Business Processes and IT in the Pharmaceutical Industry

The case of Clinical R&D at Astra Hässle

Kai A. Simon

Content

Foreword

When looking at Ph.D.-dissertations, I usually observe that they are written for a small community – researchers populating the same scientific playground as the author. Despite all good intentions, most scientific literature being published as dissertations, journal articles and conference papers fall short of being understandable by industry practitioners and the public.

With this dissertation, I have tried to make a difference. It is an effort to write a thesis that satisfies the scientific community's requirements for scientificness, method and writing, but also allows people in companies and other organizations to make sense and use of its content.

I have deliberately have chosen a simple, descriptive language and the structure is kept in a way that makes reading as easy as possible.

Unfortunately, this does not make this text an easy reader. The issues being discussed are of complex nature, but still it is my hope that this work will contribute to the development of an understanding of the difficult world of organizational change, and assist theorists and practitioners in their struggle with organization analysis and design.

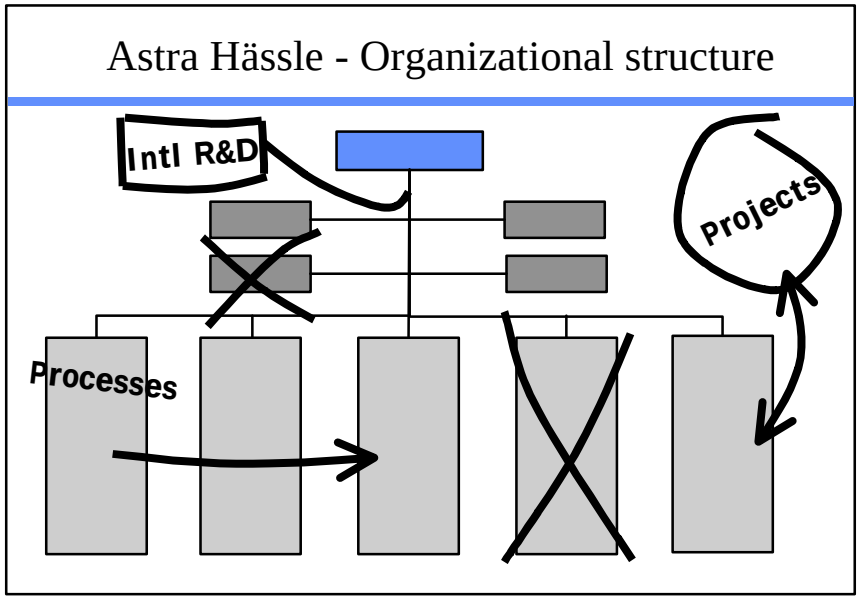
Göteborg, June 2000

Kai Artur Simon

1 Introduction

At 14.00, we arrive at the AstraZeneca (at that time Astra Hässle) office in Mölndal. We had scheduled an appointed for a meeting with a group of managers from the company to discuss possibilities for research cooperation in the field of Informatics and Organization.

"Let me briefly introduce you to our organizational structure", one manager says and puts a slide on the OH-projector. He starts explaining, but is suddenly interrupted by one of his colleagues. "These are the slides from before our last re-organization. Since then, there have been some changes in our organization"



This anecdote is not specific for AstraZeneca. It could have happened in any large organization, and it probably has in one way or the other. In my stock of business cards that I have received, there are many with additional notes regarding titles, divisions and locations. A frequent comment when handing over a business card seems to be *"We recently re-organized, but I haven't received my new business cards yet."*

During the 1990s, change was the word of the day and companies re-organized, re-engineered their business processes, down- and right-sized their organizations and introduced new technology for managing their

workflows, tying together their value chains and becoming faster, better and more competitive. This wave was sweeping over industry and the public sector alike and resulted in large-scale change initiatives under the label of Business Process Reengineering, Business Process Redesign, or company specific names such as T50 at ABB.

Also companies in the pharmaceutical industry have been initiating change programs aiming at reducing cycle time in R&D and marketing and reducing excess cost in the research pipeline. Today, virtually any pharmaceutical company has worked extensively with process improvement initiatives. Within Astra, the Swedish pharmaceutical firm that merged with UK-based Zeneca to form one of the big players in the industry, multiple projects have been conducted at corporate level and within several of their subsidiaries. Two of these initiatives are documented in this work: FASTRAC, a process improvement effort aiming at clinical research and development at Astra Hässle in Mölndal and CANDELA, a corporate wide R&D process reengineering project. As a result of the process orientation and the related organizational changes, Astra Hässle has been able to realize significant cycle-time reductions in clinical R&D.

On the other hand, these change programs were not free of problems or unexpected outcomes. As the detailed study of one part of FASTRAC revealed, the implementation of a new infrastructure, consisting of a globally designed business process and a rigid information system for data collection, resulted in local adaptations outside the pre-defined organizational procedures and use of information technology, causing a "drift" of the infrastructure in use. Also, the business process reengineering (BPR) approach was met with ambivalence in the company. While the concept of thinking out-of-the-box was highly appreciated, the requirement for designing and defining business processes at a high level of detail was not easily accepted in the organization.

This book aims at describing the change initiatives that have been conducted at Astra Hässle under the banner of BPR and to outline critical issues that arised during these inititatives. It also sets to describe the concept of BPR that has been applied as methodological approach during the FASTRAC and CANDELA projects and to discuss it in the light of these initiatives. However, it is not about the best way to create optimum organizational structures or clinical R&D processes for pharmaceutical

companies. As Galbraith (1977) has pointed out, there is no such way, and no structure that fits all organization and this conclusion leaves managers and change agents with a problem: To find and select an organizational form being effective for the specific situation and context of their company. However, since not all the ways to organize are equally effective, the second important observation made by Galbraith in his book *Organization Design* (ibid.), this problem is difficult to resolve and any research on this topic can only provide guidance and point at critical issues, but not offer a simple solution with a success-or-money-back-guarantee.

So, why making the effort of writing a doctoral dissertation as a book about organizational change, business processes and information technology in the pharmaceutical industry? Bookshelves in managers' offices are already overloaded with books, journals and other publications on management, ordered by time and trend: In Search of Excellence, Competitive Advantage, Total Quality Management, Lean Management, Business Process Reengineering, and more recently Knowledge Management.

The rather pragmatic goal for this doctoral dissertation is to deliver a theoretical and practical constribution to the area of business improvement. This attempt has been made having in mind, that this approach also provides a fertile ground for critique. A critique claiming that this book is an airport-bookstore publication for managers travelling between two meetings, rather than a theory loaded academic work. The answer is both yes and no. This publication is intentionally written in an easy-to-read style. It is aiming at being purposeful reading for academics and practitioners and to offer a contribution to research and pratice alike.

1.1 Is there a need for change?

The society we live in has brought us, who live in industrialized countries, an incredible wealth. Despite the high unemployment rates we currently experience in many countries, the standard of living has never been as high as it is today. This development, taking its departure in the industrial revolution of the 18th and 19th century, has been made possible by ”modern” organizing, where modern stands for ideas and concepts being developed 100 years ago for industrial production. Industrial processes have been rationalized and mechanized, large organizations have been built in the private and public sector, based on the ideas

developed by engineers and management theorists such as Frederick Taylor and Henri Fayol, or based on a sociological approach to bureaucracy, such as the Weberian concept. While most of these concepts originally were developed for industrial production, i.e. mass production of standardized goods, they also found their way into other sectors, including the pharmaceutical industry. Many of the pharma-giants of today were founded in this era and developed their first products during the early decades of the 20st century, governed under the same principles that have been applied on manufacturing.

It is often claimed that the ways of organizing and managing that have constituted success in the past, are no longer applicable in today's economy. The forces that influence organizations and govern companies in their striving for improved competitiveness are often condensed into three factors, labeled the three Cs or C^3: Competition, Customers and Change. The US Manufacturing Futures Survey from 1992 revealed the following outlook on managers' expectations regarding important issues for their companies' business environment (Rolstadås et. al., 1995). These factors, although they have been identified with manufacturing in mind, also influence the pharmaceutical industry.

- Increasingly global markets, resulting in higher competition, but also cooperation.
- Stronger focus on customer expectations with regard to quality and time.
- Changes in the workforce with respect to attitude, competencies and capabilities, task structures and compensation mechanisms.
- Increasing concerns for environmental issues, followed by national and transnational regulations.
- Declining or stagnating domestic markets.
- Increasing speed in technology development and shorter product life-cycles.

1.1.1 Global markets and new entrants

Many economies have for a long time been carefully protected from foreign threats. Customs barriers were high, and regulations made it practically impossible for companies to enter foreign markets, and

allowed domestic companies to prosper. Japanese car manufacturers, for instance, had to open factories within the European Union in order to circumvent the import restrictions for cars being built outside the union.

Governmental regulations also regulated the flow of investments and limited individual and corporate mobility in order to protect local companies and their national tax base. Especially high-tax countries have had a natural interest to prevent corporate and private money from free transfer across borders. Agreements such as the common market in Europe and the introduction of a common currency in 1999, and the GATT (General Agreement on Traffic and Trade) on a global level, enforced by international organizations and courts, have opened new opportunities for foreign market entrants, while increasing competitive pressure on previously protected national companies and markets.

First Asian and later also Eastern European companies have successfully taken up competition with traditional market leaders from the US and Western Europe in a variety of areas, ranging from industrial manufacturing to high-tech services in the computer and software industry. Today, India is one of the countries educating most computer engineers world-wide, and many Western companies have started to open subsidiaries in India, thus making the city of Bangalore the 2nd largest assembly of IT-development resources in the world. The concept of *global sourcing*, i.e. the mobility of tasks around the globe, will increase pressure on companies and governments.

The liberalization of capital movements and the increasing the amount of foreign direct investments, able to disrupt entire economies when used in a speculative manner, has limited national governments' navigation space and significantly contributed to shrinking the world economically.

For many companies, this development means an increasing struggle for sustained competitiveness, taking its expression in large-scale change efforts, aiming at improving corporate performance. Commonly taken measures are cost reduction efforts, staff layoffs, structural renewal and striving for reduced time-to-market. Also, information technology has come to play an important role, not only as a supportive tool for operational activities, but as a major enabler for organizational change, improved quality, and cycle-time reduction.

Pharmaceutical companies have responded to these challenges in several ways, addressing internal as well as external issues. In order to increase

effectiveness and efficiency, virtually all firms in the industry have been initiating large-scale improvement initiatives to speed up discovery and clinical research and development. In order to spread investment loads, some are pursuing horizontal integration strategies, such as Glaxo or Ciba Geigy, who have acquired Wellcome and Chiron respectively. Other are moving into new areas or aim at vertical, downstream integration, such as Merck and Smith Kline Beecham, acquiring Medco and Diversified Pharmaceutical Services.

1.1.2 Information technology development and diffusion

Since the personal computer conquered the desktop in the late 1980s, information technology and its use have developed at an accelerating pace. Computers have become more powerful, but have also found their way into new application areas. From being primarily a tool for individual work, the computer has now turned into a communication medium, allowing communication and cooperation within and outside the organization. Instant information access and distribution through networks have become standard.

The increasing use of global infrastructures, such as the Internet, has also contributed to a wide diffusion of IT, and has opened new communication and business channels, allowing companies to reach suppliers and customers in a cost-efficient and easy way.

Another considerable change has taken place in the perception of IT's role in organizations. While the traditional view has been utility-oriented, i.e. that technology was primarily conceived as a tool for supporting the daily operational work in a company, we now find a different perception.

When looking at businesses and also public organizations today, IT is considered as being the major enabler for organizational redesign. Instead of being used solely for implementing technical support for existing business and organization strategies, IT allows us to question the very existence of these strategies. Insurance companies can improve customer services by equipping field sales personnel with mobile equipment, companies with the Internet as their primary location can market their products and services and circumvent traditional sales channels, and short-term opportunistic networks of organizations can be formed.

Considering the potentially disruptive nature of IT, it is easy to understand that the major change concept of the 1990s, Business Process

Reengineering (BPR) takes its departure in the *clean-slate* approach. Instead of taking the existing organizational structures and activities as the analytical starting-point, the image of a new, business process oriented and customer focused organization is developed, based on current technology and knowledge.

At the same time, the attitude towards information technology has changed significantly, too. Traditionally, the IT-department in many companies has been an organizational appendix to the accounting department. Since IT, or electronic data processing as it was termed, was first introduced as a tool for automating payroll management and other administrative processes, this was rather natural. Now, having taken the position as a strategic asset, information technology is seen as a factor that very well can make the difference between a company's existence or disappearance from the market. In a recent study among Sweden's 500 largest companies, conducted by Ernst & Young Management Consulting, 80% of the responding companies indicated that information technology was an important aspect of their change initiatives. (Ernst & Young 1998)

The rapid development in the field of IT, combined with the progress in bio-technology has opened new windows of opportunity for many firms, but it also constitutes a significant threat to established companies. The development of blockbusters, such as AstraZeneca's Losec, is no longer depending on vast amounts of resources alone, but also on the innovative use of IT. Genomic research, combinatorial chemistry and high-throughput-screening opens for a significant increasement in the number of NCEs (New Chemical Entities), but it is not self-evident that the established firms have a competitive advantage in this development.

1.1.3 Customers and consumers

When economic globalization is discussed, the fierce competition between companies taking place on the global marketplace is frequently stressed. However, in the same way as foreign entrants now have access to markets they previously were unable to penetrate, global competition has given customers and consumers access to a much wider variety of options. While they often were limited to buying products from national vendors, they now have the opportunity to choose from a wide range of products. Having access to a wider variety of choices, customers also tend to claim a higher level of service and lower prices from their

suppliers. At the same time, product loyalty is fading away, customers become more opportunistic and quality labels such as ”Made in ...” seem to loose more and more of their importance.

Also in this area, information technology has had a major impact on the change of market structures. Many products traditionally purchased locally – e.g. books, but also food – are now available through electronic shopping areas on the Internet, and open new opportunities for customers, while traditional suppliers and national legislation struggle with maintaining their influence and domination.

The pharmaceutical industry has two client bases. (1) Doctors and healthcare institutions for prescribed drugs, and (2) consumers for non-prescribed drugs. So far, a significant share of marketing activities has been directed towards the "professional" customers, whereas patient communities have not been in the focus of marketing activities. However, this situation is about to change and many pharmaceutical companies are starting to employ IT as a means for creating and sustaining customer relations by investing in various mechanisms for creating Internet-based communities for users of their products. Also, the emergence of managed care programs has put emphasis on the cost and time aspects of product development.

1.2 Paradigm shift?

It is often proposed, that we are currently in the process of societal transition, that we are about to enter a new era, moving from a modern, industrially dominated society towards an information- or knowledge-society, more generally termed post-industrial society. The changes taking place during this transitory process may include the establishment of new economic market models, changes in the structure and content of work and the contractual arrangements surrounding it, and the emerging of new organizational forms, such as *hordes*.

These profound changes in the nature of society are often referred to as *paradigm shift*. Since this term is commonly used for describing disruptive change, it may deserve some closer attention.

In Geddes & Grossets 1994 edition of the *New English Dictionary and Thesaurus* a paradigm is defined as ”a pattern or model”, and *Webster’s New World Dictionary* (3rd College Edition, 1991) defines paradigm as

”an overall concept accepted by most people in an intellectual community”. Consequently, to be required as such, a paradigm requires consideration and acceptance by a majority of people in the field or area where it is used.

The idea of paradigm shift was introduced by Thomas Kuhn, a philosopher and science historian, in his book *The Structure of Scientific Revolutions*, published 1962. In this publication, he describes the nature and process of paradigm shifts, i.e. the process of one ruling concept being replaced by another one.

Following Kuhn’s idea, we can say that a paradigm shift is a fundamental change in the way we consider a phenomenon. A typical example of paradigm shift is the abundance of the geocentric image of the universe, developed by Claudius Ptolemy, in favor of the heliocentric worldview as Copernicus described it. However, while the geocentric worldview today has gained a 100% acceptance, paradigm shifts in other areas might just as well be incomplete, i.e. that a minority is not willing to accept the new concept.

As Tapscott and Caston (1993) notice in their discussion of paradigm shifts impacting businesses, the notion of paradigm has grown beyond the dictionary definition. When used today, the term paradigm includes the concept of framework or scheme for understanding reality.

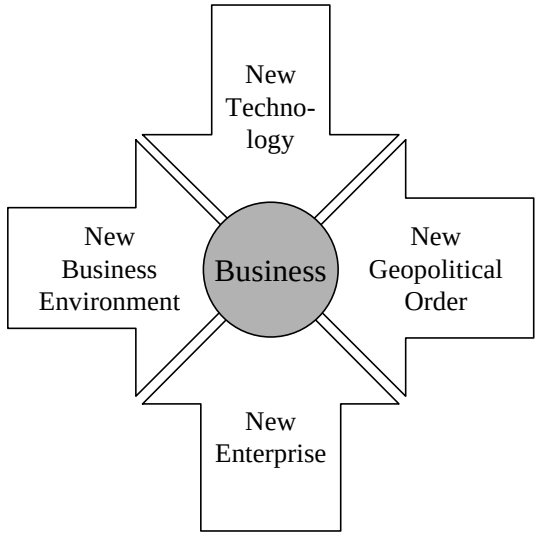


Figure 1.1:Paradigm shifts affecting businesses (Tapscott & Caston)

Tapscott and Caston (ibid.) have identified four paradigm shifts that influence businesses in the information age, and that shape a general framework for understanding the need for change. Whether the changes taking place within these areas can be considered as paradigm shifts in accordance to the dictionary definition of the term, is a question that will be left to science theorists to discuss, but it is obvious that organizations are struggling with adapting themselves to what they perceive as a new situation.

For pharmaceutical companies, this process of transition imposes changes at various levels. On the macro-level, mergers and acquisitions create new corporate giants, such as Pharmacia & Upjohn or AstraZeneca, to mention the deals involving Swedish companies. Other companies employ vertical integration strategies and acquire distributors, or engage in strategic alliances with small biotech-firms. On the micro-level, we can observe changes in drug discovery and clinical research. The traditional organizational models and sequential approaches to organizing R&D processes are abandoned and new concepts, based on common information spaces, are developed and adopted. During this journey, many companies have also embarked on large-scale business process improvement initiatives, often under the banner of BPR - Business Process Reengineering.

1.3 Research questions

In pharmaceutical companies, BPR is a potentially highly rewarding approach. Time-to-market is a lengthy and expensive process and clinical R&D accounts for a considerable share of it. Reducing time in product development can extend patent protection, keep cannibalizing generics away from the market and significantly increase return-on-investment in R&D. The promise of BPR, to deliver order-of-magnitude improvements in cost and time reduction, without compromizing the strict demands for quality that surround drug development and testing, has therefore been an appealing concept to many senior executives in the pharmaceutical industry. However, pharmaceutical companies, as all other organizations, have an organizational legacy. Being able to conduct BPR projects in this kind of organizational setting therefore presumes an understanding of how hierarchical organizations are governed.

It is also evident, that the origins of BPR can be traced back to the classic theorists of the last century. Despite the claim of Michel Hammer, one of the founders of the reengineering movement, the works of Taylor, Fayol and Gulick & Urwick have had a considerable influence on the concept of BPR.

The purpose of reeningeering exercises is to make all processes in an organization the best-in-class. This idea is mot unsimilar to the proposition of Frederick Taylor, who suggested in the that managers use scientific methods to discover the best processes for performing work, and that these processes be redesigned to optimize productivity. BPR, in that sense, echoes the belief that there is one best way to conduct tasks and that Galbraith's claim - there is no one best way to organize - does not hold true anymore.

