

Needs Analysis in a Corporate Setting

Michael Broadhurst

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Abstract

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This project draws from materials related to Human Performance Technology. It looks at individual roles as well as corporate dynamics in assessing performance and driving change within the organisation. The initial project was designed to identify performance gaps within the Infusion Pharmacology and Neurotoxicology Department (IPN Department). The objective of the analysis was to identify areas for improvement within a functioning business environment and the organisation as a whole. The resulting recommendations lead to several improvement initiatives, one of which, the redesign of the corporate reporting process, is included in the discussion. The Reporting Process change illustrates implementation of a Human Performance Technology initiative using similar analytical methodologies. A reflection on this paper provides an overview of lessons learned and considerations for Concordia University's Educational Technology graduate program.

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CHAPTER 1

INTRODUCTION TO NEEDS ANALYSIS AND HUMAN PERFORMANCE

CTBR is a contract research organisation (CRO) that provides scientific research services primarily to Pharmaceutical and Biotechnology companies. Prior to the marketing of these products, the law stipulates that they must pass stringent regulatory requirements to ensure product safety in humans. CTBR offers scientific services necessary to satisfy the regulatory requirements. At present the company employs roughly one thousand-three hundred staff and is situated in Montreal Canada. CTBR is a member of Charles River Laboratories. A major component to the services offered is the pre-clinical investigations to determine possible toxic side effects caused by a given product. These services are referred to as Toxicology services and they comprise roughly eight hundred of the staff who are grouped into several different operational areas. One such area, IPN, Infusion Pharmacology and Neurotoxicology, was targeted as the subject of this project. Further investigations and initiatives, first identified through this project, were subsequently initiated and one such example is provided in as a brief case study. This paper discusses the discipline of Human Performance Technology driven investigation as well as the implementation of solutions to enhance performance or resolve performance problems.

Human Performance Technology is an analytical approach to problem solving that drives at organizational change. It focuses action and thought on improving organizational performance through the application multiple theoretical precepts and practical applications. The systemic notion of organisation is central to this analysis as it permits the integration of multiple theoretical precepts and approaches. Problems as well as solutions are systemic. For example, consider that all functions within the organisation must operate as a dynamic system to meet the corporate goals that ultimately serve the customers needs. Actions that fulfill corporate goals must therefore be the priority (Rummler and Brache, 1995). In IPN, the analysis found that there was a discrepancy

between the communication of corporate goals and actions taken to achieve them. This was most evident at the lower levels of the department structure (Appendix 1: IPN Department Structure). This demonstrates how Human Performance Technology may focus investigation on macro, organizational performance issues as well as on individual performance issues. The investigation conducted here explores the links between these viewpoints.

Human Performance Technology (HPT) applies varied approaches from which to gain perspective and from which to address performance problems. Some of these viewpoints include operational or micro level analysis in areas such as: knowledge and skills (training needs), environment (policies, processes, communication) or incentive systems and motivation factors. These areas look into the dynamics that impact directly on people and the processes that they are involved with. However, in order to generate viable solutions there must be a consideration of the interaction between micro level dynamics as well as the larger context of the organisation as a whole. This requires a macro perspective that may employ perspectives such as evaluating the role of organizational design and structural impact on performance, or the evaluation of the organizational goals and their congruency with industry and competitive environments and market trends. Using this general framework, this investigation aimed to identify performance problems, to investigate their causes and then to propose solutions.

As an example of the synthesis of micro and macro perspectives, we may consider employee and management conceptualization of organizational goals and then determine how these are translated into the processes and structures within it. The resulting investigation might look at the communication and implementation of corporate goals at the various staff levels and determine possible inconsistencies within the organisation. This approach is but one of many means of understanding a given problem. Consideration of interactions between internal organizational design and inconsistencies with market requirements demonstrates the broad span of theoretical perspectives from which the HPT practitioner may draw. These perspectives provide guidance material for the analysis of performance issues and also direct the generation and application of viable solutions. For example, research indicates that traditional hierarchically structured organisations respond well to consistent and stable market requirements; but a change in market trend that requires a higher level of competition and customer responsiveness can result in compromised organizational performance. However, adjustment, communication and application of corporate goals can contribute to revitalizing such a company performance (Daft, 2001 and Rummler and Brache, 1995). Other approaches and solutions will also contribute to the ultimate objective that is to improve corporate performance. The Human Performance Technologists job is to find those that yield the best results.

Human performance technology also permits the understanding of more micro factors such as poor job design or inefficient or misguided training efforts. But one key element to such understanding is ensuring the reliability and validity of an investigations' findings. For example, staff autonomy and decision making power can be instrumental in creating dynamic and rewarding working environments. However, while incentive programs may be in place to encourage performance, other environmental or operational factors may exist to counteract the positive impact the programs might have (Belcourt, Bohlander, Snell and Sherman, 2002). Thus, a valid or functional solution in one context may prove unreliable in other contexts. We may consider a possible solution involving reengineering a business process to permit greater autonomy as a viable solution but not without consideration of other factors such as departmental or corporate culture to ensure viability of the solution (Ashforth, Kelly and Prince, 1991). At CTBR, during the rollout phase of a newly designed business process that placed choice of work activity back into the hands of the employees, it was found that the departmental culture was opposed to the initiative because they preferred not to have the autonomy. While the analysis had drawn a valid conclusion, that job-autonomy was a motivating factor in one department; it had neglected to determine reliability of the finding when projected beyond that group. This disconnect illustrates the necessity to ensure that sound research methodologies are employed to validate findings and to ensure reliability when projecting to different subjects. In this specific business case, the conclusion "that perceived powerlessness resulted in lower of performance achievement" was incorrect. Finding solutions therefore depend greatly on accurate, valid and reliable results.

The objective of successful business analysis is to target tangible, achievable results and while approaches to problem solving can draw from various fields such as human resources management, training technology, business process reengineering etc., a sound research methodology must be applied to ensure the approach or perspective employed is the correct one. While solutions have been used to remedy a myriad of problems they can be equally destructive when applied incorrectly. Applied HPT should therefore encourage accurate diagnosis of solutions by relying on systematic, reliable identification of problems. A sound research methodology must be employed. As illustrated in the above example, where extrapolation of findings from a selected population or sample population (e.g. one scientific area such as IPN) to a larger population (e.g. all scientific areas), the research methodology needs to consider not only the reliability of the findings but also the validity in the larger context; to do this the investigator needs to rely on proven approaches (Leedy and Ormrod, 2001).

There is no single approach or methodology to HPT. Nevertheless, organisations like humans are systemic and changes that are applied will impact on both. In the above example this

edict would have served to ensure consideration of organizational culture, variability of this within the organisation and validity of research conclusions. In short reliability and validity of the conclusions can result in either effective, ineffective or even counterproductive performance initiatives.

The solution to a problem is more complex than its identification and causal analysis. Implementation poses, in some cases, the greatest challenge of all, but it is perhaps the most interesting part of the HPT field. Keeping in mind that whatever solution proposed is worthless without possibility for application and success; implementation very often becomes the major deciding factor in the application of a solution. Very often the ideal solution is not the most feasible. In many cases a broken system can be resolved with enough people and money. But being in business and remaining in business often generates some compromises in this dynamic. The HPT perspective is used to determine the most viable and effective solution within the constraints of the business environment (Wells, 1992).

This project discusses the application of theoretical business knowledge as employed by Human Performance Technology within an organisation. The project deliverable entitled Needs Analysis IPN, introduces the methodologies of investigation employed in HPT and presents recommendations based on the analysis. The brief case study presents an initiative that demonstrates the practical application of HPT in implementing change within an organisation using similar analytical methodologies as used in the Needs Analysis IPN.

CHAPTER 2

OVERVIEW OF THEORETICAL PERSPECTIVES

Theory provides the lens through which an investigator views the system under analysis. However, many analyses befall one major shortcoming, which is the tendency to rely on only one perspective. A more eclectic approach to understanding given problems can be applied.

HPT should employ a variety of perspectives from which to determine accurate conclusions about a system or given problem. While the temptation may be to look at a problem from one particular viewpoint, human systems cannot be limited to this. An organisation's performance problems are often attributable to multiple causes and solutions should therefore be developed from multiple fields of thought (Gharajedaghi, 1999).

The Human Performance Technologist employs a variety of tools and methodologies to accommodate the given perspectives and to achieve desired results. "Interviews" can be used to acquire perceived situations, attitudes and gain understanding of processes and interactions, while "extant data analysis" can provide the concrete evidence to support conclusions made during the interviews (Rossett, 1996). There are many tools available and the investigator must determine which tools or approaches are best suited to a particular context. For example, when attempting to determine causes for employee motivational problems, interviews can provide detailed understanding of peoples attitudes, perceptions, expectations and the like, while analysis of job design and award systems can prove to be equally valuable in determining the causes for the interview findings. These complimentary techniques are used to support and verify findings (Leedy and Ormrod, 2001 and Rossett, 1996).

There is also a clear distinction between the tools of research and the drivers behind them. A confining component to any analysis is the beliefs that we hold; these drive our methodologies and also form our interpretations. Remaining flexible in our perspective can be advantageous. Where in pure sciences there is often only one underlying law to scientific perspective, in this domain the underlying principles are sometimes disputed, myriad, and conflicting. This is due to

the complexity as well as the span of uncontrolled and interrelated variables. Nevertheless an investigator is drawn towards an understanding of systems that makes sense to them. Where heuristic problems exist we may be compelled to drive investigation from a single point of view but to draw conclusions from multiple perspectives.

Business systems are often best explained not by one discipline but by many. This condition also requires we abandon strict adherence any one research practices that may confine us to persistent use of one perspective. This does not however preclude the need for systematic methodologies. Rather, systematic processes are employed in conjunction with flexible methodologies and theoretical underpinnings. For example, where questioning leads to new areas of investigation a different methodology for analysis or theoretical precept may be employed. In Needs Analysis IPN, open-ended interview questions designed to gain understanding of the organisations structural design, revealed that individuals were concerned with incentive systems. This lead the to the exploration of theoretical precepts of employee motivation in Human Resources literature in conjunction with understanding elements related to Organizational Design literature (Johns, 1992 and Ashforth, Kelly and Prince, 1991, Belcourt, Bohlander, Snell and Sherman, 2002 and Daft, 2001).

There is potential here for considerable complexity or even confusion but there are two strategies that can be used to avoid over complicating or confusing the situation. First, there is a need to ground the research somewhere so as to have a starting point and this requires that the we begin with a specific perspective, albeit one that is open to change. And secondly, maintaining a focus on the project objective should help to avoid the analysis straying too far.

Theoretical Approach

The theoretical starting point of this project held that organisations are composed of a network of systems. Although there are other perspectives as to the structures of organisations, the systemic model held practical merit because organisations will always behave as systems whether or not they are managed that way. It is unavoidable that one element of an organisation affects another (Gharajedaghi, 1999 and Rummler and Brache, 1995). Departments, their people, processes and functions are linked via people working in other departments. For example, in IPN the competency of Technicians (staff who conduct the testing procedures) is reflected in the data quality they produce, this impacts on Study Director (responsible for Study Design and oversight) responsibilities, which impacts on interdepartmental relationships and inevitably organizational achievement of customer related goals. The dynamic and interconnected nature of organisations not only requires multiple perspectives in understanding and analyzing performance problems but also

necessitates that multiple approaches and perspectives are considered in the development of “solutions”. Theoretical precepts of the Human Performance Technology field should be employed from the conceptualization of analysis tools through to the development and delivery of solutions.

The analysis phase draws from the detail of interviews and focus groups and puts the information into perspective within the global context of the organisation. This global context can draw from the organizational design literature that provides perspective in terms of organizational growth, structure and market position and may consider other elements such as designing business strategy to match the respective business environment, understanding present and required technology as well as assessing the present and desired position of the company in terms of life cycle. The cultural setting of the organisation further influences decisions based on change and possibility for organizational restructuring or redesign (Baghai, Coley and White, 2000 and Johns 1992).

Porters competitive strategy (Daft, 2001) matches organizational design against two variables; the required competitive advantage: either low cost or uniqueness of products; and competitive scope: the breadth of competition within the given industry. Positioning of the company within this matrix provides a diagnostic indicating potential reasons for performance health or problems. Alternatively, analysis may compare existing organizational structures in order to establish how well business goals are met. For example, more flexible horizontal structures cater to adaptability and rapid responsiveness to market changes. Daft compares the need for adaptability with an organisations focus (either internal or external). A balance of design and focus must be achieved for optimal performance.

Business process reengineering involves redesign of core processes that are typically cross functional in that they impact on operations in multiple departments within an organisation. While bringing about dramatic improvements in efficiency and productiveness, business process reengineering can also have a profound cultural impact. Where process becomes the focus, the resulting change often impacts on management and organizational structures (Daft, 2001). At CTBR, an initiative to improve the existing reporting process (See Report Process Case Study), to accommodate new market demands, resulted in cultural change as a result of shifted responsibilities, accountabilities and understanding. Vertical, hierarchical or top down management relationships with service departments and scientific areas changed to more horizontal relationships. Considerable resistance was experienced due to this cultural change and strategies to counteract this type of reaction were employed. In this context a switch in theoretical precepts was necessary. The business process had been reengineered leaving a considerable problem within interdepartmental dynamics. A change in perspective was required to ensure the redesigned process

survived. The new approach drew from the change management perspective. Where business process engineering left off, change management began.

Change management literature provides perspectives to establishing new systems, processes and other changes. Analysis and identification of true need for change and determining a viable solutions within the constraints are essential to the success of a change or any new initiative. In this project, Needs Analysis approaches served to gather information while the theoretical precepts of knowledge management, organizational design, training and other Human Performance perspectives drove analysis, solution development and implementation.

Communicating the need for change, understanding resistance to it, developing buy-in and encouraging participation, improve the chances of success. However, constraints such as time and resources may complicate these ideals and “good enough” strategies need to be employed. In the above situation, while having attained management buy-in and perhaps sixty-percent employee buy-in, the imposed timeline did not permit further efforts to get people on board. In later discussion we explore the impact of this and how change management can be put into practice to facilitate the transition.

Incremental change is often the best and easiest approach for the benefit of those resistant to change as well as for the success of the initiative. Setting attainable goals for implementation, while having a more global understanding of corporate direction, can result in greater overall achievement. Rummler and Brache stress that departmental goal alignment with corporate goals should serve to ensure that new initiatives are based on meeting external requirements. Keeping sight of this objective is useful not only during the analysis and solution finding phase but also during implementation to gain support for a given initiative. A key facet in building support for change is in successfully communicating the necessity of it (Daft, 2001).

Time limitations for implementation and completion existed within the CTBR context. This constraint increases the likelihood of objection and possibly sabotage to changes. However, involving those who were most in objection to the change was a strategy successfully employed to reduce undermining of initiatives. While initial involvement often proved difficult to manage, the benefit was that these individuals critically evaluated the proposed change and were instrumental in its improvement. Further, as these individuals were typically vocal and influential, their involvement dissolved some resistance to the change among others. While techniques such as this are useful, a rollout or implementation plan is necessary to affect the desired change and to ensure the project is successful.

Methodologies of change management may vary but the basic components are analysis, development, communication and rollout. These four processes are presented within the Needs

Analysis project and the case study implementation discussions. Analysis enables the definition of the problem and proposition of recommendations. The development process involves discussion of the analysis findings in order to propose viable solutions. Implementation involves the communication and application of the solution as well as the measurement and monitoring the impact of the change.

CTBR Context

CTBR was founded in 1968 and has enjoyed a history of continued growth. While growth is a mark of a healthy company, the survival after several take-overs and in fact continued vitality, stand testament to its success. In particular, CTBR has grown from a staff of eight hundred in 1999 to one thousand five hundred just five years later with revenues increasing during the same period from almost seventy million to nearly one hundred and fifty million. The operational area IPN, resides within the Toxicology division, which encompasses other groups that service it. These include, Data Co-ordination (data management) and Document Production (report publishing). With expansion, systems and processes as well as departments have been tested and have undergone add-hoc changes to adapt to the increased work demands.

Comments gathered during the Needs analysis research in IPN indicated that while business processes continued as required, some significant problems were developing operationally. Communication links between departments were noted to be more difficult, handoffs of work products from one department to another seemed to be accompanied by greater friction and frustration and there was a sense of disconnect between scientific and other operational areas. As corroborated in the “organizational meetings “ (Appendix 3: Operational Improvement Meeting Results), there was a sense that CTBR had lost the small company feeling and now, areas and people tended to work in isolation. While this change was in part due to rapid expansion, power structure and dynamics have played an instrumental role in the new company culture.

Operational strongholds had developed. Where organizational structure would lead one to assume an even balance of authority, an imbalance of power existed. Theoretical precepts of power and control gave insight in to the formation of power and organizational structure at CTBR. For example discussions with the General Manager described the growth of the IPN department through a “divide and conquer” strategy. Where operational weaknesses existed the stronger area was able to claim the functions of the unsuccessful area and make it their own. This had the affect of creating operational silos with strong vertical communication linkages but with weak horizontal linkages with other departments. With the growth of the company this dynamic became less viable as cross departmental co-ordination became laboured. While operationally efficient within the silo,

the increasing need for cross functional workflows and linkages resulted in inefficiencies interdepartmentally. The feelings of working within isolation but with the benefit of efficiency within operational area were well founded. The generation of silo's is inherent in the organizational design and its development when such operational camps develop. Daft describes the evolution of these silos as commonly part of the lifecycle of an organisation. By nature of its size, the organisation becomes progressively more complex and this necessitates the development of specialty services. Where a small organisation once relied on individuals and departments doing multiple tasks the necessity to consolidate activities and knowledge results also in the specialization of departments and individuals. Both are counterproductive to each other. The need to grow and therefore to more clearly define tasks leads to a greater necessity to communicate between the now more segregated activities, yet the act of formalizing and separating activities into areas and departments or jobs results in decreased communication across horizontal linkages.

The creation of operational silo's can also change power relationships within the silo itself. The Data Co-ordination department that services multiple operational areas across silo's resides under the Toxicology silo. This created positive Toxicology management control over the operations within the Data Co-ordination department, however the managerial power relationships associated with the Toxicology and the Pathology silo's for example, were counterproductive. The growth of the organisation with the "divide and conquer" approach sets the stage for laboured operational collaboration but provides an easy target for initiatives that improve interdepartmental horizontal linkages.

Other sources of information such as organizational behaviour may also play an important role in solution development by gaining understanding managerial power level structures and strategies. While such relationships can evolve through organizational influences such as changes to organizational design or as a result of growth, other factors such as process changes also impact on interdepartmental and individual relationships.

At CTBR a healthy customer service relationship between service departments and revenue generating departments they serve was disrupted by the Report Process redesign (See Reporting Process Case Study). The process changes brought entrenched relationships and expectations into question. In this case collaboration and communication linkages were tested and in some instances, they were broken. The Needs Analysis IPN identified an interdepartmental communication problem related to the rapid growth and development of operational silos. With this as a pre-existing organizational weakness the implementation of the report process change resulted in amplification of the problem. As a result, implementation and post implementation actions were taken to ensure success of the initiative.

CHAPTER 3

NEEDS ANALYSIS METHODS IN HUMAN PERFORMANCE

Needs Analysis Project

The research methodology described here was designed for the purposes of the initial Needs Analysis project but has been adapted to meet the needs of the ongoing initiatives that were recommended in the delivered report (Appendix 4: Needs Analysis, Full Report). The general approach was adapted from Training Needs Assessment (Rossett) which derives training solutions by use of a systematic research approach. The project applied tools such as individual interviews, group interviews, and the analysis of extant data and also permits integration of varying theoretical viewpoints in determining solutions to problems that are typically not related merely to training but more generally to performance as either an individual or organizational measurement.

While different theoretical perspectives were employed to drive the analysis, an overlying principal was applied to all scenarios. This principal is best described as defining the performance gap, its causes, and then understanding constraints and other variables to develop viable performance improvement solutions. The performance gap represents the delta between ideal performance and actual performance. For example, an actual performance measurement may describe Key Performance Indicators such as delivery timeline expectations or availability of innovative products, while optimal performance would be defined by desired delivery times as well as expected innovation indicators. Analysis of this type is referred to as purpose based analysis, the purpose being to gather information that accurately reflects the present context or problem (e.g. poor corporate performance), the ideal context or situation (e.g. profitable and competitive), attitudes to the situation (e.g. optimistic that change is possible), causes (e.g. organisation designed for stability not dynamic uncertain environment), and solutions (e.g. internal restructuring, business process reengineering).

Extant Data Analysis

The initial steps of the investigation involved extant data analysis, the review of existing material that is relevant to the subject matter. This served the purpose of familiarization with the company operations as well as some of its documentation, SOP's (Standard Operating Procedures) and COP's (Corporate Operating Procedures). Extant data analysis was also used during the interview stages to investigate specific areas such as policies and documentation that were identified as problematic. For example, redundant paperwork was identified as a significant demotivator to some staff so examples of superfluous documents were reviewed for duplication of information. During the a later initiative, investigating the reporting processes, the documentation requirements recommended by the FDA for submissions were reviewed in order to understand and develop a viable solution.

Individual Interviews

Interviews were conducted at different levels in the department. A top down methodology was applied in that understanding of the organisation from a senior management perspective was conducted first followed by interviews throughout the standard hierarchy. The intention was to gain understanding of organizational constraints in order to put lower level issues into context within the organisation.

