular troubleshooting guide which included a "System Error + Number" description. TSS and FSRs both turn the instrument off and back on to remedy. These cases were FSR phone close dispatches that were diagnosed with the same symptom, did not have a positively identified and specifically documented cause but still utilized the same remedy recommended and processed by the TSS. They were not incorporated into the troubleshooting since they were already present. There was no value added from the FSR notes or actions. In these cases the problem was closed because repeating the reboot provided success when performed again by personnel at the site when coached by the FSR. In some instances this process was repeated more than once by the TSS but did not clear the problem.

While these types of cases provide an opportunity to explore what may have been done differently by the TSS, changes to these particular suggested remedies does not seem likely. One suggested difference was amount of time that the instrument was turned off since internal circuitry provides some delay in the time to power off completely. This time off is specifically spelled out in the existing TSS troubleshooting guide so other unknown root causes may be involved. Review of symptoms and causes by Field Service Representatives were superimposed on existing documentation. Several symptoms and causes were discarded because they were already present in the Instructions for Use, Service or Troubleshooting guides.

The result ended in no discovery in spite of several instances of known remedy by the FSR since the TSS already had the same limited list of symptoms, causes and remedies.

b. Another instance where no new causes were discovered within a known problem category is when the TSS failed to perform previously documented recommended actions. An FSR performed a step a TSS should have or could have. These were symptoms with known causes and proven remedies simply not utilized by TSS as they should have been. Since they were also previously known they once again failed to add to the body of knowledge. They were known – they were not hidden or “tacit”, they simply were not used. For example some cases were remedied with electrode replacement that may have been resolved by the TSS if they had pursued all of the suggestions listed for a case. Coaching opportunities to improve TSS behavior which could have been part of the improvement program were not discussed since many failures of this type were from TSS that had left before the study started or were not part of the interview process.

c. Multiple procedures were performed by customers using non-approved processes that resulted in a cancellation. Some corrections discovered in the FSR field corrected “phone close” cases were recognized as not being allowed to be suggested to customers by TSS. They were labeled “Action x Not allowed by current procedures” or “Restricted by Policy - Not available” during initial processing on the Spread Sheet.

Many of these comments became “Dispatch FSR to perform action …x” when incorporated into final recommendations to be processed for Tech Support. Raw data in the spread sheets has flags to indicate these procedures which could not be utilized by TSS but still provided information regarding the cause of a failure and became useful information.

d. Some cancelled dispatches were followed shortly by dispatch cases. It was discovered a service call was actually needed. Quick review of case histories confirmed that the phone close did not actually resolve the problem.

e. Some identified causes on the resolution codes were unrelated to the original problem. For example, in one case a failure of the cooximeter was resolved with replacement of a component not associated with that measurement.
In cases like these, the identified cause could not be used.

f. Another example of a case that could not be used is because of incomplete documentation. One example of this documentation failure involved a Touch Screen Defective complaint. There was no known cause or remedy. Phone close analysis was forced to use a cause of “unknown” and the subsequent Recommended Corrective Actions provided no value since the note from the FSR simply stated “Helped Using Phone”. No additional details were recorded in the case. This occurred far more rarely than anticipated.

g. Some information discovered in meeting minutes was discarded to limit the scope of problems reviewed. Scope limitations had to be imposed to complete the project. Multiple other observations were captured but discarded during the processing of developing the thesis. These are ideas that could be incorporated to tech support documentation eventually. Some of these future refinements were posted in stand alone documents to be published at a later date. Some of the items excluded that were discovered during the meeting minute review include topics such as Laboratory Information System interface notes, non-supported printers, other analyzers not within the scope of this paper and other topics. Some discussion topics were considered to be so integral to daily questions received that they were included. One example is the discussion about College of American Pathologists (CAP) materials which are used for certifying labs, a Roche sold database called electronic Quality Assurance Program (eQAP) and another system called DataCare. In all instances multiple questions are fielded by technicians but with limited official supporting documentation from Roche.

3. Coding the Data

This is the formal representation of analytical thinking. In other words, it is putting the data into the coding scheme for those categories of failure generated above. *Problems (indicators*) *(know-what)* were classified by the end users description in case histories in the software and also identified from the review of documentation. C*auses (diagnosis) (know-why)* are identified when the final *Corrective Actions* (*remedies) (know-how)* are identified. Since many of these cases are resolved, the final remedy was known. Most efficient repair practices were used to link problems and causes. Discoveries linking problems to causes were sometimes proposed without a final known corrective action during interviews as technicians considered potential causes associated with the problems.

Coded data came from machine codes, existing troubleshooting guide failure classifications, or newly identified failures. A specific example can come from a machine initiated diagnostic code or a customer complaint. For instance, a sample error code may be a software generated error based on signals from the machine from a Fluid Mixing System (FMS) displayed on the machine as “FMS error 17” which could then be applied to a general troubleshooting category that comes from a customer complaint about the FMS. FMS 17 does not appear specifically in the troubleshooting guide but is still captured in the FMS troubleshooting in section 11.1.29.

Some categories are built into the PRISMA service tracking software and were available for review in the ‘phone close’ cases. When they were found useful they were utilized. For instance, the hard coding for Operator Error in the software helped identify when no underlying failure was present. Field Support Representatives and Technical Support Specialists have the ability to select this as a problem code in the software. Customer reported problems that may or may not have a particular machine associated failure were also coded through review of the free text area. Interviews recorded suspected problems, causes and remedies that were extracted from phone close case notes.

Summary of the Analysis of Problems, Causes, and Remedies

One hundred seventy three (173) total cases were reviewed. Of those 129 were for the OMNI Modular and 44 were for the OMNI S.

Discoveries found during initial case review

The number of cases reviewed led to discovery of new problem classifications, causes or remedies 14 times for the OMNI Modular and 14 times for the OMNI S. A total of 28 discoveries are documented. These were obvious and required a confirmation from another technician to confirm the discovery but did not require any additional interview to elicit the discovery.

For the OMNI S, two of the causes are specially marked on the data sheet because they represent service replaceable parts and are not Technical Support Specialists (TSS) correctable. For the OMNI Modular, eight causes were specially marked with a similar notation since they also represented Field Service Representatives (FSR) replaceable parts. In total ten cases showed this characteristic for being correctable with intervention from the FSR. They still represent a form of discovery because they identify a root cause that can assist the TSS. These cases are examples of cases that should actually be field closed by FSR who would provide installation as customers are not authorized to install the parts. These discoveries are highlighted in a red color on the data sheets. When they were superimposed on the word processing troubleshooting guides to help verify if they were actual discoveries, a darker blue color and underlining flagged these cases.

Discoveries found during interview and analysis

Interviews and review of data were tracked and mapped. The results of the entire process including phone close review, interviews, and review of data resulted in 213 discoveries for the OMNI S and 340 for the OMNI Modular. A total of 553 discoveries are documented which includes the 28 mentioned above during the initial case review. These discoveries are also distinguished by color in the troubleshooting guides in which they are framed. As mentioned above the discoveries found during initial case review are underlined and in a dark blue color and all other discoveries are highlighted in a light blue color for ease of identification. The initial framework uses typical black print.

These 553 discoveries include new problem classifications, causes and remedies. Multiple discoveries were some times utilized multiple times. If they were a new discovery they were counted in the grand total. For instance the remedy “initialization, adjustment and calibration of the T&D Needle” was repeated for multiple fluidics issues in the OMNI S review. This was repeated 10 times in the count and represents the most repeated corrective action added. Additional symptoms, causes and remedies were repeated but only represent around another 25 discovered additions.

Many of the additions come from a single suggestion to incorporate an old troubleshooting guide that had not been approved. It resulted in 60 additions. It should be noted that these suggestions often contained multiple suggestion and actually would probably result in around 300 additional discoveries if counted separately. These were not included in the count.

In general if an entire document came over with multiple steps or suggestions it was only counted once. Occasionally a document would be dissected and multiple symptoms and causes would result, but for the most part long paragraphs, multiple step processes and inserts of documents were only counted once.

Additions from documents such as meeting minutes provided multiple instances but many of these discoveries were found in more than one place. For instance, they were discussed in the interview and then found in another form of documentation or found in notes written in service manuals.

Some discoveries came from documentation that was rediscovered during the interview process and is now presented in a consolidated location. A customizable mail merge letter to customers is now embedded in the OMNI Modular guide on page 66 is an example of this amalgamation. This document actually represents an approved known objective knowledge but was included because placing it in a document made it easier to locate and thereby more useable or discoverable. Many letters and other such communication devices are archived after a two or three year time period and the most useful ones need to be more readily available.   The individual notes in this and other documents were not counted. It was included because the information about the issue is now easier to find. Another type of document that was discovered that was an authorized document but now is included is procedures known and published only in Technical Support. These Internal Technical Support Communications (ITSC) will eventually all be consolidated into a final permanent document approved for use. These were included because they required a separate monitoring process to keep them alive as they all have an expiration date. It should help keep them in the realm of objective knowledge by making them a part of a more permanent document.

Refinement of Existing Classifications of Failures During Review

Some tacit skills required extra inquiry to be expressed but some remained unmapped. Since these tasks are also expressed in concrete form in service software, the written case notes were also used to analyze what the technicians were doing. While these follow up questions were explained and planned in the interview process it became obvious that some skills and knowledge would remain hidden due to time constraints and other limits.

Coding data provides categories for the previously tacit knowledge. During the process the classifications used evolved.