In the early 1990s, Henri Fayol described the overall objective of organizations in a way that renders to be closely related to what reengineering sets to achieve:

> *To conduct the undertaking toward its objectives by seeking to derive optimum advantage from all available resources.* (Loyd 1994)

BPR advocates, such as Hammer & Champy, are claiming that BPR is an approach to abandoning traditions and to introduce radically new ways of working. Ironically, the reengineering concept and the literature

describing it are full of implicite references to theories it claims to reject. The following quote describes a central aspect of BPR, empowerment of individuals.

> *It is not enough to hold people accountable for certain activities, it is also essential to delegate to them the necessary authority to discharge that responsibility.*

However, it is not taken from a recent publication about reengineering, but was written by Lyndall Urwick in the 1930s. The same proposition can also be found in the work of Henri Fayol as one of his principles for good management (see chapter 2.1.2).

This leads to the first research question, which is addressed in chapters 2 & 3:

Research question 1. What are the classic theories in organization and management?

This question is answered through a historical excursion that identifies and discusses the most influential classic management theorists and their ideas. Introducing these theories serves two purposes which, at a first glance, seem contradictory. They provide an understanding of the governance principle for hierarchical organizations, but they also contribute to the theoretical foundation of BPR.

Changing a company into a process-based organization is neither simple, nor intuitive. It involves reconsidering structural premises, reviewing reward structures and the way tasks and people are matched. We must thus ask ourselves what the important issues are for migrating from structure to process and this is, consequently, the next question, which is addressed in chapters 4 & 5:

Research question 2. What does the concept of process organization mean and how does it relate to theory?

There is virtually no BPR-style project in large companies without the participation of consultants from one or more firm and the Astra projects are no exception. Assigning external people to change projects that are considered critical to the future competitiveness of a company naturally opens for questions regarding the consultants' methodological approaches and their ability to contribute to the change effort.

Research question 3. What methods are used by consulting firms for managing business process improvement projects?

For addressing this question, which is done in chapter 6, the BPR methods of four consulting firms - Andersen Consulting, Bain, Boston Consulting Group and McKinsey - have been described and compared with regard to common aspects and differences. Two of these firms, Andersen Consulting and McKinsey have been involved in the BPR initiatives at Astra, the other two approaches have been included to increase the number of samples and create a broader perspective.

Finally, it of course becomes interesting to investigate how the concept of process orientation is actually applied. A case study has been conducted in order to answer the fourth research question:

Research question 4. How are process improvements initiatives conducted in practice?

1.4 Disposition of this book

This book is divided into 9 chapters. Chapter 1 provides an overview of the factors that are influencing companies' change efforts, an overview of the disposition and research method being used and contains the acknowledgements of people that have contributed to this book.

Chapter 2 gives a short introduction to the history of organization design and management. It takes its starting point in classic theory, i.e. the work of Taylor, Weber, Fayol, and other early management thinkers. The classic school of thought is presented, the concept of hierarchy discussed and criticized.

Chapter 3 introduces more recent organizational models and theories. It discusses the concepts of bounded rationality, the organization design strategies proposed by Galbraith, and outlines the basics of matrix-organizations and process orientation.

Chapter 4 addresses ideas being related to the migration from a hierarchical to a process-oriented organization and also introduces the concept of network organizations. It also discusses problems being related to designing process-based organizations.

Chapter 5 introduces the concept of Business Process Reengineering and its theoretical background, as well as some of the most relevant techniques and tools.

Chapter 6 relates the theory of business processes to the methods for business process improvement used by consulting firms. The methodological approaches of four consulting firms - Andersen Consulting, Bain, Boston Consulting Group and McKinsey & Co. - are briefly introduced and compared.

Chapter 7 contains a major field study of a change project at AstraZeneca (at that time Astra Hässle), where information technology has been used for improving data collection in clinical R&D. The use of information technology is discussed from an infrastructure perspective.

Chapter 8 discusses the implementation and deployment of a project specific infrastructure at Astra in detail and discussed what has been found to be crucial factors for successfully introducing an organizational and technical infrastructure

Chapter 9 offers conclusions from the case study and takes a first step towards a new model for organizing clinical R&D that has been developed cooperatively by members of the Astra organization and the author.

1.5 Research method

The case being presented in this book is not a case study in the conventional meaning. It is rather a partnership that has been developing over the years, since the first contacts with Astra Hässle were established in year 1995. During this period, I have been "floating" around in the organization, meeting many different people for discussions and interviews. At the same time, my role has not been limited to be an observer - intervention has been a natural part of the relationship.

There are several research methods for doing research in organizations. Braa (1995) has described and compared the concepts of hard and soft case studies, action research and field experiment. She has identified the following ideal type characteristics of these methods.

	Action research	**Field experiment**	**Case study**

Duration	Long	Short	Any
Aim	Intervention	Hypothesis testing	Description/Intervention
Time focus	Building future	Real time / future	Historic perspective
Change perspective	Planned/ deliberate changes	Controlled variables	Accidental changes

Table 1.1: Characteristics of research methods

The major difference between these research methods is found in the role of intervention. Braa (ibid.) has stated that case studies attempt to minimize the impact of the research activity on the subject (organization) under concern. Field experiments, with their focus on hypothesis testing also require the context to be constant, whereas action research is aiming at supporting change in the organizational setting.

Of these ideal method types, action research is the one being most suitable for describing the nature of my research collaboration with Astra Hässle. Nonetheless, it is not fully sufficient to capture all of this collaboration's facets. As an additional method that spans over multiple of the above mentioned methods, Braa has proposed the concept of *Action case*. In order to illustrate how action cases relate to other organization research methods, Braa (ibid., page 152) has depicted the methods in a triangular model, the research space.

The research space's corners represent science, interpretation and intervention in their pure form, whereas the sides of the triangle represent the trade-offs between the different foci of the research and the dilemmas they might constitute for the researcher with regard to delivering scientific, useful and pragmatic results.

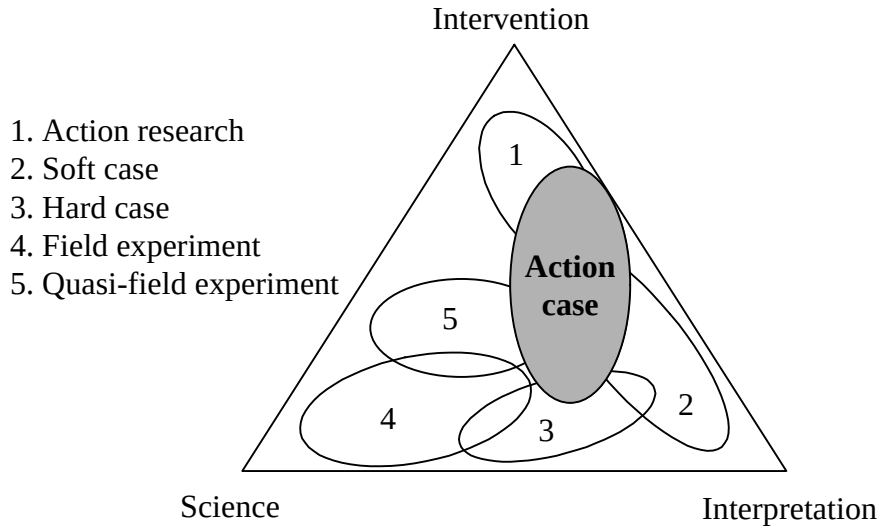


Figure 1.2: Action case research domain

The action case research method, as the name indicates, is mainly a combination of action research and case study. However, it also contains some characteristics of the field experiment, namely the requirement for reduced complexity and the reduction of variables, i.e. aspects of the organizational context might be disregarded in order to maintain the manageability of the research project.

Braa brings forwards two main arguments for the action case method. The first one is pragmatic and builds on the observation that most research projects actually involve aspects of both case study and action research and that the two methods, in practice, are difficult to distinguish. The research collaboration with Astra actually supports this argument. It was hardly possible to take on the role of either pure case study, or action researcher. The interviews and discussions, the participation in meetings, always included aspects of interpretation and intervention.

Braa's second argument refers to the applicability of the method in the investigation of information systems, since it allows the testing of theory and techniques on a small scale and does not require the same consideration of complexity in the organizational setting as full scale projects. In addition, the possible limitations of the research scope allow the researcher to better address contextual constraints. This argument did not have the same relevance for the Astra Hässle project, since the

possible problems mentioned did not appear. The scope of the research, even though it covered a range of different aspects in the organization and its IT-use, was clear. Additional issues being relevant from an intervention perspective, and having a consultative nature rather than being research oriented, were discussed and resolved separately from the research project in discussions with Astra managers.

Although the action case method seems to be the most suitable one for describing the research presented here, there are some deviations from the concept as described by Braa. The following table relates the research at Astra to the characteristics of the action case method.

Action case	Astra Hässle research
Short duration	The project was not set up with a specific duration, but was considered as a long-term mutual commitment.
Real time	Intervention took place in real time. Issues that were considered as being relevant for intervention were immediately addressed in discussions with company representatives.
Some description	The conduct of the major change initiatives that have taken place in the company during the past years and that have been the scope of the study are described.
Some intervention	Intervention took place through frequent discussions with Astra managers and other personnel.
Some experiment	No experiment until now, small-scale experiment with new organizational concept and IT-support planned for the future.
Some reduction of complexity	The project scope was not clearly defined from the beginning, but emerged during the project and changed over time. However, only one areas was focused at a time. Complex issues were handled outside the project.

Changes in small-scale	No direct changes as result of the research, but influence on the future development of organization and its use of IT.

Table 1.2: Action case and Astra Hässle research characteristics

1.5.1 Data gathering

The descriptions of process improvement approaches in chapters 6 are based on documentation material provided by the consulting firms, public sources such as hand-outs from conferences and discussions with employees of these firms taking place at various occasions. In addition, all firms were offered to comment on the description of their methodology.

The case material for the descriptions of the FASTRAC and CANDELA projects at Astra Hässle, presented in chapter 7, are based on many discussions with employees at various levels of the company, taking place over a period of four years. In addition, written material, provided by the company, has been used and the project documentation on the corporate intranet has been followed. For the SCODA description and analysis, additional semi-structured interviews with study monitors were conducted in Spain, Sweden, Germany and the USA.

1.6 Acknowledgements

A work like the one documented in this book can not be undertaken alone. Therefore, I am grateful to all my friends, colleagues and other associates who have contributing with their time and effort to making this work possible. Especially, I would like to thank the following people (in alphabetical order):

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Finally, I would like to express my gratitude for my family. My wife and children, for understanding that research can involve a lot of late work and travelling and my parents for providing me with financial and other support during my studies.

2 A historical excursion

Ever since men gathered into social groups, the issue of organizational structure and management has been a problem of certain relevance. During the dawn of mankind, the clan was the prevailing organizational form, and despite its long existence, clan structures can still be found in society, as well as in business organizations. A clan is generally defined as an organization with high entry barriers and conceptual closure (Ciborra 1993) and has been the dominating form of organization and society for several thousands of years. Also in today's organizations, clan-like structures exist, e.g. as professional communities or working groups with strong internal bonds and relatively little external contact.

Also the hierarchical organization, or bureaucracy, often condemned as the prototype for inefficiency is not an invention of our days. On a society level, it has been existing since the days of ancient Egypt. The pharaoh, corresponding to today's Chief Executive Officer, was on top of the hierarchy, and an elaborate bureaucracy (middle management) directed and controlled the workforce. Also the roman empire had a clear bureaucratic structure. However, it was the German sociologist Max Weber who first conducted a more formal and scientific analysis of the bureaucracy as a form of organizational governance.

Today, other forms of organizational governance are well established besides the strictly hierarchical organization. Based on the concept of *lateral relations*, matrix organizations were designed in order to cope with the lack of integration of tasks across functional borders. The idea of business processes and process based organizations, based on customer value creating, cross-functional processes, is well established in many organizations. However, the idea of considering organizations from a process perspective is neither new, nor revolutionary in itself. In manufacturing, processes have been the bedrock of operations for a long time, and measures for improving efficiency have been taken at an early stage, as the quote from Adam Smith's (1776) famous writing on *"The Wealth of Nations"* shows.

> *”One man draws out the wire, another straights it, a third cuts it, a fourth points it, a fifth grinds it at the top for receiving the head: to make the head requires two or three distinct operations: to put it on is a particular business, to whiten the pins is another ... and the important business of making a pin is, in this manner, divided into about eighteen distinct operations, which in some manufactories are all performed by distinct hands, though in others the same man will sometime perform two or three of them.”*

Adam Smith was very much influenced by laissez faire capitalism, and advocated a strict separation of government and economy, since he claimed, that the ”invisible hand” of the market would ensure the most efficient use of resources. For him, the division and specialization of work was an important pillar of competitive market mechanisms.

Smith also first recognized how the organizational outcome could be increased through the use of advanced labor division. Previously, in a society where production was dominated by handcrafted goods, one man would perform all the activities required during the production process, while Smith described how work in a pin factory was divided into a set of simple tasks, which would be performed by specialized workers. The result of labor division in Smith’s example resulted in productivity increasing by 24.000 percent (sic!), i.e. that the same number of workers made 240 times as many pins as they had been producing before the introduction of labor division. However, it is worth to notice that Smith did not advocate labor division at any price and as a means per se. He observed and noted, that under certain conditions several tasks could very well be integrated into one, which a single worker would then perform.

This approach to integration could be considered as an implicit proposition of a process-oriented approach, but there is one aspect that constitutes a significant difference to the idea of business processes as it is perceived today. The integration in accordance with the idea of Smith would take place only within the same functional domain and comprise activities that are in direct sequence in the manufacturing process, whereas today's process concept includes cross-functionality as an important characteristic. While Smith is widely accepted as being the first advocate of labor division and functional specialization, it is interesting

to note that the classic theorists later-on adopted only the first of Smith's observations.

Ever since the application of Smith's labor division principles on administrative science, we have had the same logical assumptions about how companies should be organized, indifferent from industry and competitive environment. Today, many of these ideas seem to be outdated, but it should be remembered, that Smith could presume different socio-economic conditions. His worldview was strongly influenced by capitalist ethic and economic individualism.

The idea of economic individualism had its root in the notion of the "calling". The Protestantism of these days, represented by Luther and Calvin, had a clear focus on work as being a goal for a good life. The waste of time, and unwillingness to work were considered as being sinful in the eyes of God. This was a clear difference from the catholic fatalism and monastic ideals that had been dominating life in the medieval age. Simultaneously, the concept of predestination enabled a wide adoption of labor division and specialization. However, this period shortly after the medieval time was still far away from mass production of standardized products, and trade was still in its infancy.

Alvin Toffler (1971) described the organizational legacy of this pre-industrial period as following:

> *”Each age produces a form of organization appropriate to its own tempo. During the long epoch of agricultural civilization, societies were marked by low transience. Delays in communication and transportation slowed the rate at which information moved. The pace of the individual life was comparatively slow. And organizations were called upon to make what we would regard as high-speed decisions.”*

As many companies increased in size, and the development of national and international infrastructures resulted in the opportunity of shipping goods over long distance and with increased work force mobility, the situation changed. Many of the entrepreneurs of the late 17th century came to face several problems, which must appear rather familiar also to today's managers:

- The size of the company did not allow a single person to control and direct all activities and organizational members.
- Due to increased mobility, there was a shortage of skilled workers and managers.
- Competition increased, both within the domestic market, and internationally.

The result was the development of rigorous control structures. Centralization, hierarchical command chains, and the clear specialization of work were measures to cope with the increasing demand for organizations that grew in size and complexity. The requirements of predictability and the relatively little influence of the single entrepreneur on the environment made this approach the only possible. We might remember, that growth was the only available strategy, since market instruments, as we know them today, were still unknown. However, as Dessler (1976, p 24) points out, we might not forget that this situation was hardly confronting the value systems of that time:

> *"But it is important to remember that this type of structure was also highly compatible with the prevailing economic, religious and political philosophies. These philosophies–and in particular those of predestination, the religious benefits of division of work, and economic self-interest and rationality–combined to permit the entrepreneur to view his "human inputs" as little more than another tool, a view which would last through the first two decades of our century."*

March and Simon (1956) described the situation of the workers in a similar way, when stating that they were basically considered as an

> *"inert instrument performing the tasks assigned him ... as a given, rather than a variable in the system."*

Following the argument brought forward by Dessler in his above quote, we realize, that the late medieval ideals about labor division, authority and control and the role of humans in the world and its organizations have been carried forward for centuries and also found their way into organizational concepts being developed during the 19th century.

2.1 Classic theory

2.1.1 Frederick W. Taylor - Scientific management

In the late 19th century Frederick Winslow Taylor, a mechanical engineer, started to develop the idea of management as a scientific discipline. He applied the premise that work and its organizational environment could be considered and designed upon scientific principles, i.e. that work processes could be studied in detail using a positivist analytic approach. Upon the basis of this analysis, an optimal organizational structure and way of performing all work tasks could be identified and implemented. However, he was not the one to originally invent the concept. In 1886, a paper entitled ”The Engineer as Economist”, written by Henry Towne for the American Society of Mechanical Engineers, had laid the bedrock for the development of scientific management.

The basic idea of scientific management was that work could be studied from an objective scientific perspective and that the analysis of the gathered information could be used for increasing productivity, especially of blue-collar work, significantly. Taylor (1911) summarized his observations in the following four principles.

1. Observation and analysis through time study to set the optimal production rate. In other words, develop a science for each man’s task–a One Best Way.

2. Scientifically select the best man for the job and train him in the procedures he is expected to follow.

3. Cooperate with the man to ensure that the work is done as described. This means establishing a differential rate system of piece work and paying the man on an incentive basis, not according to the position.

4. Divide the work between managers and workers so that managers are given the responsibility for planning and preparation of work, rather than the individual worker.

Scientific management’s main characteristic is the strict separation of planning and doing, which was implemented by the use of a functional foremanship system. This means, that a worker, depending on the task his

is performing, can report to different foreman, each of them being responsible for a small, specialized area.

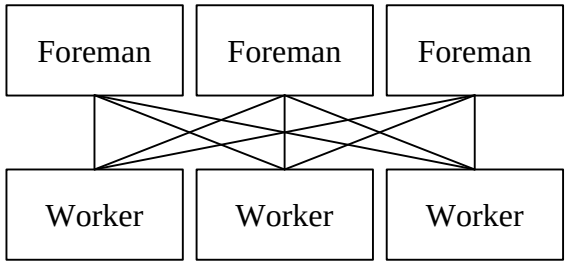


Figure 2.1: The functional foremanship system

Taylor's ideas had a major impact on manufacturing, but also administration. One of the most well-known examples is Ford Motor Co., which adopted the principles of scientific management at an early stage, and built its assembly line for the T-model based on Taylor's model of work and authority distribution. Later on, Taylor's ideas were extended by the time and motion studies performed by Frank Gilbreth and his wife Lillian. Henry Gantt[1], a co-worker of Taylor, developed Taylor's idea further, but placed more emphasis on the worker. He developed a reward system that no longer took into account only the output of the work, but was based on a fixed daily wage, and a bonus for completing the task.

[1] Henry Gantt is also well known for the "Gantt-chart". This technique for planning and phasing actitvities is still frequently used today.