Stage one interviews were conducted with management (Scientific Director and Supervisor, Director of Scientific Operations) and the Study Director group. Stage two interviews included the Team Leaders, while stage three interviews were conducted with both Senior and Junior Technicians (Appendix 4: Full Report *see Appendix I: IPN Department Structure Matrix*). The President, Chairman and CEO, was also interviewed (Appendix 4: Full Report *see Appendix III : CEO, Interview*). The approximate total interview time was about sixty hours, plus seventeen hours of focus groups (Appendix 4: Full Report *see Appendix III: Validation Meeting Tables*). The examples of interview questions asked at each level can be found in Appendix 4: Full Report *see Appendix I: Sample Interview Questions*. However, due to the broad mandate of the investigation, the interviews questions varied somewhat due to time constraints and to due the open-ended interview style.

As a result of varied responses and questioning it was not possible to quantify the responses. Nevertheless there was a high degree of commonality with major topics in the interviews.

Research Methodologies and Data Analysis

Questions for interviews consisted of open-ended questions so that the interviewees could elaborate and give examples as they liked. Using open-ended questions also allowed me to shift from general topics to more specific information. Furthermore, using this approach improved my confidence in the developing conclusions as interviews proceeded. For example, when scientists said that more junior Technical staff conducted a specific activity too quickly, I asked other interviewees about their opinions on this issue and gathered extant data to support the findings. This style allowed development of subsequent interview questions to guide questioning into specific areas of concern. This iterative style of questioning was developed to permit greater flexibility in questioning and acquisition of more complete and validated data.

As information and interview data was accumulated, it was immediately assessed to determine future questions. Using the appropriate background or research information, ongoing understanding of the developing “form” occurred. This led to the emergence of the more significant “chunks” that later comprised the key elements of the results. Lack of Technical expertise in scientific understanding for example, or the lack of opportunity to self determine their work tasks are significant issues that merited further investigation and evolved into key conclusions.

A qualitative, iterative style of data analysis was used. Commonalties were found within interview transcripts and where high levels of corroboration were found, there was greater confidence in the validity of the findings. One-off responses were followed up with extant data analysis and in many cases direct questioning with other participants to determine their validity. To further ensure validity and reliability of information provided, focus groups called validation meetings were developed (Appendix 4: Full Report *see Appendix III: Validation Meeting Tables*). These meeting were held within all levels in IPN and included all participating members within each interview group (e.g. All Study Directors). The objective of the validation meetings was to determine if outlier information that had been acquired could be extrapolated to more than single individuals. The Study Directors met to discuss their collective data, as did the Team Leader’s and Technicians on separate occasions and without the presence of management. This strategy was used to reduce the possibility of influence by management.

The validated comments were presented in tabulated form to each interview group. This was then redistributed to the respective participants for any additional commentary. None was added. The validation meetings were then reviewed by the Scientific Director and the Supervisor in order to provide added support for the statements. All interview data and comments unless specified remained confidential. Individual responses and interview documents were viewed solely

be the interviewer and the participant. The interview with the CEO provided a more global perspective of the department and added a macro perspective to the analysis of the information. This was made available to the staff.

While development of preliminary questioning relied primarily on Needs Analysis literature and some aspect of organizational design as outlined in Rummler and Brache (1995) or Daft (2001), the interview results themselves and extant data analysis processes resulted in the investigation and addition of new theoretical perspectives. Varied theoretical perspectives were incorporated into the research on an as needed basis; this allowed for a broader base upon which to work. The disadvantage of this technique is in the large volume and diversity of qualitative data acquired. Hence the need for more robust methodologies to introduce validity into the study and to make sense of the data.

Given the potential complexity of information acquired through the interview process there was a need to first separate critical issues from those of less significance. The initiating question allowed individuals to verbalise their perception of the most critical issue. The fact that people discuss a topic first was thought to lend credibility to the perception that this is the critical issue. Where corroborated by many individuals, an issue provided a good starting point of action for change. Rarely discussed issues were considered more critical and worthy of further investigation when supporting information such as that retrieved through extant data analysis corroborated the statement. Thus, "outlying data" or issues that were not universally shared or commented could become included in the analysis. Establishing validity of these data via triangulation also employed peer validation, which was attained by supplementing the interviews with more targeted, closed ended questions. Further triangulation strategies permitted follow-up of out-lying information through the management interviews as well as the validation meetings.

Finding Solutions

Solutions are developed with the primary objective in mind: to determine viable, implementable solutions. Considerations such as corporate cultural constraints, financial limitations, staff openness to change, market climate to name a few, must be addressed to establish the most appropriate solution to a given problem. Every solution involves some level of change management and while recommendations that result from the analysis can pinpoint issues or areas of concern they should also provide some direction as to what needs to be addressed. But the true benefit to having conducted the analysis cannot be determined until a solution is delivered.

A key factor to consider is feasibility of the proposed solution. The question lies in the limitations or constraint that must be mapped against the optimal solution. But there needs to be a

balance between effectiveness and efficiency (Wells, 1992). The case study presented later illustrates some of these constraints that were tackled in implementing a viable solution. The basis of a good solution however, is built on the accurate and reliable results retrieved through analysis. The first step is always to determine what it is we are after?

Defining the Project

The strategy and general benefits of Needs Analysis were presented to management. This presentation was initiated by the General Manager of Toxicology and was attended by the Director of Toxicology Technical Operations, the Manager of Special Projects, the Director of Toxicology Scientific Operations and the President, CEO of CTBR. Resulting discussion meetings were held to determine the target department as well as to establish deliverables for the project. While these meetings fulfilled these objectives, the most valuable result was to gain buy-in from senior management for the project. This was a key element to the success of the project and indisputably one of the most significant requirements for any such project. While full management support for such an initiative may seem less important initially, the ability to progress and inevitably succeed in affecting change will likely fail without first meeting this prerequisite. Achieving buy-in at this level is a necessity and must become one of the prime objectives of any such project.

While it may seem common sense to ensure that there is this type of support exists there are two major barriers to its accomplishment. Firstly, there is usually going to be someone in favour of the project and as a result it is tempting to believe that this is all the support that is necessary. We naturally seek individuals that are supportive to our cause and there is a temptation to want to believe that some support is enough support. The reality is that very often those who are not initially in favour of a project or change may later be instrumental in its success. Secondly, undertaking these initiatives is exciting and this can distract you from this goal. The data analysis, theorising, planning and so forth are interesting but the prospect of and ability to affect positive change is addictive. It is key to consider that the end objective is to affect positive change. While your enthusiasm may be genuine, those who will live with the change may not buy into it with the same fervour. And when it comes to implementation, “enthusiasm” is not synonymous with “capable”.

Establishing buy-in among key players requires gaining understanding of what they need and then devising means of catering to this. In this case the initial buy-in activity was developed through discussions with area management and conducting interviews to determine their perspectives. Activities such as communicating the intended actions as well as gaining support by participation were employed to achieve buy-in.

Like any unknown situation, change makes many people uneasy. Interviews can be perceived as intimidating. Many interviewees were hesitant to disclose information until they were comfortable with how the information would be used. When the rationale and interview questions were provided beforehand, the perceived threat was reduced. The initial presentation to management served to inform and to reduce concerns. The employee interviews were conducted with a management presence. Once a comfort level with the researcher's approach was achieved, subsequent interviews were conducted without their presence. Human Performance Technology involves exploring the dynamic between business processes and people. This dynamic exists in every business case. Buy-in and acceptance will play a key role from analysis to development and from implementation to measurement of any solution.

Critical analysis of a proposed initiative is invaluable and if it is gained from those who are most opposed to it, there is a greater opportunity for success. In many resulting change initiatives I involved the most critical individuals in order to gain constructive criticism as well as to improve overall support. In doing this, care was taken to communicate the purpose of their involvement and the objective of deriving constructive feedback was made a priority. Keeping these types of interactions on track can be difficult and while skills in managing such interactions can be developed with practice, the initial step, careful selection of participants is critical. Certain aspects of a project as well as the various stages of its lifecycle require different skill sets. Selection of the best match between the help you need and the people who can provide it is worthy of thought and deliberation.

A key element to establishing buy-in is to communicate benefits. Where individuals can see a benefit to themselves, there is a better chance of acceptance. An analysis project such as this should provide concrete recommendations that can be acted upon to develop solutions that improve existing systems. This was therefore communicated to participants as the primary objective of the analysis. This met management's need to determine possible avenues for improvement and also met individual employee needs to resolve problems that they encountered. This basic objective was used to determine deliverables in the form of written report that would define problems within systems at CTBR and provide some relationship between the problems; their causes and also provide recommended actions.

Another component to establishing buy-in as well as in maintaining the integrity of the investigation was to ensure that no negative impact would result from participation. Presentation of basic analytical processes required assurance that participants remained anonymous and promised that only compiled and generalised results would be presented. No individual interview notes were revealed to anyone other than the researcher and participant. This was important to

establish up front so as to ensure participant protection as well as to ensure a clear understanding of what management could expect to receive.

Following the preliminary presentation of the project and having selected the IPN department, the scope of the project and tangible objectives were established. The project was to be broad based with the intended result of highlighting operational weaknesses that could be translated into tangible initiatives for performance improvement. A specific weakness in IPN had been identified merely on an understanding gained by management through anecdotal responses from staff on various problems presently current to the division. The project did not have a mandate to remedy a given problem but to define existing problems and their causes as well as to identify some strengths.

As in most situations it is easier to identify weaknesses or problems and for the most part, people are more inclined to divulge such information. However, in order to provide the best opportunity for success there is a requirement to understand the operational and organizational strengths that will support resulting change initiatives (see chapter 5: Reporting Process Change and Applied Human Performance).

With the given project scope and intended objective being so broad, there was an increased necessity to establish interim reports that would help to guide the analysis. An interim report was scheduled early on in the analysis process. The objective of this report was to present emerging issues and to verify methodologies as to avoid negative impact on the department. A full report was also scheduled and to be delivered to senior management prior to distribution of findings corporately.

Before conducting the research it was necessary to establish the intent of the report for company use. Part of this is to establish it as a practical document. If people are to be asked what they feel is problematic, then there should be an initiative to address their concerns. There needs also to be a consideration of the impact of the report. Identification of operational problems can leave managers and personnel vulnerable to the criticisms of their superiors after the report is delivered. It was communicated that the research process would uncover information that is usually unreachable due to constraints of workload, focus or other corporate dynamics. It was also necessary to establish that the results should be interpreted as constructive criticism and were not designed to incriminate. Communication of this with the involved managers was critical. Nevertheless, no matter how much effort is applied to remaining impartial or diplomatic, there is a responsibility to provide accurate usable data.

The objective of the report was to provide direction for future endeavours and as such needed to be critical. Nevertheless, there is a necessity to consider the need for continued support

of the project even after report delivery. Assuring that the results of the analysis are received with support will improve the odds that the ensuing initiatives will develop and succeed. It is therefore imperative that the investigator be mindful of the personal reactions, intended objectives of the project and expectations at all levels.

Senior management requested the report be frank and unbiased. This requirement supported the intention to provide an objective analysis. Nevertheless the style of reporting needed to balance the requirement to provide critical hard findings while not personally devaluing individual managers credibility. The intention of the report was explicitly not to target individual failures but to look at operational shortcomings. Further, any ensuing change initiative would have to be supported by those that managed the operational areas criticised within the report. Finding an acceptable balance within these constraints was not self-evident. In fact the report more readily met the senior management criteria in providing a critical report and this fostered some serious concerns by the area management who felt the report to be critical of their ability.

The analysis can leave systems and naturally some individuals vulnerable. Findings that have direct personal impact need to be managed and reported in a careful manner. As results of the investigation became prevalent the ability to maintain buy-in from some managers became more taxing. However senior management support lent credibility to the project and assisted in reiterating the premise that the report was to identify problems but not lay blame. Without this intervention it is likely that the project would not have succeeded in delivering a productive document.

Another strategy employed to ensure objectivity was to have it reviewed for bias. This can only be done by someone other than the author. In this case, the report was reviewed by an objective member of senior management. This individual made recommendations that would ensure the objective communication of findings. This activity was also supported by the management team involved.

The Delivered Report

The Needs Analysis project reflects the opinions and knowledge of the individuals within the IPN department and the conclusions are drawn from the perspective achieved through the responses from all levels. It is difficult to cover the entire volume of data collected but the report presents the areas of concern determined to be of greatest importance and most frequently vocalised by the people in IPN. The results of the findings are discussed in abbreviated format in the executive summary following this chapter. This report has not been edited since its delivery and its presentation style differs from that of this text in that it is organised into short and clearly

defined subsections. For a more detailed report, including material such as interview questions and validation meeting findings, please refer to Appendix 4: Needs Analysis Full Report.

CHAPTER 4

NEEDS ANALYSIS REPORT DELIVERABLE

The executive summary included below was provided to management along with the full Needs Analysis report. The report is subdivided into four main sections, each dealing with different themes. The general themes include: corporate goals, a discussion of misaligned or misunderstood objectives at different levels within the department, customer supplier relationships: a discussion of how individuals interact with each other and how these relationships impact on the business, job performance: the implications of poor job performance on the department function and individual interactions, and finally training: its impact on individual performance and the department as a whole. The report concludes with a presentation of key recommendations for improvement.

Executive Summary

The systemic notion of an organisation is central to this analysis. Problems as well as solutions are systemic. All functions within the organisation must operate as a dynamic system to meet the corporate goals that ultimately serve the customers needs. Actions that fulfil corporate goals must therefore be the priority. In IPN, there is a discrepancy between the communication of corporate goals and actions taken to achieve them. This is most evident at the lower levels.

Part I Corporate Goals

Quality data is problematic, as is innovation in IPN. While quality problems stem from Technician responsibility and involvement, innovation lags in IPN due to the changing priorities and communication of goals into actions.

Improvement strategies need to address communication of goals and their implementation. Department goals such as increasing involvement of Technicians and regaining the innovative spirit need to be limited to tangible, measurable initiatives to reach them.

Part II Customer-Supplier Relationship

Customer supplier relationship is defined by congruency between expectations for deadline and products from one department to another. Both communication and accountability between departments is problematic.

Inefficient communication is characterised by inconsistent and changing contacts. There is a need to standardise operations in all departments to avoid misunderstood responsibilities. The roles and responsibilities of jobs need to be defined to facilitate communication. The goal should be to improve the working relationships between departments.

Internal suppliers miss deadlines and their products do not meet customer requirements while customers do not adequately communicate their needs. A strategy to alleviate this problem will involve addressing interdepartmental understanding of roles within the customer supplier relationship; individual rewards or incentives and establishing accountability measures to ensure work is done and goals are achieved. Communication routes, standardised structures, goal setting, and measured achievement are also required to improve interdepartmental performance.

Part III Job Performance

Corporate goals of quality and on-time reporting are achieved to an acceptable level but there are issues of efficiency that stem from the internal customer-supplier relationship that is problematic.

Data collection and study preparation standards are variable and the responsibility taken by technicians is of concern. The contributing factors to this problem are: inconsistent study allocation, lack of principal Technician, training allocation (perceived as unfair as is study allocation), no scheduled QC by the technician and QC is perceived to be the Team Leaders responsibility and is not a priority in the department. This is accompanied by factors that further reduce Technician involvement such as lack of recognition, lack of positive feedback and lack of inclusion in departmental decisions.

In response to these problems, approaches include: increasing Team Leader involvement in follow-up of Technician responsibilities, addressing study and training allocation, data quality accountability measures and reinstating the role of the Principal Technician. Quality goals also need to be set within the department.

Teamwork exists predominately within functional groups but problems exist between different levels within the department. Immediate concern is for the Study Director to Technician relationship.

A poor relationship effects efficient operations of processes and communication. A poor relationship is characterised by negative feedback, poor recognition, a perception of superiority and a lack of rewards and recognition of the technicians. This is caused by the Study Director role, inconsistent technician assignment to studies and the lack of understanding of each other's work. These issues need to be addressed in order to involve the Technicians in their work and to improve the study processes that will effect better QC, quality data collection and problem solving.

Difficulty in communication and ability to solve problems is not localized to the Study Director -Technician relationship. At the managerial level, the Scientific Director and the Supervisor require better general communication and goal communication in order for the department to operate more efficiently.

There are many examples where there is a mismatch between who does the work and who is accountable for it. Accountability is often perceived to lie elsewhere. As a result, time is wasted correcting work that was not done correctly the first time.

Solutions to this involve accountability measures that encourage work to be done correctly the first time but only in conjunction with encouragement of a co-operative culture, rewards and incentives.

Incentives contribute to the corporate culture and play a role in maintaining workforce stability. There are problems in terms of incentives at the Technician and Study Director level. Technicians are motivated by working on interesting studies as well as receiving training but the study and training allocation systems are perceived as unfair. There is also little positive feedback or recognition.

Study Directors identify personal development as a highly valued incentive (promotion, education). Although opportunity for promotion is negligible it is recognised that the development of specialty areas provides upward opportunity. Educational seminars could be improved upon and the vague criteria for incentive acquisition are problematic. Cross training and conferences for example, are not accessible to all.

Team Leaders showed a lower level of concern for existing incentives, identifying social benefits, computer work, team spirit and responsibility as more prominent benefits to the job.

There is a need to emphasise corporate philosophy and culture through better communication of corporate policy. Policies should be standardised across departments and they should be designed to meet the needs of the people they affect.

Part IV Training

General training and orientation need to be improved. The certification and accreditation process is problematic in that it affects data quality due to poor yet accredited competence. This also devalues importance of providing good quality data. The effectiveness and efficiency of some training activities are also in question. The training selection process is perceived as inequitable and this affects the motivation of Technicians

There are issues with planning and execution of training that affect the skill competency. As a result, trainers need to involve the Technicians in the training process to make use of their expertise and adjust their role to oversee that standards are complied with. The training allocation system needs to be re-evaluated to empower Technicians. Problems of efficiency and effectiveness of training methods should be addressed through further analysis. Training should better meet the needs of the department it serves.

New Technicians are not adequately prepared to work on a study. Ability is variable and there is a greater need for understanding the implications of errors. Reading and understanding SOP's and Protocols. Effectiveness and efficiency remain as pressing issues in orientation as well. There is a need to refer to educational research to ensure that delivery and learning are optimised. Orientation should meet the specific needs of the department as well as provide introduction to the goals and philosophy of the organisation. New employees need to understand where they fit into the big picture.

There is a need for a more formalised training and to clarify communication networks between departments. This will involve oversight of the training department to ensure that goals of the department are met (e.g., Team Leaders take on a role in the training of Technicians).

Another area of concern is the availability of cross training and feedback or evaluation of new Study Directors. There is also a need for the Study Directors to have greater understanding of the technical operations in the study rooms. Communication routes should also be improved.

Study Director orientation would be improved by providing information regarding communication routes and facilitated access to knowledge resources as well as the formalisation of constructive feedback procedures and by hands-on participation in the technical aspect and report writing.

There should be a revaluation of the training system to better suit the needs of the department. This can be achieved through goal setting that is designed to meet the needs of the department in relation to the corporate goals. Involvement and accountability needs to be addressed by emphasising the training process to reflect values such as attention to detail and responsibility. The

training department needs to take on a role that is instrumental in facilitating the processes and work done in the departments it serves.

Recommendations

Improvement can be addressed at many levels within the organisation. Corporate goal setting is the first.

Corporate goals need to be effectively communicated and translated into actions throughout the company.

There is a need to encourage a corporate culture in which people contribute to the company to share knowledge, and to co-operate to achieve the goals of the organisation such as 'innovation.'

There is a need to redefine the role of the training department to extend their responsibilities to assess and meet training needs of the departments and the organisation as a whole. This will involve participation in the goal setting and strategic planning activities within departments as well as ensuring that standards of training effectiveness and efficiency are maintained.

Communication routes, individual and departmental responsibilities and standardised roles across departments need to be addressed.

Accountability issues can be addressed through enhanced understanding, standardised department operations, communication improvements, responsibility assignment and measurement of goal achievement.

By providing incentives such as improving study and training allocation processes, positive feedback and recognition, the involvement of Technicians can be increased and data quality can be improved.

Increasing positive feedback, respect and recognition through adjusting the Study Director role and shifting responsibility to the Technicians can bring about improved working relationships and facilitate business processes. This may involve training and emphasising mutual understanding.

Orientation should provide new employees with clear expectations of responsibilities and incentives available to them as well as present policies and philosophy of the company.

Continual assessment should be an ongoing process that is adopted across all departments in order to both set goals and to ensure that solutions are grounded by evaluation of cost and benefit.

CHAPTER 5

THE REPORTING PROCESS CHANGE AND APPLIED HUMAN PERFORMANCE

The Needs Analysis report concluded that misaligned goal understanding and problematic horizontal linkages, including customer-supplier relationships, impacted negatively on the efficient and effective performance of the department and its members. And while the Needs Analysis initiative provided recommendations for change within the department it also offered a new methodology that could be applied to investigate other problems within the organisation as a whole.

One such problem was the reporting process: the report generation and verification process that required many individuals manipulate documents (e.g. adding scientific content, formatting, processing for publishing, auditing) and also required multiple interdepartmental handoffs. Needs Analysis methodologies and the Human Performance perspective identified problematic interdepartmental linkages within this process. Customer-supplier transactions were often laboured, time consuming and error prone. The requirements for report delivery were rapidly changing and work was often late or done under pressure resulting in quality concerns.

As a result of the growing concern for the report quality an analysis was undertaken to identify causes and to define the problem. The methodologies used to retrieve information were designed after the Needs Analysis project in IPN. However, the objective of this project was to implement a viable solution. The following discussion further investigates the relationship between Human Performance concepts and their application in the corporate setting.