"Unknown Symptom" – The "Unknown Symptom" category was used when the initial problem was not disclosed. This happened very few times. Symptoms were harder to decipher when a "User Replaceable Part" was designated in the problem description area.

"Unknown Causes" – Occasionally problems resolve without a specific remedy being documented or a description of what caused it. Sometime these cases may be resolved spontaneously by the machine itself because the system continues to automatically clean and calibrate itself. These suspected spontaneous resolutions are most commonly seen for problems that are attributable to fluidics issues that could be resolved with these cleanings and calibration attempts. The infamous reboot, reset, power down, etc. also provides solutions where the root cause is never detected or the cause of the symptom exhibited is never known. These unknown causes are also closely related to "unknown resolution"

"Unknown Resolution" – As data evolved from the spread sheet to be placed into existing troubleshooting guides for comparison the category of "Unknown Resolution" was used. If they were present on the spread sheet, the resolutions were captured in the cause area of the data sheets. Original data sorted on the database only had two areas for logging data for each listed problem code (Symptom code). Each category had a place to record 1) a description of the problem from the case and 2) the cause. When captured, resolutions were added to the cause area.

Many cases were closed without discovering what actually fixed them. Eventually data analysis required interjecting “Unknown Cause” and “Unknown Resolution”. In some instances multiple repairs and multiple components were replaced that may or may not have been involved with the originally diagnosed symptom / problem so the specific cause and resolution remain unknown. This type of case could also sometimes be given this category or code.

All three of these “Unknown” categories above are examples of indeterminate knowledge which occurs when data is insufficient or leads to a dead end. In each case the “Unknown Symptom”, “Unknown Cause”, or “”Unknown Resolution” serves to mark that the idea was discussed and allows the technician and interviewer to move to the next category. Indeterminate knowledge categories are given to ideas when information captured in existing *data is not sufficient to answer the questions* required by the investigation. This is a different form of tacitness in that it masks knowledge by failing to capture it for review since some times, the documentation was incomplete. Reviewing knowledge of any age and using this category, allows the capture of some initial failure classifications although it is possible the root cause or the cause will not be found. Likewise it may allow capture of a resolution when a cause is not known.

Creation of new classifications

Even within existing documentation such as the service manual’s troubleshooting guides inconsistent naming conventions were used for defining what is a problem but the terms were so similar that interchangeability was obvious to users. For example ‘problem’ was also listed as ‘symptom’. In the end classification distinctions used in the analysis were superfluous semantics and the classifications of Problem, Cause, Action, Discussion and Troubleshooting surrounding each topic were adopted throughout the data sheets used for analysis.

This formatting was applied to data superimposed into the OMNI Modular troubleshooting guide to help distinguish discovered verses existing causes. Since this troubleshooting guide had a list of symptoms followed by a list of recommended actions but not necessarily causes it became more difficult to check which causes were discovered or new. In many instances a cause was frequently deciphered from the existing remedies suggested and the format changed to help in analysis. Many troubleshooting categories remain unchanged because phone close cases failed to discover cases with matching descriptions for those problems and comparisons were not initiated. Once again a time constraint prevented overhaul of the entire trouble shooting guide since these were long extensive documents. When a point was identified by TSS as key, the identification of existing causes and remedies was pursued within the troubleshooting guide.

During the interviews, it was suggested that the text of the troubleshooting guide and supplemental suggestions be listed together for easiest use. This required pasting text from the Excel spread sheet into the already published troubleshooting guides. This option was suggested and selected for the OMNI Modular only. Revisions for the cobas b 221 are propagating so frequently from source documents that TSS specific actions referenced particular troubleshooting symptoms listed in the guide and only those 'discovered' additions were printed in a stand alone document that referred back to the published troubleshooting guide.

Multiple references to published text were included for the OMNI Modular so that additional information could be found easily. The existing troubleshooting guide had multiple embedded references listed in parenthesis so these were not removed. Only a few text references were added or corrected. For example a step of an older troubleshooting guide shows "Change PP-Tubing. (See Instructions for Use, Chapter 9, "Maintenance")" to make investigating additional related questions easier to perform. This had to be corrected to reflect the current documentation reference of (See Instructions for Use, Chapter 10. "Maintenance") to reflect the newest version of the manual.

4. Testing Emergent Understandings

The established OMNI Modular troubleshooting guide and the newer OMNI S (cobas b 221) troubleshooting guide used as the original templates served as a nearly comprehensive framework. The cases reviewed required some unique problem descriptions and causes to be created. A more comprehensive search through existing documents was conducted to check for additional problems, causes and resolutions. The discovered coded information was checked against existing documentation such as; Technical Service Bulletins, Customer Letters, Software revision notes, previous versions of troubleshooting guides, Frequently Asked Questions (FAQ) , and Internal Technical Support Communications (ITSC) which had to be incorporated. The review of existing documentation required much more time than originally anticipated.

Multiple changes were made to the documents containing troubleshooting guides and other notes so that it was easier to verify if ideas documented during case review were new or not. For instance some areas were alphabetized so that they could be checked against the list of discovered causes on the spread sheet. Sometimes a list of error codes was combined. e.g. Electrode Status Error Messages: MSS Calibrations Specifics were merged from the original two areas for calibration and polarization. Consolidated list were easier to review when alphabetized.

Some knowledge is only slightly obscured when needed because it was difficult to locate. To aid in the recovery of this knowledge the titles of the symptoms (problem description) now use synonyms to aid in retrieval in the document. This allows quick searches using electronic search function without a match to the exact word. Multiple categories now have alternate titles listed e.g. Power Fails category also shows Power Failures, UPS, PowerVar, Uninterruptible Power Supply, No Display to aid in locating using search functions. This aided the discovery process during data review and should also help future users of the proposed troubleshooting documents which will eventually be produced.

In this phase, evaluation of the plausibility and usefulness of developing understandings was explored. Since some classifications of failures and the related responses are currently in practice, many of the recommendations were variations on known classifications of failures and the related procedures. Review of new problems classification discovered were judged by Technical Support Specialists (TSS). This 'member checking' helped to validate observations and conclusions.

Validation of these suggested classifications and causes were conducted by submitting these recommendations to TSS staff with greater than three years of experience. TSS feedback during the interview process prioritized and edited the focus of subsequent interviews during data acquisition.

Causes and remedies within each symptom are prioritized so that they are listed by likelihood of occurrence. This was evaluated for plausibility by exploring the concepts with the technicians. The prioritization of troubleshooting can be difficult to assess. For instance, a cause of “dirty fluidics line” may be more likely to be resolved by cleaning so it is listed as the first remedy. But sometimes the steps suggested are influenced by cost. If a test is simple to perform and can be done quickly, sometimes it is suggested ahead of a more expensive but more likely cause to minimize cost. For instance an electrode change will be suggested after cleaning the electrode although it is more likely that replacement is necessary.

Multiple ‘problems’ had the same ‘actions’ suggested. For example on the OMNI S the Turn and Dock disk alignments were integral to many fluidics related problems and this action item was repeated multiple times for each problem.

During the Interviews

Questions were directed to Technical Support Specialists (TSS) to understand details of causes. These were not formal interviews. In the rare cases, where a clarification was required to understand the notes posted, a call was placed or a face to face discussion occurred to better understand failures of the device, discover root causes, and provide best responses. These were initiated when reviewers of the written data have unresolved questions about the case.

The interview process found multiple corrections and revisions in both round 1 and 2. One of the primary corrections made was the reclassification of failures to other categories. Round 2 found fewer corrections. A time limit on the interviews constrained the amount of confirmations available to the spread sheet of data text. In the final round of interviews two technicians reviewed the compiled OMNI S (cobas b 221) and two technicians reviewed the OMNI Modular notes.

To prepare for the interviews the documents that included the changes found on the spread sheet had to undergo a development process. In order to ensure duplicates were eliminated text from the Excel spread sheets was superimposed on the troubleshooting guides. Many formatting changes were made to free text when merging meeting minutes into master documents to check for symptoms and causes. Merging of the documents and causes must be done by a veteran equipment specialist in order to maintain content meaning.

In order to make the interview process more efficient the reviewed document had questions embedded to earmark areas that required discussion with the TSS. During interviews the electronic search functions of the word processing or database application was used to aid in locating questions which were all marked with ? a question mark. When they were discovered and resolved the questions were removed and the next was searched for electronically.

5. Searching for Alternative Explanations

Checking for alternative reasons for the patterns noted creates challenges. This analysis identified common causes to the problems. Proposed additional methods evolved as the problems were studied. Because the TSS are not trained to research their troubleshooting methods, it is hard for them to assess themselves and their methods. Dialogue captured from field engineering support and telephone support personnel focused on providing non-established methods of solving problems. This process focused on creating best classifications of problems and undiscovered explanations for failures. This included a final step for technicians to approve the finished product which lists indicators of failure and causes in the interview process.

Causes and remedies discovered are often idiosyncratic. Capturing a successful discovery regarding the cause of a problem is not always applied systematically as it is in this reviewed process. The impact of success reinforces successes for these discovered causes and remedies and these are readily shared among technicians but not necessarily completely authorized and formally documented. They fall into the realm of “Tacit Skills that can be articulated”. Many of these references were referred to by the Technical Support Specialists during the interviews. Specific alternatives were also suggested and shared in the meeting minutes with other techs which made the meeting minutes a very productive source.

Fortunately some systematically studied processes were available in alternative documentation. These previously constructed but not authorized troubleshooting guides and other historic documents provided a long list of alternative explanations.

Software and hardware changes to the analyzers caused some changes to responses when modifications occurred to the instruments. The older instrument model did not have as many changes and provided the most stable baseline in terms of troubleshooting techniques in use.