Figure 2.2: Ford's assembly line, 1907

Taylor's work can be, and has been, criticized many times for degrading individuals to become machinelike. One of the most famous critiques of the situation that an application of scientific management could result in, is shown in Charles Chaplin's movie "Modern Times". Despite that fact, Taylor was inspired by the vision of creating a workplace that is beneficial to all members of the organization, both management and workers.

> *"The great revolution that takes place in the mental attitude of the two parties under scientific management is that both sides take their eyes off the division of the surplus as the all-important matter, and together turn their attention towards increasing the size of the surplus until this surplus becomes so large that it is unnecessary to quarrel over how it should be divided. They come to see that when they stop pulling against one another, and instead both turn and push shoulder to shoulder in the same direction, the size of the surplus created by their joint efforts is truly astounding."* (Wren 1972)

When looking at Taylor's ideas retrospectively, we can conclude, that they very well fitted the organizations of the early 20th century. The kind of organization he proposed requires certain pre-conditions, which were satisfied in the technological and socio-economic environment of his

time and the heritance from economic individualism and a Protestant view of work.

However, despite the good intention of designing organizations where managers and workers could jointly contribute to the common achievements, Taylor missed the fact that he had been building his principles on wrong assumptions. There are three major critical issues that can be brought forward.

The strict belief in man being totally rational, and the history of protestant ethic, which considered work as being a manifestation of religious grace, made him disregard the crucial issue of human behavior and the fact that money is insufficient as the single source of motivation (Tawney 1954).

Besides the disregard of human behavior in an organizational context, Thompson (1969) identified another deficiency in Taylor's theories, namely the lack of considering the organizational environment as a conceivable factor, and the overemphasis on organizational efficiency. As he notes:

> *"Scientific management, focusing primarily on manufacturing or similar production activities, clearly employs economic efficiency as its ultimate criterion and achieves conceptual closure of the organization by assuming that goals are known, tasks are repetitive, output of the production process somehow disappears, and resources in uniform qualities are available."*

If accepting Thompson's critique as valid and relevant, we can conclude that the strict hierarchical organization seems to be unfit to take on the challenges that are imposed by fierce competition and dynamic market structures. Due to the focus on improvement through repetition and resource uniformity, the applicability on organizations and processes without these characteristics, such as pharmaceutical R&D, can be questioned. Consequently, the lack of organizational flexibility was also one of the justifications for the process improvement initiatives at Astra.

Peter Drucker noted a third problem related to scientific management, namely that there was no real concern about technology, i.e. that Taylor considered his theory as being general, and that it could be applied to any

organization, independently of the technology used. Drucker (1972) stated:

> *"Scientific management was not concerned with technology. It took tools and technology as givens."*

2.1.2 Henry Fayol - Administrative science

With his background in mechanical engineering, Taylor was very little concerned with aspects of organizations beyond production. He had a primary concern with industrial manufacturing, and so had his colleagues Gantt and the Gilbreths. Since a company does not only consist of a manufacturing function, but contains managerial tasks, such as organizing, controlling, and staffing, other writers extended the tayloristic view to include these broader issues. However, it still had to take several years before Taylor's ideas were adopted into the administrative work arena. The classic theorists in this field, termed *administrative science* during the 1920-30s were then influenced significantly by Taylor's work.

The first to develop a more general theory of management was Henri Fayol, who built his approach on a set of managerial activities, and 14 principles, which he had developed during his time as general manager of a coal and steel company, the Commentry-Fourchambault Company. He took his starting point in six groups of generic industrial activities, i.e. activities that occur in every firm, independent of size or industry. Differing in his approach from Taylor, who had his point of departure at the shop-floor level, Fayol adopted an executive point of view, which he then applied on the lower hierarchical levels in the firm. He identified the following generic activities within 6 categories (Dessler 1976):

- Technical (production)
- Commercial (buying, selling, trading)
- Financial (Search for, and optimum use of, capital)
- Security (Protection of property and individuals)
- Accounting (including statistics)
- Managerial (planning, organizing, commanding, coordinating, controlling)

While he considered the first five of these categories as being well understood, he noted a considerable lack of understanding within the managerial field. The 14 principles he developed for improving management from a general perspective were first published in his book *Administration Industrielle et Genèràle* in 1916. However, the book was not translated into English until 1949 (Fayol 1949). Fayol was familiar with the writings of Taylor, and considered their work as complementary, especially since both approaches take their starting point in the concept of the economic man and focus on economic efficiency.

In order to improve managerial work, and to make it better understood, Fayol codified the following principles he had been using during his own time as a CEO. While these principles were developed almost 100 years ago, they can be considered as being still relevant.

1. **Division of work.** The first principle bringd forward the notion of labour division and specialization, i.e. that different people carry out different activities. Specialization takes place in two dimensions, vertical and horizontal. Vertical specialization is the equivalent to the separation of planning and doing as it was promoted also by Taylor. Horizontal specialization refers to the division of labour into different functional areas. Despite the high level of specialization that can be achieved through horizontal and vertical labour division, division of work, as described by Fayol, also includes the notion of limitation in the number of activities people can focus their attention on and this holds true for management and workers.

2. **Authority and responsibility.** Responsibility should be commensurate with authority. In this context, the concept of authority can be seen as the right to give orders and expect obedience. On the other hand, responsibility is the corollary to authority, and a necessary precondition for exercising it. In other words, people should not be given responsibility without the authority necessary to achieve the objectives they are given. With this, and the following principle, Fayol implicitely described the constitution of leadership, consisting of formal authority, assigned and assumed responsibility and good superiority.

3. **Discipline.** This includes to honor agreements aimed at exercising authority, and controlling human behavior in order to achieve the common goal. Discipline can be accomplished by exercising good

superiority throughout the firm. The concept of discipline, as described by Fayol, was still largely based on formal aspects and the exercising of management control. However, it is obious that good superiority cannot be achieved on the basis of formal control mechanisms and the demand for obedience alone. This is especially evident in organizations with a generally high level of knowledge at all levels, such as pharmaceutical R&D organizations. In these cases, discipline is achieved through demonstrated knowledge and capabilities by superiors, rather than a command and control system.

4. **Unity of command.** The unity-of-command principle presumes, that employees should receive orders from one superior only. The underlying reason is to avoid shared loyalties of individuals and goal conflicts that might arise from contradicting commands. Compared to Taylor's functional foremanship system, the unity-of-cmmand principle represents a clearer line of authority and Fayol has also underpinned this viewpoint with the concept of the scalar chain.

5. **Unity of direction.** This principle imposes, that there should be only one person in charge of a group of activities having the same objective, and that only one action plan should exist for the group. It claims, that activities should be logically grouped according to their goal and this logical structure should not be subjected to commands from different directions. It is thus an activity-based equivalent to the unity of command

6. **Subordination of individual interest to general interest.** The interest of a single person, or a group of persons, is not allowed to prevail over that of the organization. This principle also implies that the organizational interest - its goals and objectives - are clearly established and communicated throughout the organization.

7. **Remuneration of personnel.** There should be a system of remuneration which is fair, which rewards well-directed effort, but does not produce unreasonable overpayments, i.e. the system must satisfy employer and employees at the same time.

8. **Centralization.** All measures increasing the importance of employees' roles in the organization is decentralization, all measures decreasing it are centralization. For each organization, there is an optimum balance which is determined by the capabilities of the employees at all levels. This principle implies, that it is possible to

identify the optimum balance and to structure the organization in a way that the optimum can be achieved and sustained. The crucial issue here is to define feasible and measurable criteria for determining the optimum.

9. **Scalar chain.** There should be a scalar chain of authority and communication, that goes throughout the entire organization, ranging from the highest rank (ultimate power) to the lowest rank. In order to make the scalar chain a relevant tool and to avoid that it becomes a structure for top-down command and ontrol, the excercize of authority must, in accordance with the above described relation (see principle # 2, be combined with responsibility.

10. **Order.** The organization takes responsibility for providing both the material and social order with everything and everyone in the appointed place.

11. **Equity.** There must exist a sense of justice throughout the entire organization, i.e. employees must be treated with respect and equality.

12. **Stability of tenure of personnel.** High personnel turnover should be avoided. It is a result of bad management, as well as a cause for it.

13. **Initiative.** There should be the opportunity to take initiative for all employees. This must be encouraged by management by ensuring integrity.

14. **Esprit de corps.** Union among all employees, workers and management, provides a platform for common success.

There are several aspects in Fayol's principles that deserve closer attention. The first we will be having a closer look at is the scalar chain. This principle has its basis in the need for vertical integration of activities, imposed by management' s need for control and information. However, Fayol noted the difficulties related to a full implementation of the scalar chain, and developed a mechanism to reduce complexity in the control structure, Fayol's bridge.

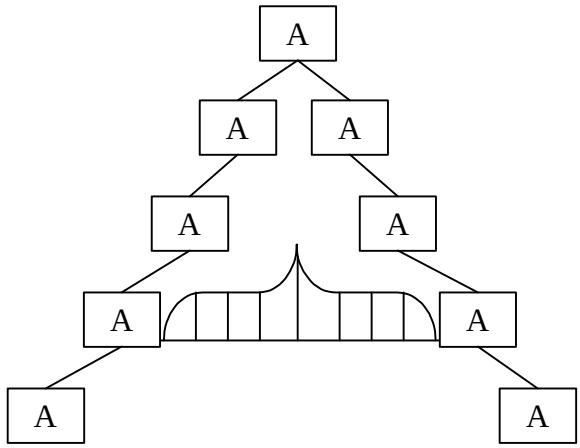


Figure 2.3: Scalar chain and Fayol's bridge

Let us assume, that employee D in the above depicted organization would require information from H. Following the scalar chain, the information request would travel along the following route: D-C-B-A-F-G-H and then back, thus passing five stations on its way from sender to recipient in each direction. Since in reality, contrary to the simplified example above, most managers have more than one subordinate, the information flow through the organization would soon exceed a manageable level. Therefore, Fayol proposed that subordinate employees should be allowed to communicate directly with each other, given that their superiors had agreed upon this procedure. We will discuss the issue of span-of-control, i.e. the number of employees a manager can supervise in more detail later on.

The use of Fayol's bridge resulted in a number of other aspects needing to be taken into consideration. In order to put this system to work, Taylor's functional foremanship had to be abandoned, and the unity of command had to be established. At the same time, decision power is distributed to individuals on lower levels in the organization, and only decisions that exceed the pre-defined decision scope of an employee are referred upwards. This, in turn, strengthened the co-equality of authority and responsibility.

2.1.3 Excursion - The span of control

The question of the optimum span of control has been widely discussed, ever since Graicunas' attempt to develop a mathematical formula for its

calculation in the year 1933 (Gulick and Urwick, 1937). Basically, the span of control is defined as

> *"the number of subordinates with whom a supervisor interacts"*.
> (Mackenzie 1978)

Each of these interactions consumes a certain amount of resources, time in the first place, and the limitation in time being available to managers for interaction with their subordinates describes the problem in a nutshell. Closely related to this is the problem of hierarchical depth, i.e. the number of hierarchical levels from the top of the organization to shop floor level, in Fayol's terms the length of the scalar chain.

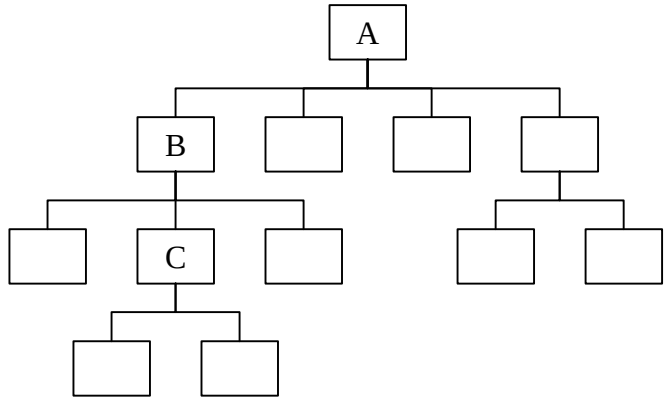


Figure 2.4: Basic organizational structure

In the above picture, A has a span of control of 4, B of 3, and C of 2. The hierarchical depth is 4, as there is a total of four hierarchical levels. As already Fayol had noted, the amount of information flowing through different nodes in this organizational tree can increase significantly with a broad span of control and a deep hierarchical structure. In the above case, B would be responsible for controlling and directing five people, and for A it would mean the supervision of 11 direct or indirect subordinates. For illustrating this effect for a larger organization, let us use the following, constructed example.

An organization uses the span of control of 2, i.e. each supervisor has exactly two subordinates. If the organization has around 1.000 employees, the result would be a scalar chain (hierarchical depth) with a length of 10, with a doubling number of people on each level. Of the total

amount of people in the organization, ~50% would be supervisors, and the remaining shop floor personnel. Also, the number of people to be supervised is increasing significantly for each level upwards in the hierarchy. In this example, we have only considered direct interactions between supervisor and subordinates, while a full adoption of the unity of command principle would require the inclusion of all interactions.

Graicunas distinguished three types of interactions–direct single relationships, cross-relationships, and direct group relationships–each of them contributing to the total amount of interactions within the organization. According to Graicunas, the number of possible interactions can be computed in the following way. Let n be the number of subordinates reporting to a supervisor. Then, the number of relationships of direct single type the supervisor could possibly engage into is

$$n.$$

The number of interactions between subordinates (cross relationships) he has to monitor is

$$n\,(n - 1),$$

and the number of direct group relationships is

$$n\,(2^n/2 - 1).$$

The sum of these three types of interactions is the number of potential relationships of a supervisor. Graicunas showed with these formulas, that each additional subordinate increases the number of potential interactions significantly. A manager with four subordinates, adding a fifth, faces 20 additional relationships, and a number of 18 subordinates would mean a total of 2.359.602 potential possibilities of interaction. This would either mean a need for increasing the number of supervisors, or the development of mechanisms for reducing this complexity.

It appears natural, that no organization can afford to maintain a control structure of this dimension. Therefore other mechanisms had to be found for dealing with the dilemma of maintaining managerial control, while keeping the cost and time effort at a reasonable level, thus making the span of control a critical figure for the organization.

Therefore, for a long time, finding the optimum span of control has been a major challenge to organization design. As Mackenzie (1978, p 121) describes it:

> *"One could argue that with larger spans, the costs of supervision would tend to be reduced, because a smaller percentage of the members of the organization are supervisors. On the other hand, if the span of control is too large, the supervisor may not have the capacity to supervise effectively such large numbers of immediate subordinates. Thus, there is a possible trade-off to be made in an attempt to balance these possibly opposing tendencies."*

Mackenzie and others (Massie 1965, Pugh et. al., 1972) also noted that there is no generally applicable optimum span of control. There are instead several factors influencing the balance between the desired level of control, and the manageability of the organization.

Firstly, it depends on the capabilities of the organizational members, managers and workers. It was assumed, that no manager would be capable of supervising more than 5-6 direct subordinates. However, this conclusion built on the assumption, that the superior must actively monitor the work of all subordinates. Later on, this statement was diversified, and Davis (1951) divided managerial work into two categories, one requiring the attention to physical work, the other one requiring mental activity. Depending on the type of supervision, a span of 3-8 subordinates for managers at higher levels were considered adequate, while first-level supervisors, i.e. those supervising shop floor personnel could have up to 30 subordinates.

The neoclassical theorists have developed a different solution. They assumed that a considerable amount of decisions could be delegated to organizational members at lower organizational levels (as proposed already by Fayol). Thus, the need for supervision would be reduced from direct control to exception handling. According to this assumption, they considered the opportunity of having access to a supervising manager would be sufficient to satisfy the need for control in standard situations. Peter Drucker (1954) refers to this principle as the span of managerial responsibility.

2.1.4 Max Weber - The concept of bureaucracy

Max Weber, a German economist and social scientist, published his ideas of the ideal organization in 1921. Despite the fact, that his writings remained unknown to writers in others than German-speaking countries (his work was not translated into English before 1947), there are several similarities to the work of Fayol and Glico & Ureic.

Weber had observed how growth of an organization changed its need for administrative efficiency, and his efforts were mainly directed towards the crucial issue of handling complexity in large organizations. The organizational model he developed, and which he termed bureaucracy, describes a rational, formal organization, which generally possesses the following characteristics (Girth and Mills, 1958):

- A high degree of division of work at both the task and administrative levels.
- A hierarchy of authority so that all organizational units short of the top are supervised by a higher organizational unit.
- Use of formal, written documents in everyday activity and an extensive filing system.
- Expert training of the administrative officials involved.
- Written rules and procedures, to guide decisions and operations.

When talking about bureaucracy today, we normally use the term to describe an inefficient, inflexible organization, and often, public administrations are characterized in this way. However, when Weber developed his original concept of the bureaucracy as a ”pure” organizational form, it did not possess these negative attributes. In fact, Weber stated that the bureaucracy actually was superior to other organizational forms in measures of efficiency. However, when looking at the virtues being promoted today, many of the characteristics of the bureaucracy would be considered as organizational pathologies.

> *”Precision, speed, unambiguity, knowledge of the files, continuity, discretion, unity, strict subordination, reduction of friction and of material and personnel costs– these are raised to the optimum in the strictly bureaucratic administration.” (Gerth and Mills, 1958)*

When taking a closer look at the main characteristics of bureaucracy, as described above, we can note that the two first are similar to the concepts developed by the administrative scientists. The remaining, however, were specific for Weber's approach.

Division of work. According to Weber, each organization is divided into several areas of responsibility, which he termed "jurisdictional areas". These areas are defined upon the organization's officially sanctioned rules and regulations. At the same time, the managers of the different areas have the right to take certain decisions, and the power to assign tasks to their subordinates to get the work done. Although this process, called departmentalization, has been implicitly used ever since the early days of mankind, Weber was the first to explicitly outline its advantages for administrative work. Later on, the concept of departmentalization was, independently from Weber, further developed by Gulick and Urwick.

Hierarchy of authority. As the administrative theorists, Weber discovered that an increasing degree of work division and specialization even has a considerable impact on the interdependencies between the units which perform the different tasks. The major challenge was to coordinate the efforts of different units in order to ensure that all tasks contribute to the achievement of the organization's overall objectives. In a similar way as Fayol, he proposed a hierarchy of authority, where each organizational unit was controlled by a higher unit. However, while Fayol developed his scalar chain on the basis of individual control, Weber took his starting point in the organizational unit.

Written documents and files. During the early times of formal organizations, those were considerably dependent on the founder, often the owner of the company, who would possess the required knowledge on the overall level as well as about operational details within the organization. As companies grew in size, and the delegation of tasks increased, the independence from a specific individual's will increased. People can enter the organization, and leave it, without changing its functioning. This implies, that some mechanism is developed for storing the knowledge an organizational member needs to be aware of, an organizational memory. This can be achieved by an extensive use of written documents and filing systems. This means, that there will be no need for the individual to remember specific actions or decisions, but that

the files serve as a storage for the knowledge about all events concerning the organization.

Expert training. The thorough training of individuals on the job they are doing is enabled by a high degree of specialization. In an organization where all members perform a relatively small range of activities, they can be better specialized in the specific tasks assigned to them. In the bureaucratic organization, this means being familiar with the rules and procedures, the filing system, and the technology being used in the organization.

Rules and procedures. One of the cornerstones of bureaucracy is the existence of written rules and procedures, describing in detail how the different tasks are to be carried out. These rules must be relatively stable, learnable, and more or less exhaustive. The rules and procedures describe different areas of responsibilities, the internal reporting structure, and job categories and contents. In addition, they contain the description for behavior in interactions with internal and external parties. Their purpose is threefold.