Reporting Process and Discussion

CTBR produces scientific reports that are assembled from multiple supporting documents. These documents range in size and quantity from just a few pages to many hundreds and with some complete reports being assembled from two hundred or more separate components. A total of

roughly three hundred staff across all scientific divisions act as contributing authors who generate documents for inclusion in these reports. All reports are custom assembled from components submitted by the various authors, each with unique scientific content. Publishing requirements and scientific content is negotiated with each sponsor to meet their specific requirements. No one component in any report is identical to one another although similarities in overall structure exist (e.g. table of contents and parameters reported).

The contributing documents are predominantly built from Windows based software and are saved for reporting on an electronic file structure. Scientific contributions for text and data was saved and distributed over a network of servers with each contributing operational area working within their own system. For example, Pathology and Toxicology scientists as well as Chemists worked within separate file structures. Several supporting service areas such as Toxicology Data Coordination, a department that generates Toxicology data tables and appendices, also worked within their own file structure.

Report assembly employed two different methods. Where an electronically assembled report was required all contributions were e-mailed by respective authors to an assigned individual charged with the compilation responsibility. Scheduled assembly of reports relied on prompt e-mailing of files to the individual assembling the report. Meeting delivery deadlines relied on all authors co-operating to meet the timeline for submission. Delays were common in acquiring various reports. To compound this problem, multiple saved iterations of the same contribution made it difficult to determine which version was the “good” version.

The necessity to assemble reports electronically had only recently been introduced as a requirement by some sponsors and therefore the lack of availability of trained staff and the absence of a standard process by which to submit, assemble and ship the reports was problematic. Where hard copy reports were required, the process was far more effective. Internal processes were originally designed to cater to paper based deliverables and technology. All components were printed by each submitting area, assembled in correct order and then paginated and referenced accordingly using a typewriter. Internal tracking of documents operated much like a manually operated library check-in and check-out system by which hard copies were followed from one step in the process to the next. This process included quality control as well as quality assurance audits performed on hard copy materials.

These processes remained unchanged whether the final product was to be hard copy or electronic. While hard copy quality control processes enabled a high level of certainty that hard copy only reports would include correct versions, the circulation of electronic versions and assembly of which was not as reliable. Two basic and critical questions came of this situation; how

did the author identify which version in their electronic file was circulated for quality or publishing processes and upon final assembly, how could we be sure that the final electronic version was the version previously audited by quality assurance?

The necessity for a rapid change is often spurred by critical events. Comments from several sponsors indicated that draft reports had incorrect inclusions within the report. Some cases were reported such that later versions of reports sent to the sponsor now had previously addressed problems reoccurring. Versioning and document management was now an issue that was jeopardising the core corporate goal of providing a quality report.

Critical decisions need to be made based on global understanding of a situation as well as on more detailed findings. Gaining understanding of the immediate business context as well as external industry pressures to change was critical. Without this analysis there would have been a great risk of making the wrong decisions. In this case the industry regulatory body (The United States Food and Drug Administration, FDA) was preparing to accept electronic files. CTBR needed to accommodate this into its service and also rectify the internal version control problem.

Ensuring organisations remain competitive requires that the right decisions are made. However, on occasion these decisions may need to be made rapidly and they may not necessarily be popular ones. While attainment of buy-in to an initiative is always desirable, it is not always possible. For this reason, during implementation it may be necessary to make the decision as to what is an acceptable level of buy-in or general support for project.

Performance problems can be identified by some sort of external indicator. In this context an error in report integrity was an indicator of corporate performance. Critical issues, whether they impact on internal deliverables or external ones, need to be resolved as soon as possible. Here, an internal problem had a direct impact on the external customer. Having identified the problem, the pressure to fix it was considerable. The urgency to resolve a performance problem is a significant factor in developing a solution and will govern in how quickly it needs to be resolved. Critical decisions then need to be made which balance effectiveness of a solution with efficiency. For example, speed of delivery may result in some compromises in effectiveness.

Elaborate implementation plans are sometimes hatched with high degrees of buy-in only to find that the project was too broad reaching and infeasible to implement. The analysis of resources is necessary and must be evaluated against limitations. Time and money are often going to be the most engaging factors here. Time is a major resource that must be considered in the development of solutions as well as in their implementation. For example the development of solutions typically requires resources such as subject matter experts or perhaps programmers with subject matter

expertise. Communication and understanding of given contexts then become influential factors in determining the development and implementation of a solution.

The errors that had been sent to the sponsor identified a serious concern for the integrity of the product provided and therefore raised doubts about CTBR's internal controls. If permitted to continue, consequences such as loss of client confidence and potentially loss of business may have resulted. Further potentially crippling consequences may have resulted from regulatory assessment of our internal systems that require that fully audited reports be provided. The net result of the initial analysis found that to avoid lengthily development schedules the solution needed to be relatively simple and to use the people and technology resources available. The business process needed redesigning and an implementation plan needed to be communicated.

The solution chosen was a process driven version control and assembly procedure. While software solutions promised to deliver data repositories as well as versioning functionality, the development and testing time would take months, a timeline that could not be afforded. A process driven system using the Windows network had advantages in that a solution could be implemented immediately. With the acknowledgement that there was a major problem, senior management had bought into the necessity for change. The Windows environment was also familiar to all users and they did not require application training. While the products they produce (components to each report) remained the same, the major change for them was to the reengineering of the submission and assembly processes. With the requirement to provide a quality-assured product, the report component audit process also needed to be redesigned. The lack of versioning software meant that the solution would need to rely heavily on "managed" processes. Two major changes needed to be orchestrated, firstly the reporting / assembly process needed to be redesigned and secondly an assembly and shipping department needed to be created.

The initial step was to centralise all file structures to one area within the Windows network. To do this, a project number driven filing system was created into which all contributors could submit their files to be reported. Secondly the submission process was defined, (Appendix 2: Report Process Overview) ensuring that authors were responsible for timely submission of report component to the folder. It was understood that working files were necessary during the document development process however, the new process required only one version of each document was submitted to the folder. While this could not be electronically enforced monitoring systems and assistance teams were set up to ensure compliance and support wherever needed.

The assembly process was redefined to include a small assembly and shipment group and the new processes were communicated to all areas. Immediate and effective interdepartmental communication was critical to the initiative. Most staff bought into the need for change due to the

recent reporting problems as well as expressed frustration with lack of process to begin with. But the rapidity of implementation and limited consultation timeline left many users wary and hesitant to support the initiative. Nevertheless, implementation followed the typical change sequence of preparation, acceptance and then commitment to the change. Additional communication and training sessions were necessary to ensure that users understood the need for change and that they were well informed as to how it was to be applied.

Departments at CTBR are typically structured functionally within each division and the management is typically organised as a matrix structure in each scientific area. These areas are designed with a crew of core technical staff that accomplish the study activities. Technical staff report to Team Leaders and both collaborate with the Study Directors who design and oversee the studies. The matrix management system is divided along operational and scientific lines. Here, Study Directors and Scientific Directors provide scientific oversight while Operational Managers and Supervisors manage scheduling, team organisation and daily business activities. A Study Director for example will report to the Scientific Director for scientific issues but to the Operational Manager for operational issues. This structure permits individuals with specific skills to apply them accordingly as well as the specialisation in specific scientific areas. Further, it supports the ability react quickly to new demands from sponsors by allowing operational managers to focus on the business. However, a drawback to this system is that it requires additional communication across all levels and roles of management. The more typical functional company structure (Direct management control i.e. combined scientific and management roles) is seen in the service and staff departments such as HR, Finance and Data Co-ordination.

The new assembly group was added to the Data Co-ordination department. This significantly changed the Study director role in the reporting process. The existing process required the report contributions be submitted as hard copy to Study Directors who supervised the assembly and shipment personally. The addition of the new electronic assembly process meant that oversight and management of report shipment changed ownership. The Data Co-ordination department, whose original service was to supply tabulated data to the Study Director now required the Study Director submit their report to Data Coordination for assembly purposes; thus reversing the customer supplier relationship. Within this dynamic, the introduction of the new process brought a significant change in interdepartmental interactions. Nevertheless the reengineered process still called for data to be submitted to the Study Director that was in congruence with traditional relationships. While newly hired Study Directors staff adjusted immediately to this, some preferred the original system and at the time vehemently opposed the process change.

A further significant change that caused sincere objection was the adjustment from paper-based systems to electronic based systems. While processes had been set up to accommodate the change the final product had always been paper based. The progression of regulatory and industry requirements and resulting process changes now brought sudden emphasis on the electronic report. This marked a considerable conceptual change for more senior staff and was cause for resistance to the change.

Conceptual change, process changes as well as the change in customer supplier relationships resulted in a significant cultural change with in the organisation and was the cause for resistance to the initiative. Nevertheless individuals later adopted and now see the benefits of the change. While repeated communication with regard to the new process was somewhat effective, greater benefit was achieved through peer support for the change. While presently some outlier resistance still exists, for the most part the process has been adopted and many look forward to new directions and improvements to come. Having now established the climate or culture for change, there is an expectation that systems will not remain static and that to maintain competitive advantage systems, structures and processes will be continually adjusted for improvement.

An alternate view of the initiative is to look at the company lifecycle. Where stagnation and inefficiency, characterised by bureaucracy, was ingrained in the system the macro level perspective identified a need to revitalise the company by reopening channels of communication on an inter and intradepartmental level, improving processes, removing red tape and thereby injecting vitality. The reporting process change is but part of this more global initiative. Other initiatives such as Technician self allocation to studies to improve empowerment and autonomy as well as communications systems distributions and upgrades and many others contribute to the growing trend towards continual analysis, improvement and change.

There is a need to continually ask the question “is there something we should be doing differently?” With the nature of rapidly changing business environments, continually asking this question is a necessity. The objective is to look critically at business requirements as they change and to plan for them in advance. This approach is essential to the longevity of an organisation.

There are two major benefits to identifying required changes and taking action early. Firstly, with the intention of problem identification and proactive approach to adapting to the requirements new systems and processes can be put into place prior to serious problem development. Secondly early identification of a problem permits the opportunity to bring about least disruptive changes to individual stability. Where change is necessary, the longer lead in time generally the better prepared you can be to affect change. However there is a price to pay for delayed implementation and this may be your credibility as a manger or HPT professional. In

many cases doing something is better than doing nothing at all. Action shows leadership and determination to move forward, while inaction can lead to the less desirable condition of needing to make change under crisis conditions.

The interim solution discussed above was successful in part by the facility with which individuals could adapt to the new process. This was in part due to the relative stability in their individual jobs and only minor change in their overall job responsibilities. Authors still used the same interface to create and submit their reports and little new skills were required. While some may argue that changes keep people sharp and attentive, the counter to this argument is that performance improves with familiarity with the task. Poor performance however can be associated with lack of interest and involvement in the work, which is as much a factor of job design.

It is worth mentioning that the initiative was implemented with a more global understanding of the problem in mind. The weakness of this system is that it relies heavily on individuals following and understanding the process and their role within it. A great deal of support and management oversight is required from all areas to manage and maintain the process and to ensure its success. Electronic filing, assembly and versioning tools are available and are presently under assessment and in some cases development. The long-term view is to automate much of the process and to improve efficiency as well as reduce error rates significantly as well as turnaround times. Nevertheless, the “human” part of all changes and systems needs to be considered and this involves understanding people's needs and designing solutions that permit business requirements be met as well as the human requirements. The pitfalls of which, can be seen in limitations of business movements such as “just in time” processing which may improve efficiency at the cost of job satisfaction and in many cases quality.

A further disadvantage of the implementation process applied was the short timeline. It was accepted that a greater number of individuals than would ordinarily be acceptable would not buy-in to the new process. As previously mentioned, rapid implementation has its drawbacks but it's worth keeping in mind that not everyone will be supportive of the change no matter how well you implement a change or how gentle the transition. Nevertheless, with time as a major constraint, employing more intense communication initiatives can accelerate the buy-in development process.

People tend to feel most comfortable with what is familiar. Change provides a threat to this stability, which is to the detriment of enabling efficient transition of changes. Too rapid and drastic change, while at times inevitable, must be weighed with the benefits of stability and efficiency within well-known systems. As with all new systems there is a learning curve associated with the change. This is true also of the reaction to change. Often the initial few months are not reflective of the actual system, as it will be. The adjustment period is instrumental in allowing

people to learn new systems and provides for development of support and communication of the system. Managing the change therefore involves ensuring ongoing support, especially during this transitional phase.

Mediating factors such as power relationships, interdepartmental relationships, organizational growth trends (divide and conquer) as well as individual role relationships, have a significant impact on the operations of given processes and can work to depersonalise human interactions. As with the silo discussion, smaller companies typically create less refined job roles and permit interdependencies between departments and divisions to exist in order to make do. This dynamic facilitates rapid and effective communication between individuals. Individual job roles are better understood, as there is more interdependency and interaction.

An interesting effect of company growth is seen here, job roles become more defined and departments become more independent of each other. These changes are in reaction to the need to formalise operations as an organisation moves from what is referred to as the growth stage to the entrepreneurial stage and then to the collectivity stage where there is a need for additional internal systems (Daft, 2001). In effect, both departmental and individual roles need to become more defined and formalised in order to accommodate a need to improve efficiency, essentially by reducing multitasking. Interdepartmental communication or horizontal organizational linkages become weaker while roles and functions become more rigidly defined.

Nevertheless, with greater job differentiation comes the potential for increased misunderstanding of other departmental and individual functions and responsibilities. On the interpersonal level, these factors can impede effective communication processes. For example, the added complexity of the matrix structure, while serving to better manage different functions can, if not managed effectively, contribute to this condition. The impact is poor collaboration and reluctance to co-operate. When there is no personal connection between individuals, constructive communication suffers which negatively impacts the likelihood of people collaborating to get work done. The necessity of horizontal linkages becomes all the more important as the organisation grows and there is a need to determine how best to ensure that these linkages remain in tact and support collaborative, productive and inherently efficient relationships within it.

CHAPTER 6

LESSONS LEARNED AND RECOMMENDATIONS

Lessons Learned

Finding balance within the constraints of the context requires thought and experience to develop a viable solution and in some business cases there is no balance to be struck. For example literature suggests that there should be a balance between effectiveness of a solution and efficiency. In many training solutions, this may be true. High cost training, but less efficient as a result, often yields better training results. The trick is to locate the project along the spectrum, where efficiency is at one end and effectiveness is at the other, so as to provide the best product for least cost. However, most business cases are far more complex than this one-dimensional model. Factors such as feasibility within the business culture, cost reduction versus efficiency gains, process adaptability, interdepartmental linkages and so on generate heuristic problems that require a more three dimensional analysis to find viable solutions.

No matter how heuristic, complex or dynamic a problem may be, there is a better bipolar description than the efficiency/effectiveness model. This is the human and the non-human one. The non-human or the analytical part is best developed within an objective environment; however action, implementation, deliverable delivery and the like all involve people, their reactions, their preconceived notions, their preferences and idiosyncrasies. It is here that the most difficult balance is struck. The requirement to change should become evident through objective analysis but the engine to change always involves people.

The temptation is often to rely heavily on the merit of ones analysis to drive change, but buy-in and willingness to accept change are not given merely by understanding logic, rather by understanding benefit to themselves and sometimes to the organisation, the greater good. As in the case study, in some cases, the conscious decision to implement change must be made without this balance. The problem was so urgent that there was little time to implement buy-in strategies such

as group involvement, discussion groups and pilot tests. As a result some individuals were adamantly opposed to the initiative. But such is life and strategies to address the majority of concerns were employed.

Continued analysis and assessment is essential. All business systems are human systems and as such are dynamic and changing; this requires that we revisit delivered solutions. In the case study the cultural change within the Study Director group was not fully understood. Ongoing communication and coaching was necessary in order to manage the cultural change. Failure to do so would have resulted in continued obstruction and interdepartmental conflict.

In defining the project parameters, the Needs Analysis report was to be objective and unbiased. Senior management had requested a frank description as of the current environment. It was also understood that the results would be translated into implementable recommendations for change. Given these conditions, it is natural to assume that there would be some kind of impact on individuals. While standard precautions for protection of interviewees was taken, there was less understanding on my part as to the impact on other stakeholders. As a contracted analyst I was not at all familiar with the business environment, politics or culture. While some familiarity was gained through management interviews, the subtle interpersonal dynamics that create the less tangible aspect of business culture, politics and power structures were largely not known.

In some ways, my outsider understanding provided the advantage of objectivity. I had no personal bias. Nevertheless such reports can have significant impacts on peoples perception of themselves and sometimes on their careers. The understanding of such impact is key in being able to prepare for it as well as to control the release or use of the report. The objective of an analysis is to get at the truth. Considering the impact of the report on participants, readers, managers and other stakeholders prior to embarking on the initiative should be made in communication with senior management. In doing this, it is necessary to make a distinction between the objective of the report and that of the analysis.

The stakeholders defined the objective of the report, which was simply to identify areas for improvement within a functioning environment. However the results were interpreted by some senior stakeholders as a criticism of their ability. The release of such information or reports therefore needs to be tempered with the senior management objective to provide a critical but constructive view of the subject matter. In this case the objective was not to find fault in the management rather to use the information to their advantage in order to improve the functioning of their staff and departmental systems. This message was not consistently provided throughout the investigation and could have been more effective. Nevertheless, analyses of this nature are designed to help make business decisions. At times it is used to pass judgements as to individual

competencies but these should be especially carefully weighed and thorough analysis from many perspectives is in order.

Unlike physical scientific research, this analysis involved many different means of investigation and many different interpretations of the results. In hindsight, knowledge of internal culture, politics and interpersonal relationships would have perhaps enabled a more rounded analysis of the issues at hand. But it may also have reduced objectivity. None the less, if this analysis is to be judged by the number of change initiatives that ensued, it appears to have been successful.

Working within the company has provided the opportunity to tap into aspects of understanding that can only be achieved over time. Likewise personal development of Human Performance techniques and perspectives is an ongoing learning experience. Skills such as developing interview techniques, managing focus groups, analysing unfamiliar business processes are improved upon with experience. The ability to synthesise information down to the most important issues is paramount to the success of a Human Performance Technologist and permeates all activities and deliverables. While these skills develop with time and practice, maintaining focus on important issues as well as the overall objective can help keep a project on track and reduce wasted resources.

The Educational Technology Program

This project looks at individual roles as well as corporate dynamics in assessing performance and driving change. Educational Technology essentially encompasses two areas of expertise, Training Technology and Human Performance technology. While both are closely related fields they should be clearly differentiated on the basis of performance drivers. For example, training is an individual performance driver which impacts on corporate performance whereas HPT assesses training as one driver of corporate performance among many.

In my experience, training can be, but is often not the most effective method of improving individual or corporate performance. Apprenticeship or instruction in HPT must therefore rely as heavily on the acquisition of knowledge related to training as it should in Business Process Reengineering, Knowledge Management, Organisational Design or any other business analysis perspective.

The Educational Technology program may be at a crossroads in its lifecycle and this is reflected in its graduate's skill sets. Educational Technology is generating Educational Technologists as well as Human Performance technologists. The department provides first year students exposure to some of the basic building blocks in preparation for either field with regard to

statistical analysis, qualitative and quantitative analysis techniques, interview methodologies and so forth but the reality may be that to fully prepare students for a new career in Human Performance requires either considerable luck or years of experience. I was a lucky one.

The logic associated in developing a Training technology specialisation field within the all-encompassing field of education makes sense. With the development of Human Performance technology there is a need to create links to even broader fields such as within business. Crossover courses with the masters of Business Administration program would be advantageous as an immediate suggestion. However, I believe that the program could benefit from it's own medicine – performance analysis. Without having made the analysis but with having experienced the process of education first hand I would consider the following issues, perhaps as drivers to the analysis.

The exposure to the choice between Training technology or Human Performance Technology could be explored with each student and guidance may be given in consideration of their skill sets. The practical and analytical skills required to do both are similar and should be dealt with in the first year after which there could be a separation between the two specialisation's. The department offers significant support and in my experience has the staff with the ability to direct students towards their strength. While there is some overlap between HPT and Training technology individual interests and skill-sets need to be considered as few individuals qualify for both.