Synergy from review of two similar models

Tacit knowledge emerged to the realm of the concrete by performing comparison across two similar instruments. When two pieces of equipment are designed so similarly, the troubleshooting analysis can also be similar. The two common factors allow us to draw a common conclusion. In other words ideas from one instrument sometime apply to the other. The failure review found shared symptoms and causes of failures on these platforms which were very similar. Checking from one analyzer to the other turned out to be a fruitful idea that increased total discoveries for both analyzers. One examples of this gain was found in the QC symptoms. Mature troubleshooting techniques developed for the OMNI Modular allowed heavy borrowing when creating a list for the cobas b 221. Likewise causes and discussion items that were discovered at different times in the interview and data collection process for both analyzers provided input in the College of American Pathologist section. Comparison of the two analyzers allowed fortification of both instrument's lists.

6. Writing the Report

A summary of findings is included in this paper. It includes an overview of the method used to collect, sort, and analyze data that was refined and republished for this paper. Specific accounts of the incidents studied and recommend practices revised from those previously submitted and suggested by new data are presented.

Supplemental documents and data sheets show collected data. Changes in problem categories are highlighted for review and some additions to causes and corrective actions for each of these categories. The data presented are tied closely to the Troubleshooting Guides associated with each instrument. New classifications of failures and identified causes proposed by in-house staff were framed by existing documents.

Because so many symptoms, causes and remedies were discovered they were incorporated into a heavily revised document from the original troubleshooting guides in use by TSS to frame them. The authorization of the changes in the troubleshooting guides within the organization requires a long term review and approval. After more revisions the additional discoveries from phone close cases and document review process will serve as a launch point for those documents to be published in the future.

CHAPTER FIVE: DISCUSSION

Summary of the Process of Discovery

As designed, the manuals identified as frameworks were the Operator Manual for the OMNI Modular and the OMNI S (cobas b 221) Service Manual. The Operator Manual for OMNI Modular had the benefit of a multiple revisions and a most recent thorough revision by United States based technical support specialists. It had the most usable categories for classification. The OMNI S Service Manual which had the richest detailed list of symptoms, causes and remedies provided a very refined grid of problems to check against.

The list of problem codes from these two manuals was the initial source of error codes used to classify “indicators of device failure”. These are frequently referred to in the data analysis as “symptoms” or “problems”. The “factors that contribute to user reported device failures” were recurrently shown as “causes”. Classified symptoms and causes emerged first in the analysis of data from the computerized database. They were confirmed in both the first and second round of interviews as expected. These additional categories were created and evaluated compared to existing categories within a troubleshooting frame work for each piece of equipment. A variety of additions were made but additional key knowledge also emerged in areas that were not specific to a piece of equipment.

This step of generating categories caught central themes and concepts that are sometimes overlapping and useful for multiple pieces of equipment. These were not expected. For instance, the need for information about compliance to regulatory bodies became obvious after the topic was discovered multiple times during review of section meeting minutes. The meeting minutes were checked hoping to discover specific equipment technical tips which they did, but they also yielded other technical support key knowledge that was not specific to one piece of equipment. For instance, after several instances were captured a central category evolved regarding certification from College of American Pathologists (CAP).

Internal Validity

Internal validity was threatened by the following

i. History – Software changes to the database during the investigation did not threaten understanding. Coding changes and minor modifications to nomenclature of specific events that may have effected technician recording had only a minor effect because the codes were so unusable both before and after the changes were enacted. History was not effected by problem and cause coding changes. If software has coding that can be effectively used, this would have a greater effect.

One recent change enacted during the data review period is the renaming of Customer Inquiries to Quality Escalated Dispatches also now known as Escalated Complaints to reflect the naming used by the FDA. Since these changes are minor labeling difference and free text was unchanged, this minor software change had no impact. No cases reviewed merited the escalation so there was never an opportunity for misinterpretation of this change in the service software description of the case.

ii. Testing – Participation in the survey by Technical Support Specialists who reviewed cases raised awareness of the goals of the program within the technical support arm of the facility. This appeared to have a minor change in behavior. During the review, influences from outside the study from management emphasizing documentation had much more influence than participation in the study. Technicians are now more conscientious about recording data because case audits check for multiple key components in the case notes and in the coding used. Testing had a very minimal effect by comparison.

iii. Regression – Interview with service personnel had a tendency to frame their activities in terms of successes and to mask failures for service. This propensity to elucidate activity in a positive light had a minimal effect. The interviewer sought to clearly understand new methods of success rather than recreating scenarios of failure during reporting of the problems, causes and corrective actions. The technique described during TSS discussions in the interview process and a history of shared explorations in difficult problems allowed an emphasis on what could and should be done rather than what should not have been done although some failures were made manifest.

iv. Attrition (Growth) – Some instruments were retired. In fact more instruments were retired than anticipated due to a shift in emphasis from sales and marketing during the program. Older instruments were removed more frequently and likewise some newer style instruments were introduced with new purchase / trade-in programs occurring over the course of the time period studied. The age of the instruments has a tendency to remain steady.

Table 2. Age of Analyzers and Total Number in Service

Omni Modular Total Number of Analyzers in Service Jan. 1, 2005	780	Avg. Age in years of Omni Modular Analyzers in Service Jan. 1, 2005	4.43
Omni S Series Total Number of Analyzers in Service Jan. 1, 2005	5	Avg. Age in years Omni S Series Analyzers in Service Jan. 1, 2005	0.63
Grand Total Number of OMNI Modular and S Analyzers in Service Jan. 1, 2005	785	Avg. Age in years for Omni Modular and S in Service Jan. 1, 2005	4.40
Omni Modular Total Number of Analyzers in Service Dec. 31, 2006	672	Avg. Age in years Omni Modular Analyzers in Service Dec. 31, 2006	5.53
Omni S Series Total Number of Analyzers in Service Dec. 31, 2006	70	Avg. Age in years Omni S Series in Service Dec. 31, 2006	0.92
Grand Total Number of Omni Modular and S Analyzers in Service Dec. 31, 2006	742	Avg. Age in years for Omni Modular and S in Service Dec. 31, 2006	5.10

The balance of models shifted throughout the study. There were a few additional OMNI Modular models that were sold during this study but many were traded in or retired and the balance of newly acquired analyzers were made up of cobas b 221 analyzer series. As the study proceeded, the overall number of OMNI Modular analyzers in service decreased but the balance shifted to a greater percentage of cobas b 221 analyzers. This had helpful effect when trying to locate failures for the cobas b 221 since more failures became available for review.

Attrition did not occur with the pool of technicians utilized during the process. Some staff turnover was anticipated but did not occur.

Although not anticipated in the original list of validity threats changes in the organizations response to outside regulatory influences became a threat in that a list of user replaceable available parts suggested by TSS for customer use is shrinking. It presented a form of attrition not anticipated. Several parts will no longer available due to a lack of documentation of the process available to the customer. This represents a form of "Attrition" listed in the proposal as a validity threat although not as it was originally or commonly considered. In this instance the available remedies were restricted. Because these could also be considered changing conditions in the available process the threat to validity may also be considered “Dependability” as outlined in the paper but once again it was not exactly anticipated. Total effectiveness of all discovered symptoms, causes, and remedies were effected in the long term by changes.

The User Replaceable Parts List is an example of how a moving active organization makes changes that can change the outcome of the research. For example the T2 waste cap and a majority of parts are targeted to no longer be available from the list of parts that can be changed by users.

Another simpler example of how a dynamic organization makes recommending changes difficult is when part numbers change. Originally the cable used to connect the OMNI Modular to a computer was recommended as one part number but before the paper was completed the part number for cable that connects from the OMNI to the changed so that it used a 9 pin to 9 pin connector in stead of a 9 pin to 25 pin connector which is discontinued.

v. Diffusion – Technicians interviewed discussed the ongoing process and made revisions to processes that they used throughout the process but these were undocumented (tacit) changes. While some of the changes in behavior may have come about from the exchange of ideas in the interview process they were somewhat limited. This can also be viewed as a positive result instead of a threat to validity because it could not effect results of previously documented cases. As refinements were enacted throughout the study it served to share previously tacit knowledge which actually served the intention of the project. This may have had some effect on discussions with the technicians but that effect was not measured. It is estimated to have had a minimal effect.

Some diffusion occurred during review of troubleshooting guides and suggestions made by other technicians during the process. The words “I had forgotten about that” or “Really, I didn’t know that.” were heard a few times. Changes in practice as a result of the investigation have begun because of the knowledge shared during the process but they are minimal. Additional changes are anticipated to occur when documentation is available in a published form. These documents will likely have a stronger effect when permanent revisions are made that can be used for technician in day to day work or training future employees.

vi. Compensatory equalization – There was no effect on the cases reviewed since the cases reviewed were all from the past. The investigation did not find a life threatening or alarming change that had to be immediately enacted. Changes discovered will have an impact in the future because they provides a consistent, reliable approach that may more easily be achieved by the Technical Support Specialists as they seek to keep instruments performing. The changes will be presented for approval before they can reduce cost or improve reliability. These changes require an extensive formalized approval process that will slow and minimize the effect.

vii. Dependability - Minor hardware and software modifications were introduced throughout the past year and will continue for the OMNI S (cobas b 221). Revisions make some previous troubleshooting steps obsolete for new versions and limit the effectiveness of those past corrective actions if all instruments are upgraded as they should be. Rarely, analyzers are discovered that have been resold through third party vendors or somehow missed updates for some other reason so this historic data still has some very minor value but it is typically unusable. The OMNI S received a software upgrade during review and a few minor hardware changes to parts. The older OMNI Modular was not changed. Raw data were kept for review of others who may want to check conclusions made.