1. They make the organization independent of any single person.
2. They ensure stability in terms of decision taking.
3. They reduce the need for frequent interaction between supervisor and subordinate.

Summarizing their role in commonsense words, we could say they describe ”the way things get done around here”. However, the principle of a rule-based organization builds on certain implications–rules must be followed, and human behavior is rational and predictable–which limit the usability of the concept as soon as variations in individual behavior occur due to bounded rationality.

Also, an organization being based on strict obedience of rules and pre-described procedures is badly prepared for coping with environmental dynamics that impact the organization, but which are not covered by the rulebook.

2.1.5 Gulick & Urwick - Concepts of departmentalization

As March and Simon (1958) noted when tracing a first approach to departmentalization back to Aristotle (Politics, Book IV, Chap. 15), the

problem of distributing work, authority and responsibility throughout an organization is hardly new. In modern times, Gulick and Urwick (1937) were the first to introduce a theory of different departmentalization strategies, which were referred to as *departmentalization by purpose* and *departmentalization by process.*

> *”First [organization by major process] ... by bringing together in a single office a large amount of each kind of work (technologically measured), makes it possible in each case to make use of the most effective divisions of work and specialization. Second, it makes possible also the economies of the maximum use of labor saving machinery and mass production.*
>
> *... there is danger that an organization erected on the basis of purpose will fail to make use of the most up-to-date technical devices and specialists because ... there may not be enough work of a given technical sort to permit efficient subdivision.*
>
> *Is there any advantage in placing specialized services like private secretaries or filing in [process departments]? In a very small organization, yes; in a large organization, no. In a small organization, where there is not a full-time job on some days for a secretary, it is better to have a central secretarial pool than to have a private secretary for each man. In a large organization, the reverse is true.”* (Gulick & Urwick, 1937)

Studying the above characterizations of the two forms of departmentalization we note that purpose decentralization is concerned with building work around specific products, customers, or geographic locations, while process departmentalization encompasses the efficiency of ”production”. March and Simon (1958) described the basic difference between the two ways of departmentalization as following:

> *”Process departmentalization generally takes greater advantage of the potentialities for economy of specialization than does purpose departmentalization: purpose departmentalization leads to greater self-containment and lower coordination costs than process departmentalization.”*

When taking a closer look at the three ways of departmentalization by purpose–product, customer, and location–we note that there are some specific advantages related to it.

First, self-containment tends to improve the ability for internal coordination within the unit. At the same time, the need for developing and maintaining extensive external coordination mechanisms is reduced.

Second, a clearer focus on the purpose itself–serving a specific customer or market–is enabled. On the other hand, the sense of independence may result in a drift-off from the achievement of the overall objectives of the organization. Therefore, several authors have emphasized the need for establishing control systems that serve the purpose of allowing decentralized decisions, while still aligning all sub-units to the overall goals of the organization (Drucker 1954, Koontz & O'Donnell 1964).

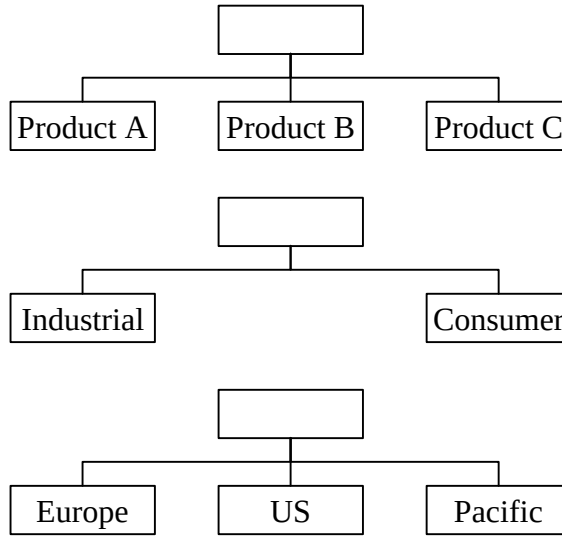


Figure 2.5: Departmentalization by purpose: product, customer, and region

Departmentalization by process, on the other hand, seeks to benefit from the advantages that are found in high specialization, and tends to be very efficient in some instances. A high degree of specialization leads to the development of proficiency and professional competence, as well as it enables, and implies, the development of centralized control functions.

On the other hand, the problem of aligning individual and organizational goals remains. In addition, in this case, we would also need to consider departmental goals. Also, the high level of specialization is a barrier for

the flexible reallocation of resources within the organization, i.e. people can not perform other tasks than those they are working with in their functional occupation. The most common way of process departmentalization is the division of the firm into business functions, such as purchasing, manufacturing, sales, accounting, etc.

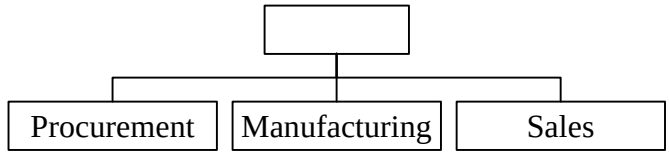


Figure 2.6: Departmentalization by process: business functions

Looking at the circumstances encompassing the use of either of the departmentalization strategies, we find that departmentalization by process generally is advantageous in cases of stable environments, while departmentalization by purpose, featuring self-containment and certain amounts of independence, appears to be the appropriate strategy for handling changing or unpredictable circumstances. Chandler (in: March 1958) identified a correlation between the application of purpose departmentalization and the use of a diversification strategy:

> *"The dominant centralized structure had one basic weakness. A very few men were still entrusted with a great number of complex decisions. ... As long as an enterprise belonged in an industry whose market, sources of raw materials, and production processes remained relatively unchanged, few entrepreneurial decisions have to be reached. In that situation, such a weakness was not critical, but where technology, market, and sources of supplies were changed rapidly, the defect of such a structure became more obvious."*

2.2 Classic theory - A critique

The approach to organization design, the ideas about the distribution of work, responsibility and control developed within classic theory can be criticized from various perspectives–empirical, behavioral and economical. The major critique can be condensed into three statements:

1. There is a lack of empirical validity.

2. The assumptions about human behavior as being rational are insufficient.
3. The organization's environment is not considered.

March and Simon have argued, that the principles being applied by classic theorists have no empirical validation, and can not be applied universally. They state:

> *"There is in the literature a great disparity between hypothesis and evidence. Much of what we know or believe about organizations is distilled from common sense and from the practical experience of executives. The great bulk of this wisdom and lore has never been subjected to the rigorous scrutiny of scientific method. The literature contains many assertions, but little evidence to determine–by the usual scientific standards of public testability and reproducibility–whether these assumptions really hold up in the world of fact."* (March and Simon 1958)

Regarding the perspective on individuals being exposed in classic theory, alternative theories were developed already in the 1920s. The Human-Relations school, represented by Mayo and Roethlisberger, suggested that there were other factors influencing human behavior than strictly rational thinking. Under their guidance, an empirical study was conducted at the Hawthorne plant of the Western Electric Company, which revealed that productivity was not a result of physical work conditions alone. Also, the social situation of the workers in the workplace had a strong impact, especially changes in motivation, satisfaction, and the control structure (Roethlisberger & Dickson 1964).

The Behavioral-Systems school, with Kurt Lewin as its generally accepted founder, developed a perspective grounding on the interaction between the individual and its organizational surroundings. Lewin proposed a model, that considers the worker's behavior (B) as a function of personal characteristics (P), and the environment (E), thus resulting in the formula (Lewin 1951, p 241):

$$B = f (P, E)$$

While Lewin was primarily concerned with the interaction between the individual and her working environment, Chandler elaborated on aspects

of diversification, i.e. the development of new products and markets. This development was accelerated during the worldwide depression in the beginning of the 1930s, when many firms embarked on extensive research and development programs, thus spreading their risk over a wide range of markets. Chandler (1962) pointed out, that diversification resulted in a significant increase of a firm's activities, which challenged the existing centralized structures. Eventually, the increasingly complex environment, with its technological development and the competition, would result in more decentralized organizational structures, abandoning the strict control mechanisms employed earlier and providing individuals with a higher degree of responsibility.

McGregor (1960) questioned the basic assumption, that the hierarchical organization was an economic necessity. He claimed that "Theory X", as he called it, rather was a product of certain assumptions about the nature of human behavior, namely that people dislike work and prefer to be directed rather than developing their own working principles. His alternative "Theory Y" was based on the premises, that people have a basic motivation to do a good job, and that they basically strive for affiliation with their peers, rather than financial benefits. Argyris (1964) developed a theory of maturity, claiming that traditional control structures would prevent individuals from fully using their potential. His theory consists of a seven step maturity scale, and the exercise of extensive control would encourage employees to become passive and subordinate, thus hampering their development to full maturity.

2.3 Concluding remarks

In the above, the Weberian concept of bureaucracy and the concepts developed by the administrative scientists have basically been treated as being synonymous, as in most other publications.

However, Dessler (1976) has claimed that these two models share a lot of commonalties but, in fact, are not equal. While both stress the importance of specialization, scalar chain and unity of command, there is a significant difference in the rigidity of application.

While Fayol and his followers used a pragmatic approach to the implementation of their ideas, stemming from their industrial experience, Weber's bureaucratic concept is a universal theory in a stricter sense, i.e.

as an ideal type of organization, where all deviations are treated as threats to optimum efficiency.

3 Current organizational concepts

In response to the deficiencies of the strictly bureaucratic organization[2], new theories on organization and organization design have been developed. March and Simon (1958) elaborated on their critique of the classic approach as being too rationalistic in assuming individuals' economic behavior and claimed that the information and decision processes are largely influenced by *bounded rationality*. As an attempt to attack the problems regarding efficient mechanisms for coordination work across functional departmental borders, the matrix organization, based on the idea of *lateral relations*, was introduced. With start in the late 1980s, the ideas of *business processes* took ground and dominated organization design for several years.

3.1 Theoretical foundations

3.1.1 Bounded rationality

According to the Carnegie-Mellon School, mainly represented by Barnard, Cyert, March and Simon, most of what goes on in organizations is actually decision making and information processes. The crucial factor in the information and decision process analysis is thus individuals' limited ability to process information and to take decisions under these limitations.

According to March and Simon, organizations have to be considered as cooperative systems with a high level of information processing and a vast need for decision making at various levels. They also claimed that there are factors that would prevent individuals from acting strictly rational, in opposite to what has been proposed and advocated by classic theorists. Instead, they proposed that any decision would be sub-optimum due to the *bounded rationality* of the decision-maker.

[2] The term *bureaucracy* is here used in the commonsense meaning to include both the Weberian concept and the ideas developed within administrative science.

Instead of using the model of the *economic man*, as advocated in classic theory, they proposed the *administrative man* as an alternative based on their argumentation about the cognitive limits of rationality.

While the theories developed at Carnegie Mellon clearly filled some theoretical gaps in the discipline, March and Simon did not propose a certain organizational form that they considered especially feasible for coping with cognitive limitations of decision-makers. Through their own argumentation against normative decision-making models, i.e. models that prescribe people how they *ought* to choose, they also abandoned the idea of an ideal organizational form.

In addition to the factors mentioned by March and Simon, there are two other considerable aspects, stemming from environmental and organizational dynamics. Firstly, it is not possible to access, collect and evaluate all environmental information being relevant for taking a certain decision at a reasonable price (time and effort). In other words, following a national economic framework, the transaction costs associated with the informating process are too high. Secondly, established organizational rules and procedures can prevent the taking of the most appropriate decision, i.e. that a sub-optimum solution is chosen in accordance to the institutional rules, guidelines and procedures.

3.1.2 Galbraith's organization design strategies

According to the Carnegie Mellon School and its followers, information management, i.e. the organization's ability to process information, is at the core of organizational and managerial competencies. Consequently, strategies for organization design must be aiming at improved information processing capability. Galbraith (1977, p 49 ff.) has identified five main organization design strategies within two categories - increased information processing capacity and reduced need for information processing.

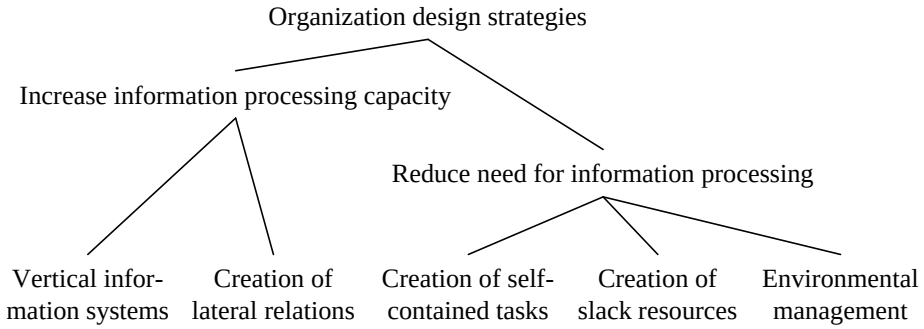


Figure 3.1: Organization design strategies according to Galbraith

Environmental management. Instead of adapting to changing environmental circumstances, the organization can aim at modifying its environment. Vertical and horizontal collaboration, i.e. cooperation or integration with other organizations in the industry value system are typical means for reducing uncertainty. An example for reducing uncertainty in the relation with the prior or demanding stage of the industry system is the concept of Supplier-Retailer collaboration or Efficient Customer Response.

Creation of slack resources. In order to reduce exceptions, performance levels can be reduced, thus decreasing the information load on the hierarchy. These additional slack resources, required to reduce information processing in the hierarchy, are representing an additional cost to the organization and the choice of this method is clearly depending on the alternative costs of other strategies.

Creation of self-contained tasks. Achieving a conceptual closure of tasks is another way of reducing information processing. In this case, the task-performing unit has all the resources required to perform the task. This approach is concerned with task (de-)composition and interaction between different organizational units, i.e. organizational and information interfaces.

Investment in vertical information systems. Instead of processing information through the existing hierarchical channels, the organization can establish vertical information systems. In this case, the information flow for a specific task (or set of tasks) is routed in accordance to the applied business logic, rather than the hierarchical organization.

Creation of lateral relations. In this case, lateral decision processes are established that cut across functional organizational units. The aim is to apply a system of decision subsidiarity, i.e. to move decision power to the process, instead of moving information from the process into the hierarchy for decision-making.

Following the lateral relations concept, it also becomes possible to employ an organizational form that is different from the simple hierarchical information: The Matrix organization.

3.2 The Matrix organization

The Matrix organization is aiming at bringing together the functional and product departmental bases and achieving a balance in information processing and decision making between the vertical (hierarchical) and the horizontal (product or project) structure. The creation of a matrix organization can also be considered as management's response to a persistent or permanent demand for adaptation to environmental dynamics, instead of the response to episodic demands, which would result in temporary measures, as proposed by Galbraith.

The matrix organization comes in two basic flavors, *product* or *project* oriented. In both cases, personnel will report to two managers, one in their functional unit and the other in the product unit or project. While the matrix organization has several advantages, the latent conflicts between the two matrix dimensions are the most serious drawback.

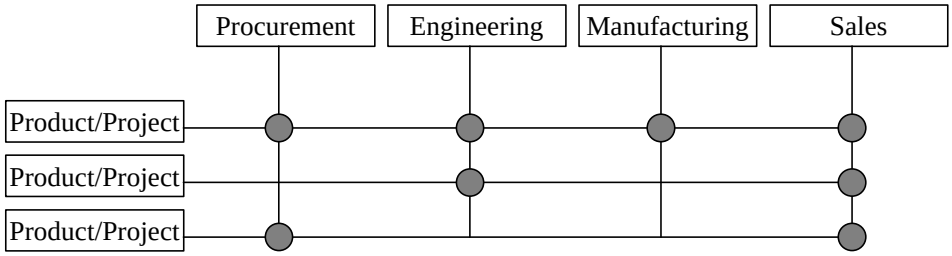


Figure 3.2: Matrix organization

3.2.1 Characteristics of matrix organizations

Matrix organizations are generally associated with characteristics that highlight the improved internal interaction mechanisms between different

functional units. Gibson et. al. (1985) have identified the following positive attributes of the matrix organization.

- Better utilization of specialized staff and equipment, since these resources can be shared among different projects or product units, instead of being replicated.
- Flexibility in conditions of change and uncertainty due to improved internal organizational communication.
- Technical excellence through knowledge exchange between specialist from different functional units.
- Increased capacity for top-management to engage in long-term planning.
- Improved motivation and commitment due to delegation of decisions to project/product groups.
- Opportunities for personal development by cross-fertilization of knowledge.

On the other hand, the matrix organization also has a major drawback. As Margulies and Raya (1978) have pointed out, there is a risk for internal competition for resources and conflicts between functional managers and product or project managers. These conditions may stimulate managers to overstate needs, to hoard resources, and to restrict the necessary flow of information. The result is then a traditional production-oriented organization with a high conflict potential attached to it. Margulies and Raya (ibid.) have proposed the use of *collateral modes* for overcoming these potential deficiencies. The application of collateral modes means to apply an authority/production-centered organizational mode, as well as a knowledge/problem-centered one. Depending on the kind of tasks to be resolved, the organization chooses either mode to work in. While the production-oriented mode is best suited for well-known and structured problems, the knowledge-centered mode is used for ill-structured problems with unpredictable outcome.

The matrix organization has been widely applied in a wide variety of organizations in multiple industries. It has been able to resolve several of the most relevant problems being associated with the strictly hierarchical organization, such as the lack of communication between functional units working on the same task and the distance between deciding and doing.

However, it must be admitted it earlier attempts have been made also within the administrative science field, e.g. Fayol's bridge can be seen as a measure for improved inter-departmental communication similar to the mechanisms being used in the matrix organization.

3.3 The process organization

In the early 1990s, a new approach to organization design, and consequently organizational change, began to attract attention from academia and business: The concept of business processes and process-orientation.

Based on the idea of considering organizations in terms of customer-focused, value-creating sets of activities, business processes, the corporate world embarked on large scale projects aiming at cycle-time and cost reduction, quality improvement and elevated customer service.

In the following, the business process concept will be explored, described and analyzed with regard to implications for organizational change and the use of information technology.

3.3.1 Definition of a (business) process

Let us start our investigations with reviewing several process definitions, as they are used in current management literature. In this context it is necessary to point out, that the following definitions are referring to business processes, not to a general definition of the term process as it is given in dictionaries (e.g. Geddes & Grosset), where a process is defined as

> *”course or state of going on, a series of events or actions, a method of operation, to handle something following set procedures.”*

Davenport (1993) defines a (business) process as

> *”a structured, measured set of activities designed to produce a specific output for a particular customer or market. It implies a strong emphasis on how work is done within an organization, in contrast to a product focus’s emphasis on what. A process is thus a specific ordering of work activities across time and space, with a beginning and an end, and clearly defined inputs and outputs: a structure for action. ... Taking a process approach implies adopting the customer’s point of view. Processes are the structure by which an organization does what is necessary to produce value for its customers.”*

From this definition, we can draw certain conclusions about the requirements a process must fulfill. These characteristics are achieved by a focus on the business logic of the process (how work is done), instead of taking a product perspective (what is done). First, a process must have clearly defined boundaries, input and output. Second, it consists of smaller parts, activities, which are ordered in time and space. Third, there must be a receiver of the process outcome, a customer. Fourth, the transformation taking place within the process must add customer value.