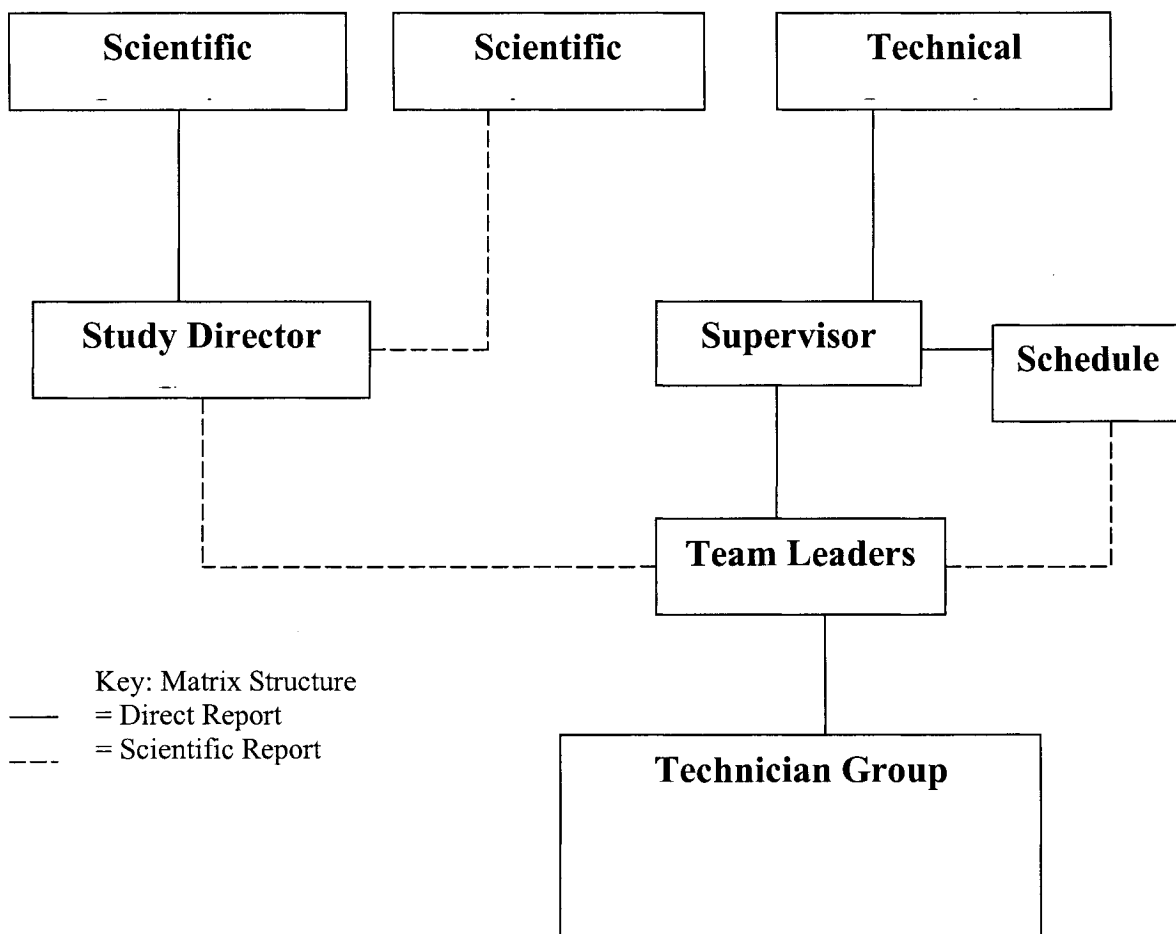
There is little value in analysis without a plan to change or improve something in the end. Training and performance Technology share this requirement yet skill sets to achieve them tend to differ. The core skill sets for analysis for example, involve interview skills, qualitative and quantitative analysis, focus group management etc, and rely heavily on individual communication skills. Training, as a business solution, also demands employment of these skills but may rely more heavily on the academic activities of design and development. In fact a Training Technologist should be able to provide a beneficial service by redesigning or improving training programs interfaces and other materials. This is not always the case with Human Performance Technology. Change management is an important area of expertise for both areas of specialisation but it is critical for the Human Performance Technologist. This distinction could be used to guide students in the program.

Within the first year there could be more emphasis on change management, potentially as a core competency but also to provide an overview of multiple facets, perspectives and competencies of the field. This may be a key element governing their success within business contexts. Knowledge management perspective could be used to leverage heuristic perspectives on

performance issues. The department may consider redesigning the program to provide these competencies first and permit specialisation in HPT or Training Technology from this base.

APPENDIX 1

IPN DEPARTMENT STRUCTURE (MATRIX)



APPENDIX 2

REPORT PROCESS OVERVIEW

CTBR Report Process

Timeline	Test Period	Data Preparation Period	Reporting Period	Assembly and Shipping
Activity	Raw Data is generated	Data is Tabulated and statistics are run	Data is analyzed and text including discussions and conclusions are generated	All tabulated data, statistics and text reports are assembled, reviewed, and shipped to sponsor
Interdepartmental interaction	Scientific staff Technical staff Support services Data tracking services Scheduling services	Technical staff Data Coordination Scientific staff Biometry staff Tracking services QA staff Scheduling services	Scientific groups Data Coordination Biometry staff Tracking services Scheduling services QA staff	Report assembly team Scientific group Data Coordination QA staff Shipping team Data tracking services Archiving services
Horizontal linkage				

APPENDIX 3

OPERATIONAL IMPROVEMENT MEETING RESULTS

No.	Priority	Areas to Improve	Description
1	1	QA	<p>Communication: Routes of Communication need to be clarified. Phone list is not accurate and who to contact for what is unclear.</p> <p>Information is requested from QA on different occasions by different people. Seem to lack internal communication. E.g. Study specific data is not kept in the QA study file and this results in multiple requests for the same documents from different individuals</p> <p>Work-flow in QA seems to be problematic. Study Directors are unsure as to who gets the work in QA and where information is located and continuity of personnel assigned to the studies is problematic</p> <p>Organization: Internal scheduling in QA is problematic. Dates seem to change and work does not get processed efficiently. Timeliness of report process is a problem. Assignment of inspectors to studies within QA is vague. Location of reports and data in QA is difficult. Last minute findings indicate disorganization and create Study Director frustration. There is little follow-up on in-life audits until finalization.</p> <p>Knowledge: Inspectors lack knowledge, seem to lack training which is compounded by a lack of management oversight or review before being sent to the Study Directors. There is a lack of basic working knowledge as well as specific expertise which is demonstrated by the comments they generate and by their asking Study Directors to find information such as SOP's.</p>
2	1	Accountability Process and Scheduling	Support labs do not understand who is accountable for what. Specialists in support labs do not appreciate the need to support and provide information to the Study Directors. They have not understood the need for or rational behind, the CPP. As a result, do not appreciate needs to provide a timely service.

No.	Priority	Areas to Improve	Description
		Scheduling Mutual Understanding	<p>Individuals lack the understanding of the impact of their work on studies. There is a need for greater understanding of the functions and responsibilities of others.</p> <p>Do not see their role in the context of the organization as a whole. Do not yet understand or buy-into the "big picture" and as a result tend to operate individually instead of with other departments.</p> <p>There is a need for improved communication between the departments to facilitate processes between them.</p>
1	1	Flexibility for the Client	CTBR is able to accommodate the clients needs in terms of reporting, study complexity and changes. This is Primarily in Tox and Path.
2	1	Scheduling	<p>While comprehension of the rational for CPP seems to be problematic in some of the lab services, it is seen as an asset to the company by facilitating planning.</p> <p>Fiona in Cost-Scheduling greatly facilitates the process. There is a concern that there is no backup person with her skills.</p>
3	1	Client Service	CTBR provides superior client service from the scientific areas (Carol in marketing is considered to have a major influence here).
4	2	Technical Staff	There has been a major improvement in the skill of the technical staff over the last few years (Geoff is credited). The supervision and training of Technicians is seen to have attributed to this, as is the support from supervisors and management. The quality of the technical work has improved, although there are some concerns about ownership and involvement or commitment of the technical staff.
5	2	Training	Technician training is seen to have improved. Study Director training, both ongoing and orientation is adequate. Seminars, conferences and posters are informative and seen as positive initiatives.
6	2	Path Services	Path services is seen to be a major asset to the company due to their expertise and good scientific reputation.

No.	Priority	Areas to Improve	Description
7	3	Cross Training	There is opportunity for cross-training (i.e. working in different departments on different studies) at CTBR. Many of the more senior Study Directors report that they have been cross-trained in many areas. This is seen as a major incentive to working at CTBR but one that is becoming increasingly more difficult to accommodate as departments become more insular. The perception is that when CTBR was smaller, there was a greater need for assistance from other departments in times of rush. As areas become larger there is less opportunity for cross-training due to less need to "import" Study Directors from another area. Also, as areas become more specialized the process of cross training becomes more difficult.
8	3	Security	With the present prosperity of the company and availability of work, there is a perception of security that is attractive at CTBR.
9	3	Scientific Overview	Scientific overview is seen to be an asset to the company. Clients are impressed with the degree of precaution.
10	3	Reporting Structure	Accessibility of management is a positive attribute to CTBR. The flat structure has facilitated this but is seen to be in danger of losing this asset as the company expands. While the present structure is perceived as a positive factor, there are concerns that, although there is an opportunity to be heard, concerns are not addressed with actions.
		Overall Reaction	CTBR is perceived to be experiencing some growing pains as departments become more fragmented, communicate less and cooperate less to get work done, than in the past. CTBR has lost some of the "small company" feeling that brought people together. Insular operation of departments has resulted in feelings of inequitable or special treatment in other departments. People comment that working at CTBR, while still positive, is becoming less so. This is caused by decreased opportunity for input and fewer actions taken, less freedom or autonomy at work and more frustrations. When asked if the positives outweigh the negatives the vote was split. Three individuals felt it was more positive two felt it was negative while two felt that the negatives and positives were balanced. Those who felt the negatives outweighed the positives or were undecided, were those who had been with the company longer and had seen the transition from the small to large size.

No.	Priority	Areas to Improve	Description
		Perception of Client View	CTBR has a good reputation which is supported by quality work and strong customer service. CTBR's customer is supported by good communication with the client as well as quality marketing information such as the Big Blue's and the CTBR Researcher. Client confidence in CTBR is believed to be due to responsiveness to client requests by the Tox group and the high degree of scientific oversight, even on week-ends. CTBR is believed to be a good place conduct studies requiring technical expertise. Clients often comment on the quality of the work and superiority of work done in certain areas, compared with other CROs (e.g. Inhalation).

The following comments were added after the meeting via e-mail:

Clarifications on the marketing/scheduling weaknesses.

- *Overlap between the role of the account manager and the study director/scientific director*
- *Apparent lack of pricing policy*
- *Lack of competitive information (marketing intelligence)*
- *Lack of knowledge of potential clients and the market*
- *Emphasis of the account manager should be shifted away from sending price quotations, obtaining schedules and discussing study designs (i.e. chasing red folders and schedules) to marketing research and planning with emphasis on the above listed weaknesses*
- *Costing process is becoming too complex and multi-layered*
- *Need to simplify the costing process for inquiries that are received from the client with a detailed outline protocol. Current procedure has too much duplication and leads to unnecessary delays in providing price quotations to Sponsor*
- *Scientific directors and those of us who deputize for them should be given a comprehensive list of basic costs similar to that given to the account managers*
- *As the responsibility for justifying study cost and pricing is given to the study director and the scientific director, the control over these costs should also be within this group (decisions on costs made without consultations with the scientific directors or Chris Banks)*

GENERAL:

Over the past few years, we have established internal tracking systems to identify additional costs and to move the responsibility of identifying potential overruns at the source (technical supervisors). Although these systems have been very effective, they have recently become the driving force behind the decisions made in performing our work which at times becomes a point of contention with the client and would have impacted on the quality of the studies if allowed. For example, the buffers that are added to the costings, repeat analysis of an aberrant value too expensive.

These systems should remain as internal tools and cannot impact on the quality and should not be transparent to the client.

APPENDIX 4

NEEDS ANALYSIS FULL REPORT

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Introduction

This report reflects the opinions and knowledge of the individuals within the IPN department. The conclusions drawn are therefore gained by the perspective achieved through the responses from all levels. As it is difficult to cover the entire volume of data collected, this report presents the areas of concern most frequently vocalized by the people in IPN. As the corporation defines itself by statements such as this:

CTBR is dedicated to superior quality research, data integrity, meeting reporting deadlines...and technological innovation...it strives to provide an achievement atmosphere for personnel to grow to their full potential, since achieving employees are the best guarantee that we will continue to provide the superior quality research and responsiveness that our sponsors have come to expect (Posted in the front lobby, CTBR).

The initiative to conduct Needs Analysis indicates the company's continued commitment to these directions and values.

Purpose

There are three areas of investigation that drove the inquiry; knowledge and skills (training needs), environment (policies, processes, communication), incentive systems and motivation factors. Using this framework the investigation aimed to identify performance problems and to investigate their causes and propose solutions.

Needs Analysis also aims to understand employee and management conceptualization of the goals of the organization and to determine how these are translated into the processes and structures within it. The investigation looked at the communication and implementation of these goals at the various levels and determined possible inconsistencies within the organization.

Research Method

Extant Data Analysis

The initial steps of the investigation involved extant data analysis which is the review of existing material that is relevant to the subject matter. This investigation served the purpose of familiarization with the company operations as well as some of its documentation, SOP's and COP's, CPP etc... Extant data analysis was also used during the interview stages to investigate specific areas such as policies or SOP's and documentation that were identified as problematic.

Interviews

Interviews were conducted at different levels in the department. Stage one interviews were conducted with management (Scientific Director and Supervisor, Director of Scientific Operations) and the Study Director group. Stage two interviews included the Team Leaders while stage three interviews were conducted with both Senior and Junior Technicians. The President, Chairman and CEO, Mike Ankcorn was also interviewed. The approximate total interview time was about sixty hours, plus seventeen hours of validation meetings.

Interview Questioning

The examples of general question asked at each level can be found in the appendices. However due to the broad mandate of the investigation, the interviews varied somewhat in their questioning due to time constraints and to some extent, the open-ended interview style.

As a result of varied responses and questioning it was not possible to quantify the responses. Nevertheless there was a high degree of commonality with major topics in the interviews.

Validity

The validation meetings ensured that the information acquired was valid and important to more than single individuals. These validation meeting were held within the levels in IPN. The Study Directors met to discuss their collective data, as did the Team Leader's and Technicians on separate occasion and without the presence of management. This strategy was used to reduce the possibility of influence of respondents due to management presence.

The validated comments, included in the appendices, were presented in tabulated form per interview group. This was then redistributed to the respective participants for any additional commentary. None was added.

The validation meetings were then reviewed by the Scientific Director and the Supervisor in order to provide added perspective on the statements.

All interview data and comments unless specified remained confidential. Individual responses and interview documents have been viewed solely by the interviewer and the participant.

The interview with the CEO provided a more global perspective of the department and guided the analysis of the information.

Results and Discussion

Part I Corporate Goals

Introduction

This investigation and the resulting analysis is built on a single tenet; that organizations are composed of a network of systems. Although there are other perspectives as to the structures of organizations, the systemic model holds the greatest practical merit as organizations will always behave as systems whether or not they are managed that way. It is unavoidable that one element of an organization affects another. Departments are linked and interdependent via processes and people operating in jobs within these processes and departments. For example, the capability of Technicians reflects on data quality, that impacts on Study Director responsibilities which impacts on interdepartmental relationships and inevitably organizational achievement of customer related goals. For this reason the solution to problems exposed through Needs Analysis are not resolved with one single approach. A change in one of these elements will affect another.

Needs Analysis, in the analysis phase, must withdraw from the detail of interview and focus groups and puts the information into perspective within the global context of the organization.

Goals

CTBR functions through meeting the needs of its customers. The goals of the organization are essentially to serve or satisfy the immediate needs of the clients and to ensure that it will be able to meet the needs of the client in the future. Immediate needs are met through responsiveness, quality and everyone's favorite, on-time reporting. The longevity of the company hinges on ensuring it meets the present needs of the client and in ensuring that new products and services are available in order to maintain and further develop its competitive advantage in the market. The goal of "Innovation" serves this purpose.

This report assumes the integrity of these goals on the basis of the long-term success that they have afforded the company as well as the knowledge that this is a stable industry. As this analysis was targeted at the IPN department it first examines the performance of IPN with regard to how it serves these goals. Although the discussion is restricted to the perspective gained through IPN, it may be possible to extrapolate some of these findings to other departments as there are certain commonalities that suggest that issues such as communication are shared across departmental or service area lines. This supports the premise that organizations operate in a systemic manner even though they may have different departmental functions.

Analytical Perspective of Goals

"Quality" and "on-time reporting" are well engrained in the IPN culture and figures such as 98% on time reporting as well as consistent achievement of budgeted revenues and margins, suggest that these goals are met. However this does not imply that the processes that contribute to these factors are operating most efficiently. Needs Analysis is used to determine where efficiency could be improved. On time in less time may in fact be a feasible goal.

The Needs Analysis model stipulates that the processes and jobs within the organization should serve the ultimate customer driven corporate goals. If they do not, or do so poorly, they should be redesigned, reassessed or refocused. The theoretical precept is that the corporate goals are reflected by sub-goals throughout the processes and jobs that people perform. This is in turn supported by the design or strategy which enables these goals to be achieved and by the management that ensures that these actions are taken.

IPN and Corporate Goals

The corporate goals are vocalized and disseminated yet there is a disparity between the communication of the goals and the actions taken to achieve them in IPN.

Quality

In IPN, quality is stated in almost all interviews as being a goal of IPN and CTBR in general. However this goal becomes less important toward the bottom of the organizational chart. Technicians are concerned only with quality issues that affect them immediately. They will avoid making an error on a study they are accountable for, yet data are often not properly QC'd as it is perceived as someone else's job. There is a disconnect between the role of Technicians and the goal of the company for quality.

There is no job requirement for the Technician to review their data nor are their jobs designed to enhance their involvement and responsibility for the data they produce. Technicians generally see the QC of data as a cumbersome responsibility that is redundant as they perceive that the Team Leader duplicates their QC efforts. The system provides no incentive to provide quality data nor does it provide an opportunity for responsibility on the part of the Technician.

However, data are generated, errors are corrected and QC'd and a final product of acceptable quality is shipped on time but other processes and people are making up for this performance issue which is inefficient.

Solution

The solution is not merely to redesign the process to incorporate accountability for data generation no matter how productive or attractive it may seem in the short term and this has been the general approach to problem solving at CTBR. In the long term, when attention is focussed elsewhere or priorities change or processes are adjusted to accommodate changes, these problems are likely to resurface which leads to yet more process adjustment. Feedback, teamwork, responsibility, involvement accountability, and culture are all factors that can be used to improve productivity and efficiency more permanently.

Innovation

“Innovation” has been targeted as an area for improvement in the IPN department by executive management. This stems from a perception that the traditional dynamic entrepreneurial spirit has waned somewhat in recent times for no apparent reason. This criticism may also be applicable to other departments within the company underlining the possibility that corporate goals are either not understood, not communicated or not properly implemented throughout the organization.

At present, although the goal of innovation is readily identified as a corporate goal by Study Directors there is perception that this entails less of the entrepreneurial spirit than is stressed by executive management. The perception that the innovative spirit has waned recently is in part due to the miscommunication of the meaning of the goal and the actions expected to attain it.

There is also the suggestion that as CTBR enjoys increasing success there is less of the team spirit and cohesion characterized by a “we can do it” attitude that enabled the company to persevere through the tough times. The emphasis on driving forward to break new ground has therefore reduced, at least partly, due to the acceptance or comfort level that is expressed in IPN. Present culture is characterized by staffing stability, not only in the management but also to a high degree in the Study Director and Team Leader and even Technician level. Essentially there is a lack of visible necessity to strive further. While the “war time” spirit has passed, the peacetime complacency and possible focus on other personal priorities has prevailed.

It is a common occurrence within organizations to see a split in the workforce with regard to their activity in terms of making changes that are beneficial to the company. Typically 20% may be considered unchangeable dinosaurs that will resist innovative change, 60% are content within the present status-quo and 20% are naturally involved in implementing changes for the betterment of the company, their job and the processes within it. Strategies to increase involvement can be most effective when targeting the 60% group.

Improvement Using Goals

In creating a strategy to ensure the desired communication of goals and their implementation, it is necessary to look at the internal methods of achievement of the corporate goals and how processes and individuals contribute. For example, Study Directors and Team Leaders agree that there is a need for better data quality generated by the Technicians. This can be translated into a goal such as increasing involvement and responsibility, as well as smaller process goals that target particular areas i.e., scheduling to ensure people attend pre-study meetings.

The key is to identify the need that is connected to the corporate goal and then to define departmental goals, process goals and job goals that serve it. Many interviewees believed that the solution to data quality is to increase the consistency of technician assignment to each study. However, it is unlikely that the overall goal would be achieved unless several other factors that are important for increasing data quality, such as accountability, responsibility, definition of roles on study (i.e. Principal Technician) or the development of processes that ensure tech QC, are also addressed.

Part II Customer-Supplier Relationship

Goal alignment should be adopted across an organization. Congruency between the work in one department as a product for the next must reflect congruency with corporate goals. This is not apparent in many of the existing interdepartmental relationships and is a source of poor communication and sometimes problematic product handoffs between departments.

Although the information gathered was derived solely from within IPN, the high degree of concordance among all levels (Study Director, Team Leader, and Technician) indicate that these conclusions are valid and likely generalizable. There are commonalities from one department to another. For example, accountability for providing timely products to IPN is problematic. Other sources such as the Dale Carnegie report (See Appendices) support this conclusion. There is also recognition in IPN that they play a part in the interdepartmental accountability problems.

The following discussion looks at this relationship through the understanding of the internal customer supplier relationship.

Interdepartmental Customer-Supplier Relationship

Efficient customer-supplier relationships are defined by the congruency between the products and expectations that are handed off from one department to another. This involves facilitated communication routes and supplier understanding of the needs of the customer in terms of products and services as well as the customer effectively communicating their needs.

Currently, communication routes are hampered by changing and subjective access to information, responsibility and accountability for products that tend to be passed off from department to department and person to person while understanding of the needs and priorities of different departments acting as either supplier or customer is problematic.

Interdepartmental relationships present two categories of immediate concern: communication and accountability for products and deadlines. The systems are not in crisis, but there are barriers to efficient working relationships between departments. The following conclusions are supported at all levels within IPN.

Communication

Interdepartmental communication poses problems that are apparent through inefficiency in information transfer. Verbal communication is hindered through inconsistent contacts and routes of communication differ depending on personal contact and also tend to change over time resulting in overall variable and unspecified contact routes. Although some departments have more structured and defined communication routes, there are still problems with notification of contact changes and assignment of roles (E.g., Team Leaders report that Necropsy is difficult to contact and loses information. Study Directors report difficulty locating data within QA.).

Standardization of Departments Contacts

There is a need to define the roles and responsibilities that serve as the contact for specific information and to create a mechanism by which changes to these roles can be disseminated. It may also be of value to investigate whether the structure of departments best suit customer-supplier relationships.