Causes identified by FSRs were typically limited to a single cause although multiple corrections capturing multiple actions were simply extracted from case note review if they were present.

viii. Confirmability – Qualitative data does not claim to be replicable but the solutions presented seek to provide repeatable solutions to frequently seen causes. The research often involves unique nonreproducible situations but allowed confirmation during the interview process. Technical Support Specialists were asked to verify if results recorded were an accurate representation of what they intended to communicate. Confirmation is also available to some extent by the trail of documentation during the interviews. As decisions regarding causes and classifications were changed the revisions were kept in the database lists.

One limitation was that the Field Service Representatives (FSR) interviews were not conducted during this process.

"Recall Bias" may have some impact since we are reviewing historic data. It appears that the fading memory of FSR was not critical since almost every case involving failures had at some cause identified in the response. It is true, as a general rule, that the longer the time lapses between the call and the analysis the worse the recall for the case is.

There were very few times when a Technical Support Specialist had to be contacted for clarification. FSR were not contacted.

Another factor that offsets this “Recall Bias” is that particularly frustrating cases seem to stick with technicians when they learn something the hard way. Many of the cases could use additional detail, but to a large degree it appears that the essential kernel of the cause is captured.

Results of the interviews were typed and sent to the technician to verify that what was recorded was what they said or meant to say after the interviews.

Customers were not contacted at any point in the process although there is a chance that they could have provided insight to some problems.

ix. Sample size – Since the OMNI S (cobas b 221) is a new variation of the OMNI Modular, fewer analyzers and thus fewer cases are available for review. To aid in developing trends for the instrument with the smaller number of instruments base, the data collection was expanded to cover an extended period of time. The OMNI Modular covered one year and the OMNI S covered two years.

“Saturation point” is the limit of how many records are needed to be analyzed to discover or verify a subject. The idea is that analyzing data should continue till no additional information is forthcoming in the analysis. That is to say, the sample size is sufficient when it is not disclosing additional concepts. There will always be at least some new concept that can be determined but diminishing returns prohibits the process based on cost. We arrived at that point for the OMNI Modular using cases pulled from the database for one year but that was mostly because the troubleshooting was so mature and multiple notes were present in some form so the largest gains came from the compilation of unapproved notes from technicians. The OMNI S will have additional information uncovered as the instrument ages and as software and hardware revisions persist.

For the OMNI S (cobas b 221) cases were studied over an extended time for two years. Many problems had not been seen on the OMNI S. While any new case can disclose a new problem there is a limit to how many can be uncovered. Those problems that are repeated in case analysis are likely to repeat again. These repeated cases bear the greatest payback for future problem solving so a limit is imposed by the need to find cases that can aid productivity of the Technical Support Specialists.

x. Limitations - Time and resources limit study. Since resources are limited it may be difficult to relate to others or be of limited usefulness because of the frequency of use. Cowan and Foray (1999) argue that very little knowledge is inherently tacit and impossible to codify and that from an economist's point of view it is a question of benefits and costs if codification takes place or not. One limitation noted above of sample size reflects this resource limitation. Not every case was reviewed but we have targeted a grouping of cases that will likely show new techniques to be used by Technical Support Specialists after further documentation is processed. It was considered important to prioritize failures and apply mapping only when a payoff was likely. The judgment of when to use newly discovered tacit data that has become defined (for instance a new classification of failure or corresponding remedies) was rarely suppressed because it was not considered beneficial enough to the organization but instead was generally suppressed because it was so difficult to discern. See Fragmentation below.

xi. Fragmentation - The elicited knowledge was fragmented into small pieces and difficult to comprehend. Multiple reviews were required for many cases to put it into practical use. Some case information that was not translated was lost since discussions on how to capture them did not have adequate detail to be incorporated. Some problem areas occur more frequently and pieces from each complaint helps to create a useful list of causes for an indicator category.

xii. Personal Bias – One challenge in qualitative research is to maintain objectivity while embroiled in the process. Since the researcher has a personal interest in the success some tendency to color the results seems likely but the need for objectivity to create solid solutions provides the greatest incentive to those involved in the day to day operation. To some extent this work does reflect a personal bias but it is minimized by the need to come to the correct conclusions regarding the work. The incentive to improve the work conditions outweighs the need to frame the refinement of the method as a success.

The researcher's participation varied from distant observer to being intertwined. The extent of participation was revealed to all involved. To help compensate structured formats were used. While questions were well developed beforehand some exploratory questions required a more flexible exploration that required spontaneous questioning. This research has been shaped by methods discussed in the literature and previous work. Logical choices of methods were confirmed by the committee before proceeding.

The design required an involved writer to make reasonable edits to maintain the goal of improving analyzer performance and so also effecting patient care. The need to understand the tacit processes requires a writer who is involved because we are searching for unanticipated outcomes. Assumptions of fact were always confirmed by other technician’s observations and comments. Usually three times during the process but sometimes less depending on which point in the process of the discovery the refinement was discovered.

Objectivity was maintained although personal opinion was expressed and was included in the development of the method and in refinement of the data. This objectivity is primarily verifiable through the review of data in its various stages.

How the Process Evolved

The method of recording information from the phone close cases changed. After the first interview it became necessary to find a process to track which individual performed revisions. Originally a numbering system was to be used or tech initials were to be added to track each comment. Color coding these comments kept the text cleaner since no extra numbers were inserted and less text was present to be reviewed. Color coding still allowed each comment to be tracked back to the person making the clarification or suggestions for improvement when performing data collection on the Spread Sheet.

Table 3. Color Coding Example

Error exporting data 88				Troubleshooting If this test indicates a leak or block check for actual root cause of T and D issue. Possible remedy is adjust T and D go to **System > Component Test > Aggregates > T & D Module** to attempt initialization, adjustment and T and D Needle calibration
Data exported to floppy disk instead of USB 88				Check T and D Cleaning and if needed recommend cleaning. Check if there were any problems on reinstalling fill port or T and D recently.
Important test routines 89				Refer to Service Manual > Important Test Routines > Troubleshooting Guide > General Fluidics Test
Contact path test 89				
Aggregates 92				
Control sensors 95				
Meas. sensors 97				
General fluidics test 102		2/12/2007	S4	V2 and V4 failing on the General fluidics test - (Root Cause T and D Disk - If indicates Leak or block is to check for actual root cause of T and D issue - Possible remedy is to attempt initialization, adjustment and T and D Needle calibration also check or recommend T and D Cleaning. Check if there were any problems on reinstalling)
Stability monitor 115				SE tech observation
General hardware test 121				
Sensor limits (Sensor report) 126				
The following error messages were not listed in existing documentation				
QC Measurement AQC Sampling Error	2040914	11/18/2005	S2	AQC Sampling Errors (Root Cause pp tubing Solution pp tubing change)

During recording the term ‘root cause’ was changed to use ‘cause’ or ‘possible causes’ for almost all cases since the original cause was usually not known. For instance, an electrode failure may have been the cause for a calibration failure but the reason, the root cause of why that the electrode failed was not known. Cause was seen as more accurate than root cause. Likewise some cases had multiple causes listed. In these instances ‘possible cause’ was used. Also in some reviewed text there was no or low level of certainty regarding the cause and so ‘possible cause’ was used.

Observations About Tacit Knowledge

Sometimes tacit knowledge is hidden because it has been lost. Within the organization some is literally lost in translation as it changes from one language to another. While these are frequently recovered after multiple revisions in the editing process some words still manage to slip by and at least some meaning is lost.

Some information is lost in the approval process as it is changed for presentation to an audience targeted within the United States. It is suppressed by being forced to conform to regulations or another internal influence by an editor but also due to multiple edits and revisions in the approval process.

Sometimes the loss occurs during transition of ownership. This happened with this analyzer when the product was moved from one company to another. It was previously owned by AVL and was purchased by Roche. For example a list of operating system commands that was previously published was resurrected due to the persistence and diligence of a TSS who needed the commands. This list was lost because the document was not included in the conversion process when documents were reviewed during purchase and stocking of documentation.

Knowledge is also lost due to archiving. These archived documents are not listed with other current documents. For example one of the discoveries came from an explanation of instrument codes used in the data manager from GSS note 2001-15. This letter which was originally intended to be an addendum to the Operator Manual was not converted when the manual was updated and so was never added to permanent documentation. Multiple letters were archived and not available for review in the electronic documentation system due to a built in forced archiving system. This occurred again for a website that also posted the documents for customer review. While these should be available they were retired and lost as a resource. Persistence was required to uncover the source of these archived letters.

Previously known facts submitted to one area may not receive a presentation to all parts of the organization. One example of this is when COOX offset values were requested by FSRs. These values are centrally located in an email folder, but its location was not widely known to TSS until the information was provided by engineering support and then shared to others in the TSS group.

Some knowledge is erased by changes in process or revisions in manuals that change processes. It becomes hidden because the recording of the information is removed. An example of this is the discovery that the instrument reset function on a 9180 electrolyte analyzer is no longer present in the Operator or Service manual. An old version of the manual had this process but it was not transferred over during a manual revision.