Hammer & Champy’s (1993) definition can be considered as a subset of Davenport’s. They define a process as

> *”a collection of activities that takes one or more kinds of input and creates an output that is of value to the customer.”*

As we can note, Hammer & Champy have a more transformation oriented perception, and put less emphasis on the structural component–process boundaries and the order of activities in time and space.

Rummler & Brache (1995) use a definition that clearly encompasses a focus on the organization’s external customers, when stating that

> *"a business process is a series of steps designed to produce a product or service. Most processes (...) are cross-functional, spanning the 'white space' between the boxes on the organization chart. Some processes result in a product or service that is received by an organization's external customer. We call these primary processes. Other processes produce products that are invisible to the external customer but essential to the effective management of the business. We call these support processes."*

The above definition distinguishes two types of processes, primary and support processes, depending on whether a process is directly involved in the creation of customer value, or concerned with the organization's internal activities. Second, it describes that processes are embedded in some form of organizational structure. Third, a process can range over several business functions.

Finally, let us consider the process definition of Johansson et. al. (1993). They define a process as

> *"a set of linked activities that take an input and transform it to create an output. Ideally, the transformation that occurs in the process should add value to the input and create an output that is more useful and effective to the recipient either upstream or downstream."*

Summarizing the four definitions above, we can compile the following list of conditions for a business process.

- It must have clearly defined boundaries, input and output.
- It must consist of activities that are ordered according to their position in time and space.
- There must be a receiver of the process outcome (a customer).
- The transformation taking place within the process must add customer value.
- The process must be embedded in an organizational structure.
- A process regularly can, but not necessarily must, span several functions.

For the following schematic description, the additional condition $Value_{Input} < Value_{Output}$, where value is defined in terms of the recipient's perception of value, is valid.

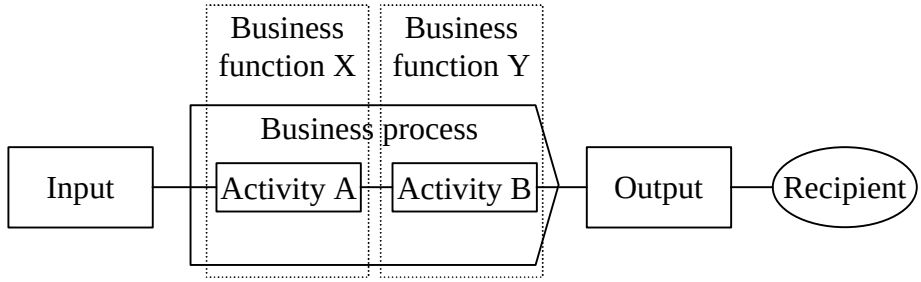


Figure 3.3: Schematic description of business process

3.3.2 Processes and hierarchies

From our previous, brief consideration of organization history we find that the predominant organizational legacy is the grouping of similar tasks into functional units or departments. This view has generated corps of specialists, each of them focusing on his own bounded functional task, and often being unaware of the own role in the organization as a whole. In addition, the exercise of close managerial control is a potential source of dissatisfaction of employees.

One earlier attempt to overcome these problems has been the matrix organization, which has been introduced above. Also advocates of the process-based approach claim, that process-orientation can allow the overcoming of hierarchical pathologies, thus enabling organizational forms that are better at serving customer needs, and that are more adaptive to changing environmental conditions.

However, when looking at the basic process implications we have identified above, we can conclude that these requirements principally can be satisfied by a traditional, hierarchical organization.

- **Clearly defined boundaries, input and output.** The flow of work and information is clearly defined in the hierarchy. There are rules prescribing the handling of events and cases, the involvement of people and alternative actions to be taken. These procedures are documented as written rules and guidelines, will result in predictable outputs.

- **Activities ordered in time and space.** The concept of hierarchy builds on the dissection of work into a number of task (activities), which must be carried out in a specific sequence, and, depending on the technology used, at a specific place.

- **Recipient of the process outcome.** The concept of a ”customer” as being the recipient of the outcome of a process is not clearly outspoken. However, it is well defined to whom the output of a specific task is handed over.

- **Customer value adding.** Early classic theory considered the outcome as something that ”just disappears” (Thompson 1969). Including a behavioral-systems view, as done since the 1930s, the organizational environment has been considered. Consequently, customers have become part of the organizational considerations. Since also a hierarchically organized company works under the condition of selling its products/services to a customer, it is obvious that there must be a value-adding capability.

- **Structural embeddedness.** Well-defined structures are imperative for hierarchical organizations; thus business processes performed within a hierarchical organization are necessarily embedded in a well-defined organizational structure.

- **Cross-functionality.** Despite the high degree of functional specialization, processes in hierarchical organizations often cross functional boundaries in order to produce the required formal outcome. Even though cross-departmental communication requires either an extensive amount of transactions between organizational members on different hierarchical levels, or the application of Fayol’s bridge, cross-functionality can nevertheless be achieved in a hierarchy.

The question to ask is why a company should apply a process view on the organization, if the principles of hierarchy can satisfy the requirements for business processes? Instead of engaging in large-scale and risky change efforts, the hierarchical organization could be maintained, while workflows are designed and implemented as a layer on top of the formal structure. While process-orientation conceptually can be applied within an existing hierarchical structure, it can also be argued that the practical implementation in fact is virtually impossible due to several reasons.

- The institutionalization of management control in the hierarchy is preventing the implementation of empowerment and downward delegation of decisions.
- The underlying formal authority structures would prevail and subsequently dominate the process layer.
- There is no inherent focus on performance improvement in the hierarchy.
- The concept of customer is not outspoken. Efficiency in rule compliance is focused, rather than effectiveness in terms of customer satisfaction.
- The reward system would not allow incentives and promotion based on performance.

In addition we can argue that there in fact is no major difference between the organizational structure and the processes being performed within it. Consequently, a discussion about processes versus structures would be rather irrelevant. The German economist Erich Kosiol (1962) considered the distinction of structure and processes as a ”scientific trick”, aimed at reducing complexity in organization analysis. He claims that organizational structure and processes represent two perspectives on the same phenomenon, and consequently the division into structures and processes is an abstraction. Consequently, organization design must be simultaneously concerned with the analysis and design of both elements.

In the following, we will identify and describe some of the key issues that must be addressed in order to allow an organizational transformation towards a process-oriented structure.

4 From structure to process

The process of process-based change is neither simple, nor intuitive. Corporations considering the transformation of a structure-oriented organization into a process-based form, must address a variety of aspects. The flow of work and information, the division of main processes into sub-processes and activities and the remaining level of task complexity, goal congruence between different process levels and the organizational

reward system, to name a few. Some of the most important factors will be addressed in the following.

4.1 Business processes and manufacturing

Production-oriented firms have been using a process-view on manufacturing for a considerable time. The assembly line is an example for process optimization in a production-oriented organization. It is therefore important to point out, that process-orientation in the way it is expressed in the managerial literature does not mean to apply manufacturing principles on administrative work, despite the fact that this view is not uncommon among managers and scholars. Professor Scheer, founder and CEO of IDS Prof. Scheer GmbH, a firm in the BPR-tool industry has claimed that ”it is about time to apply a manufacturing perspective on administration”.[3]

When looking at the way manufacturing has been organized, we can observe that it has been designed for bringing together multiple functional competencies in a structured and sequential way. In order to handle transactions among the process elements, there has been a focus on independence, instituted by buffering and stocking, rather than integration. However, since the middle of the 1980s, a new view on manufacturing processes emerged, driven by the increasing adoption of Total Quality Management and its relatives, but also by the need for cost reduction due to increasing competition.

General Motors was one of the first manufacturing companies to adopt a "cellular" view on manufacturing. During 1995, a pilot project was initiated in one plant. Instead of organizing its manufacturing process in accordance to the traditional assembly line structure, the factory was divided into a number of autonomous cells. Each of these cells possessed its own resources and was responsible for its own operations. A central purchasing unit was laying tenders for production assignments and each cell could bid on each assignment in competition with others.

[3] Keynote speech given at the BIS Strategic Decisions' Business Process & Workflow Conference in Frankfurt, Germany, in October 1996.

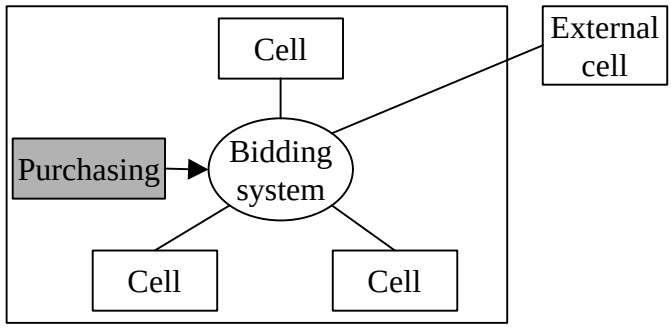


Figure 4.1: Cell-oriented manufacturing

While it was not considered as a primary aim in the pilot project, the cell-oriented structure also allows a more efficient competition between internal and external providers of services. Possessing the required resources, an external cell can compete with internal organizational cells for manufacturing tenders. Today, many automotive companies have adopted a hybrid between internal and external production by involving suppliers into product development and component manufacturing at an accelerating pace. This form of inter-organizational cooperation also requires a stronger focus on business processes that not only span over several functional areas within the organization, but that tie together multiple value chains within the same industry system.

4.2 Network organizations

In order to overcome the limitations of bureaucratic organizational forms, multiple new approaches to structure organizations have been proposed. Some of them, the matrix- and process-organization have been introduced and discussed in chapter 3. Rockart and Short (1991) have advocated networked organizations as a possible solution to the problem.

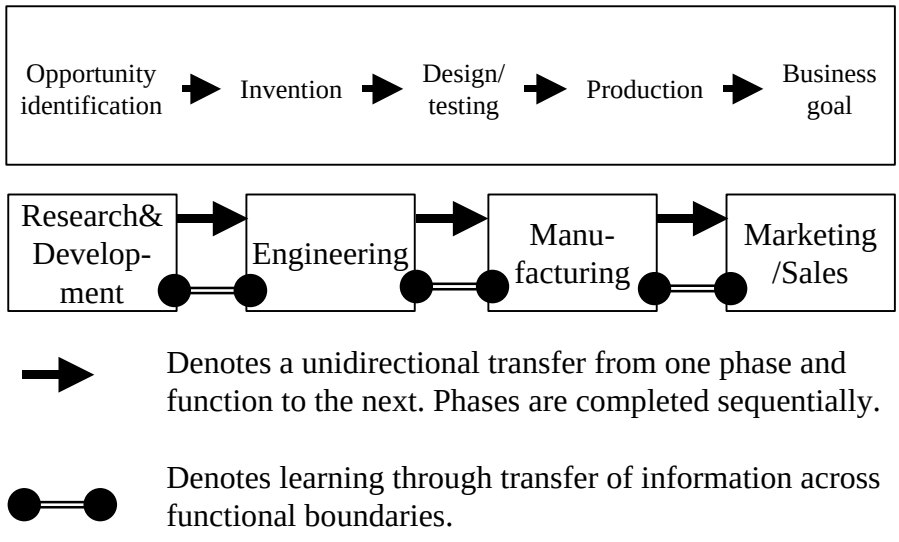
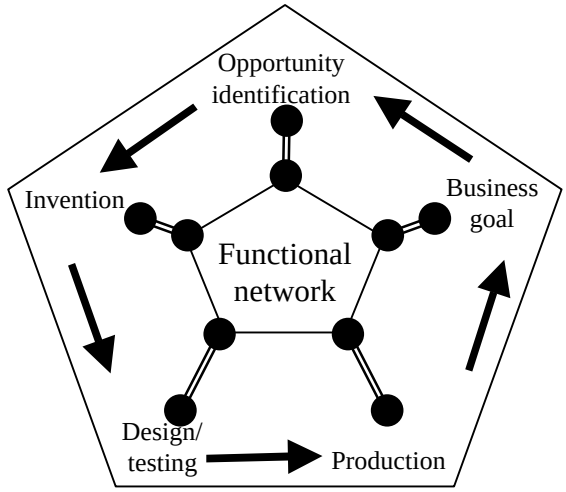


Figure 4.2: Sequential model of technical innovation according to Bush and Frohman

Bush and Frohman (1991) have proposed a similar view. They criticized the traditional up-and-down communication model, as well as the sequential flow of functional activities, and instead proposed a model for a concurrent network organization. They claim that a network organization is better equipped for dealing with complex innovation processes as the prevailing, hierarchical and sequential approach. They identify the following reason for the dominance of the sequential model:

> *The sequential model has established itself primarily because of its compatibility with the bureaucratic command and control concept of management in complex organizations. It "civilized" the innovation process by bringing it within the frame of reference of traditional corporate management; hierarchical organization, specialized functions, segmented tasks, and clear responsibility with individual accountability.*



Denotes transition from one phase to the next.
For complex innovations, phases may be conducted concurrently.

Denotes learning through transfer into and out of the collective knowledge- pool of the innovative organization.

Figure 4.3: Concurrent model of technical innovation according to Bush and Frohman

Both proposals are, however, concerned with the design of conceptual communication models and do not address implementation aspects. Neither do they propose specific organizational forms as a way of realizing the networking structures they have proposed.

4.3 Analyzing processes and designing structures

Many of the current change concepts are claiming to have a primary focus on business processes instead of organizational structures. When looking at the methodological set-up, this claim holds true. However, when looking at the outcome of many projects being conducted under the banner of Business Process Reengineering, Time-based Management, or Core Process Redesign we can conclude that the actual outcome of the projects is falling short of implementing a real process perspective. Instead, the new organization design is still a conglomerate of structural

relationships, with a process layer interwoven with the existing structural elements.

This discrepancy between the analysis and the re-design stages can be considered as being a main barrier for successfully implementing organizational forms that are entirely based on business processes. Repeatedly occurring measures in process-oriented change projects are the removal of hierarchy levels, the establishment of teams, and expanded spans of responsibility for remaining managers. These measures are based upon the assumption, that process management requires stable structures in the bottom, on which processes can be implemented.

Naturally, this view is valid from a change perspective. However, one can claim that it does not allow to fully reap the achievable benefits from the change process. Consequently, the *clean-slate approach* has become increasingly popular during the past years. Instead of taking the existing organization as the point of departure for the analysis of current organizational structures and work processes, the change work is initiated with a design phase in order to overcome mental limitations and facilitate out-of-the-box thinking.

When, in addition, a process perspective is added, considerable changes in the way of conceiving organizations, the distribution of work, reward systems and managerial are required in order to leave the existing constraints. This view also enables a stronger consideration of the organizational outcome and the means to achieve it, rather than of the organization itself.

4.4 Some conceptual considerations

In order to overcome the deficiencies of focusing on the design of structural relationships, instead of process design, it is necessary to make a clear distinction between two sub-elements of organizations. This duality has already been addressed on page 61, where it was concluded that both structures and processes would need to be included in organization design processes. However, for developing some conceptual foundations for organizational processes, let us first outline the difference between structure and process and then consider it as sufficient to regard the process component of the organization.

4.4.1 Organizational processes and work processes

The following picture describes the flow of a document according to the rules and procedures of the formal organizational structures, and the work process respectively.

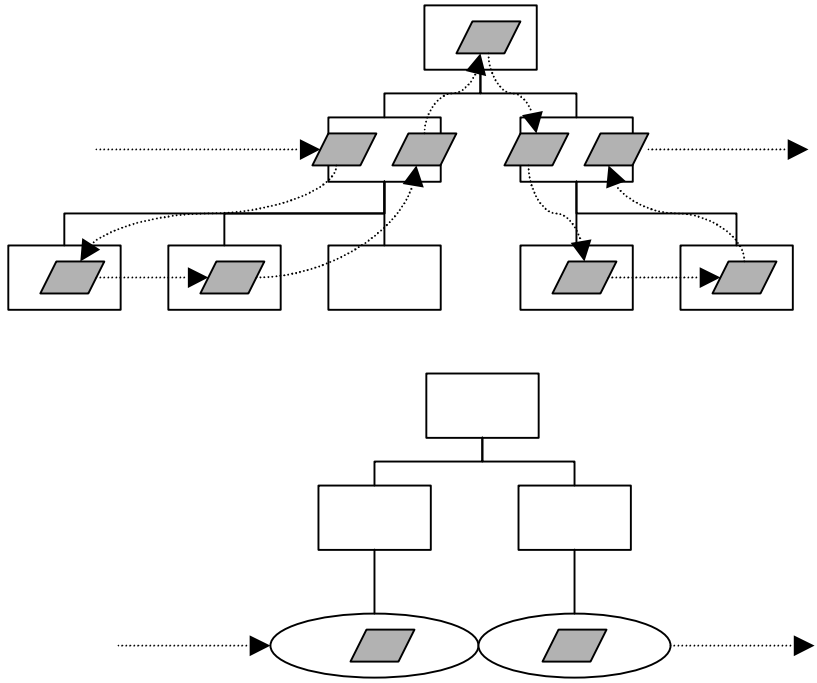


Figure 4.4: Organizational process and work process

In the case of a structurally dominated process, a supervisor, who assigns a work task to one of his/her sub-ordinates, receives the document. After resolving the task, the document is transferred to another person within the same functional department for further work, and finally passed back to the supervisor. It is here already assumed, that a certain level of independence is applied, since the two sub-ordinates communicate directly with each other. The original recipient passes the document to his supervisor, who will assign a task to another manager who, in turn, will delegate the work to a sub-ordinate. After a further transfer, the document is finally sent to a recipient outside the unit.

On the other hand, when looking at the actual work process being conducted, a different picture emerges. In order to resolve the work, only two instances would participate and the involvement of supervisors or managers is kept at a minimum or even unnecessary. As it can be learned

from this picture, the number of transactions being required to resolve a certain task, and which are imposed by hierarchical structures and the rules of supervision and subordination, is significantly higher than those being the result of actual work being performed.

In change management literature and seminars, e.g. Davenport (1993) and Gartner Group (1993), organizational processes are often depicted as in the below picture, i.e. as a set of straight, sequential activities, lying above the existing, functional structure, and crossing multiple functional borders.

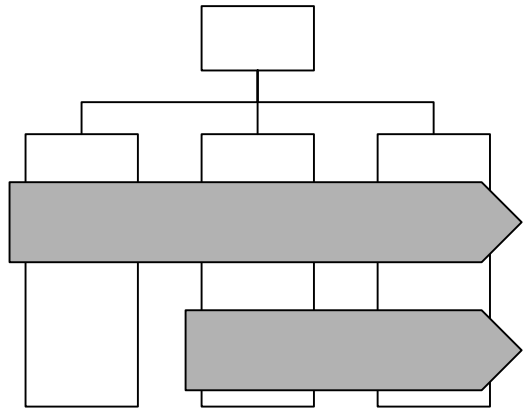


Figure 4.5: Processes as straight, sequential sets of activities

While this model is sufficient as a basic explanatory model, it is not very useful as the basis for a conceptualization of business processes, since it provides an image of processes as being a sequential flow of co-ordinated functional activities. Also, this form of graphical representation implies that the preservation of underlying functional structures is a necessary requirement for organization design on a process basis.

In the following, we will take a step beyond these foundations and assume that organizations can be designed upon the basis of organizational processes only. While this, in reality, proves to be extremely difficult, it is a reasonable approach for outlining the most crucial aspects to be considered when applying a process perspective on organizations. For our further considerations, let us first develop some basic assumptions about organizations, conceptually defined in process terms.