At present problems arise due to misunderstanding of the operations. Individuals with the same job title are responsible for different activities in different departments. For example, a Team Leader from IPN may be asked to assist in leading a Gentox study but unclear understanding of the roles and responsibilities of Technician and Team Leader in Gentox causes confusion and poor preparation (In Gentox the Team Leader prepares the raw data and the Technician prepares the random verification while in IPN it is the Technician that does the raw data and the Team Leader that prepares the random verification).

As the company evolves these problems are likely to resurface repeatedly. It makes sense to maintain flexibility of Team Leaders, Technicians and Study Directors in order to meet the fluctuating demands for studies. The opportunity to do this is strongly agreed upon among Team Leaders and Study Directors as a key incentive to working at CTBR. For this reason alone, cross training should be maintained but there is a need to standardize structures and roles interdepartmentally in order to facilitate the efficient transfer of expertise and personnel.

Standardization of roles and functions offers a long term solution to reduce the need for continual communication of different operational processes, but also provides additional incentive through increased cross training opportunities to add change and challenge to jobs. In addition, the working relationships between departments, including the more senior levels, would be facilitated.

Goal / Action / Strategy

The goal is to improve interdepartmental relationships. The action to achieve this may be to standardize operations across departments and to provide mutual understanding of the functioning and priorities of other departments. Strategy to implement these goals will need investigation into the functioning of departments, communication, training some structural changes and job description changes

Accountability and Responsibility

Communication issues comprise a part of the customer supplier relationship. At present, accountability and responsibility represent barriers to performance and have direct effects on working relationships in meeting the corporate goals.

The problem is characterized by the failure of internal suppliers to meet deadlines and products that do not meet the requirements of the internal customer. This creates relationships interdepartmentally that are characterized by customers who are frustrated at receiving what they consider a poor product and suppliers who insist the product is good. This problem is exacerbated by misconceptions of priorities, products and services that are not suited to the customers needs i.e., reports coming from Anchem are often late, data are often in the wrong format for the customer and as a result deadlines are missed.

The accountability equation therefore involves three key factors; *understanding*, *reward* and *action*.

Understanding

The first need is to address departmental understanding. At all levels (Study Director, Technician, and Team Leader) there are needs for greater comprehension of the work that they do and the impact that unsuitable products or missed deadlines have on them. While communication routes are essential to establish information transfer and retrieval, it is of no use if

the understanding of products and needs at each end of the customer supplier-relationship is not congruent.

The supplier must understand a), what is needed b), why it is needed and c), implications of not creating a product that meets customer needs. The customer must clearly understand their own needs and communicate them effectively.

The major task is to communicate the principle that all departments operate to serve a customer.

Reward

There also needs to be reward for achievement as well as action for non-achievement which must be effectively communicated. Rewards or incentives may be tangible or not but the goal must be perceived as attainable. Ideally individuals understand the benefit of a particular behavior and are intrinsically motivated to do it. Intrinsic rewards can be generated by understanding personal benefit to improved customer-supplier relationships. External rewards (extrinsic motivators) would reward and motivate groups or teams for their effort to improve these relationships.

Action

Action refers to the accountability measures that ensure that work is done according to the goals that are set. Monitoring of internal deadlines within CPP is a measure that can be used to track the hand offs and hold individuals accountable for products and deadlines. Actions such as measurement of internal on time reporting should be implemented. However, the rewards and communications systems that allow improved customer supplier relationships between departments must be addressed first. Activities such as the pre-study meeting will then serve as a measure to ensure accountability and as a process to coordinate study activities more efficiently.

Strategy

Strategy implementation must consider buy in of individuals which requires that they are involved in the development of a better system and that they clearly understand the goal of the initiative. All individuals in all roles in each department must understand the relevance of their job and the role of others in order to understand and involve themselves into the process.

Communication routes, standardized structures, goal setting and measurement are required in order to improve interdepartmental performance. However, just as accountability issues emerge as the drivers towards successful performance at the departmental level; responsibility, involvement in work and accountability, all contribute to effective and efficient job performance at the individual level.

Part III Job Performance

Customer Supplier Relationships

It is important to note the influence of corporate goals on the functioning of the company. On-time reporting and quality, the most prominent goals are attended to with the most vigor. Work gets done and the final product is acceptable to the external customer, yet there are disconnects in the transfer of these goals into actions throughout the job performance within IPN.

In some instances these disconnects are characterized by customer supplier relationships that are at times ill defined within the department. As in the earlier discussion, understanding of how one role or product impacts on another affects interdepartmental functioning, this dynamic exists in IPN between the Study Directors, Team Leaders and Technicians.

Providing a quality product, on-time must be the objective of all staff and all the processes and systems should be focussed on these goals. It must be equally important throughout the organization.

The priority of these goals is diluted from the top to the bottom of the organization. Although it is acknowledged as a goal of the organization, it is not necessarily a goal or priority of the employee. This is primarily indicated among the Technicians. There are many reasons for this, but the main ones are involvement and responsibility towards the job.

Data Quality and Activity Preparation

A recent concern has been the quality of the raw data which affects the reporting process. Data that are not “clean” need longer Team Leader review. At present data in the rooms is collected at different quality standards and is sometimes reviewed by the Technicians while sometimes it is not. The responsibility taken by Technician in the preparation for activities on study is of concern.

Perceived Responsibility

Although there is a general spirit of teamwork among the Technicians there is some lack of commitment to the work that they do. Work that they perceive is within their responsibility is generally done well, yet this is also coupled with an attitude that some things are “not my problem.” This is fostered through the structure or work environment. The QC process is often deferred to the Team Leader for two reasons. First Technicians see QC as the Team Leaders responsibility and they would be duplicating the effort; second, the process is not a priority.

Inconsistent Study Assignment

Present levels of inconsistent assignment on studies as a result of the need for trained staff contributes to reduced feelings of commitment and accountability which inevitably affects quality and study preparation

Technicians who have a vested interest in the study are more likely to prepare in advance or review data appropriately. Those who are there for a short term have no such interest and are unlikely to prepare or review carefully.

Lack of responsibility and involvement result in less well organized study activities that require more last minute activity. Preparation for activities is also prolonged and less efficient when done by a replacement who may not have participated in previous activities on that study.

Principal Technician

While Principal Technicians are assigned, i.e. their name appears at the top of the study list, the role of the “Principal Technician” is no longer accepted or understood. The Principal Technician might not attend the pre-study meeting or be present on day one of the study.

Training Allocation

Technicians have little choice as to the study they want to work on and the training they receive (this is not a criticism of management or scheduling rather it is reflective of the environment). Although the selection system considers those who request training, not all who request it report getting it. Perceived powerlessness results in lower levels of involvement.

Scheduled Time

Review time is not scheduled. No scheduled time implies it is not a priority, but in the past when time was assigned, Technicians made poor use of it. The reason for this failure is systemic. Scheduling alone will not remedy the problem.

The lack of positive feedback, lack of decisions available to them, the lack of inclusion in the department direction (new innovations), perception that expertise is not recognized by the Study Director and that the Study Director does not take their requests seriously, vague policies (disciplinary and health and safety), lack of consultation, poor recognition (posters) and poor inclusion are other contributing factors. The result is complacency and less involvement and responsibility in their work

Approaches to Quality Data and Activity Preparation

Technician Role and Priority

Ideally the Technicians produce quality data. A procedural solution is needed to change the role of the Technician in the review process. This will involve attitudinal changes that must be brought about through the communication of expectations and responsibilities and reeducation of what is done in the review process; with a more broad objective for review at the Team Leader level where they address how the information or data relates to the protocol. This responsibility must be made a priority of the department.

Typically the Technician is given the least amount of credit for the work that gets done while performing a crucial element of the work. It is because of this, that increasing recognition of Technicians is critical.

Team Leader Involvement

Team Leaders need to involve themselves more in the follow-up with Technicians and should take responsibility for ensuring that recording sheets are prepared in advance of the study or in reviewing the books during the study as opposed to believing that it is not their job.

Consistency/Ownership

There is also a need for consistency, not just during the in vivo phase but throughout the process right up to reporting. The QA comments that pertain to the Technicians should be passed on to them for action or for information.

While some Technicians desire greater ownership of studies others enjoy the freedom of movement in IPN. Movement from study to study is a strong form of incentive for them. Thus it may be feasible to create a study assignment system that allows responsibility and ownership for those who want it and movement for those who do not. For the most part Technicians like to have some degree of change. This could be accommodated through allowing them to work on a variety of different studies and allow for floating during non-activity periods on a study. The floating Technicians would be held accountable by the principal Technician who would be responsible for ensuring that quality work was done.

Accountability

Accountability can be encouraged through reviews that check whether individual contribution has been towards these goals. This must be through all levels from Technician to Study Director and management.

Principal Technician Role

This role should provide oversight on study, ensure data review as well as quality of preparation and activity.

Recognition / Feedback

Recognition for both their expertise and for quality work done is necessary and should be combined with an initiative to increase positive feedback.

Goals

As several factors influence the quality of the data collected and prepared, the goal is to increase the involvement and encourage self-motivated accountability in the Technician generating data.

The best way to address the problem of accountability is through establishing goals for the department and jobs. To do this it is necessary to address the areas identified above that effect poor performance.

Ideally the goal should be to encourage a culture within the workforce that is self-motivated to be accountable, responsible and involved. Quality data are produced because good work is important to individuals.

The Technician group is not contributing to the company in a way the reaches their full potential. Optimally people should be willing to attend to the details that are presently “someone else’s problem” (e.g. the leaking cage that never gets fixed but requires daily cleanup from Tox services, the phone in the hall that remains broken for three months, the equipment that is labeled broken but with no indication of really where or what needs to be done to fix it). Responsibility and involvement are key to solving these problems.

Intradepartmental Relationships

The team spirit within IPN is held to a large degree within the functional groups, Technicians cooperate to get work done as do Team Leaders and Study directors. However the degree of cooperation can be improved. The concerns for intradepartmental relationships match those of interdepartmental relationships. It is at the interfaces between these working groups that problems arise.

Study Director / Technician Relationship

The most obvious and problematic interface is between the Study Director and the Technician. Study Directors, Technicians and Team Leaders recognize the problems in this relationship. Many Technicians believe Study Directors do not consider their opinions valid, they give mostly negative feedback, little recognition and as a result are intimidated by Study Directors and are uncomfortable approaching them. This affects efficient operation of processes and communication.

Lack of Rewards

Study Directors agree that there is a need to reward the Technicians for work well done, yet the barrier is the question of whom to reward when so many people are involved in the study. Consistency of staff may help this but not completely resolve the problem. In addition not every Study Director will reward or appreciate uniformly, creating room for de-motivation of uninvolved Technicians.

Lack of Mutual Understanding

There is a concern among the Study Directors and Team Leaders that the Technicians require greater understanding of the scientific aspect of the work. Likewise, Team Leaders and Technicians believe the Study Director requires greater understanding of the technical aspects of the work, stating that Study Directors do not always consider or understand the implications of changes or requirements on study. Team Leaders and Technicians do not fully understand the constraints imposed by the customer on the Study Director and the Study Director role in a regulated environment work.

Job roles

The present situation is less to do with the personal practices of Study Directors than with the position and responsibility that they hold. While being responsible for the client contacts and working the scientific aspect, the Study Director also takes on a semi-managerial role without the personnel responsibilities. This dynamic alone encourages the present relationship that essentially renders the role of the Technician to a commodity that operates to get work done. There is no requirement or perhaps incentive on the part of the Study Director to provide positive feedback or facilitate communication, involvement etc because they have no managerial responsibility for the Technicians.

Therefore, there is no reason for the Study Director to support the Technicians. Hence, Study Directors do not feel obliged to help in the animal rooms when last minute changes result in overtime, Study Directors rarely provide positive feedback or recognition and rarely introduce the Technicians to visiting clients. For example, Study Directors tell Technicians what to do but it's not the Study Director problem if the Technician makes an error because of it; Study Director makes protocol amendments last minute due to their own error yet the Technicians must work the overtime to fix it. The present work environment and Study Director role is the cause.

Conclusion: Study Director / Technician Relationship

Understanding

Technician training needs to improve upon developing deeper understanding rather than simple procedural knowledge as well as an overview of the Study Director role in a CRO. The Study Director also needs better understanding of technical aspects and constraints.

Communication Recognition and Feedback

There is urgent need to improve communication between the Study Director and the Technician, as well as a need for inclusion, recognition, respect and positive feedback. Study Director attention to these will play a large role in the improvement of Technician involvement.

Structural Change

At Inveresk the Study Director role incorporates responsibilities for doing paperwork done at CTBR by Team Leaders and signed off by Study Directors, as well as Technician supervision. This system may require greater oversight of the study by the Study Director but allows greater interaction and cooperation between the Study Director and the Technician. Elements of this system may benefit the working relationships within IPN and the efficiency of work and reduce the time wasted checking other peoples work that is done poorly the first time.

Evaluation of Other Sources

It may be useful to consider deeper investigation into the practices at other companies and to evaluate the implications and feasibility of these approaches within the system at CTBR.

Rewards

Technicians indicate reasonable expectations for themselves. There is a need to involve them in the decisions of the department. They too would like to participate in initiatives that constitute innovation. Not only does this coincide with corporate goal attainment but it can also serve as a motivating factor for Technicians. Recognition can be provided in the form of names of Technicians that contributed to a study appearing on a study report or a poster etc.

Scientific-Technical Separation

The organizational chart makes no connection between Study Director and Technicians or Supervisors and Scientific Director; operations is separated from science is separated from technical yet each is critical to the operation of the other.

There is a lack of communication between the scientific and technical aspect of the work at the Study Director level as well as the managerial level. Problems, such as the frequent last minute demands by Study Directors for weekly data that causes last minute rush and overtime are not effectively addressed. Problems with documentation provided by Team Leaders or signed by Study Directors are not resolved.

The cause is related to the management structure. The Scientific Director and Supervisor do not meet to discuss the processes of the department. Problems identified by their respective teams are channeled through upper management making it difficult to effect change.

Perspective on Scientific-Technical Separation

The organizational chart needs to represent the relationship between science and operations and technical. Their relationship needs to be represented.

It will be advantageous for the Supervisor and Scientific Director to discuss and resolve functional problems between their teams. There is also a need to discuss the development of goals and directions of the department so that the department operates with clear direction.

Individual Responsibility

There are similar accountability and involvement issues within the other ranks that affect internal customer supplier relationships within the department. Avoidance of responsibility is a critical issue. Team Leaders rely on the training department to train; Technicians let the Team Leader take the responsibility for data review; poorly proofread protocols are submitted to the Scientific Director; Team Leaders do not check that Technicians have prepared the necessary paperwork

until day one; poorly proofread dosing sheets are handed into the Study Director; reports arriving late to administration for pagination etc become the Administrative Assistants responsibility; the Team Leader provides the Study Director with unchecked treatment sheets; e-mail sent to “everyone” is considered proactive and redirects responsibility; Team Leaders may have contributed to the creation of a centralized training group to avoid implicating themselves in the Technician training process. In many of these cases, the perception is that accountability lies elsewhere.

There is a mismatch between who does the work and who is accountable or responsible. This results in a great deal of time spent fixing things that were not done correctly the first time and the tendency to pass responsibility on to others affecting teamwork.

Solution:

Accountability Measures

Responsibility for products needs to be attached to the people who produce the work. This can involve measures that provide incentive for people to “do it right the first time” i.e., when one error is found, all documents are rejected; Team leaders need to encourage Technicians to check the protocol etc. Initiatives such as these need to be applied as a general and communicated objective to improve work quality and must be done in conjunction with positive approaches such as team rewards.

Involvement (Cooperative Culture)

There is a need to encourage a team culture in IPN that includes all three levels through the application of the team approach. There needs to be incentive for people to help others, to share knowledge and expertise and to encourage discussion. One approach can be in providing reward for team achievement. Training in how to encourage cooperation and teamwork will be beneficial especially for Team Leaders and Study Directors.

Responsibility Change

There needs to be a definition of individual responsibilities. It may be attractive to return some products back to the person accountable but this will mean consideration of training needs and workload implications.

Motivation

Self motivated initiative and involvement fosters the most desirable form of accountability. Individuals work because they want to and do it well because they are involved and proud of the results. This will require the emphasis on goals and their achievement and matching incentives and rewards.

Incentives that Affect Performance

Incentives are essentially those actions or opportunities or benefits that the company provides the employee that motivate them to work to a defined level. Incentives may include salary increases, opportunities for promotion, assignment of special projects or personal recognition. The following discussion summarizes the incentives identified by the staff in IPN.

Study Directors

The Study Directors identified opportunity for personal development as being a valued incentive. This category includes cross training, continued education, and progress in terms of career opportunities.

The company is considered to provide a fair amount of opportunity to do more interesting work that, although salary may be lower, is an incentive to remain at CTBR as other companies do not necessarily allow the same flexibility.

Promotion is seen as an incentive although there is a belief that there is little room at CTBR for promotion. It is recognized however, that there is an opportunity to develop specialized areas that can allow further promotion. CTBR's flexibility with individual work schedules is also seen as an attractive attribute.

It is perceived that there are no monetary rewards for academic achievement unless you leave the company and then return at a higher level. The selection criteria for going to conferences seem to be vague in IPN and also inequitable in comparison to other departments. SOT was used as an example of this.

Opportunity for continued education is seen as highly attractive yet the present seminar forum could be improved to include more in-depth scientific lectures and greater choice of topics.

In general the Study Directors are content with the present system yet raise some concerns as to the equity of pay and monetary incentives compared to other departments. While salary is considered to be lower than jobs with equivalent responsibility, the incentives to stay at CTBR outweigh this discrepancy.

Problematic is the vague criteria for incentive achievement in some cases (i.e. conferences) and the perception that not all rewards are accessible to all. There is a need to clarify how to attain these incentives.

Team Leaders

Team leaders consider the fast pace of IPN and the opportunity to learn new techniques as well as the team spirit among group as the main incentives. Also noted was working with computers, having work responsibility and the social advantages (healthcare).

Technicians

Technicians found learning new techniques, working on different studies, opportunity for overtime, teamwork, social advantages and animal contact as the main incentives. Ownership on study was found to be an incentive to some while others preferred to have no responsibility.

The most negative elements of the job consisted of unfair training assignment and poor study assignment. Some people reported being stuck on the same types of study repeatedly or not given an opportunity for training.

The greatest factors that affect the Technicians are the need for recognition and inclusion in the department decisions. The Technicians work is characterized by lack of autonomy in making decisions as to training and study assignment.

At the moment IPN has more technical staff stability than in the past, perhaps due to salary improvement. Incentives can be used as part of the long-term reduction in turnover. The other major factor involved is the corporate culture at the Technician level. Initiatives to increase involvement and responsibility on study will improve data quality but also benefit the company in terms of turnover. With reduced rate of turnover, the department can increase the knowledge base of the Technicians and therefore focus on training in specialized techniques.

Policy

While incentives contribute to the functioning of the organization and to the involvement of employees, policies also play a significant role in setting the corporate culture. There is a need to clarify some of the policies.

Warning Policy

The reprimand or warning policy for errors made on study needs to be clarified. Technicians, although not seriously concerned have a varied understanding of what merits a warning. Although Technicians believe that Team Leaders are supportive and look for solutions to problems more than punishment for errors, there is a popular belief that the negative element is focussed on much more by both Study Directors and management. This emphasis on negative feedback concerning errors affects the work environment and culture and Technicians involvement in their work.

Need for Corporate Philosophy and Approach

All policies should be assessed to reflect the corporate philosophy that focuses on solutions rather than problems. Mutual agreement for improvement can foster better employee relations and gain better accountability for repeated errors. This needs to be coupled with an effort to reemphasize positive feedback towards the Technicians.

Although in general, management is seen to be supportive of the employees, with no clear understanding of the policies, there is an opportunity for individuals to misinterpret disciplinary actions.

Communication of Policy

Technicians also show concern as to health and safety issues such as the policy for employees that develop allergic reaction to animals. The company's position on this is not effectively communicated. Although there is mixed sentiment as to the company management of this, there is a danger that the present system may be regarded as a negative gesture towards the Technicians and reinforces the belief that management perceives them as the least important employee group.

Need for Accessible, Relevant Policy

The solution then is not necessarily to redo the policies but to make them more accessible to employees and to address changing concerns.

Perception of Policy Development and Application

There is an underlying belief that policies are made by individuals disconnected from the situation or context of the policy. Hence policies such as education leave, repayment etc. are largely interpreted and applied differently from one department to another. Although management styles differ and certain constraints affect the application of policy, the diversity

from department to department is in some cases, a source of conflict. I.e. Gen Tox versus IPN conferences attendance and how much leeway is given with regard to travel arrangements or expenses. Greater flexibility affords reciprocity in terms of returned good will.

Need to Formalize and Standardize

An organizational goal should be to formalize the most important policies and to standardize their application. This will assist in a goal to enhance cooperation and teamwork in order to ensure a healthy interdepartmental customer supplier relationship.

Part IV Training

Two areas need to be targeted to improve the training system in IPN: general training and orientation. It is important to keep in mind that while the conclusions drawn in this section reflect the feedback of individuals within IPN and do not include those of the training department, the problems are perceived as real and therefore need to be addressed.

General Training

Certification / Accreditation

Team Leaders can sign off Technician training whether or not they are themselves trained and proficient. Not only is certification signed by those who are not trained on the task but also the training itself is sometimes provided by someone who does not have adequate understanding or is not signed off themselves i.e., the trainer is not certified but demonstrates the technique and then asks Team Leader to sign.