Some knowledge is never developed. In this particular situation the manufacturer's documentation leaves a gap during the review of guides available for TSS. A TSS specific document was not developed. Reference, Instructions for Use, and Service manuals have similar formats for main troubleshooting sections and varying levels of operating and repair instructions are provided in each. The troubleshooting chapters of these manuals for the OMNI S (cobas b 221) and OMNI Modular contain lists of failures that are presented to the user as software codes or error messages on the instrument with varying levels of thoroughness of the response. In these manuals, the failures identified in the trouble shooting guide frequently have in their final step a message directing the customer or service engineer to "call technical support". Limited documentation has been formally presented that covers the responses to these troubleshooting tips beyond the point that directs the end user to "Call technical support". The more developed OMNI Modular has these failure messages from the analyzer listed and an additional more useful troubleshooting guide based on customer complaints but it had not been updated for about two years. Some basic troubleshooting guides have been developed in the past to assist with the analysis of problems primarily for the older OMNI Modular analyzer but were not converted over when Roche adopted the original manufacturing company. Failure review has resulted in the engineering evolution from the previous OMNI Modular analyzer to the new version of OMNI S. Many improvements are present but the revisions have created an analyzer that does not have particular solutions to the innovations that make it distinct from the similar previous model for these “call technical support” directed issues.

Some knowledge is hidden because it is not centrally located. While one section of the analyzer manual for the OMNI Modular is dedicated to troubleshooting, there are also a wide collection of meeting minutes, emails, and previous troubleshooting guides developed not considered. A central updated consolidated source is not present nor had an attempt been made to incorporate “lessons learned” from service software log entries, interviews from technicians or from other sources of first hand experience. Unexpected failures occur that cannot be anticipated by engineering and only surface when the instrument is in the field. An updated list of actions for Technical Support Specialist is nonexistent for the OMNI S (cobas b 221). For the OMNI S, data are collected and now has been analyzed and reviewed to create new material for use by Technical Support Specialists.

Multiple countries have various levels of access to repair depending on regulatory constraints, training of technicians, and other variables so sculpting an individualized troubleshooting guide for the Technical Support Specialists requires input from the particular country. The start point will be the same for many countries and some of this documentation could be shared but exploration of other countries technical support documents remains as another step. It is possible that additional borrowing can occur to fortify the proposed additions.

CHAPTER SIX: CONCLUSIONS

A model has been outlined for use in eliciting tacit knowledge so that it can become objective. The hidden knowledge in this study discovered descriptions, causes, and corrective actions associated with failures on medical equipment. Tacit knowledge is a resource for the company. The extrapolation of this information within the company allows it to keep a dynamic perspective on an ever evolving data base.

The primary target for extracting data came from service software cases closed by telephone by field service personnel. The Field Service Representatives responses to observed failures were compared to troubleshooting guides in use by telephone support personnel to find new processes that would increase effectiveness of telephone support staff. We asked "What are indicators of device failure reported in technical support calls?" and then "What factors contribute to user reported device failures identified by callers to technical support?" A series of interviews with veteran personnel were used to validate responses from the "phone closed" cases along with ideas pulled from a review of documentation. Analysis resulted in additional recommendations to focus the telephone support personnel's responses so that they are more accurately targeted to each failure and more easily located based on the initial complaint listed by the customer. When a problem was identified, a more comprehensive list of causes was created that makes finding causes and corrective actions more consistent among telephone support personnel. Since these responses have been tested by veteran technicians, their input should serve to make responses of others in the same position more efficient and thereby improve equipment reliability.

Previous service support analysis processes performed at Roche have considered the service process to begin with the FSR dispatch. This process of service analysis was different in that it tried to target resolution and cost avoidance before the dispatch occurs. This process started with first contact by the customer and follow through to dispatch of field personnel to establish root cause of failures.

Impact of the Subject

This research question; 1. Has implications to larger theoretical constructs, 2. Serves as a response to policy issues raised by regulatory bodies, and 3. Provides increased efficiencies in practical applications.

1. Implications to larger theoretical constructs

This research outlined a systematic method used for building practical guidelines in response to observed failures. This method could serve as a model for additional similar analysis for other instruments if adopted. This work provides a model of how repair processes can be streamlined based on collected previously undocumented or tacit data and observation.

This research provided a construct by presenting a systematic method for building practical adjustments to existing guidelines for repair based on knowledge within the organization. It provides both a small stepwise model and a detailed explanation of the process. It shows how repair processes can be streamlined from a review of recorded data that represents a 'collective conscious' experience. The research demonstrates how a systematic review of historical data and careful analysis provided practical solutions and improvements for service to medical instruments. Data were focused during analysis to achieve insight into the way that customers report failures for the OMNI analyzer series. Final deliverables included; documentation regarding the development of this process, new categories of failures, and identification of causes. In the long term, these documents containing failures and causes led to an updated troubleshooting guide based on the existing OMNI Modular analyzer and a second troubleshooting guide for a new series of models called OMNI S (cobas b 221).

It located failures and provided solutions to adjust maintenance tasks but was unable to assess maintenance intervals. Risk Based analysis traditionally shifts maintenance frequency but the responses discovered were responses to unexpected and urgent, critical failures rather than adjustments to the machine maintenance in it's normal operating state.

The study was not suitable for finding operator error codes.
The following describes a method to uncover tacit knowledge.

Summary of Steps to Discover Tacit Knowledge Using Case Review

1. Design and seek approval for the project
    a. Present concept and submit to management for approval.
2. Create a framework
    a. Use existing known frameworks to create classifications. This could include; existing trouble shooting guides; lists from existing manuals of failures; any document that includes symptoms, causes and remedies;

meeting minutes; personal notes from technicians, trainers and engineers; retired documents, and others.

3. Capture key ideas from cases in service software
    a. Identify cases closed by the field and generate a list that provides raw data for review.
    b. Review data, categorize failures, and verify content with veteran technician and interviewer to help complete the framework. Translate to a standard format that includes symptoms, causes and corrective actions as much as possible.
    c. Compare to existing failure codes from framework in step 2 and add to existing codes when possible. Add failure classifications when necessary.
    d. Categorize and refine using the case information and the database framework.
    e. Refine problems listed to fit into an alphabetical sort of failure descriptions.
4. Interview technicians – See detailed list above for all steps which are presented in an abbreviated form here.
    a. Capture problem descriptions with changed indicators of failure based on initial tech feedback from interview questions. Search for changes should include asking for notes made in manuals, older documents no longer. available to others, emails etc. for additional tips checked on a problem.
    b. Prioritize and validate failures to be explored. Failures are targeted by end users for emphasis in review for maximum impact since time and money will constrain review.
    c. Capture problem descriptions including those newly created. Capture causes. When presented corrective actions and remedies are captured during review.
    d. Provide feedback from interviews. A summary written document that reflects the interview initiated changes is presented to techs to check if content is captured correctly. Problem descriptions with changed indicators of failure can be presented in any written format.
5. Repeat interviews with feedback from all technicians included in review material

   a. Revise again using newly created problem descriptions. Focus on identifying failures but more emphasis is placed on identifying causes. Corrective actions (remedies) are captured during review.

6. Add newly discovered symptoms, causes and remedies to master documents
   a. Remove redundant data. Data that were uncovered will already be present for a number of indicators on closer inspection.
   b. Add new data to frameworks and place in master documents. Validate through official channels and publish.

2. Responses to issues raised by regulatory bodies

When approved, the final documentation will assist the Technical Support Specialists by increasing the amount of documentation available for resolving problems. These changes will help Roche to meet guidelines required by the Food and Drug Administration (FDA). This process addressed the needs within the institution of Roche Diagnostics to answer questions posed by customers that require validated documentation by the Food and Drug Administration which now has increased emphasis on the use of verifiable documentation for responses from personnel. The process resulted in a guide with validated responses grouped according to the categories already familiar to the technicians and now revised to suit their specific requests.

Failures requiring investigation specified by the FDA are escalated through a review process. These specific failures are routinely scrutinized through the quality assurance process at Roche but these cases are filtered, required responses based on policies that designate specific instances and types of failures. This inquiry of tacit knowledge provides an alternative method for investigating performance of the device which addresses the needs to document and validate innovative responses that are conceived in the field. Documenting previously unshared methods ensures compliance by allowing a validation of methods and simultaneously provides a format for sharing those ideas with others in the organization and with outside regulatory agencies. None of the cases reviewed would have been investigated by this escalated quality process but the benefit may still come since many questions are escalated.

Review of these records checked for common errors created by users. This alternative method of detection of device related problems had a low efficiency in detecting Adverse Medical Device Events (AMDE). As far as we could tell from the review of these cases no patient experienced harm as a result of these failures. While there were undoubtedly delays in processing samples while instruments are broken these delays in treatment are not considered reportable by the FDA. No patients experienced harm that could be detected by review of case notes. This process does not work well for detecting AMDE. It yielded 0% device related hazards. It is not suitable for finding AMDE.

3. Increased efficiencies in practical applications

Some of the increased efficiencies which resulted in this review include the following.

a. - Allowed troubleshooting procedures from similar models to be applied to new models.

Utilizing formalized inquiry of complaints for newer instrument models allowed application of troubleshooting procedures from similar models to be applied. This borrowing increases the efficiency of obtaining troubleshooting responses for the new analyzer. Revisions to processes will continue and need to be modified to address shifting needs resulting from design enhancements but the baseline and immediate response is presented much more quickly. The anticipated revisions that will require further changes include hardware and software changes.

b. - Discovered common causes for failures using a risk based prioritizing system to emphasize most important problems and productive solutions.