Instead of defining organizations in functional terms, dividing them into departments or other structural units, they can conceptually be defined as being networks of processes. This perspective enables a focus shift from the organization as an institutional phenomenon to its ends and the required activities and means to achieve them.

The identification of activities and the integration of those into processes, their relations and outcome, according to the organizations mission and process objectives then becomes the primary task for organization development, rather than providing a formal structural framework. As a result of this focus shift, an organizational structure occurs temporarily based upon the actual processes under performance.

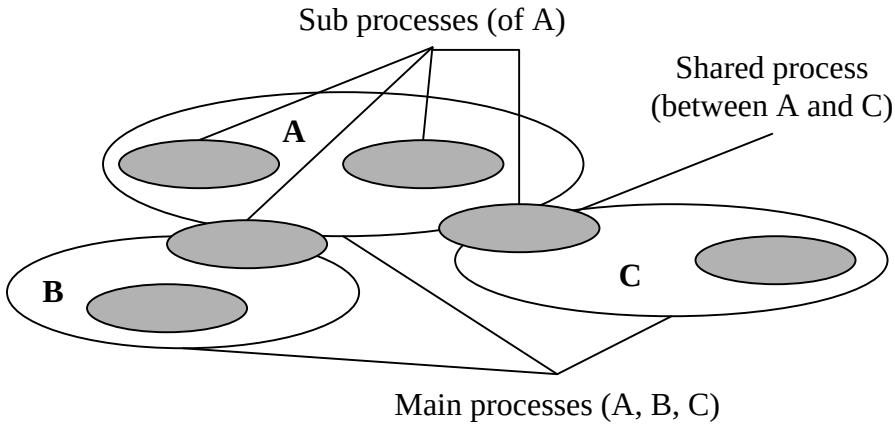


Figure 4.6: A process network model

4.4.2 Processes have a dialectic nature

Dialectic, according to Webster's Dictionary (1988), means

> *the method of logic used by Hegel and adapted by Marx to observable social and economic processes: it is based on the principle that an idea or event (thesis) generates its opposite (antithesis), leading to a reconciliation of opposites (synthesis) or the general application of this principle in analysis, criticism, exposition, etc.*

A dialectic process, in this context, means the inclusion of learning, knowledge development and process improvement in the process. When conducting certain activities in the process, based on existing experience

(thesis), new knowledge is gained (antithesis) and incorporated into the knowledge body of the organization, thus allowing the improved conduct of the process in the future (synthesis).

4.4.3 Hierarchical relations between processes

As complexity is considered as being the major source of reduced manageability in organizations, mechanisms for reducing complexity and increasing perspectiveness, independence and manageability must be developed and implemented. We have discussed the mechanisms proposed by Galbraith (in section 3.1.2). For maintaining an appropriate process overview, a process can be divided into a set of sub-processes. Each of these sub-processes then contributes to the achievement of the objectives of its super-process.

Emery (1969) has analyzed the effect of hierarchical de-composition of functional organizations. He argues that each task can be de-composed until the desired level of complexity to remain is reached. Herbert Simon (1981) has argued that organizations, when being considered from a systems perspective, can be broken down into nearly de-composable sub-systems.

The concept of process hierarchies opens for a discussion about the appropriate level of detail and specification in the process design work. Also in the case of Astra, the number of process design levels has been discussed widely.

4.4.4 Processes are integrated

In the same way as processes can be considered as being sets of interacting sub-processes, they can be part of one, or several, super-processes, given that they share common objectives. Process integration allows us to conceive a set of processes as a whole, instead of an assembly of parts. Thereby, co-ordination among the incorporated elements is improved, as the scope of process management includes the consideration of interactions as a critical factor, instead of focusing on the production of functional outcomes.

From the characteristics of processes as being de-composable as well as integratable, we can conclude, that process analysis and design is an activity being concerned with top-down and bottom-up aspects.

4.4.5 Goal congruence

An aspect not yet discussed is the basis upon which processes are fragmented, respectively integrated. In hierarchical organizations, the similarity of tasks is the determining factor, but this principle appears not to be usable in a process organization, due to the diversity of the activities being performed within the processes. Using goal congruence as determinant appears to be a more feasible way for fragmenting and integrating in a process-organization, i.e. processes are put into relation to each other depending on their capability to contribute to achieve objectives. Depending on the characteristics of the processes under concern, these objectives may be of qualitative, as well as quantitative nature. This can be exemplified by looking at the qualitative objectives of a sales- , service-, and customer contact process:

- **Sales objective:** Presenting our products as the solution to customers problems. This can be achieved by establishing and maintaining close relationships with existing and prospective customers, since we thereby show our concern for customers problems.
- **Service objective:** Through close customer contacts we can provide a superior service, since we are aware of the specific situation of our customers and can thereby respond quickly to their service needs.
- **Customer contact objective:** Maintaining close relationships with our customers.

Apparently, both the sales- and the service-process are depending on good customer relationships. The customer contact process' objective, in turn, is a sub-set of the objectives of both other processes. When fragmenting the process-hierarchy, i.e. using a top-down approach, the customer contact process is therefore considered as a sub-process by both super-processes, while an analysis of process-integration would reveal customer contacts as being integrated into two super-processes.

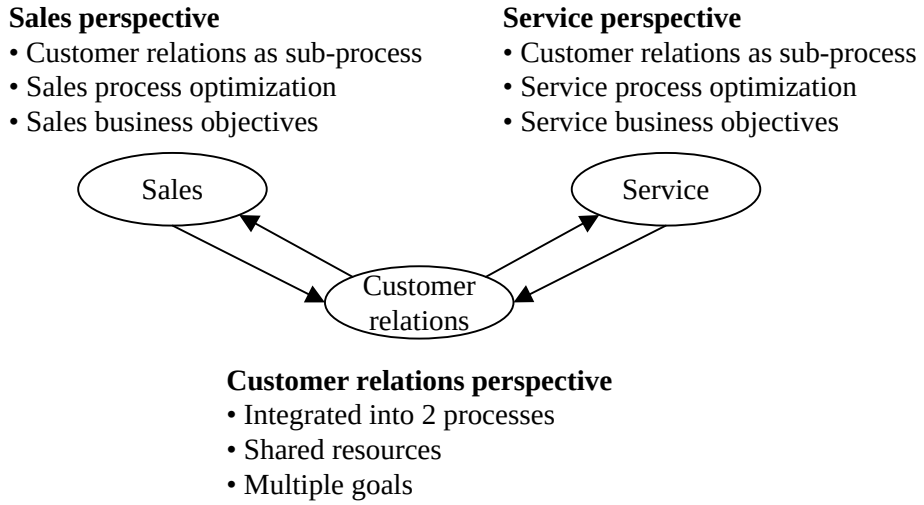


Figure 4.7: Process perspectives

One could consider this as a zero-sum game, since fragmentation, as well as integration will result in the same number of relationships, however, taking a perspective from a singular process, the results will lead to different conclusions. Both super-processes are intended to maximize their own performance, i.e. to employ the resources of customer contacts in a way that maximizes their own goal achievement, while, on the other hand, customer contacts has to co-ordinate its activities with those of two super-processes, share its resources of its activities among them and contribute to the achievement of different goals. The difference between those two perspectives is depicted in figure 4.6. To increase the workability of both super-processes, there must be an agreement that satisfies the mutual expectations of the parts involved.

4.4.6 Superiority and sub-ordination

Authority, superiority and sub-ordination are the current determining factors for depicting organizational structures. The hierarchical organizations resulting from this design principle are based upon a fragmentation of the organization into similar functional tasks, instead of value adding processes, often resulting in a departmental self-containment and a focus on the production of functional outcomes. The structure then tends to become a self-purpose, i.e. an institution, where the primary focus is to maintain the current state, power-bases and control structures. Within these organizations, the career of

organizational members is determined by a person's formal position within the hierarchy, not the individuals contribution to added value, his skills, and commitment to the objectives to achieve. Additionally, promotion is single-directed, i.e. upwards. As described by the "Peter principle", this may result in promotion to incompetence, i.e. an individual is promoted until it reaches an hierarchical level, where task solving is beyond its capacities.

4.4.7 Job assignment

For avoiding the institutionalizing of established structural relations within the organization, temporary assignments of individuals to processes appear to be an feasible approach, since this focus on process performance instead of functional positions keeps the organization in a permanent state of change, and the emerging "structure", i.e. a "snapshot" of the process network in a specific point of time, is continuously changing upon the basis of an ongoing re-evaluation of processes' contribution to the fulfillment of organizational objectives and process-elevation on the basis of enhanced organizational learning.

Even though a process perspective on organizations is intended to disregard formal structures, the need for co-ordination, within a process as well as among interacting processes, remains unchanged. However, this authority is not based on a formally determined span of control, but on the temporarily assigned position within an organizational process. These positions are assigned to people based upon their personal skill profile and their ability and will of committing to the objectives of the process.

By assigning positions within processes to people temporarily, a continuous performance evaluation is enabled according to the required performance of the process. The individual may now qualify, or disqualify, itself for the assigned position. As these assignments are temporary, determined by processes' cycle-time, it is ensured that positions are not occupied by people with competence lacks for an unpredictable period of time ahead. It is a common phenomenon to "promote away" individuals who are not fulfilling the expectations focused on them. Through temporary assignments this proceeding becomes obsolete, since individuals not being able or willing to fulfil the requirements related to their position will not be allowed to be assigned

to positions beyond their capabilities, due to the required match between their skill-profile and the process requirements.

4.4.8 Skill-profiles and reward-systems

In order to ensure the qualification and competence of individuals having process positions assigned to themselves, the individual's skill profile must be corresponding to the required competence for the position within the process. It may be desirable, however, to allow individuals with a potential capability to assign positions beyond their core competencies to themselves, since competence broadening and individual skill development is a necessary implication for incorporating organizational learning and the continuous improvement of process performance.

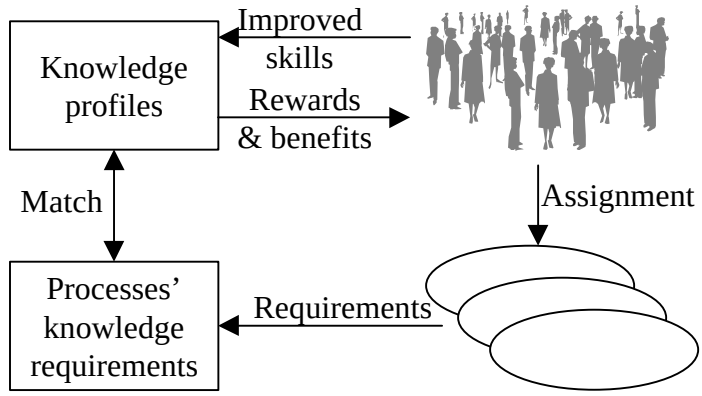


Figure 4.8: Reward system structure

Due to the temporary nature of positions, the conventionally used reward systems occur to be inapplicable and it becomes necessary to develop alternative structures for rewarding and promoting individuals. For this purpose, we can choose from two options: Either can individuals be rewarded upon the duration of their organizational membership, or upon the temporary positions they currently possess. While the first alternative implies that experience and competence is a matter of age and will increase automatically, there are no incentives for gaining increased competence and knowledge, which is a de-motivating factor and hinder for the continuous competence development that is required in dynamic environments. Since rewards have to be related to the responsibilities taken by the individual and its commitment to organizational objectives, it occurs natural to base the reward structure on the current assignments. This may result in a reward structure, where a basic reward is allowed to

all employees, but all additional rewards are based upon the position within the process. By continuous competence development, the individual may then be allowed to assignments on a higher co-ordinative level within the process network.

A methodology approach to employee ranking is described by Nadler and Gerstein (1992). Their concept consists of thirteen steps, starting with a job or job-cluster identification, and appears, even though being originally developed for executive staffing, to be a feasible approach to matching individual skills with job requirements.

4.4.9 Competence-pools

Since organizational members are not belonging to pre-defined organizational units, and the processes being performed within the organization are not stable as far as their existence is concerned, new forms have to be found to define organizational membership. It appears suitable, to use a competence-pool, basically containing all organizational members, and used for training and education, as the basic unit. This would include a concept of the organization as being intentionally peer-based, where superiority and sub-ordination is determined by the actual position within a process that the member is currently assigned to, as it was described above. Basically belonging to the pool, individuals are then temporarily assigned to process-positions, and returning to the pool after having finished their assignment. Since there are e.g. legal implications, a need for continuity in strategic decision-taking, policy definition etc., the concept is, however, not applicable on all organizational members. A small group of top executive staff members has to be excluded in order to ensure the requirements for continuity.

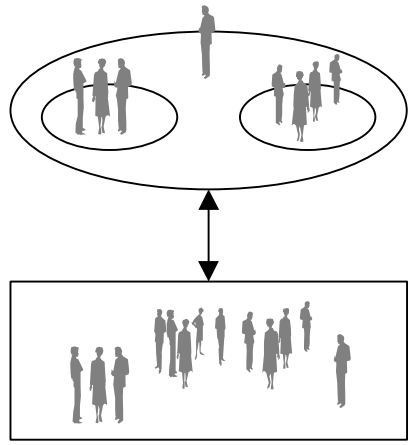


Figure 4.9: The competence-pool

4.4.10 Process evolution

In their striving for reduced time-to-markets, many organizations being involved in product development are using concurrent engineering (CE) as a tool for reducing the waiting states of interdependent entities within the organization and to integrate the organization's activities across the firm's value adding chain. This integration, described by Lawrence and Lorsch (1967) provides opportunities for reducing the time required from product-design to -delivery, quality improvement regarding the conformance to customer requirements, and cost-reduction. Even though this concept was originally defined for functional integration, it occurs to be applicable on process-organizations as well. By taking needs, capabilities, and results of interacting processes into account and re-considering them dialectically, lengthy, iterative development processes can be eliminated.

This can be practically achieved by defining "transaction tokens", i.e. points of times when preliminary process outcomes are transferred to depending processes, thus providing them with a basis for their own activities at an early stage, and thereby reducing the need for achieving final results before transferring them to the next process. The output of one sub-process is then successively incorporated into the results of depending processes to become a part of the outcome of the super-process. Since these preliminary results are rapidly spread throughout the entire process-network, a "prototype" of the final outcome of the super-

process can be achieved faster, allowing to match it against customer requirements and fine-tuning it during the further development process.

This concept can be considered as a "dialectic process evolution" and is comparable to the concept of incremental system development, being widely used in software engineering. There is one major difference, however: While incremental development is based upon modularity, i.e. entire clusters of the system are produced and delivered, the evolutionary approach uses preliminary results through the entire development process as a basis for incorporation and fine-tuning.

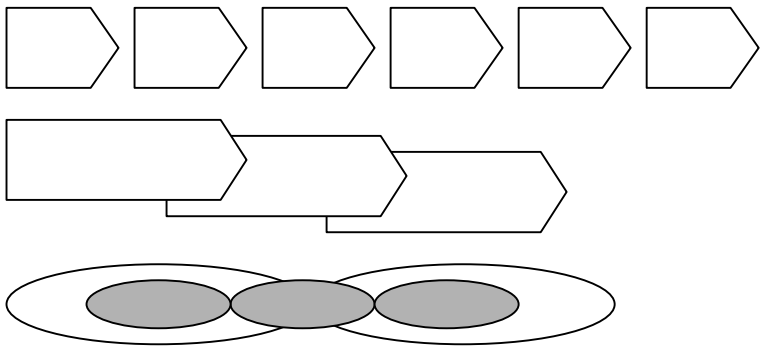


Figure 4.10: Value chain, "collapsed" value chain, and "process evolution"

5 Business Process Reengineering

In 1990, Michael Hammer, a former professor of computer science at the Massachusetts Institute of Technology (MIT), published an article in the Harvard Business Review, in which he claimed, that the major challenge for managers is to obliterate non-value adding work, rather than using technology for automating it (Hammer 1989). This statement implicitly accused managers of having focused the wrong issues, namely that technology, and especially information technology, has primarily been used for automating existing work. Hammer's claim was simple: Most of the work being done does not add any value for customers, and this work should be removed, not accelerated through automation. Instead, companies should reconsider their processes in order maximize customer value, while minimizing the consumption of resources required for delivering their product or service.

A similar idea was advocated by Thomas Davenport, at that time a member of the Ernst & Young research center, in a paper published in the Sloan Management review the same year as Hammer published his paper.

This idea, to unbiased review a company's business processes, was rapidly adopted by a huge number of firms, which were striving for renewed competitiveness, which they had lost due to the market entrance of foreign competitors, their inability to satisfy customer needs, and their insufficient cost structure. Even well established management thinkers, such as Peter Drucker[4] and Tom Peters, were accepting and advocating BPR as a new tool for (re-)achieving success in a dynamic world. During the following years, a fast growing number of publications, books as well as journal articles, was dedicated to BPR, and any consulting firm with self-respect developed a BPR method[5].

However, the critics were fast to claim that BPR was firstly a rebirth of taylorism, and secondly a way to dishumanize the work place, increase

[4] On the cover of Hammer's and Champy's book on BPR, the following statement of Peter Drucker can be found: "Reengineering is new, and it has to be done".

[5] E.g. Andersen Consulting: Value driven reengineering, McKinsey: Core process redesign, Coopers& Lybrand: Break-point BPR, Frontec (Sweden): Value added control

managerial control, and to justify downsizing, i.e. major reductions of the work force (Greenbaum 1995, Industry Week 1994).

Despite this critique, reengineering has been adopted at an accelerating pace, and as many as 65% of the Fortune 500 companies claim to either have initiated reengineering efforts, or to have plans to do so until the end of year 1995.

In the following, we will briefly discuss why BPR has become such an enormous wave in the world of organizational change. Subsequently, we will identify and describe the basics of BPR, and the theoretical basis it is built upon, which we have found to be derivable from three main areas: Organization theory, informatics, and marketing (Simon 1994).

5.1 The MIT study Made in America

In 1986, the MIT (Massachusetts Institute of Technology) established the MIT Commission on Industrial Productivity. The task assigned to this formation was to study the performance of industry in the US, but also to compare it to industry in other countries and to consider global economic developments that might impact the requirements for successful performance in the future. The commission also aimed at defining recommendations that should allow America's industry to sustain productivity growth and competitiveness. The study, named *Made in America*, included firms in eight industries - automobile, chemical, commercial aircraft, consumer electronics, machine tools, computer and office equipment, steel, and textiles - and researchers scrutinized the participating organizations with respect to efficiency, quality, productivity, innovativeness, agility, etc. About 200 firms were visited and more than 500 interviews were conducted.

5.1.1 Performance barriers

The study revealed some serious shortcomings of US companies in comparison with their foreign, especially Japanese, counterparts. In all industries, except chemicals and aerospace, productivity development had fallen behind. The analysis identified six areas in which significant weaknesses were found.

Obsolete strategies. During the 1980s, the economic environment had begun to change significantly. Competition had become global and companies were attacked by foreign entrants on their previously protected

home markets. Since foreign competition had been largely ignored and the size of the US market had limited the need for export, many companies were taken by surprise when their home turf was invaded by foreign products.

After World War II, most US forms had developed towards mass production, i.e. the manufacturing of commodity goods in large volumes. Due to market size and high demand, many firms neglected the concept of product customization for different market segments. Consequently, customers were attracted by foreign products that offered more choice. This factor became especially obvious in the automobile industry, where Japanese companies had managed to achieve considerably shorter time-to-market, higher quality, and a wide range of products.