Data Quality

Training does meet its purpose within IPN but data quality and study efficiency are affected by poor yet accredited competencies.

Perception of Certification Process

The result of this process problem is the message it sends to the Technicians. Training from their perspective seems to perpetuate the notion that their contribution is of little consequence. While some Technicians consider themselves experts in certain techniques, those who are less capable are given the responsibility and authority to train others and sign off. The implication that training is not important or respected impacts directly on the perceived importance of quality data.

Training Selection Process

There is a general perception among the Technicians that there is a lack of equity in the training selection process. While training on activities such as surgery is by seniority, the general opinion among Technicians is that training opportunities are not offered fairly. It appears that the least vocal Technicians get the lowest priority

Whether the training allocation system is really unfair or not, perception of bias and inequity further contributes to lessened commitment of individuals to the goals of the company and reduces motivation.

In addition, Technicians see little benefit in the time spent training stagiaires during their internship as more than half do not return. This is perceived as a waste of training that could have been given to them.

Effectiveness

Planning and Execution

There are many examples where training is scheduled yet poorly planned or executed e.g., animal shortages halt training that should not, in hindsight have been initiated; training is done too far in advance to be of use. There are examples of training that does not apparently serve a purpose for the individual e.g., Word training for a Technician that does not use Word. There is a need to set objectives for training in order to create a clear match between needs and instruction provided.

Proficiency Acquired

There is a concern for the level of proficiency acquired with regard to more complex skills such as ECG. While some training provides for trouble shooting, much of the training does not. For the most part individuals report that these tasks require greater understanding and problem solving techniques.

The commentary indicates a need for further investigation into the effectiveness and efficiency of the approaches and content of the training system.

General Training Conclusions

Trainer Role

Trainers need to take a different role by involving Technicians in the training. This gives responsibility, makes more efficient use of the Technicians expertise and avoids the demotivation of having non-experts providing the training. Trainers need to play more of a supporting role in ensuring the training is done to standards (i.e., SOP) while experts train the techniques.

Training / Study Allocation

Solutions should also include evaluation of the training allocation system. There is a need to provide the Technicians with a greater responsibility for their own training. Currently most Technicians neither have choice over training nor the studies they work on. This results in a low sense of responsibility, unwillingness to prepare effectively for future activities on study and reluctance to accept responsibility for data quality.

Goal Setting

Goal setting can help create a more effective training practice. More complex tasks may be broken down into objectives which can be used to guide the trainee by giving clear expectations and the criteria for success.

The training goals of IPN need to be defined. Consistent assignment on study can increase ownership and commitment to work done. Overtime is sometimes caused by the need for qualified staff on a study and inefficiencies occur where staff on study are not trained to do all the tasks required. The goals should provide ways to alleviate these problems and increase the flexibility of the technical team.

Evaluate Efficiency

There is a need to evaluate the efficiency of present training systems. Some training is not necessary and other training is too long. It should be possible to reduce the amount of time spent on certain procedures.

Better planning and group training for some procedures would result in greater efficiency. There needs to be better use of the previous skills of individuals and a need to consider individual aptitude and competency as well as efficient use of animals

Further analysis is needed to look at rearrangement of the training selection process, to train a wider base of skills, focus on the “most important” skills to be trained and better use resources.

.Orientation

There is a lack of focus on the needs of the department and skills necessary for people new to the job.

Technician Orientation

New Staff Ability

Technicians and Team Leaders believe that the orientation program does not prepare the Technicians for work on study. There is a great deal of variation in the ability of people to do the SIRTs, they also do not understand pumps and what to do if there is trouble. There is a general consensus amongst Team Leaders and Study Directors, that new Technicians need a greater understanding of the implications of errors, understanding of SOP's and how to read protocols.

Effectiveness, Efficiency

The training is neither efficient nor that effective. The problem is that although topics are addressed the skills are not acquired. Delivery and educational approach may be at fault. Technicians report that the theoretical part of orientation is long, boring and disconnected from the practical aspect. The result is that the Technicians become uninterested and do not see the relevance and have difficulty remembering the theory when the practical is presented.

Conclusions:

Refer to Educational Research

It may be useful to refer to educational research if it is necessary to separate the practical and theoretical aspect of training. There are strategies that can be implemented to increase motivational attributes of instruction and develop more effective theoretical training systems. There needs to be more attention to the relevancy of some information and to the transfer of understanding from one context to another.

Provide Orientation Suited to Department

There is a need to provide training in the orientation session that is specific to the department in which the trainee will work. For example, there is little need to train someone extensively on giving eye-drops if it is not a skill that is commonly used. Trainees are given material to read or activities that seemingly have little purpose (e.g., reading SOPs is a daunting task without practical experience to support the descriptions, weighing two-hundred rats is excessive). If these tasks are believed to be essential, then the new Technician needs clear understanding of why and how they will apply to their job.

More Effective Training- Assess Needs

Technicians also report not always having access to trainers as there are too many individuals at one time in the training rooms. There needs to be an assessment of what is really necessary for new Technicians to know. For example, GLP training provides a good general overview but needs to focus on the reasons for GLP. The objective is to encourage the new Technicians to ask

if they are not sure if their actions are GLP. This requires understanding of the reasons and implication of GLP on the study process. GLP history, although interesting, is not necessary. Feedback from Senior Technicians, Study Directors and Team Leaders concur that the new Technicians do not have strong enough understanding of the implications of GLP.

Orientation Training Structure

Technicians express a high variability in satisfaction with the hiring process. Common conclusions are that there is a mismatch between the promises that the company makes and the opportunities it delivers. At the Technician level, training is of great importance and serves both to attract individuals to the company and is an incentive to stay. However opportunity for training varies greatly in the first year or two. Some are provided with training (e.g. for bleeds) within a short time frame (3 months) while others wait up to a year. Although not all employees are as vocal about their desire to be trained, it appears there is a need to solidify the training dissemination process to be more equitable and to provide the new Technicians entering with a clear understanding of the process. The present situation causes tension between some Technicians and results in dissatisfaction.

Conclusions:

Approach to Training Structure

Suggestions were made to create a structure for training by which individuals could work towards achieving “echelons” of qualifications based on skill level. This returns the responsibility for opportunities, back to the Technician. People working in environments where choices are made for them are generally more likely to be apathetic about taking work responsibility. The concept is to provide higher expectations, not only from the company but also from the Technicians of themselves.

Team Leader Orientation

The Team Leader is typically promoted from the Technician ranks and is then trained by a more experienced Team Leader. There are sometimes problems associated with this type of learning. Usually a Technician is promoted to Team Leader when there is a high volume of work making training rushed for the trainee and a burden on the trainer. Also, the learning is governed solely by the influence of other workers. Responsibilities such as training Technicians become less emphasized and QC is not taught rigorously.

Guides in the form of written material provided by other Team Leaders exist but are not standardized for the department or placed into a single binder for reference.

Conclusion:

Information, Formalized Training

Some suggested a single source for information (e.g. reference files) is needed by the new Team Leaders and a better communication network with the service departments.

Ideally the training department would have some input into Team Leader training to ensure that the goals of the department were met e.g., Team Leaders become more involved in training of new Technicians, a function that should be key function of the Team Leader.

Team Leaders also report a need to have more formalized training that could avoid having to continually ask experienced Team Leaders.

Study Director Orientation

Cross training is a major work incentive for experienced and new Study Directors. During hiring or in orientation it is not made explicit as to when and how this may be made available. Study Directors also identified a need to have access to information on communication routes, processes and procedures. Interviews indicate that the review process with new Study Directors to provide feedback as to their performance needs improvement.

Team Leader and Technicians stated to that the Study Directors need better understanding of the operations in the animal rooms.

Conclusion:

Formalize and Focus Training

The Study Directors orientation would benefit from being more formalized by creating communication routes with other departments, linked not only to individuals but also to their responsibilities.

If cross training is to be a major selling point for CTBR then it is worth formalizing the process. In some cases there is a need to increase their knowledge of the technical aspect of the work to better understand the constraints and realities. This would also encourage the interaction between the Study Director and the Technicians. It may also be beneficial to provide instruction in effective report writing as this is seen as a skill that is important and not necessarily a skill that everyone who enters is able to perform adequately.

New Study Directors require feedback as to their progress.

Overall Orientation

Generalized comments about orientation are that there is a lack of presentation of corporate policy and philosophy. Not only is it important to provide new employees with the understanding of what the company feels is important but also to provide the employees with a sense of the direction to which they should contribute. Thus the initial steps of individual goal setting can coincide with the goals of the company and individuals understand how they contribute to its success. It is important for employees to see the relevance in their work as this can be a source of pride which is only attainable if the connection between an individuals' role in the company and its goals and products are connected. It is here that the corporate culture can be set in place.

Conclusion:

Policies and Documentation (Orientation)

Employees are not given much information of practical use after orientation. Technicians do not seem to have any use for their binders that contain exercises and examples of SOPs and GLP regulation. The information that is of importance such as how to set up the "books" on a study is not provided. This document is supplied only when the Technician enters the department. This is one of the most important skills needed to function in the department but it is omitted at orientation. Technicians report difficulty when they enter the department and rely heavily on this document.

Study Directors report that the training binder contains mostly unneeded information. There is talk of a new manual that is in progress. Orientation in general needs to present the employee with information such as policies and corporate philosophy and goals. Although policies, such as supported education and health and safety policy are perceived as significant incentives to the employees, many are unaware of them until they ask. Ideally these policies should be available upon entry into the company.

Strategy for Training: Re-evaluate Training System

The present centralized system should be reevaluated. Decentralization could enable a specialized training department that is attractive to IPN due to the complexity and evolution of new techniques. However, a disadvantage is the difficulty in standardizing techniques. In the present centralized training system, there are concerns for the mutation of techniques when imported to the new department (e.g. dog holding techniques). The need for standardized practices supports the centralization of training in order to minimize variability on study.

The training department should evaluate training needs of individual departments, assure that these needs are met and recorded (e.g., the present training binder is poorly organized and difficult to read. It should be overseen by the training department).

Goal Setting

Instructional goals should be set for the department that meet the goals of the organization. This should involve all departments to ensure training is efficient and complete. The key factor is to use needs and goals of the organization to describe and define the role of training. The general needs of IPN are as follows:

there is a need to monitor and disseminate standards i.e. SOP; there is a need to ensure that training is available external to any study (while some tasks can be trained on study); there is a need to train for understanding not simply for procedural knowledge, there is a need to evaluate the training needs of the department continually.

Involvement and Accountability

Involvement and accountability can be encouraged with the use of a more decentralized system. Present problems such as trainers that are not adequately trained themselves for a procedure and Team Leaders that are not trained signing off for procedures, send a message that, despite their expertise, the organization does not consider trained Technicians as a resource. There is a need to demonstrate attention to detail, pride in work, and teamwork in order to instill these practices as values of the corporation.

Role of Training Department

At present the training department operates independently of the departments it serves. The training department needs to be involved in the planning and activity of each department; this aligns it with the concept of the internal customers and supplier. The goals of departments and services should match the needs of the customer departments.

Thus a goal of IPN may be to increase communication and positive relationship between Technicians and Study Directors while increasing involvement of the Technician and general accountability of the Technicians and Study Directors. The training goal, to increase Technician understanding of science behind the technical aspects also serves this goal. There was a suggestion to involve the Study Director in the Technician Friday meeting to talk specifically about the science behind procedures. The pre-study meeting offers another opportunity to meet this goal.

Pre-Study Meeting

Recent quality issues have resulted in the reevaluation of this meeting as a source of quality and communication problems. There are two issues: communication in terms of information dissemination and understanding, and goals.

The pre-study meeting, as stated in the SOP functions to provide information through discussion of the protocol so that “key people are able to work in an organized, knowledgeable manner and to define responsibility.” However, Technician participation according to SOP is optional and “Principal Technician” does not really exist. The purpose, as stated in the SOP, may not comprise all the necessary elements. There is a perception that the meeting can be accommodated by simply signing a checklist to confirm understanding of the protocol and responsibilities to it. People feel that they accomplish their duties when the time comes.

The most useful results of this meeting occur when a problem is identified, that subsequently either avoids errors on study or facilitates process on study. Simply making this meeting a priority will not improve results. It is necessary to clearly define the objective of this meeting.

Presently Technicians attend yet may be merely representative of the “Technician” group and not the person who will work on the study. At other times the Technician may be scheduled to work on another study on day one. The consistency of staff is therefore a component in the failure of pre-study meetings. Yet so is the lack of Principal Technician role; as is the involvement of Technicians.

Conclusions:

Define Goal, Leadership

The goal is to determine if the protocol is feasible and to ensure that those involved understand the protocol and their responsibility to each other. This is essential for the Technician. The focus should be to determine possible problems and to ensure understanding of activities required as a group. Teamwork, accountability and responsibility need to be a set goal of this meeting. The meeting needs to become a high priority for everyone.

Understanding

Through understanding the reasons for activities, Technicians can both anticipate problems and find solutions as a group. All members of the group must understand the impact of their job on each other as well as the responsibilities and roles that the others play. The Study Directors should be responsible for communicating this.

The pre-study meeting functions as a focal point of the study process. It is imperative that the people involved operate as a team. This requires leadership and group dynamics skills on the part of the Study Directors.

Study Director / Technician Relationship

Further, a stronger Study Director to Technician relationship would increase the likelihood that that Technicians will bring up concerns in these meetings.

Conclusion

It is necessary to address improvement at many levels within the organization. Priorities and processes need to be matched from the most general and global corporate goals through to the

smallest detailed work that is done. For this reason, corporate goal setting strategy needs to be the first step in improvement.

Goal Strategy

Before interdepartmental relationships can be improved or individual performance can be addressed there needs to be an initiative to address goal setting strategy to clearly define and communicate the corporate goals. There needs to be congruency between the senior and executive management understanding that is then translated into implementation of these goals. If “innovation” is to be a priority, it should be across departments. The process should then translate down, defining goals per department, processes and jobs. This will be the first step in improving the customer-supplier relationships so that people can begin working together rather than as insular units.

Corporate Culture

There needs to be a culture that encourages people to contribute to the company, to share knowledge and to cooperate to achieve goals of the organization. While involvement strategies can help, strategies such as Continual Improvement may provide incentives to increase involvement. This is essentially a process by which employees themselves evaluate and suggest improvements on an ongoing basis and are rewarded for the results. This approach would also fit with the executive management emphasis on “innovation;”

In the spirit of encouraging innovation, any new idea will be accepted. There needs to be an impetus to make improvements on a regular basis. Innovation or improvement will then become the measurements of individual and departmental achievement and can translate into creating individual recognition and career opportunity within the organization. This would form the basis for a corporate culture that emphasizes action and contribution to the organization and rewards achievement (MFA May 24, 2001).

Training

The role of the training department needs definition and direction. Their responsibility should involve continual assessment of the needs of the departments and match the services provided with these needs.

The department needs to operate on a corporate level, not only to ensure uniform SOP practice but also to ensure the philosophy and goals of the corporation are communicated and understood. This will also involve close ties with HR to ensure policy comprehension. This role must also extend across other boundaries such as QA. QA can identify problems that occur while the training department must evaluate if training will resolve the problem.

The training department should take on a more evaluative direction and ensure that training is effective and efficient. It should consider frequency and impact and causes for errors and determine if training is a solution. The training department therefore needs to be present when

departmental goals and needs are discussed. This will enable them to meet needs such as making sure that the knowledge or expertise within the department is taken advantage of. If IPN wants a broader base of skills, the training department must help this to happen. The training department needs to have oversight of apprenticeship type learning and to communicate with Supervisors and Scientific Directors to ensure that the needs of the department are met.

Interdepartmental Relationships

There is a need to establish an initiative that will address communication routes, individual and departmental responsibilities and standardize the roles across departments. The goals should be to improve interdepartmental relationships by addressing these areas.

Scientific-Operation Separation

There needs to be an initiative to facilitate the communication and working relationship between scientific and operational domains. In IPN the Supervisor and the Scientific Director relationship is critical and will involve setting a goal to narrow the gap between their respective staff in terms of scientific and technical knowledge. Better communication and working collaboratively between scientific and technical is a training issue as well as a management issue.

Accountability and Responsibility Issues

Accountability issues need to be addressed through initiatives that enhance the understanding of other peoples roles, standardize department operations to facilitate functioning and communication, assigning the responsibility of work to those who do it and measuring achievement by the degree to which set goals are met. Rewards for achieving these goals need to be delivered on a group basis. Individuals must be held accountable.

Study Director / Technician Relationship

There is an immediate need to address the Study Directors role and implications it has on Technician involvement.

Technician Involvement

The first initiative must be to consider incentives to motivate Technicians. This will require adjusting the study and training allocations system, increasing positive feedback and recognition, involving the Technicians in the department decisions before holding them accountable for data quality and QC. This may also involve strategies such as Continuous Improvement Incentives, re-instating the Principal Technician, consistency on study and pre-study meeting evaluation.

Hiring and Orientation

HR and Training need to collaborate to match selling points with actuality, to ensure that people have clear expectations. Strategies for hiring and orientation need to consider the corporate goals and philosophy and incentives for individuals combined with policy. Orientation provides the opportunity to present the corporate philosophy and goals and to set the corporate culture. Individuals must understand how their role contributes to the company. Clear personal goals should be set accordingly while new employees should be given clear communication routes and know how incentives are distributed by merit.

Pre-Study Meeting

The focal point in the study process is the pre-study meeting. It can improve the efficient operation of studies. Not only must there be an evaluation of the goals of this meeting but there must also be an initiative to improve the skills of the Study Directors as facilitators of the process. The training must focus on enhancing the Study Directors skills in creating teamwork within the group and taking on a leadership role that facilitates the process.

Continual Analysis

Continual analysis should be part of the organizational culture. The training department must ask what is needed, so too must the other departments ask of their customer departments. Departments need to ask their employees where the problems lie and how to solve them. They need to ask if goals that are set are still current.

This information should then be used to determine solutions that are supported by individuals and systemic understanding. “There needs to be a mechanism in place that encourages and allows for the proposal of several solutions with associated quantifiable costs. These solutions will not all be found in house and must be sought after externally (MFA May 14, 2001).”

Change

Often, change in organizations is effected through physical change, downsizing, restructuring, reengineering and so forth. Often what is left is something that is changed but that is not any better. The changes were not effective in solving the problems that were targeted in the first place. What is needed is, “the kind of change that requires that people ‘emphasize improvement’ and that encourages the implementation of change effecting positive solutions to problems through a process that considers multiple solutions that can be assessed for cost and benefit to the company (MFA May 24, 2001).” Change can be brought about by strategies that use the information gained by needs analysis to implement solutions. The next phase must be to evaluate strategies that will effect constructive and beneficial change in IPN.

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Appendix I: Sample Interview Questions

Agenda for Interview

Interview Date _____

Time _____

Participants:

Goals: To investigate the relationships of functions within the IPN department. To identify potential problems and solutions.

Questions:

Relationships in IPN Department

Given the relationship map, describe what matters most to the individuals at each interface (i.e., between _____ arrows)?

What matters most at the interfaces that apply to you.

Are you aware of problems that arise at these interfaces? (E.g., Between study directors and team leaders _____)

Regarding study design?)

Can you attribute problems in these interfaces to problems to do with motivation, incentives, skills or knowledge, policies, procedures, resources, equipment, time constraints or goals?

E.g., How would you describe the relationship with QA in terms of expectations, problems and solution development? I.e. if identify a problem in out of QA date when major mistakes are found, what would help this situation. Are you able to identify major problems early? Do you know when problems will be more likely?

Goals of Department

What are the goals of the IPN department?

Are these goals measured? (Or measurable)

Do these goals match the corporate goals of quality, responsiveness, innovation, individual service, and on-time reporting?

Do you set goals on an ongoing basis? What is the process? Who is involved? Who knows of goals?

How do you see these goals changing with an increase of 35% staff?

What issues are related to quality goals of work products?

What will it take to achieve 100% on time reporting? What causes 2% late reports?

What are the obstacles that stand in the way of achieving the set goals? What would solve these problems?

If you were to set goals for yourself what would they be? What would the process goals be...Department goals..?

Skills and Knowledge of Employees

In your opinion;

Are training systems adequate for now? ? Is it efficient, effective. How much retraining is necessary?

Do people have access to necessary information to carry out their jobs?

Are there any problems that are related to training or knowledge?

Are new employees adequately skilled when they enter?

Are the orientation processes sufficient?

Do you have adequate opportunity for training? Is this important to you?

What will a 35% increase in Technicians mean to training issues?

Employee Motivation

Do you think employees can describe the value of doing the jobs they are doing?

Are they aware of the function it has in the larger process?

Do your people show commitment to the direction or goals of the department or organization?

Are your employees confident? Do they expect to succeed?

What do you find motivating in your job? What would help?

Do you expect to succeed in your work? What task (s) do you feel least confident in doing?

Do you think the work you do is valuable? Is there any task that you perform that you see as having little value, irrelevant or not your responsibility?

Environment Factors

Are policies supportive of the goals of their jobs?

Do people have all the necessary tools to do their jobs?

Do equipment failures or maintenance hinder work?

Are there problems associated with processes that arise?

Is there anything that the company could do or should do to provide incentives?

Do people ask to see the final product they are part of? Is this important to them other? What is important to you...your people? Feedback, responsibility, promotion possibility.

Do you know what to do in order to be promoted? Is this important to you and others?

What hinders these incentives?

Incentive Opportunities

How is accomplishment recognized?

How is effort encouraged? Training, money, promotion, recognition, responsibility

Are there mixed messages? I.e. focus on quality only cost control recognized or rewarded.

Are people aware of the performance criteria required for promotion?