After problems were listed causes for failures were explored. This work did not serve as a model to adjust risk based maintenance assessment for equipment as it ages since a longer term study would be needed. While many technicians have years of experience to assess this, no intervals for routine maintenance were changed. Limitations of time forced a focus of identifying problems and discovering the causes for acute (immediately in need of repair) failures. In a sense this application of risk based assessment was a variation of traditional risk based preventive maintenance which anticipates failures and tries to prevent them with scheduled maintenance.

Variable risk based maintenance assessments change frequency and specific maintenance tasks based on experience and risk assessment of the users. As this study was designed, this research focused on the following steps of this process; Determine potential failures/degradations of each device, ranking likelihood of potential failures and ranking the potential consequences of each occurrence.

The step of this process “Determine potential failures…”, occurred as expected. But in a sense the process varied slightly in that the assessment became “Determine actual failures…”. If the failures repeat as anticipated they are also potential failures.

Ranking the likelihood of potential failures also occurred. It was required since time limited the number of troubleshooting categories reviewed. All incidents discovered through case review were considered, but many problem categories already documented effectively were not involved with extensive investigation. When there was no case that fit a problem category, no investigation through the ‘phone close’ was possible but some were discussed during the interview process. Ranking the likelihood of the failure occurred in part by conducting a count of cases that ranged from zero incidents to several incidents per problem category. Listing the problems by category made finding frequent failures easy. When failures, causes or corrective actions were found, they were always listed but not necessarily made a priority. None were deleted from the raw data but some problems were not investigated. For instance, problems associated with peripheral devices were not scrutinized.

After a problem was listed an assessment could be made of the likelihood of causes and most effective methods of resolution for identified problems that occurred. While some assessment can be performed by a simple count of the number of times a cause occurred within a problem category, the experiences of the TSS were the main driving force in prioritizing the steps used in investigating the possible causes when number of cases did not clearly indicate how to prioritize. There was a informal ranking regarding the likelihood of these actual failures to repeat so in a sense we were also looking at potential failures and the potential consequences of each failure so that we could address the failures that are most important.

The ranking in this study considered the importance and frequency of problems and then ranked the likelihood of causes within each of the problem categories. We have addressed what were perceived as the most common and potentially dangerous failures and provided unique solutions to these failures but it is not a part of a preventive maintenance process. These are classifications imposed as part of an “acute” maintenance process. In a sense this paper utilizes risk based analysis which has always included checking for failures and adjusting maintenance intervals to focus on changing responses to specific tasks associated with failures that have occurred.

Briefly problems, causes, and corrective actions were all assessed based on likelihood to occur and the consequences and importance assigned by the interviewees.

Many questions remain about risk assessment and are addressed in the section “Recommendations for Future Practice” in this paper.

c. The methods of troubleshooting increase Technical Support Specialists (TSS) efficiency.

This study was aimed at and achieved adjustments only for TSS, not total maintenance needs by Field Service Representatives (FSR) and Engineers. A successful analysis which provides recommendations could be applied to other support areas such as the FSR working on the same device but they have Service Manuals directed at their needs. The process could also be applied for other devices being supported by TSS. Utilizing the review process could lead to a shared resource for other support personnel leading to long term improvements.

d. Documentation leads to improved consistency and effectiveness of responses.

The anticipated but not proven primary immediate benefits for the company from the research are increased reliability, greater customer satisfaction through improved consistency in response by TSS and thereby improved performance of the instrument for patients, and decreased service cost. These improvements in the customer experience and profitability should follow if recommendations involving analysis of cause and remedy are effective. Providing a framework which identifies a best method to perform initial troubleshooting will decrease the time that the equipment is not working.

Merger of existing troubleshooting guides and review rediscovered and refined a wealth of documented information currently in use by techs. This review and submission to approval channels will eventually allow the creation of official validated processes to make them authorized. When this process is completed TSS responses will be more systematic and consistent.

Data analysis resulted in multiple problem categories, causes, and corrective actions to be recommended to be added to existing formally adopted documentation used by the Technical Support Specialists (TSS). The improvements are targeted to make responses to customer questions more discernable so that they were presented more consistently. The results of the entire process including phone close review, interviews, and review of data resulted in 213 discoveries for the OMNI S and 340 for the OMNI Modular. A total of 553 discoveries are documented which includes the 28 during the initial case review.

The most unexpected result came from how fruitful the document research portion of creating categories of problem codes was. While performing the second step in the "Summary of Steps to Discover Tacit Knowledge" listed above in this conclusion section, the step of "Creating the Framework" turned out to be surprisingly productive. Many useful tips were consolidated from a variety of sources that would be categorized by Ambrosini and Bowman (2001) as "Tacit skills that can be articulated".

e. Field Service Representatives (FSR) and Technical Installation Specialists (TIS) may be able to avoid repeat travel to sites. Recommendations for customer training are not included except as individual corrective actions. They are not included except as outlined as Technical Support Specialist's responses to customers.

Final presentations of recommended changes in repair technique are improvements outside the scope of this project. A draft document created supports the discoveries made from the raw data are extensive. While observations of remedies were captured, they are provided as incidental recommendations. The primary emphasis during the initial investigation was to capture the failures and associated causes. Documents that include repair techniques are being pursued as a follow up project within the facility.

f. Sometimes instead of discovering new causes there was a benefit in reinforcing what was commonly suspected by the TSS.

Recommendations for Future Practice

Recommendations for future practice include Recommended Future Actions that can improve the process and Recommended Future Study to Validate the Method as being productive. This need can be addressed in a manner which is outlined in a similar case study published by Bobrow, Cheslow and Whalen's on Community Knowledge Sharing in Practice: The Eureka Story (2002). The Eureka Story is a case study of how an organization's most valuable asset of intellectual capital is not limited to information contained in official documents but may also evolve to utilize best tactics in problem solving in a corporate setting. That article included measures of long term effectiveness that are suggested below after Recommended Future Actions to improve the process.

Recommended Future Actions

The process is fruitful enough to warrant future attempts to discover tacit knowledge. Future process could benefit from refinements in the existing process to increase capture of tacit knowledge. These revisions are listed in order from those thought most likely to produce improvements or most efficient processes to those thought to be least likely or least efficient. Several methods that have been suggested after the case study of the method include:

1. Present final ideas in writing for the final interview
2. Sharpen the focus
3. Emphasize corrective actions
4. Expand the variety of roles for interviews
5. Use automated text search
6. Repeat the process
7. Alter the process of coding to aid in targeting and trending areas of need.
    a. Modify problem, cause, and repair codes
    b. Utilize instrument specific error codes
    c. Modify coding processes for user replaceable parts
    d. Add annotations to documentation.
8. Check Technical Support Specialist's documents from other countries

1. Present final ideas in writing for the final interview

The final interview should be changed so that the ideas captured are included in a document that can make it part of the objective knowledge for the organization. It should be near the final form where it can be reviewed and approved. This requires changing the format from the spread sheet to a useable troubleshooting guide to capture and complete the process. Unfortunately uncovering the symptom and the problem can uncover useful suggestions but until they are processed into a useable form they remain tacit.

Review of written notes as a launching point provides an efficiency during the interview which allows the interviewer to capture more ideas and the interviewee a chance to reflect and capture notes as time allows before the interview which can make the process more productive.

2. Sharpen the focus by locating common concerns

Another alternative strategy should include locating the top concerns of technicians as a focus of the interview. There should be a step to poll technicians for problems before scouring for solutions either through the text of specific cases or checking for solutions to the failures in other areas. This process of restricting the number of problems has the benefit of keeping the scope under control. This does not utilize the process of discovery through phone close notes but can still provide fruitful ground to uncover important knowledge.

In this study, review of two different analyzers provided unexpected benefits because many troubleshooting processes could be shared by both analyzers. Exclusion of a similar analyzer is not recommended to restrict the focus. But the focus has to be narrowed to make the scope manageable. In the final round of interviews TSS were limited by time to the number of areas that could be reviewed since so many symptoms and reasons were uncovered.

Another way to narrow the focus is to assess the frequency of the failure noted in case review. There could be a focus on reviewing skills most frequently used. In particular in this study calls about QC and calibration outnumbered many other calls and became the focus based on frequency of comments during the interviews since so little was written about those types of failures. Reviewing the total number of calls and focusing on those calls will target productive areas.

3. Emphasize corrective actions

One of the most important aspects for Technical Support Specialists is the corrective action. Field personnel may or may not always understand why an activity works. Cause (the know-why) is key for understanding and locating the problem (the know-what) because it can lead to an action (the know-how). But there are times when given enough information to define the problem, success can still be achieved if the correct action is taken. All three components are critical and this know-how or action should be included in the focus of any future methods used for building guidelines. Root Cause investigation may be uncovered with long term investigation but problems will typically have a discovered cause that requires immediate corrective actions.

These corrective actions should be merged into troubleshooting guides from the operator manual, TSS guide and service manual to one document. This evolving guide should be available to service personnel so that all available steps are seen in one location along with an indication of which tips are approved to be shared with customers.

4. Expand the variety of roles for interviews

Solutions are discovered by alternate staff that were not interviewed during this process. In particular the Field Service Representative (FSR), Training Specialist Representative, or Training and Installation Specialists could likely contribute multiple suggestions if given a chance to discuss the cases. Increased interaction with the FSRs should be enacted on a regular basis. Some cases during this process could have benefited directly from FSR feedback. For example the case where a peristaltic pump cartridge was replaced might have been the tubing only but was indicated in the case review as a peristaltic pump valve cartridge directly below it.