High expectations for ROI. Many investors have a short horizon for investments, i.e. they expect a return in considerably shorter time than their foreign counterparts. This forces companies to seek for faster pay-off and limits the ability to achieve financial stability. This is, however, a problem that is not directly related to companies' performance, but to the attitude and behavior of investors and financial institutions.

Weakness in product development and production. The study also revealed, that US companies had a lack of ability to exploit research results in a commercially effective way. Inventions such as radio, color TV and VCR were made in the US, but these markets are dominated by foreign companies. Especially Japanese firms have taken a large share of the consumer electronics market. However, in the IT-field, which was not covered by the MIT study, US firms still have a market leading position in most areas.

Beside the inability to exploit new inventions through rapid acquisition of key knowledge and capabilities, weaknesses were also found in other areas:

- Design, especially with regard to simplicity and reliability.
- Consideration of quality aspects in design and production processes.
- Long product development times and time-to-market.
- Problems are solved as they occur, instead of proactively.

- Continuous improvement of products and processes is underestimated, or even neglected.

Inappropriate use of human resources. The study pointed out two major weaknesses about human resource deployment. (A) The shortcomings of the basic education system to provide schooling with industrial relevance and (B) insufficient training of employees within companies. To keep pace with their foreign counterparts and to be able to implement the concepts of self-managing teams and empowerment companies need to provide their workforce with the appropriate skills through training and education.

Lack of coordination and cooperation within organizations. The effective coordination of work within and between organizations is a critical factor for sustaining and improving performance and productivity. Lack of coordination and cooperation is hampering the development and exploitation of new products and sets up barriers for the efficient employment of resources within and between organizational value chains. Within the *Made in America* project, lack of coordination was identified at various levels: (A) Between individuals and groups within companies, (B) between firms and their suppliers and customers, (C) among firms within the same industry, and (D) between firms and government and its regulatory authorities. As an additional factor, many companies suffered from a lack of vertical communication within their organization, i.e. poor contacts between managers and workers.

Interest conflicts between industry and government. Companies behavior is directed not only by internally developed strategies and their global business environment, but also by the macro-economic situation created by local governments and the restrictions, guidelines and policies of various authorities with regulatory power. This includes aspects such as taxation, basic research, the education system and social regulations and welfare policies. Consequently, government has a considerable, though mainly indirect, influence on corporate performance. A discrepancy between the politics driven by government and the need of companies for stable business areas can impose constraints on companies' abilities to sustain performance and productivity.

5.1.2 Industry best practice

When looking at the above mentioned factors that the MIT study identified we can conclude, that they are basically congruent with the pathologies pointed out in the reengineering literature. The study, however, did not only outline problems, but suggested also a set of actions that were described as industrial best practice. Also these practices show a significant congruence with the measures proposed by the reengineers.

Improvement in cost, quality and delivery. In can be claimed, that low cost, high quality and fast and accurate delivery of products and services are characteristics that should be paramount for all business organizations. However, many companies are not aiming at the simultaneous improvement of all these properties, but are focusing their improvement efforts at only one or two areas. The MIT study has shown, that best practice companies had developed the ability to achieve simultaneous improvement in all three areas.

Cooperation with customer and suppliers. Close relationships with suppliers and customers can improve performance throughout an entire value system. Collaboration with customers can elevate responsiveness to market signals and allows firms to pick up changing customer demands faster. The development of concepts such as Supplier-Retailer Collaboration and Efficient Customer Response indicate the emphasis that many customers put on establishing tighter relationships with their customers. In the same way, closer cooperation with suppliers can improve the flow of goods and information between companies' value chains and reduce transaction costs and time.

Use of information technology. The use of information technology for improving efficiency in product development, time-to-market and other areas of internal and external communication was another feature shared by best-practice companies. Successful organizations had included technology management into the managerial agenda and used IT purposefully for achieving competitive advantages.

Flatter organizations. Another common trait for companies that were successful in their industry segments was a focus on cross-functional work and flatter organizations with fewer hierarchy levels. Following this rationale allows faster reaction to changing business environments and reduces departmental barriers and closure. The establishment of cross-

functional teams and concurrent work, together with the associated increasing responsibility for individuals, has proven to be a successful concept. Teamwork also allows to bring individuals with various skills and competencies together for fast problem solving.

Human resource policies. In order to break ground for new organizational forms, flatter organizations and individual empowerment, it is necessary to employ human resource strategies and policies that promote commitment, the taking of responsibility, learning and knowledge sharing. This includes also reconsidering incentive mechanisms and career paths and must allow employees to take part in the development of their work environment and the future of the firm.

5.2 Reengineering defined

While there are almost as many definitions of BPR as there are authors publishing on the topic, we can identify multiple aspects that they have in common. Let us first review a number of definitions.

Hammer and Champy (1993) define BPR as

> *"the fundamental rethinking and radical redesign of business processes to achieve dramatic improvements in critical contemporary measures of performance, such as cost, quality, service, and speed"*.

Thomas Davenport (1993), another well-known BPR theorist, uses the term process innovation, which he says

> *"encompasses the envisioning of new work strategies, the actual process design activity, and the implementation of the change in all its complex technological, human, and organizational dimensions"*.

Additionally, Davenport (ibid.) points out the major difference between BPR and other approaches to organization development (OD), especially the continuous improvement or TQM movement, when he states:

> *"Today firms must seek not fractional, but multiplicative levels of improvement – 10x rather than 10%."*

Finally, Johansson et.al. provide a description of BPR relative to other process-oriented views, such as Total Quality Management (TQM) and Just-in-time (JIT), and state:

> *"Business Process Reengineering, although a close relative, seeks radical rather than merely continuous improvement. It escalates the efforts of JIT and TQM to make process orientation a strategic tool and a core competence of the organization. BPR concentrates on core business processes, and uses the specific techniques within the JIT and TQM "toolboxes" as enablers, while broadening the process vision."*

In a previous chapter, we have already discussed the basic implications for business processes. In the following, we will

- A consideration of the organization in terms of value adding business processes.
- Radical changes of the way in which work is performed.
- Significant improvements in multiple areas simultaneously, i.e. reduction of cost and cycle time, while concurrently increasing quality and service.

In order to achieve the major improvements BPR is seeking for, the change of structural organizational variables, and other ways of managing and performing work is often considered as being insufficient. For being able to reap the achievable benefits fully, the use of information technology is conceived as a major factor. While IT traditionally has been used for supporting the existing business functions, i.e. it was used for increasing organizational efficiency, it now plays a role as enabler of new organizational forms, and patterns of collaboration within and between organizations.

5.3 Theoretical implications

As we could see, BPR derives its existence from different disciplines, and we can identify four major areas being subjected to change in BPR - organization, technology, strategy, and people - where a process view is used as common platform for consideration. This four-dimensional

approach can be graphically depicted by a modification of Leavitt's "diamond" (Leavitt 1965).

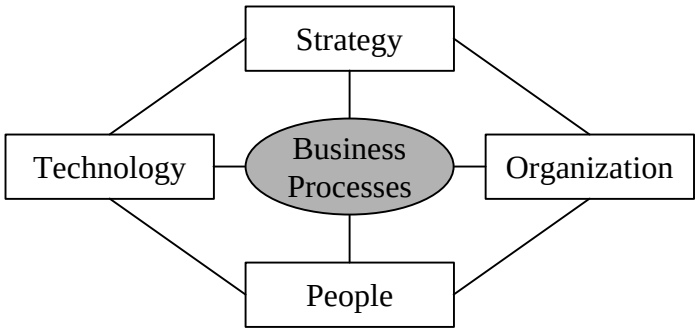


Figure 5.1: Leavitt's diamond, modified

The strategic dimension refers to a set of three sub areas, which are congruent with the remaining dimensions, i.e. that organization, technology, and human resources are considered as areas of strategic importance. Organization strategy reflects the structural elements of the company, such as hierarchical levels, the composition of organizational units, and the distribution of work between them. Technology is concerned with the use of computer systems and other forms of communication technology in the business. In BPR, information technology is generally considered as playing a role as enabler of new forms of organizing and collaborating, rather than supporting existing business functions. The people, or human resources dimension is the most crucial one, and deals with aspects such as education, training, and reward systems. The concept of business processes, i.e. sets of interrelated activities aiming at creating an value added output to a customer, is the basic underlying idea of BPR. These processes are characterized by a number of attributes.

Process ownership. A business process is "owned" by the role of the owner, that takes responsibility for the performance and outcome of the process. The process owner coordinates the sub-processes and activities, and manages the process' resources.

Customer focus. Business processes are designed from a customer perspective, i.e. they are focused on satisfying a customer need, where a

customer is defined as a person or group that receives the output of the process.

Value adding. Business processes are designed upon the premise of a value-adding capability, i.e. the value of the output being higher than the input value, where value is determined in terms of the customer's willingness to pay a certain amount for the process product.

Cross-functionality. Regularly, but not necessarily, business processes are covering multiple functional areas, since the activities being performed within its boundaries belong to different areas of the charted, functional organization.

As far as BPR theory and its application is concerned, there is a great disparity between BPR proponents and critics, and even within the camps multiple fractions can be found, offering different levels of radicalness and theoretical underpinnings. The common opinion is, however, that there are three major theoretical areas that have influenced BPR – organization theory, informatics[6], and marketing.

5.4 BPR and organization theory

By its critics, BPR is often accused to be a re-animation of Fredrick Winslow Taylor's principles of scientific management (Taylor 1911). Taylor's theories, in conjunction with the work of the early administrative scientists, e.g. Henry Fayol (1930), have had a considerable impact on the management discipline for more than 50 years, and are still used as the building blocks of hierarchical organizations. It may not be denied, that reengineering possesses several attributes of the tayloristic approach, however, these similarities can even be derived from the fact that scientific management isn't a negative idea per se, but that its application with an overemphasis on managerial control has resulted in negative effects.

On the other hand, BPR proponents claim that taking BPR for Taylorism is a major misunderstanding of the concept, and responsible for a

[6] With informatics, we mean "information technology and its use", which is derived from the definition of the informatics discipline at Göteborg University: "Informatics is concerned with the study of information technology and its use, in order to develop information technology and its use."

considerable number of reengineering project failures. When examining the major anchoring points for BPR in organization theory, the following aspects are revealed as being of major importance.

Organizational structure. While traditional organizations are emphasizing the structural component of the company, i.e. hierarchical levels, span of control, superiority and sub-ordination, BPR intentionally focuses on business processes as the starting point for considering the organization. As described above, these processes possess several characteristics, which determine the organizational structure in which they are embedded.

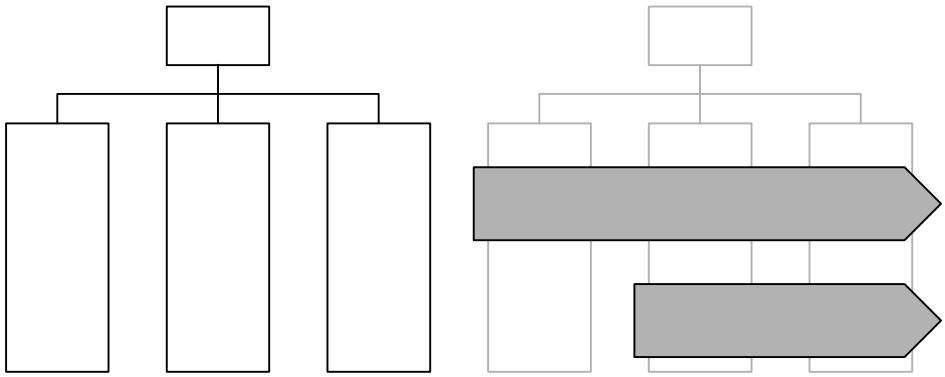


Figure 5.2: Hierarchical organization and process-based organization

Despite its frequent use, the above picture lacks of considering the fact, that business processes are not simply a set of different functional tasks performed in a specific sequence. In this case, the criticism of BPR as being tayloristic would be justified, but since the concept of business processes seeks for satisfying customer needs, and must include a striving for individual and organizational learning, a consideration of business processes as having a dialectic nature and an iterative structure appears to be more suitable.

Teams. The basic organizational unit in process-based organizations is the self-managing team, i.e. a group of people managing all elements of the process. The members of process teams must possess general knowledge about all partial elements of the process and their interrelation, i.e. they must understand the process in its wholeness, and secondly they must be able to contribute with certain functional competencies.

5.5 Marketing

In 1985, Michael Porter, a professor at Harvard Business School considered at length the concept of the value chain (Porter 1985). He describes the firm as

"a collection of activities that are performed to design, produce, market, deliver, and support its product. All these activities can be represented using a value chain. Value chains can only be understood in the context of the business unit."

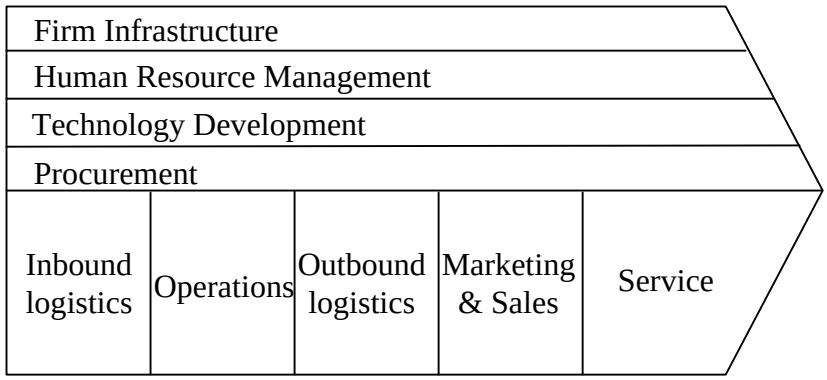


Figure 5.3: The value chain according to Porter

Basically, the value chain is a model for decomposing an enterprise into smaller parts, thus an approach for reducing complexity in organization analysis and design. However, since it is built upon the analysis of business activities rather than structural elements of the organization, it has a number of special features (Ward et. al. 1990). These features make the value chain an anticipation and precessor of the process approach that is used in BPR.

Separation of primary and secondary business activities. Basically, we can divide the activities being performed within the value chain into two categories, primary and secondary activities. Primary activities – inbound logistics, operations, outbound logistics, sales and marketing, services – contribute directly to the creation of customer value, while secondary activities – administration and infrastructure, human resource management, product and technology development, procurement – are considered as support activities which are necessary for the business, but do not directly add customer value.

Delivery of customer value. The value chain concept emphasizes on the primary task of the business being to provide a value to the customer, i.e. offering a product or service that the customer is able and willing to pay a certain price for. The achieved price for the product/service minus the costs for all activities being performed within the business and the procurement of the necessary input are the company's margin.

Independence from organizational structure. Since the value chain approach only describes the activities being performed, and not takes their belonging to specific functional organizational units into account, it allows to describe the value creation process free from structural considerations. This enables a design of an organizational structure that is strictly focused on business processes, i.e. activities are grouped into units upon the basis of their logical, rather than physical belonging.

The term ”business unit” as Porter uses it, can in this concern mean a set of activities that are grouped according to legal or administrative conventions. This does not necessarily mean a functional charter, but might as well include cross-functional business processes as the building blocks for the business unit.

5.6 The role of IT

Ever since the 1950s, when computers first were employed in business organizations, information technology has played a major role in businesses, and with increasing computing power at constantly lowered prices, powerful applications for all business areas, and the development of networks, computers have come to play a more and more important role in most organizations. While the use of IT in the 1950s and 60s was mainly restricted to transaction-processing, such as in banks and insurance companies, the development of database technology in the following decade enabled the rise of Management Information Systems (MIS). When personal computers (PC) appeared on the desktops in the 1980s and they became connected to local networks (LAN), and later on wide networks (WAN), information technology started to gain a reputation as strategic asset, thus the discussion in the 1980s was dominated by the term ”strategic information systems” (SIS). However, even though many companies were already highly depending on their information systems, the real break-through for business critical applications came during the recent years, with the development of extremely powerful desktop computers, computer support for

collaborative work (CSCW and workflow technology), and the recognition of IT as enabler of organizational transformation.

In the BPR field, information technology is considered as being the major enabler, and even driving force for organizational change. Hammer & Champy (1993) have identified eight areas where IT, as they call it, can play a disruptive role. Similarly, Davenport (1993) has identified a set of areas, where IT can play an important role for substantially changing the way business is done. When looking at the most frequently proposed application areas of information technology in conjunction with BPR efforts, we find the following.

Shared databases. The concept of database sharing, in order to allow a wide distribution of critical business information, is considered to be one of the most important areas where IT can contribute to a more effective and efficient performance of business processes, and has gained considerable attention since client/server technology has become a widely used solution. Shared databases allow companies to move from a sequential to a parallel performance of activities in a process, and provides information to all people involved in it.

Expert systems. This type of technology, which has its root in the Artificial Intelligence (AI) field, can possibly allow non-experts to perform experts work by capturing and widely distributing knowledge. As Hammer (1993) points out, however, the concept of expert systems in BPR does not refer to the earlier attempts of replacing experts by computer systems, but means to provide specialized knowledge to individuals in order to elevate their skills. Despite the term ”expert systems”, the applications described in literature[7] has relatively little to do with artificial intelligence, but could be categorized as decision support systems, since they most often lack several of the characteristics of expert systems.[8]

Mobile computing and communication. With the development of powerful laptop computers and new telecommunications technology, such as GSM (Global System for Mobile Communication), ISDN (Integrated Services Digital Network), ATM (Asynchronous Transfer Mode), new forms of work have been made possible. This includes

[7] See for example: Tapscott & Caston (1993), pp 69-70

[8] For a discussion of the characteristics of expert systems, see Jackson (1986).

telecommuting, and field staff being able to keep in contact with their company.

Workflow technology and groupware. Business processes are sets of activities performed by individuals, thus improving their capabilities of working together will improve the performance of the process. Even though workflow technology and groupware have different application scopes, they both share the intention of managing the transaction of work. While workflow systems generally are designed for supporting a smooth flow of a case through the organization, often following pre-defined routing rules, groupware is focused on collaboration within working groups and teams, and provides mechanisms for sharing knowledge and ideas.

5.7 Methods and toolbox

Since the appearance of BPR, multiple methods have been developed in the academic world and by consulting firms. Even though they have different names, and eventually are built on different assumptions and theories, they share a common understanding about which steps that should be performed during a BPR exercise, and they usually employ the same techniques. The main difference can usually be found in the starting point for the process identification and analysis.

Davenport and Short (1990) have identified two basic methods for process identification, which they termed ”targeted” and ”comprehensive” methods. Targeted methods take their starting point in the identification of a relatively small number of processes being critical to the business, which are determined by interviews or discussion with managers of the organization. This approach can provide a fast pay-off and results often occur relatively fast.

In opposite, the comprehensive approach is striving for first identifying all business processes, and then prioritizing them according to their reengineering-need and potential. This method is more time and effort consuming, but allows a more well thought out rationale for BPR in terms of project prioritization that fits into the overall strategic goals of the organization. (Grover & Kettinger, 1995)

There are no general recommendations for organizations, willing to embark on reengineering projects, which approach may be the more feasible. This choice generally depends on the specific firms or

institutions situation. We can identify two main reasons for initiating BPR efforts, either the firm is in a critical situation and needs rapid improvements in order to ensure survival, or the reengineering effort is started from a position of strength, and strives for sustaining leadership, rather than regaining competitiveness. Given these two extremes, a firm can choose different options, each of them with different attributes.