Do people have access to final products of the department? How is this made available?

What is perceived as an incentive for employees?

Expansion:

What does expansion mean to you? What do you believe will happen to the structure of IPN?
What are your concerns?

Assuming an increase of 35% (personnel, rooms, studies...) what impact will this have on IPN?

How might the goals of the department change given this change?

What is working well enough now but will have difficulty in the future? Processes, procedures, scheduling,
QA...

Are there sub-processes within the department which will need to be improved? I.e. Turnaround time only
just accomplishing goals. Scheduling

What relationships are the weakest and will have to be improved if expansion is to be successful?
Do you have solutions to the identified problems? What would be the ideal in each instance?

Can identify obstacles that stand in the way of expansion?

Are there other challenges that will be encountered soon that will effect needs for training, skills, information dissemination, communication issues, scheduling, processes?

Process:

Are there procedures or paper work that do not serve a purpose?

Given the process map (to be shown at meeting), can you identify errors I have made? How do you conceive of the "study-report" process? Is there a difference between what it should look like and what it does look like?

What paperwork is done at each part?

If changes are made to a study at the last minute, how does this effect the techs, team leaders, study directors... What might be some solutions to these problems?

Given the map, can you identify sub-processes that have problematic elements? Can the problems be characterized i.e. skills missing, info missing, communication issues, expectations, policies, goals unknown or not relevant, incentives not in place?

Are there common errors that occur in the reporting process? What are they? What are they caused by? Can these errors be avoided?

In an ideal situation, are there resources of staff numbers or characteristics, equipment, knowledge, policies that would better processes and products and job performance with in the IPN department?

Job Performance:

Can you describe what the most effective people do or what the less effective people don't do? What problems arise that people solve? What is done to solve these problems and what are they caused by? Will these problems arise in the future? Are they common?

Can you give me an example of flawed performance or errors that occur and how they were resolved?

What general concerns or questions do you have?

In general, what improvements would you like to see?

If you were to implement a change now, what would it be? Think of a large change such as new information system and a small change such as changing a cage lock that is problematic (i.e. a change that will simply make thing easier).

Do you have any questions for me?

Appendix II: CEO, Interview

Needs Analysis Interview

Interview Date: May 24 Time: 2:30-4:00

Participant: CEO.

Interviewer: Mike Broadhurst

Objective: To investigate CEOs opinion as to the direction of the company.

Expansion

The focus of company has been, and continues to be, on core competencies such as In-vivo Tox and support lab services. This will continue to be the direction.

As a brief historical background to put the present direction into context, what is now CTBR has evolved from a series of critical events that have shaped both the present structure of CTBR as well as its corporate priorities. In the 80's the company was characterized by a solid entrepreneurial management base that, after a crippling hostile takeover bid involving Merieux in '87-'89, saw the dissipation of many of the original management team and seriously effected the viability of the company. In '95 the company was again prosperous and was poised to expand, when it was bought by (CAI) Merchant bank, Caisse de Depot and the, Ontario Teachers Pension fund). In '96 the company was bought by ClinTrials (CTR) and became CTBR. The purchase of CTBR by Inveresk this year, the resulting changes in major shareholders and the prospect of going IPO in three years, will mean only modest growth for the company. The expansion will be directed towards the core competencies with an investment of 30 million this year and another 7.5 million in 2002. This will translate to an increased room capacity of between fifteen and twenty rooms (13% or 17% increase in rooms) on top of the present 115 rooms and increased volume through the support labs.

Given this external constraint, and the present prosperity of the company, strategic planning need concentrate more heavily on the systems and processes within the company.

Strategic Planning

In terms of planning processes and tactics, the company moves forward through the implementation of corporate objectives that are collectively agreed upon by senior management. This process provides the direction of the company and establishes the areas of emphasis. Objectives are put into business plans that span two to three years and are quantified in financial terms. This plan is put into action at managerial levels where it is organized, documented and measured providing accountability for results.

Goal Priority

The priority of the organization in terms of its corporate goals should be placed on innovation. The Research and Development committee is designed to assess the market and determine the area of potential development such as, cutting edge technology or study capability, technique etc. At present there seems to be a perception that "innovation" entails validation of new study techniques, developing new research expertise and so on. The ideal application of this corporate goal would encompass more radical departures from the present service areas.

It is possible that there is a certain amount of complacency within departments that is encouraging this perception of 'innovation'. There is a need to reemphasize the standpoint that innovation should become a priority goal and should mean bringing "something new to the table." The addition of validations or smaller subsidiary studies or analytical techniques should be considered part of the normal responsibility of the department. An example of true innovation was the idea to manufacture infusion IV equipment. "IPN used to be seen as the crucible" of innovation but seems to have lost this edge. There is therefore a need for a renewed entrepreneurial spirit. This is the conceptualization of 'Innovation' that is expected of IPN and the R&D committee.

Expectations of IPN

IPN is the department "that does the sexiest work" and should be the area with innovative "spark" that serves as a model for other areas. Success in IPN should spill over into other areas.

"As the well of innovation begins to run dry, the question to ask is, 'why?'" While individual contribution should be questioned, there is also a necessity to look at individual understanding of the corporate goals and to investigate the emphasis they place on these goals as well as how they are being implemented.

Evaluation of Processes

In the past, initiatives have been taken to resolve certain problems or to meet certain demands; yet there has been no attempt to put a price tag on these initiatives. In times of general prosperity, the opportunity should be seized to analyze these initiatives so as to better prepare for the future. For example, it is worth investigating the cost of implementing the CPP process and then comparing it with the worth of the business result. If the on-time reporting were reduced to 75% or 86% what would be the result? Would reduction in on-time reporting be more cost-effective or would it damage the business?

Quality is another similar issue. CTBR is required to be GLP compliant however, present QA standards are set at a higher than GLP standard. The question is then, "what is the cost of quality" and "what is the benefit?" For example, "if the platform is set at 20% above GLP what is the cost and what is the benefit?" Although it is difficult to assess these costs using qualitative data such as information solicited from clients, it may be possible to quantify their responses in order to gain tangible understanding using qualitative measurements.

These questions need to be asked now and need be applied to all processes such as those described above.

Need for multiple quantifiable solutions

Processes are put into place in order to achieve certain goals but they are done with little regard for the cost. Solutions should therefore be quantified. Single solutions to problems are offered however there may potentially be several other possibilities. For this reason, there needs to be a mechanism in place that encourages and allows for the proposal of several solutions with associated quantifiable costs. These solutions will not all be found in house and must be sought after externally. This is rarely done.

Emphasis on Improvement

There is a need for leadership towards developing dynamic and varied solutions through processes as well as in finding and implementing mechanisms that will encourage or motivate people to partake in strategies and goals such as innovation.

There is a need to inspire buy-in into these strategies and to instill them as values within the company culture.

Senior management need to take a closer look at, “ what their area is doing, how it is done, and the way they are doing it.” They must ask the question, “is there a better way?” For this to occur, a catalyst or impetus is required.

Given these criticisms, it is important to state that people are doing a good job and are working hard but we must still maintain the competitive edge. To do this we need to use the “good times” to understand what we are doing and finding better ways of doing it.

Industry

The industry is relatively stable. Regulations do not change too much over time, although regulation changes typically mean more business for CROs. CROs have the advantage of being able to do these studies well and more efficiently than the companies that contract them.

Responsiveness

CTBR is generally capable of responding to change. This is very much a result of its dynamic culture and people, such as Chris P. who act as “agents of change.” The IPN department and to a larger extent Tox in general, has been the center of dynamism in the company. It is feared that this dynamism in terms of innovation, has begun to flag in recent times. Although IPN has recently added Neurotox, which came from another area, the dept is no longer showing its customary growth and vitality.

Strategic Vision

Information is not always disseminated, as it should be throughout the organization. The larger corporate goals, achievements and directions should be emphasized and communicated at managerial levels. The entire company meets three times per year for the purpose of informing employees of the company progress and growth. There needs to be greater opportunity to transmit this information and recognize company achievement. Essentially, individuals and departments in general must become more goal oriented. This can be done by asking, “what are the key factors and what do I measure myself against.” This will involve measuring success on profitability and identified benchmarks that indicate success.

In the spirit of encouraging innovation, any new idea will be accepted. There needs to be an impetus to make improvements on a regular basis. Innovation or improvement will then become the measurements of individual and departmental achievement and can translate into creating individual recognition and career opportunity within the organization. This would form the basis for a corporate culture that emphasizes action and contribution to the organization and rewards achievement.

Summary:

While IPN represents a strength within the company by its ability to respond to different demands, the greatest area of concern is identified by initiatives for innovative, entrepreneurial projects. It may be necessary to reiterate and define the corporate goals so that they may be better translated into action. There is a need to investigate the processes that are in place and to determine the cost and benefit associated with them. The next few years will see modest growth of the company.

Appendix III: Validation Meeting Tables*Needs Analysis***Technician Validation Meeting****June 13 & 18, 2001****Purpose: To identify and prioritize common concerns and areas of need.***(Supervisor Comments added June 22)*

Headings	Primary Responses	Comments
Service Departments (in general)	Need team work between departments (help each other out) less insular All departments lack understanding of needs and priorities of others Communication (routes, who?)	Uniform department operations Customer –supplier relationship Understanding
QA	Communication: Send e-mail. But would be helpful to know in room (not a help) Intimidating in room (Day one mostly)	Hindrance to work. Poor role and communication
Necropsy	Need understanding of IPN (Cross training initiative will help) Scheduling issues Communication (who? Don't tell details)	Customer-supplier relationship (products and communication) <i>Tech's don't like to do Tox Services work</i>
Tox Services	Need to consider who hiring i.e. hire students who leave end of summer creates pressure on IPN in rush in Autumn. Communication (i.e. of dates errors) Quality: pride in work Scheduling <i>Need to arrive before scheduled time</i>	Customer-supplier relationship (products and communication) (Definition of roles)
Pharmacy	Communication (attitude) Lack preparation, organization (sometimes an issue) Need understanding of impact of late TA	

Headings	Primary Responses	Comments
Training		Training efficiency issues:
Planning	<p>Need to take advantage of the quiet times more</p> <p>Not well planned (i.e. surgery run out of rats so must go hunting for more) or start again in few months techniques change over time therefore by time restart training must start from beginning <i>Not a big impact- rare occurrence</i></p>	Scheduling
Effectiveness	<p><u>Some</u> training waste of time (i.e. word) not all useful) need to look at needs of training more closely i.e. computer: where to find master and how to save a new document without changing the master)</p> <p>Some training does not prepare the trainee for unexpected events, trouble, problems i.e. ECG, or pumps (others do i.e. Artemis)</p> <p>Gap between training and use too long so need retraining: Artemis 6 months before use <i>Sometimes cant help it</i></p> <p>Time spent on refresher when may be better to have waited to close to use date for initial training. Avoid need for retraining</p>	<p>Evaluation of training needs</p> <p>Evaluate true context needs</p> <p>Link understanding with procedural Knowledge</p> <p>Transfer and time</p>
Strategy	<p>Need to group techniques</p> <p>Need to consider aptitude and skill: Some people need less time to learn others more (seems to vary depending on trainer: Not Standardized)</p> <p>Need to train more common animals first</p> <p>Training need to be more broad rather than specialized. To meet needs of “most” studies (Will reduce need to constantly replace people on study who do not have certification for a procedure)</p> <p>Need more diverse training (versatile techs)</p> <p>Need to establish a structure – empower techs to make own choices(training and studies)</p> <p>some Techs a little unsure about this seemed hard to think beyond present structure</p> <p>Follow-up training is</p>	<p>Efficient use of resources:</p> <p>Animals- combined procedures</p>

Headings	Primary Responses	Comments
	<p>Last minute training (rushed less thorough) OK (Poor training results in misdoing and late bleeds etc...) Training given to stagiaires first- need to ask what priorities are.</p> <p>Need more people to do specialized activities so same techs not always stuck doing the same thing</p>	<p>(studies, innovations...goals IPN)</p> <p><i>May be more selective but only lasts 3 months and when work are already more functional than most new staff.</i> <i>Perhaps need to spread over SR. Tech's. Usually rare techniques</i></p>
<p>Training Processes</p> <p><i>Etches don't take opportunity to change SOP's often don't read new SOP</i></p>	<p>Team leader sign for tech certification even when unfamiliar with procedure should at least be able to verify method but this questionable <i>Follow SOP but technique may be off.</i></p> <p>Tech will do training TL or trainer will sign</p> <p>Trainer will train while not certified and ask TL to sign</p> <p>Occur under rush conditions and moments of need. Trainer does not know the techniques specific to IPN in enough detail to train effectively Trainer trains procedures for which he is not certified and then has a TL sign off</p>	<p>Process effects efficiency and quality of training. Need to assess best methods of training for IPN</p> <p>Training staffing criteria: i.e. by department, by number of people, by training needs and diversity of skills (evaluate complexity of tasks to train and priority)</p> <p>Is this GLP?</p> <p>Evaluate best practice for IPN</p>
<p><i>Will train if new technique only if available to do overtime due to study need. This will only happen with minor techniques. I.e. with ECG this is unlikely.</i></p>	<p>Criteria for certification varies: Some competent yet <u>not</u> signed off Some <u>not</u> competent yet signed off (i.e. for rush)</p> <p>Criteria for training choice of tech is not standardized (if do overtime, ask repeatedly, personal preference some perceive there is more opportunity for males , if have study coming where skill is needed) Causes conflict and less teamwork when is a need will train and certify on the spot. When tech asks for overtime is used as excuse to refuse- When in a jam- indicates that when in a jam is acceptable to bend the rules. – in fact happens quite frequently when busy</p>	<p>Assess to what extent this system is problematic</p> <p>Assess alternatives to training selection process based on need to increase accountability and involvement as well as IPN goals. Look at factors involved</p> <p>(Surgery is done by seniority list – other training may be identified to be done this way)</p>

Headings	Primary Responses	Comments
Tech Orientation	<p>Inadequately prepared to work on study (most learning takes place by working with senior techs)</p> <p>Training not meeting specific needs of IPN</p> <p>Some training not necessary if working in IPN i.e. gavage</p> <p>New techs don't understand implications of protocol, how it works, importance of it...(even though a lot of time is spent in orientation)</p> <p>Need emphasis on the impact of errors and importance of work on study (somewhat important)</p> <p>Need training on how to make a book i.e. prepare, organize a study most important and not covered in orientation.</p> <p>Some training not producing strong enough skills</p> <p>Inadequate range of skills taught (need pumps SIRTIS more practice and understanding)</p> <p><i>May be that when stagiaires present more people in orientation</i></p>	<p>Need to assess needs specific to IPN</p> <p>Establish priorities</p> <p>Wasted time and effort in training: Efficiency</p>
Effectiveness of orientation	<p>Need to consider previous experience</p> <p>Hard to see relevance of some info given (i.e. eye drops, some tasks irrelevant others need explicit relevance i.e. handle animal practice)</p> <p>Orientation could cover a lot more</p> <p>Too many trainees in practical exercises for the number of trainers (can't ask questions) not always the case</p> <p>Need to combine theory with practical</p> <p>Not efficient use of time (Spaces of nothing to do)</p> <p>Method of instruction poor (i.e. read SOP's or sample protocol) read but don't understand</p> <p>Too much time on simple tasks (BW 200 rats) need to focus on the process i.e. working on the HP system so see value (relevance) in training</p> <p>Shortage of people to do the orientation and animals</p>	<p>Again: planning, strategy, effectiveness, efficiency</p> <p>Needs for orientation specific to department: IPN much diversity and complexity</p> <p><i>Need to meet the specific needs of IPN</i></p>

Headings	Primary Responses	Comments
	<p>Need to improve quality of data output, preparation of studies:</p> <p>Increase responsibility of techs for data and study prep etc... not really desirable to techs</p> <p><i>Training group does the work on validations techs don't really have a chance to do this</i></p> <p>Increase consistency on study may reduce errors <i>Routine can also create errors</i></p> <p>Have study number appear on list from beginning to end used to have one week wrap up and 1 week prep now condensed less time for prep and often no time for wrap up - need to prep in holes in schedule so often results in overtime</p> <p>Schedule time for Techs to do wrap-up of study (review data)</p> <p>Need to bring back principal tech</p> <p>Need to rely less on TL's (i.e. read protocol) need consistency for this.</p> <p>Need to involve techs in studies:</p> <p>Give better recognition, feedback</p> <p>Solicit tech input (i.e. SOP's, procedures..)</p> <p>Use tech knowledge</p> <p>Show contribution i.e. summary, or poster include tech names others not interested</p> <p>Create structure in training the allows Tech to chose direction.</p> <p>Discuss goals of IPN and organization with techs some feel that management don't listen to suggestions by techs</p> <p>SD to consult tech in techs area of expertise</p> <p>Ask techs to participate in new projects in department (innovations ..)</p> <p>Some contact with senior management (not in rooms) senior techs suggest advantageous to know senior management if need to voice concerns also source of encouragement</p> <p>thanks for Kentucky Fried in ice storm</p> <p>See client satisfaction letter</p>	<p>contribute to solving problems</p> <ul style="list-style-type: none"> - when do QC , just go through quickly ("PMP- Pas mon problem") - Agree that need positive feedback <p>Tech's in general resistant to this idea. Don't want added responsibility.</p> <p>Some don't want to do review – clin signs worst</p> <p>Schedule wrap-up needed</p> <p>Seems repetition of TL review- pointless. Pass over data quickly</p>
	<p>(Supervisor does take suggestions from techs.)</p> <p>Some movement is desirable for techs</p>	

Headings	Primary Responses	Comments
	Wrap up meeting needed on certain studies (Congratulations for good job, discussion of problems on poor studies) not much positive feedback	
SD	<p>Improve SD-tech relationship SD need to hear tech concerns</p> <p>Not concerned with tech opinion sometimes or animal welfare some SD's only Need to acknowledge tech in room Should consult with tech and use their expertise Visit rooms more often Understand the implications of their job on the techs (wait until come in, in am to get sheets. This pushes schedules into overtime..) Better communication with techs Understanding of technical side (what is feasible)</p>	<p>Introduce tech to SD <i>Peoples opinion on this is variable</i></p>
TL's	<p>In general emphasize solutions to problems rather than blame techs (Although some don't take responsibility for errors themselves) Depends on the individual</p>	
Goals Goals IPN Individual goals	<p>Techs not involved in the projects or company goals No discussion about what skills needed to be TL Talk about areas of improvement (accomplishments not recorded) No personal goals set</p>	
Equipment	<p>Repairs take a long, long time Many small details not notified as too busy HP BW system creates wasted time when not working (hours of time delay- knock on effect) Operating tables. Need more Need initiative to or process to identify problems and to fix equipment</p>	<p><i>Tech's don't take responsibility take equipment to room but do not write details of what is broken. Also need to take responsibility in calling or bringing equipment to maintenance (ownership) Need to take better care of equipment themselves</i></p>

Headings	Primary Responses	Comments
Processes and Policy SOP Certification Rules Communication Euthanasia Authorization Scheduling Training and study assignment	<p>SOP amendments frequent. Need to come to consensus so do not change so often. need to involve techs in decision making, Use their expertise to reduce frequency of changes to SOP's)</p> <p>Application of rules vague: Procedure done when not certified = warning Procedure done when not certified but asked to is OK.</p> <p>Need to clarify when to go to SD and when not to. Techs are contacted anytime and breaks and lunch flexible while TL not to be disturbed during lunch hour</p> <p>SD only can sign off but need more authority to make the decision Too many techs on one study to few on another (not a major issue) Creates rush or overtime</p> <p>May not schedule person for short period so techs find help on own. (often but not all the time) sometimes depends on techs judgement of situation</p> <p>Not equitable. No real process simply as needs or who asks most ask why waste time training stagiaires when only 50% stay and are not really useful anyway</p>	<p>I.e. ECG many changes. Now back to what was years ago. Techs need more in depth understanding i.e. to understand reasons for repeats or to adjust to achieve best results –trouble shoot, problem solve</p> <p><i>TL don't all eat at same time but will answer page as this is a sign of urgency</i></p> <p><i>May not always be costed if tech's don't tell Scheduler that extra hands were used on a study</i> Recorded on the study log</p> <p>need to ask if want training but even then no guarantee</p>
Tech breaks Health and safety Discrepancy between promises in interview and reality at CTBR: Management	<p>Need to allow to have break when in room for five hours not an issue for all</p> <p>Issues need to be addressed. Make policy known, Proactive. More important to some than others</p> <p>Opportunity for training not available for all</p> <p>Some need for tact and personnel management skills (i.e. when discussing errors)</p>	<p><i>Need to call if need a break. Usually there is time but sometime circumstances intervene</i></p> <p>Poor training selection system</p>

Headings	Primary Responses	Comments
Salary Equity	One year tox services become tech 3 years in animal health become tech Both same pay.	<i>Restrained by hiring – not enough new graduates</i>
Warnings	Need set criteria that constitute warning Errors are recorded but not positive i.e. accomplishments (Need consistency of reaction to errors, SD and supervisors seems to vary depending on circumstances such as sponsor involved and who made the error)	<i>Context: depends on error nothing to do with client or impact.</i>
Strengths and Weaknesses meeting	Best if done without management Need management to be there Gives opportunity positive feedback and to vent. Also helps to discuss the problems that exist between departments. Results are slow to come from these meetings	Some feel management presence causes people to not respond while other feel the it is important to use this opportunity for management to hear their concerns as well as an opportunity to receive positive feedback (strengths)

Needs Analysis

Team Leader Validation Meeting

June 12, 2001

Purpose: To identify and prioritize common concerns and areas of need.