FSRs should be interviewed in real time after each ‘phone close’ case on an ongoing basis to close the communication loop between what is recommended over the telephone by TSS and what is recommended by telephone by FSRs. Alternately Technical Support Specialists (TSS) can ask FSRs to call when they have a dispatch to provide a solution and close the communication loop. When feedback is needed a call can be placed to the technicians. For cases where the communication does not present a new solution it would still have the advantage of confirming the present process.

Interviewing all of these members of the staff could also yield multiple suggestions regarding causes and steps for resolution. Customers could also provide solutions to cases that show unknown symptom, unknown cause, or unknown resolution for specific cases. This would be especially helpful for cases where the dispatch was cancelled before the FSR arrived. Focus groups could be staged to discover solutions but telephone calls to identified technicians at the facility would probably provide the most useful insights to specific cases.

Periodic updates to documents should be created after discussion with these additional staff. Causes and remedies will be validated by those designated as journeymen for that instrument. For instance within the Blood Gas Section, regular meetings can serve as a platform to discuss discovered tips to keep all involved informed and to review cases before submitting them for change to a more permanent format. Eventually formal channels will authorize and grant a stamp of approval.

This process could be expanded to include data reviewed by engineering and quality who investigate root causes of failures. Direct FSR interview and other techniques needs to be compared to the phone close case review techniques to check which are the most effective.

5. Use automated text search.

PRISMA software has the ability to scan for key words in open text entries. Now that improvements have been noted and verified by TSS using a manual method, future review can utilize this automatic search feature to scan case notes in Service software to aid in finding tips in the future.

Pursuing the scanning for key words in free text areas can automatically locate text and should probably be targeted at the OMNI S for future cases. This can be used to target a list of cases or used to sort through a subset of cases that will be linked together for manual review. The process is immediately available at no cost.

The PRISMA service software has the ability to look for up to six keywords. These keywords can narrow the number of cases to review by matching "All" or "Any" of these keywords. These matching function are the equivalent of using "And" logic for the "All" category and or "Or" for the "Any" category to include cases whose text include these terms. For instance a search could be initiated using 'vacuum' and 'error'. Likewise a search could be initiated for 'AQC' or 'Quality Control' And 'high' And 'O2'to target problems when quality control materials are registering high for pO2.

6. Repeat the process

Repeat the process for TSS interviews and data review of meeting minutes on a regular basis with smaller data sets. Tacit knowledge is continually brewing. More information is available and will continue to evolve as new software releases move forward and experience broadens. As discussed in the section about internal validity it was felt that the "saturation point" has been reached for the OMNI Modular. When another group of data are present for the OMNI S the process could be repeated.

7. Coding should be improved.

7a. Refine Problem, Cause, and Remedy Codes

Different types of tacit knowledge are classified in a coding scheme using the categories of know-*what, know- why and know-how* (Johnson and Lundvall, 2001) which correspond with *problem, cause and remedy* codes that are currently classified by the service software in use at Roche. Unfortunately these more specific and potentially useful category codes located in the service software from Roche were unusable. Ideally these categories would have been available for extricating trends associated with precise equipment failure but were unavailable because the coding was not specific enough in its design. These problem, cause, and remedy categories offered in the software were not considered searchable because they were arbitrarily assigned by technicians trying to make best matches to inexact classification categories. The study was designed not to use these codes.

Current software has limitations because the coding is shared with so many platforms. Unfortunately the cryptic coding used in this software does not allow meaningful data to be pulled regarding repairs since the coding which classifies function, cause and remedial codes were developed for other instruments. It is possible that some trends could be found, but can not be analyzed until coding is refined. These problem and cause codes will not be analyzed in part because they do not provide exclusive and exhaustive categories and are not used consistently to identify problems. Specific coding intended for problem and cause in the software was not used.

Available codes should cascade based on the previously entered problem code. This "dependency" would apply to cause codes and remedy codes. More specifically when a failure is entered, a restricted list of cause codes should surface to help ensure correct selection by the TSS. When a cause code is selected a list of remedies should be presented restricted by the cause code listed. In other words the dependency is created when the problem codes are selected. The dependency algorithm would actually restrict the list of available failure codes which in turn restrict the number of choice available for remedy codes.

7b. Increase the Use of Instrument Error and First Classification Codes

After review it appears that refining the problem, cause, and remedy codes may always have a somewhat limited value if they are forced to be shared by multiple platforms. The problem, cause, and remedy codes should be supplemented by an increased use of an Instrument Error code that captures specific machine generated codes or a message on the machine for trending of specific problems. Specific machine codes would allow tracking of similar cases that are related.

This instrument code should also exhibit the dependency noted above in 5a. Instrument Error codes should be available based on the instrument model number selected in the case. For instance the OMNI S which has a specific instrument error code of “Error 10023, Power fail" would appear from a list of possible choices.

Similarly the First Classification code which is available in the software could be used as a funnel to examine similar symptom cases if a coding list could be customized based on equipment model. By serving as a classification about how problems are presented by customers it could serve as a logical classification of initial gateways to the troubleshooting process. For instance a customer might report a problem as being a calibration problem or a delivery problem that would allow further classification based on the product or part involved. That initial symptom of the problem, labeled First Classification in the software could be used as an entry point for troubleshooting.

7c. Modify Processes Used in Software

Processes for documenting failures and causes should be modified so that future data can be discovered in the service software. The original design of the User Replaceable Parts program required this “User Replaceable Parts” designation as a symptom classification so that the actual symptom was blocked.

To be useful to the Technical Support Specialists (TSS), these solutions must be used as part of a more specific troubleshooting symptom, cause and remedy categories. With the remedy/action as “send user replaceable part x, T&D Disk, etc.” instead of a listing as a symptom as recommended by procedure.

Many parts are no longer available on the User Replaceable Parts Lists. The cases in service software and the Troubleshooting Guide for Tech support that guides the TSS should show an initial category as it does in the troubleshooting guide such as Waste Sensor Error, Check Fill Levels, Vacuum Error, SD Rinse Error, Fill Sensor Error, Fill Error Please Change Bottle and Bypass Rinse Error.

The fact that these cases do not show initial complaint is an indication that we should preface comments and add failures to an Instrument Specific Error code line. User Replaceable part should be an attribute of the part or documented in case notes so that the troubleshooting and initial symptom and cause information are not lost. Keeping the initial failure would help to track these remedies to the correct initial symptom category in future troubleshooting guides.

The Waste Cap is a part previously recommended for replacement in Tech Support Troubleshooting Guides that is now restricted because of internal process changes. This Waste Cap which has been removed from the User Replaceable Part List was suggested in the Troubleshooting Guide used by Tech support in a variety of processes including; Waste Sensor Error, Check Fill Levels, Vacuum Error, SD Rinse Error, Fill Sensor Error, Fill Error Please Change Bottle and Bypass Rinse Error.

The initial symptom classification of "User Replaceable Part" discussed briefly in the validity threat "Attrition" is an example of how discovery of symptoms could be aided by a change in process.

User Replaceable Parts such as the Barcode Scanner, Sample Drip Tray, T&D Disk, T&D Lock Center Screw and others remain on the list and could benefit from both of these changes in process.

7d. Add annotations to documentation

All documents reviewed could use a process to allow field personnel and other support personnel to add annotations to documentation as discoveries are made. This would allow errors in the documentation to be documented for future corrections when discovered. Likewise as new problems and their causes are discovered it would provide a method of capturing them for subsequent revisions after review and validation.

If available, electronic documents need a method for book marking frequently used pages. Written documentation is frequently used to capture the ideas regarding troubleshooting noted above but printed copies also have the ability to be physically bookmarked.

8. Check Technical Support Specialists (TSS) documents from other countries

TSS may be able to borrow heavily from other countries TSS. The United States branch should check for input of TSS specific solutions from the other countries. This would have been rated as a much higher revision if an existing guide had been verified. Sharing could bring very quick dividends if other written documents can be translated and shared. This idea could pay rewards for other service organizations that have isolated pockets that do not communicate with each other. For instance isolated regions or sections within a service organization that do not communicate regularly could benefit from sharing.

Recommended Future Study to Validate the Method

Although they were not utilized to measure effectiveness at this time, several measurements were made to prepare for tracking long term usefulness. These figures are not a part of any published papers. A short list of these established baseline measures are available to aid others who might want to consider metrics for effectiveness of similar programs. Since this is considered sensitive information, the gathered baseline information will be presented in another document called “Service Costs and Failure Information” for review by the thesis committee or the company.

Short List of metrics and definitions

Metrics from Call Statistics

Average Total Time per Call = Average Call Time + Average After Call Work (for TSS)

Average Call Time = Time on the telephones talking to customers about problems

Average After Call Work = The time a telephone tech remains unavailable for the next call due to work associated from a call.

Inbound Calls = Calls from customers into the call center

Outbound Calls = Follow up calls to customers

Total calls = Inbound Calls + Outbound Calls

Live Hit Rate = Calls Answered Live/Total Calls Offered

Service Level = Calls Answered within 60 Seconds/Total Calls Offered

Cost per service call resolved by telephone = Average repair hours per call x cost per hour

Metrics from Field Service Failures

Cost per service call resolved by Field Service Representatives

Average equipment age by model number

Failure Rate

Field service calls per month

Mean Time Between Failure

Mean Time Between Service Calls

Number of “Telephone Close” Cases per year

Total field service cost per instrument = Average repair hours per call x cost per hour

Total number of analyzers by model number

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APPENDICES

Appendix A. Problem, Cause, and Corrective Action Synonyms

During case review and the creation of this paper many terms were used interchangeably. Below is a list of synonyms used. The synonyms for Problem, Cause, and Action are listed in columns. Problem, Cause, and Action are the primary term used in this paper.

Reading across the first four rows the table shows terms that are grouped by how they are related by their other common usage. The other interchangeable terms in each column are somewhat loosely associated with the original terms but still help define the meaning of Problem, Cause, and Action.

Table 4. Synonyms for Problem, Cause, and Corrective Action

Problem	Cause	Action
Symptom	Diagnosis	Remedy
Know what	Know why	Know how
Question		Answer
Indicator	Reason	Repair
Failure	Root Cause	Fix
Category	Factors	Behavior
Description	Origin	Correction
Error	Source	Corrective Action
Error Code	Trigger	Cure
Fault		how-to skill
Function		Maintenance
Indication		Modify
Instrument Code		Replace
Measurement Flags		Resolution
Module Stops		Response
Phenomena		Solution
Sign		Upgrade
System Stops		
System Warnings		
Value Flags		
Warnings		

Appendix B. Definition of Tacit Knowledge with Antonyms and Synonyms

Tacit Knowledge is defined in Webster's Dictionary as "expressed or carried without words, implied or indicated but not actually expressed." (Webster's New Collegiate Dictionary, Ninth edition, p. 1007) Tacit knowledge has several variations in meanings as expressed in informatics. Traditionally tacit knowledge is compared to objective knowledge which is also known as articulable, explicit, verbal or declarative knowledge. Polanyi (1966) states that we can know more than we can tell. Emphasizing the aspect of mental models and practical processes Ambrosini and Bowman (2001) argue that tacit knowledge is more of a skill. They refer to previous authors (Kogut and Zander, 1992, Nonaka, 1991) who use the term 'know-how'. This thesis explores the development of capturing tacit knowledge and translating it to objective knowledge.

Some authors have identified degrees of tacitness that range from explicit to deeply ingrained tacit skills. The list below is shown in order of expressability or as they call it from the highest degree of tacitness down to the lowest.

Deeply ingrained tacit skills

Tacit skills that can be imperfectly articulated

Tacit skills that can be articulated

Explicit skills. (Ambrosini and Bowman, 2001, p. 816)

Table 5. Antonyms and Synonyms that Help Define Tacit

Antonym Objective, explicit, declarative, also accurate, actual, approved, articulable, clear, concrete, consistent, discernable, evident, explicit, expressible, factual, formal theory, heard, indisputable, known, obvious, overt, palpable, perceptible, plain, precise, proven, real, recorded, reliable, seen, shared, solid, spoken, stated, substantial, substantiated, supported, tangible, unambiguous, unequivocal, undeniable, verbal, verifiable, or written
Synonyms subjective, implicit, hidden, also assumption, barely visible, buried, concealed, covered, faint, know-how, imperceptible, implicit, implied, inaccessible, inexpressible, inferred, ingrained, invisible, forgotten, lost in history, obscured, out of sight, personal understanding, scattered knowledge, skill, suppressed, unnoticeable, understood, unknown, unspoken, or unstated.

"Litera scripta manet" ("The written word endures.") "Vax audita perit" ("The spoken word perishes.") Horace

Appendix C. Analyzer Information

The OMNI Modular (OMNI 1 - 9) and OMNI S (cobas b 221) analyzers are desktop size and used as “point of care” devices. They are used primarily by respiratory therapy and laboratory personnel to analyze a variety of parameters which always includes blood gas parameters such as pH (a measure of acidity), pO2 (partial pressure of oxygen) and pCO2 (partial pressure of carbon dioxide) but depending on the configuration may also be used to analyze other parameters. The OMNI Modular includes 9 different model configurations. The OMNI S includes 6 different configurations. These additional parameters include tHb (total hemoglobin) and hemoglobin derivatives, electrolytes including iCa (ionized calcium), Na (sodium), Cl (chloride), K (potassium), SO2 (functional oxygen saturation), bilirubin, Hct (hematocrit) and metabolites which include glucose, lactate and BUN (Blood Urea Nitrogen also commonly known as urea).

The analyzers being reviewed are the Roche OMNI blood gas analyzer series. Supplemental material labeled OMNI 1 - 9 Product Fact Sheet.pdf and OMNI Modular Additional Product Information.pdf are also available that describe the instrument to be analyzed for more details.

The newer OMNI S analyzer model is actively undergoing software revisions and hardware modifications. The OMNI Modular will not have any additional changes unless forced by regulatory agencies. Because the OMNI S is newer and changing, the methods of repair are more obscure and enigmatic. While similar in nature to previous models, they have unique work flow processes and so require a unique identification of problems and solutions but can share some aspects of troubleshooting.

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Experience

Roche Diagnostics, Indianapolis IN 2003 – Present
The diagnostics division of an international laboratory instrument and drug company.
Tech Support Consultant (2004 – Present)
Team lead for product group. Facilitate improvements in product line. Represent department for product issues including launch and product recalls and revisions. Assist in new service software installation. Analyze telephone service response failures and recommend improvements in performance.
Tech Support Specialist (2003 – 2004)
Laboratory Instrument Support -

Clarian Health Partners, Indianapolis, IN 2001- 2003
A care provider network consisting of several hospitals.
Consultant, Educational Services
Develop curriculum for Area Maintenance workers at Clarian Health Systems.

- Interview key staff and managers to specify training needs. Select training material and competency testing material. Arrange instructors and supervise pilot project.

TRIMEDX, Indianapolis, IN 1992 - 2001
An equipment service company providing support to Healthcare affiliates throughout the U.S. TriMedx began as a department of St. Vincent Hospital, Indianapolis.

Manager, Clinical Engineering, Education (1998 – 2001)
Taught a variety of technical training and applications classes. Developed self-studies, instructor led classes, video assisted training, and competency testing. Facilitated and coordinated training programs and orientation for end users and technical staff. Managed Human Resources functions. Researched, edited and wrote policies, procedures, instructions, and reports.

- Served as Project Manager for software installation team that integrated billing, purchasing and equipment service tracking into one program.
- Increased efficiency of staff and improved information flow by publishing policies and procedures on the internet.

Radiological Engineer (1997 – 1998)
Engineer for the Clinical Electro-Physiology program and Radiology Services. Supervisor of five techs. Education Coordinator.

- Implemented the use of a Request for Proposal model to obtain capital equipment.
- Created and implemented departmental incentive and bonus plan.
- Successfully led department through regulatory inspections.

Clinical Engineer (1995 – 1997)
Equipment engineer specializing in critical life support systems such as pacemakers, anesthesia, and monitoring. Served as Education Coordinator for department.

- Initiated over 80 training sessions per year.
- Developed software application training offered throughout the hospital.

- Chaired Quality Improvement Committee. Improvements include better communication with customers and compliance to regulatory requirements.
- Designed and conducted customer surveys to monitor and increase customer satisfaction.
- Facilitated team focus groups. Create improvements in education and expanding services. The "Reshaping Our Work" team designed plans that reduced operating costs and generate revenue providing $1,600,000.00 in savings over an 18 month period.

Senior BioMedical Engineer Technician (1992 – 1995)
Repaired and calibrated medical equipment. Products supported included external pacemakers, monitoring, anesthesia, and other medical electronic equipment.

- Reduced labor needs while simultaneously reducing repair rates by initiating a risk based PM system.
- Led a team of techs that updated PM procedures for over 1000 devices.

WISHARD MEMORIAL HOSPITAL, Indianapolis, IN 1979 - 1992
Service and support for medical equipment. Includes a variety of electronic, pneumatic, hydraulic, and mechanical medical devices.

Senior Biomedical Engineer (1989 –1992)
Respiratory Therapy shop supervisor. Performed all Respiratory Therapy and Pulmonary Functions equipment repair including ventilators. Initiated inservice training program for department. Coordinated education and training for department.

- Nominated for Employee of the Month for outstanding service.

BioMedical Engineer (1983 – 1989)
Serviced numerous pieces associated with the electronics, and Electro-mechanical shop including monitoring, infusion pumps, defibrillators and others. Provide radiology equipment service.

Repair Assistant (1980 – 1983)
Serviced equipment in the Electro-mechanical shop such as beds, surgery tables, blood pressure monitors and others.

Parts Clerk (1979 – 1980)
Stocked, repaired and ordered parts for biomedical equipment.

Academic Teaching Experience

INDIANA UNIVERSITY PURDUE UNIVERSITY, Indianapolis, IN (IUPUI) 1993 - 2002

Instructor, Purdue School of Engineering and Technology

"Applied Human Biology for the Clinical Laboratory" BMET 360 (Spring 2002)
"Electronics for Clinical Laboratory Equipment Technology" BMET 330 (Fall 2001, Spring 2002)
"Medical Equipment Service Practicum" BMET 290 (Summer 2001, 1995)
"Medical Equipment Service Practicum" BMET 290 (Summer 2001, 1995)
"Electrical Circuits" EET 116 (Fall 1998)
"Introduction to Medical Electronics" BMET 240 (Spring 1994, 1995)
"Advanced Biomedical Electronics" BMET 320 (Fall 1994, 1993)

Education

Masters Health Informatics Indiana University, IUPUI, Indianapolis, IN
BS Electrical Engineering Technology, Purdue University, IUPUI, Indianapolis, IN
BS School of Social Work, Indiana University, IUPUI, Indianapolis, IN
Numerous professional training classes available for review in supplemental list.

Professional Memberships and Certification

American Association for Clinical Chemistry (AACC) Member Number 136673
Association for the Advancement of Medical Instrumentation (AAMI) CBET, Member #164492
Indiana Biomedical Society (IBS)