(Supervisor Comments added June 22)

Headings	Primary Responses	Comments
Departments (in general)	Lack accountability (i.e. read protocol) Long term habits need reevaluation Better methods of filing data needed All departments lack understanding of needs and priorities of other department (customer supplier relationship) (IPN unique in volume of data and studies more deadlines...) Communication (routes, who?) All departments need to operate in similar way (management)	Accountability Understanding Standard operation Communication
QA	Make unfounded, inappropriate, redundant comments Wrong attitude (help Vs Hindrance) Report days after in room. Not a help. New QA: Get in way in room Sometimes identify problem too late Lack understanding of other departments and technical side. Need to have QA experts per department	Need greater understanding of science Role definition Understanding
Necropsy	Communication (who?) Need voice-mail Scheduling problems	Communication
Tox Services	Communication (i.e. of dates) Scheduling	Communication
Pharmacy	Communication Lack preparation, organization sometimes Need understanding of impact of late TA most important	Understanding
Training General	Need more training: constrained by animals, room, lack of trainers Decentralized training not as good as it was.(old system gave more control and had more consistent trainers) Studies becoming more complex need more specialized training. (need greater variety of skills) Training records need to be redone. Unclean and unclear.	More opportunity Specialized Broader training Quality of training Records

Headings	Primary Responses	Comments
Techs	Need GLP understanding (new techs and ongoing)	Depth of understanding (Implications) Continual updating
Tech Orientation	Need science or understanding of “why” technical set up that way. Also helps to problem solve) Need understanding of implications of work, reasons for.. (Science, GLP??) Need to establish a structure – empower techs to make own choices(training and studies) Need more efficient training (i.e. coupled techniques, time) Need more effective training in some cases i.e. ECG need better understanding and trouble shooting skills. Need more diverse training (versatile techs) Need training new techs on software used in study Inadequately prepared to work on study: Effectiveness of training: Some training is unnecessary while some training not producing strong enough skills Inadequate range of skills taught (need pumps, SIRTIS more practice and understanding) Need more emphasis on implications of errors very important	Autonomy Efficient / Effective Content validity Efficient / Effective TL’s not implicated in training techs. Old system the follow-up by TL’s was better because now tech training is perceived to be entirely the training departments responsibility <i>Need long term solution TL need greater involvement in technical aspect.</i>
TL Orientation	Need process (i.e. what to do when) Communication: Need Contacts who and for what Need computer skills training use HP system more in-depth training- understanding and trouble shooting Being with experienced TL is best way to learn Need manual for new TL.	Content – Materials, skills needed, communication routes...
Trainers	Need retraining e.g. ECG...	
Pre-study meeting <i>TL’s need to work with scheduler not just the SD.</i>	Need for more consistency of techs at meeting (i.e. tech on study is one in meeting) Need to discuss science (reasons for design.) Techs don’t understand enough	Consistency Focus on understanding to enable trouble shooting

Headings	Primary Responses	Comments
	Department needs to put more emphasis on this meeting	emphasis
Incentives		
Positive Techs	Learning new procedures, techniques Working on different studies Overtime Schedule flexibility Surgery Novelty of job Ownership of study	
TL	Fast pace and stress Opportunity to work elsewhere (CTBR in general) Opportunity for promotion if want. Learning new techniques People work with / Team Social advantages Computer work Responsibility	
Negative Tech	Not clear description of how to be promoted (vague) Techs not involved in decisions Little ownership (time is the issue) Poor recognition Lack teamwork with SD's: techs, TL's work late, SD leaves at 5 p.m.	SD should come to see how things are going , acknowledge that people are working late and make sacrifices to stay late
Middle ground	Lack of training at moment Salary (not great at the moment seems disproportionate for the responsibility that have compared to TL tox services only make a bit less salary)	
Techs	Need to improve quality of data output, preparation of studies: Increase ownership Increase accountability of techs for data Increase consistency on study Techs should see QA comments Have study number appear on list from beginning to end (time is the issue) Techs do wrap-up of study (review data) booking and time issue	Accountability, Responsibility Involvement, feedback TL's do not check the books before end of study as seen as the tech's job. Need to take

Headings	Primary Responses	Comments
	<p>Need to bring back principal tech need to make a priority</p> <p>Need to rely less on TL's (i.e. read protocol) need consistency for this.</p> <p>Need to involve techs in studies:</p> <p>Give better recognition, feedback</p> <p>Solicit their input (i.e. SOP's, procedures..) Use their knowledge</p> <p>Show contribution i.e. summary, or poster</p> <p>Create structure in training foster pride in work.</p> <p>Tech chose direction.</p> <p>Need more ownership of study</p> <p>Discuss goals of IPN and organization with techs</p> <p>Need greater understanding of the big picture</p> <p>Improve SD-tech relationship</p> <p>SD need to hear tech concerns</p> <p>Wrap up meeting needed on certain studies (Appreciation for good job, discussion of problems on poor studies...)</p>	<p>responsibility in the follow-up of tech's work. <i>This will also mean making better use of principal tech need to clarify the role of TL's and clarify their responsibility.</i></p> <p>SD interaction would help</p> <p>Introduce tech to SD</p>
SD	<p>Need to make notification of changes more timely Produce products (i.e. signed sheets when needed)</p> <p>Need understanding of the TL job and tech job so understand the implications Understanding of the study in room i.e. what is feasible</p> <p>May not consider TL's input as valid only certain SD's</p> <p>Visit rooms more often</p> <p>SD relationship with techs is poor (some not approachable , condescending, don't value opinions)</p>	<p>Often need to ask repeatedly</p> <p>Need to increase contact with techs</p> <p>Feedback to the techs (errors and positive)</p>
Data output	<p>Need to reduce review time</p> <p>Need tech to do wrap-up review of data</p> <p>Reduction in review time may mean TL can handle more studies.</p> <p>Need to reduce time in Data coord</p> <p>Data coord needs to be ongoing (tabulated as recorded) not always possible</p>	<p>Need to increase the responsibility of the tech to review data (accountability)</p> <p>Need principal Tech</p> <p>Need electronic data capture, and I.T. needs.</p> <p>Artemis up and running</p> <p>Need to reduce manpower</p> <p>Need to spread data coord over the study this may be difficult to do with short studies</p>

Headings	Primary Responses	Comments
Consistency Will provide: Accountability	More time for prep Better QC: easier to locate who made error , less time Time to read protocol Decrease questions to TL <u>May</u> reduce rate errors or dosing errors Consistency and quality of data (ownership) Read protocol (fewer q's by techs to TL's) Better review of data (QC) Better quality data Less TL oversight TL will be able to handle more studies	Will need more widely trained staff to do this.
Expansion	Will need to focus more on training More specialized and greater study volume will mean need for specialized skills and more training Communication - as access to people less possible- other departments Scheduling: Scheduler need help... this depends on the number of staff Even less consistency will be likely if continue present system Need to maintain social gatherings to maintain team	Quality of training & Opportunity for training
Goals Goals IPN Individual goals	Need to emphasize quality more and production less Goals are rarely discussed Need to have goal of consistency of tech on the study Need to discuss goals of IPN or directions of the organization with the techs Do not really set personal goals No real appraisal of the team leaders more a (strengths and weaknesses meeting)	
Equipment room	Misplaced items Accountability - strong attitude of "not responsible" Don't know the equipment i.e. don't know if it works or even how to check it.	Accountability

Needs Analysis

Study Director Validation Meeting

June 11& 18, 2001

Purpose: To identify and prioritize common concerns and areas of need.

(Scientific Director Comments added June 27)

Headings	Primary Responses	Comments
Service Departments (in general)	Lack accountability / responsibility attach actions Do not meet deadlines Lack understanding of needs and priorities of other department (customer supplier relationship) <i>Further from client, less feel urgency</i> Need more readable data from departments Communication (routes, who?) <i>High importance.</i> <i>Means of communication poor too many CC'd e-mails face to face better- apathy, someone will do it.</i>	Customer supplier-relationship: Product hand-offs problematic access Communication: Routes and systems. <i>E-mail used as CYA-defers blame</i> Accountability: Action Standard structure
Marketing Account managers function well as a safety valve for complaints but SD's could absorb their role if needed. They should handle a lot more work- quote data, business needs, market trend analysis, upcoming research, wins and losses per client...	Combine account managers and C/S (speed up system) SD spend too much time with accounts (managers more responsibility for answering own questions - answers found in the protocol) <i>Account managers need to be on top of things. SD's have to remind them quotes, outlines, schedule needs to be done by set date...account manger should find out why bit are missing</i> System is slow (time lag between when SD sends info to account manager and when they deal with it – more work for SD to follow-up and causes frustration) Need account managers to specialize in a department (this may increase responsibility but may not meet requirement for client specific knowledge) Responsibility of department / account manager is unclear (should facilitate direction of clients to services but often SD takes this responsibility) Recognition or reward for work is not seen as equitable (SD versus Account managers) SD responsibility for problems account managers not accountable...	Greater accountability and responsibility needed Do not use resources available to them (i.e. protocol) <i>Refers to 'change requests' -</i> <i>Often due to poor understanding</i> <i>Client do understand they are not scientists but do need more general understanding</i> "Cruise directors on the Love boat" <i>Need greater scientific background as well as departmental functions understanding may need to resurrect info sessions</i>
C/S	Use of Anne as "filter" – central contact to direct C/S enquiry's from SD's	

Headings	Primary Responses	Comments
<p>QA</p> <p><i>New QA people need to check their findings with experienced QA people</i></p>	<p>Make unfounded, inappropriate, redundant comments Need greater understanding of department, test systems <i>Often last minute</i></p> <p>Wrong attitude (help Vs Hindrance) Should be more constructive</p> <p>Both QA Need GLP / FDA understanding of spectrum of interpretation possible within regulation.</p> <p>Accessibility and communication routes Need to return to one data reviewer, one inspector. Too many people (Consistency of QA to reduce repetition of SD) <i>Very significant</i> Need to identify more major problems earlier <i>With "contributing scientist reports" 90% have errors but are not audited to the end</i></p>	<p>Need to define Role and goal of QA <i>Tend to get involved in more than GLP. QA asks for protocol amendments that are perceived by client as poor quality .get involved in interpreting client preferences. Often QC issues not QA issues</i> <i>Need to reduce this</i></p> <p>Spectrum of acceptable interpretation universal understanding Standardized structure, communication routes</p> <p>Too many people to clear efficiently <i>These are Training and system issues</i></p>
Path and Anchem	<p>Who to contact to get data?</p> <p>Lack accountability Need action for not meeting deadlines etc...</p> <p>Customer supplier relationship poor Need understanding of customer service (miss dates, quality data)</p> <p>Communication (who?)</p> <p>Data not readable to client <i>general format acceptable</i></p>	<p><i>Path has completely different data Coord services. Makes more sense to combine with Tox DC's for consistency</i></p>
<p>Data Coord</p> <p><i>Best to have SD ask for special DC</i></p>	<p>Tabulation inconsistent Need automation Inveresk system?</p> <p>Need global data coord as well as localized</p> <p>Need Data coord to identify cases where special tables needed (up and down studies)</p> <p>Do not need science training Greater attention to protocol needed</p>	<p>Structure of data coord <i>Experimental procedures used by SD's is not well done</i></p>
Anchem	Communication (need closer com'n with SD)	Quality control

Headings	Primary Responses	Comments
<i>Many new people here, need teamwork to start working together, understanding of impact etc and need help</i>	QC is biggest need here <i>due to pressure to do high volume of work fast</i> Accountability	<i>Missed deadlines major problem also data is not readable it is not in a coherent table</i>
Training		
Techs	Need GLP understanding (effects data recording) may lack involvement, motivation Need science Presented at Friday meetings somewhat agree	Efficiency of training Need to increase Involvement, implication of techs in their work - SD role in this - Tech directed structure
SD	Need understanding of implications of work, reasons for.. (Science, GLP??) Need to establish a structure – empower techs to make own choices (training and studies) Need more efficient training (i.e. coupled techniques, time)	
SD orientation	Need to improve education training provided less repetition Need ongoing FDA, GLP changes Need to provide choice of topics (consensus) experts Need to improve feedback Expectations set not met Training needed (processes, communication routes...) Attention to matching trainer with new SD Attention to matching department with new SD Training in report writing	Quality, originality Incentive focus And Functional focus Assessment of needs of SD training and orientation Correspondence of reality and promotion
TL	Need implications of activities, actions (Could be presented by SD's on Friday meetings)	Assess needs for technical explanation
Trainers	Need training on customizing sheets Greater understanding of procedures Need retraining e.g. ECG...	Specific application training Training, trainer processes and structure
Pre-study meeting	Need for more consistency of techs at meeting need techs that are on study <u>only</u> Meeting not a priority	Emphasis on meeting Need to set goal i.e. To eliminate problems

Headings	Primary Responses	Comments
	<p>Need to discuss science (reasons for design.) Techs don't understand enough when study out of ordinary</p> <p>Minutes not read need to reevaluate benefit of minutes- use a substitute for protocol – check list?</p> <p>Department needs to put more emphasis on this meeting</p>	<p>in order to set criteria to achieve this. I.e. Focus on understanding technical . Priority of department</p>
Incentives Positive Negative <i>Same criteria not always applied (SOT)</i> Middle ground	<p>Cross training</p> <p>Education</p> <p>Camaraderie / teamwork / Cohesion</p> <p>Receptiveness of management (hear point of view)</p> <p>Opportunity to progress</p> <p>Special projects</p> <p>Flexible –days off ...</p> <p>Need awareness of opportunities I.e. education, cross training</p> <p>HR policies restrictive</p> <p>Selection criteria for conference, education are vague <i>knowledge specific sometimes generally need a poster but need to ask as well</i></p> <p>Opportunity to participate in committees etc unknown criteria</p> <p>Cross training not available to all</p> <p>No openings for promotion May need to split <i>department if grows larger</i></p> <p>No recognition for education (DABT)</p> <p>No published salary scale</p> <p>Salary</p> <p>Competitiveness between SD –less teamwork</p>	<p>Problematic areas:</p> <p>Vague criteria for incentive attainment (value/expectancy dynamic), access to incentives not available to all or equally, communication of means opportunity attainment needs to be overt.</p>
Techs	<p>Need to improve quality of data output:</p> <p>Increase ownership</p> <p>Increase accountability of techs (Per task basis monitoring of quality)</p> <p>Increase consistency</p> <p>Need to involve techs in studies:</p> <p>Give better recognition</p> <p>Solicit their input (i.e. SOP's, procedures..) Use their knowledge</p> <p>Show contribution i.e. summary, or poster not all care</p> <p>Create structure in training foster pride in work. Tech chose direction.</p> <p>Improve SD-tech relationship(Introduce tech to SD)</p> <p>SD need to hear tech concerns</p>	<p>Responsibility and ownership needed to improve:</p> <ol style="list-style-type: none"> 1. Data quality 2. Study organization and prep 3. Involvement and responsibility for details (general oversight) <p>Achievable through:</p> <ol style="list-style-type: none"> 1. Accountability-expectations 2. Scheduling for accountability 3. Involvement and

Headings	Primary Responses	Comments
	<p>Wrap up meeting needed on certain studies (appreciation for good job, discussion of problems on poor studies) ideal but Very hard to schedule</p> <p>Need to show techs the QA comments (as used to)</p> <p><i>May be interesting to show summary i.e. hot issues.</i></p>	<p>inclusion</p> <p>4. Feedback pos/neg</p> <p>5. Structure training, study allocation for choice</p>
Information and communication:	<p>Need e-mail (customer service issue)</p> <p><i>Need to make sure all people are CC'd properly.</i></p> <p><i>Only CRO that does not have it.</i></p> <p>Need library e-mail, internet, conference, journals...</p> <p>Central location of updated files.</p> <p>Better automation of documentation</p>	<p>Access to information</p> <p>Data management system</p>
Paperwork	<p>Still some that is superfluous. Some could be done in other departments and signed of by SD (Shipping letter? CITES permit? Specification for test systems? Animal # and P/O's in C/S?)</p>	<p>Full assessment of paperwork needed (follow reporting process A-Z): Who should fill out what, why, when? What is not necessary or could be done differently.</p>
Data output	<p>Need to reduce TL review time</p> <p>Need to improve TL review quality</p> <p>Need to ensure better quality data goes to QA</p> <p>Need to reduce time in Data coord</p> <p>Data coord needs to be ongoing (tabulated as recorded)</p> <p>Need electronic data capture, and I.T. needs. Artemis up and running</p> <p>Need to reduce manpower <i>still needs data coord to input data from all sources. Data coord may be area to save more time.</i></p> <p>Need day in CPP for the SD's to have raw data for EP's <i>This may not coincide with when the SD can review it- realistically may need a week</i></p>	<p>Review time</p> <p>Refocus QC: TL and tech.</p> <p>Automation</p> <p>Refocus QC: TL and tech. Also increase tech accountability with balance of incentives / involvement...</p>
TL's	<p>Need more time to review data</p> <p>Need to increase the quality of the work given to SD (reduction in mistakes)</p>	<p>(increase tech responsibility)</p> <p>Adjustment of TL review for better</p>

Headings	Primary Responses	Comments
	<p>Focus review on "whole picture" I.e. look at data in relation to Protocol.</p> <p>Focus on TL role (some do too much hands on and others not enough) i.e. define role.</p>	<p>review (effect DC time, QA report time in general) How much time can be saved in reporting?</p> <p>Same as SD</p>
SD workload:	<p>Generally O.K.</p> <p>Greater efficiency in other areas will reduce workload of SD's (i.e. data coord, tech TL review, errors...)</p> <p>Can take on more work if above considered</p>	<p>Distribution of workload: SD seem least loaded. Need verification</p> <p>Question: quantity, responsibilities.</p> <p>Almost managerial role without supervisory function</p>
Expansion	<p>Weaker relationships effecting accountability of people and departments (possibly- continuing problem)</p> <p>Quality of training (possibly)</p> <p>Less opportunity for training / education (possible)</p> <p>Communication - as access to people / departments less</p> <p>Less room for promotion (possible- little room now))</p> <p>Less able to give hand-on oversight if increased w-load</p> <p>Reduction in qualified techs as promoted to TL (more strongly agreed upon)</p> <p>Greater versatility of techs needed</p> <p>Need more consistency of staff on study</p>	<p>Potential problems</p>
<p>Goals:</p> <p>Goals IPN</p> <p>Individual goals</p>	<p><i>Recognition of specialty expertise/ developing novel techniques or areas of business development and revenues.</i></p> <p>Quality</p> <p>On-time</p> <p>Individuals goals set but not necessarily measurable (quantifiable)</p> <p>Do not ask or state how individual goals contribute to corporate goals</p>	<p>Obstacles to reaching these goals are awareness of customer service in other departments, review time and process...</p> <p>??</p>

Appendix IV: Additional Comments

Information Dissemination

Study Directors also identified a need to enhance the information dissemination system. There was a suggestion that a library of sorts be developed that would not only allow greater access to the internet and external e-mail but would also serve as a central location for articles, information on conferences, posters etc. Problems responding to customer needs are sometimes related to the lack of external e-mail.

It was identified that there is a need for central location of updated retrievable protocols. Presently protocols are used that are not always the most up to date. There is presently an initiative to address this using a database.

Equipment Room

Equipment is easily lost, not cared for and no proper inventory control resulting in greater cost (i.e., battery charge is not maintained so a new one must be purchased more frequently, some materials are lost and therefore repurchased) and difficulty retrieving equipment. There is need for greater oversight of this service and training in the function of the equipment and its care. The equipment room could be a service that identifies and resolves equipment problems before they are problematic on study.

Strengths and Weaknesses Meeting

Technicians differed in their response to the Strengths and Weaknesses meeting. Some felt the meeting was a useful and important source of feedback and encouragement; others felt that management presence impeded the responses of individuals and that it yielded no results. Technicians concurred that there was little knowledge as to who upper management were but although some wanted to vocalize concerns to them they perceived them as not approachable. Few were comfortable while others found no reason to approach senior management.

APPENDIX 5

PROJECT SUMMARY CHART

<u>Lesson learned</u>	<u>HPT process</u>	<u>Ed tech Recommendation</u>	<u>Best practice /recommendation</u>
Senior management Buy-in prior to start	Preliminary setup essential. Ongoing	Business case experience.	Establish up front. Avoid project without it. Maintain throughout.
Buy In from stakeholders. Different stakeholders experience different impact	Throughout	Practical experience recommended.	Identify impact on different stakeholders.
Basic goal is to address or implement change.	Most basic premise. No opportunity for this means no point.	Core competency for HPT. Proficient communication using various media invaluable.	If there is no intent to address finding of analysis avoid its undertaking .
Set and communicate objectives for the project.	Critical at Analysis and Implementation.		Clearly define deliverables and their intended use.
Continued analysis / assessment.	Post implementation or delivery but best if baseline is established beforehand.	Formative/Summative. Evaluation. ROI calculation.	Systems change and require continued adjustment over time.
Maintain focus on “Important” issues.	Throughout	Require monitoring and evaluation throughout project cycle.	Problems are diverse and complex. Finding core issues is key. To be assessed on an ongoing basis.

<u>Lesson learned</u>	<u>HPT process</u>	<u>Ed tech Recommendation</u>	<u>Best practice /recommendation</u>
Determine your target population and assess validity of your conclusions and findings	Analysis and implementation.	Practical experience will permit growth of creativity here. Research methodologies.	Find innovative ways of triangulating findings.
Remain cognisant of impact of results	Report / Solution delivery and planning.	Focus on possible sensitivities and impacts on people with curriculum.	Ensure participant protection and define deliverables up front.

APPENDIX 6

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