	”Crisis” reengineering	**”Forecast” reengineering**
Time scope	Short	Medium
Primary method	Targeted	Comprehensive
# of processes	Small	High
Primary aspects	Cost, time	Strategy
Tools	Financial, time-based	Full range
Role of IT	Cost efficiency	Strategic impact

Table 5.1: Generic reengineering approaches

5.7.1 The reengineering life-cycle

Even though a formalized standard methodology, based on a common framework that ensures success in reengineering projects hasn't yet been developed, several attempts have been made to develop such an approach. The existing methodologies, often developed by consulting companies share, however, several commonalties.

In order to improve the understanding of how BPR works I will in this thesis briefly present a methodology approach known as PURL - Process Reengineering Life Cycle, as it has been described by Guha, Kettinger and Teng (1993). The methodology consists of 6 stages which will be described and shortly discussed. A graphical description of the PURL approach can be found below.

It is important to point out, that presenting this particular methodology does not mean advocating it instead of others. The purpose is to provide insight for inexperienced, or prospective members of the BPR-community on how BPR could be done.

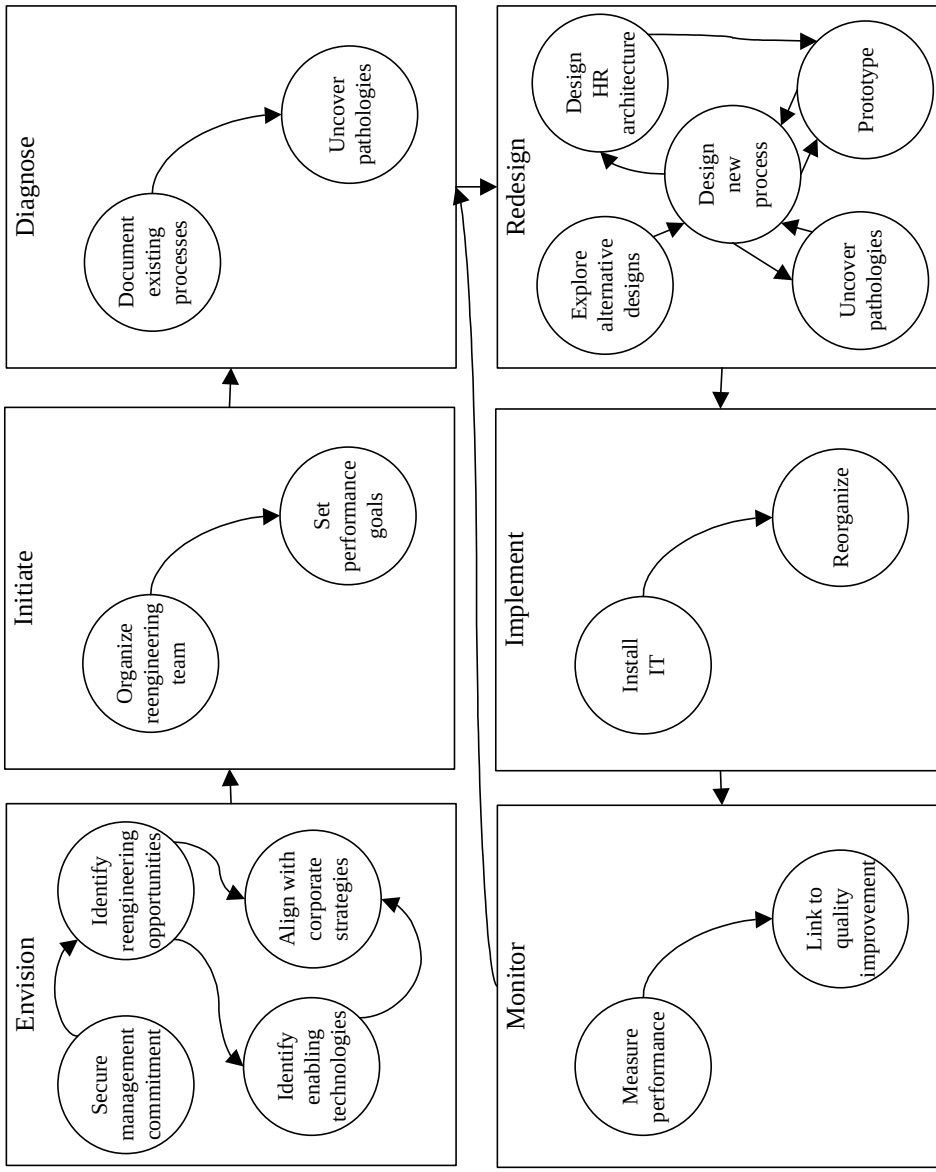


Figure 5.4: Reengineering life-cycle

5.7.2 Envisioning new processes

Due to the radicalness and the overall character of BPR, such a venture requires absolute support from the organization's top management. The organization's leaders start with an examination of how they would run their business without any constraints whatsoever. This process does not address the question of how current work can be improved, but how it

should be done to achieve maximum performance in all measures. This stage even involves the aspect of aligning the reengineering effort with the corporate strategies and organizational goals. Nevertheless, if these strategies show out to be obsolete or inappropriate, a reexamination and redefinition might be necessary in order to adopt new externalities to the organization.

Within this first step, the necessary senior management support is secured, the vital processes are identified and enabling information technology is examined.

Secure senior management support. It is substantial, that top management is willing to support reengineering projects. This involves the chief executive officer (CEO), as well as the heads of departments in the reengineering effort which is a necessary presumption for anchoring BPR throughout the entire organization. A critical success factor in this concern is convincing management of the necessity of disregarding existing constraints and abandoning existing procedures and methods. Achieving this requires to make management understanding BPR within their frame of reference.

Identify reengineering opportunities. Business consist of a large number of processes and the crucial matter is to identify those of them being adequate for reengineering efforts. This task requires firstly a commonly accepted definition of what a business process means, secondly genuine knowledge about the changing needs of customers and processes' potential for customer value adding.

Identify enabling technology. The rapid pace of information technology development has removed many constraints in information handling. However, it is important to remember, that using IT is no self-purpose, but a way of supporting the activities within the business processes to be performed. Keeping this in mind, companies can use IT for achieving gains in speed, productivity a. o., while they, at the same time, are able to ignore geography.

Aligning with corporate strategy. This step includes the examination of internal and external strategies related to the reengineering opportunities and enabling technologies being identified. The reengineering direction is determined according to the companies strategic market intentions and reengineering potentials without strategic significance are removed.

5.7.3 Initiating change

In this stage, the reengineering project is prepared for performance. The reengineering team is assembled from a multiplicity of units within the organization and external change agents are, if necessary, allocated to the project. At the same time, the reengineering route is staked out and performance goals are defined and set.

The reengineering team. Due to the multifunctional character of processes, the reengineering team has to be assembled from a various number of departments. An overall company project may involve people from all departments, while minor projects may consist of members from the affected departments only. A result responsible team leader is assigned by top management and this team leader is then, in turn, assigning roles to the other members of the team.

Performance goals. The desired performance for the new processes is determined in this step. According to CSC Index Inc., there are three areas where potential benefits can be realized, as there are *time*, *cost* and *number of defects*. However, determining appropriate measures for performance improvement is a topic under discussion, so Nolan, Norton & CO, another consultancy, proposes four dimensions of performance, namely: *Financial success, customer satisfaction, internal processes, organizational learning*.

5.7.4 Process diagnosis

On the basis of the performance goals to be accomplished the reengineering is able to perform an in-depth analysis of the processes to be reengineered. Existing processes are described and hidden pathologies are uncovered. This stage is critical for the further success of the reengineering efforts due to its importance to process redesign.

Describing existing processes. A presumption for business process redesign is to gain genuine understanding how existing processes work, their span, linkages and bottlenecks. The following factors are important to take under consideration in process documentation:

- Description of the entire process.
- Identification of process elements and resources.
- Current process performance.

- Analytic decomposition of processes.

Uncovering pathologies. The pathologies of processes may have different nature, as there may be inefficient work-flows and sequences of activities, high costs, insignificant value adding for customers, a. o. These inadequacies have to be detected and documented. For this, quantitative as well as qualitative methods should be applied, depending on the nature of pathologies.

5.7.5 Process redesign

Several dimensions are available as measures for redesigning business processes, as there are time, cost, productivity, quality and capital commitment. Using a single dimensional approach would lead to sub-optimization of processes, so a consideration of multiple dimensions is to be used. However, some of the performance measures are concurrent, a fact that requires the definition of preferences.

Alternative process designs. Obviously, several design alternatives exist for every process under concern. This step includes the exploration of alternative designs and their possible implementations in order to identify and determine the most appropriate process structure and enabling **technologies.**

New process design. Designing new processes is a task of constantly questioning the necessity of performing a certain activity and how, it all, it should be performed. Several factors are critical for the design of processes and have to be dealt with in order to succeed. A list of the most critical ones can be found below.

- Break patterns and disregard "common sense".
- Align processes with strategies and performance goals.
- Assign people to processes instead of single tasks.
- Dismiss hierarchical structures.
- Eliminate pathologies.
- Improve productivity by integrating fragmented work.
- Appraise enabling technology.

Designing the human resources architecture. It can be assumed that there is a common agreement on the claim, that no organization is better than the individuals working in it. This makes the design of the human resources architecture being a most critical task within the reengineering effort, especially as major change in the human resource area comes along with reengineering. The following aspects are important for a successful restructuring of the human resources architecture:

- Redefinition of work descriptions, titles and positions.
- Application of team based management techniques.
- Encouraging organizational learning.
- Performance evaluation on team basis instead of individuals.
- Reward structures based on group performance.
- The double role of managers as team members and superiors.
- Continuous reengineering communication with employees.

Prototyping. Prototyping provides an instant feedback to the reengineering on the progress and acceptance of the reengineering effort. Prototyping provides opportunities for simulating and evaluating reengineering potentials within the organizational, as well as the system development area. Continuous prototyping enables the reengineering team and management to make necessary adjustments before a final process design is chosen.

Selection of IT platform. The IT platform has to be chosen based on its ability of supporting the new designed processes. Other aspects to be taken under consideration should be the adaptability to changing processes and new technologies. The information system architecture has to be chosen with respect to actual and future information requirements. Several alternatives are available and the choice of the IT platform should, in the spirit of reengineering, be performed without regarding constraints, whether they may come from the computer department, organizational actors, or any other interest group.

5.7.6 Reconstruction

This stage includes implementing change and anchoring it in the organization and addresses the organizations ability of adopting change.

Failure during change implementation may result in costly project failure and potential future unconfidence of employees.

Installing IT. Using IT as an enabling technology for implementing change and supporting processes is one of the steps within the reconstruction stage. Depending on the radicalness of change and the adaptability of the existing information technology, the existing systems may be changed, or replaced entirely. While the first alternative involves software engineering without affecting the hardware, the second way often includes overhauling the current systems totally, including a new technical platform.

Reorganizing activities. Adapting the organizational structure to make it fit the new defined processes is a crucial task. The changes in the human resources architecture have to be realized carefully in a new organizational structure without more than marginal disturbances of the motivation of the individuals being affected. While employee empowerment, sub-unit reorganization and job rotation often can be achieved without major disruptions, the reduction of staff, often coming along with reengineering projects, can cause major disruptions.

5.7.7 Process monitoring

The identified and implemented process have to be monitored in an continuous process in order to scan their performance and contribution to quality improvement. This is made possible by an iterative process, in which the new process are used as input to stage 3 (diagnosis) of the methodology, and then being "looped". This includes, that reengineering projects are not handled in the conventional way of being initiated, performed and finished, but that reengineering is an ongoing process of permanent improvement.

Performance measurement. For determining the reengineering efforts' success, or failure, the new processes' performance must be measured and compared to the processes being replaced. This performance measuring is performed in terms of the following aspects:

- Process performance: Cycle times, customer value adding, quality.
- IT performance: Information rates, system use, a. o.
- Productivity: employees, production, service operations.

Links to quality improvement. Reengineering is closely related to quality improvement and should be linked with quality programs. However, there is a major difference in focus between reengineering and approaches like TQM (Total Quality Management): While reengineering is concerned with abrupt changes and improvement, TQM is concerned with continuous improvement. Nevertheless, quality improvement is a major concern for reengineering as well.

6 Consulting approaches to process improvement

Managing the transformation process to an adaptive, process-based organization is neither simple, nor intuitive. It requires a deliberate approach, using a methodological concept, and techniques and tools. In this chapter, we will introduce a toolkit for managing change. However, it will not be a handbook in terms of "Follow these steps and we will guarantee success", but it comprises and discusses a selection of valuable techniques and tools for the use in change management projects. In addition, we will briefly introduce and compare some methodological approaches being used by four major consulting firms.

6.1 The importance and role of methodologies

There are probably as many methodologies for process improvement and change management as there are consulting firms and even scholars from various disciplines, mainly the Business Administration field, have contributed to this flora of improvement approaches in a conceivable way. Any of the major internationally working consulting firms keeps itself with a change methodology and also smaller, local firms have developed their own approaches to business and process improvement. The applied approaches range from complete concepts, covering all steps of the transformation process, to techniques and tools used for specific purposes during a specific part of the change process.

We will not advocate any approach as being superior to any other. The aim of this chapter is to provide an overview of some approaches that are used by large, internationally working management and IT consulting firms and to discuss them with regard to their steps and tools, as well as to relate them to more theoretical aspects, which have been discussed in chapter 5.

In the work of consulting firms, methods play an important role for different reasons. Methods are normally considered as explicit mechanisms for problem-solving (Jayaratna, 1994). However, their role

is not limited to solving problems, they can also be used for other purposes. Werr (1999) has analyzed the role of methods in the work of management consultants, with a focus on BPR-style improvement projects. He identified three major areas in which methods are important.

6.1.1 The project work with the client

Methods can be considered as being a medium for constructing reality, i.e. that the method serves as a tool for describing how reality is perceived. This social construction process is fed by the images of all participants in the project group and the common image of reality derives from the individual contributions.

A second role a method can play is to provide a structure for action. In this case, the method provides guidelines, techniques and tools for supporting the problem analysis and diagnosis, as well as the change implementation process. The level of detail can vary from simple rules for facilitating meetings to a detailed rulebook with elaborate descriptions of each step in the change process, its deliverables and the tools and techniques being required, e.g. for process modeling.

Finally, a method can also be seen as an argumentative structure for justifying and driving a change process. Werr (ibid., p 317) concludes that a method ca provide a "discursive framework for communication", i.e. that the logic of the method is used for legitimizes the direction and steps of the change process.

6.1.2 The use of methods for problem solving

A methodology[9] can be defined as

> *a coherent collection of concepts, beliefs, values and principles supported by resources to help problem-solving groups to perceive, generate, assess and carry out, in a non-random way, changes to an information situation.* (Jayaratna, 1994)

Consequently, problem formulation, solution design and solution implementation are important parts of methods and problem-solving processes. In order to support this process, a method normally contains a

[9] The difference between methodology and method, although existing, can be considered as merely semantic, since both terms are regularly used as synonyms.

set of tools and techniques for these steps and also for documenting results.

6.1.3 The knowledge creating aspect of methods

In addition to the purposes mentioned above, methods are also part of the organizational knowledge system. In his study of the use of methods in management consultancies, Werr (1999) has found that methods actually play an important role in these firms' knowledge systems. Werr (ibid., p 320) described the knowledge system in the following way.

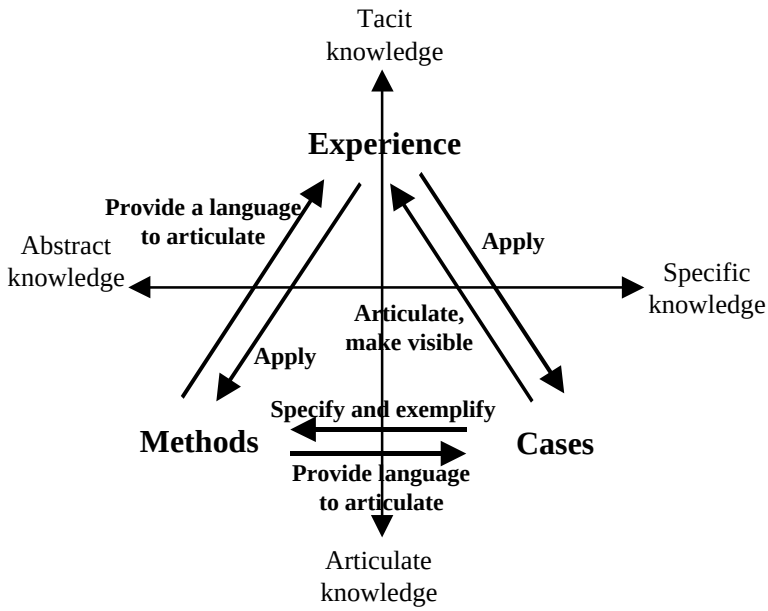


Figure 6.1: Methods as part of the knowledge system

Consequently, methods are an integrated part of the knowledge creation and sharing process of organizations and support the process of extending and transferring individual knowledge through the language they provide, and that is shared among all members of the organization.

6.2 Comparison of four process improvement approaches

The concept of Business Process Reengineering has already been introduced as an approach to business improvement, based on the consideration of business processes as the primary source of added value

and during the past years, many firms have embarked on BPR-projects. However, due to several reasons, the concept of reengineering has become less popular during the past years and for many people, reengineering has become a concept non-grata, an approach that is hardly mentioned anymore. Thomas Davenport, one of the early reengineering advocates stated that

> … *once out of the bottle, the reengineering genie quickly turned ugly. So ugly that today, to most businesspeople in the United States, reengineering has become a word that stands for restructuring, layoffs, and too-often failed change programs.* (Davenport, 1995)

Nevertheless, the idea of business process improvement and radical change has become part of the standard change portfolio and is frequently applied in most organizations undertaking improvement projects. Davenport provides the following argument:

> *The most profound lesson of business process reengineering was never reengineering, but business processes. Processes are how we work. Any company that ignores its business processes or fails to improve them risks its future.* (Davenport, ibid.)

In many firms, the need for consultants for complex change projects, such as BPR projects is generally accepted. It may be discussed, however, which kind of characteristics a project must fulfill to be termed BPR project. In this concern, the prophecy of BPR being doomed may hold true to the extent that the term itself will loose importance, while the underlying principles will remain.

The impact of BPR on companies and consulting practice can be illustrated with the fact, that BPR consulting revenues in 1994 were 3,5 bill. US$, with an estimated growth rate of 20% on annual basis. In 1994, 69% of US and 75% of European firms were involved in projects with BPR label, or strong BPR characteristics. Of the remaining firms, 50% intended to embark on reengineering during 1995-1996.

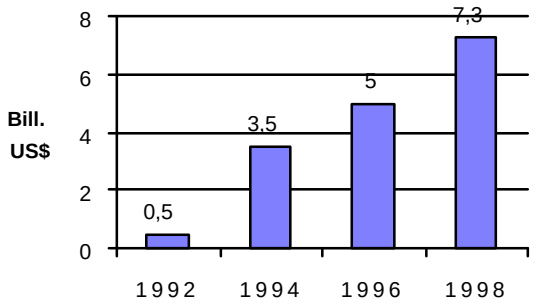


Chart 6.1: BPR consulting market, source: Industry data

A general observation is that the reengineering market, and the project intentions have changed from being cost-reduction oriented, to become initiatives for growth and improved customer relations, service, and product development.

6.3 Consulting firms and BPR

Virtually all international and also national consulting firms being involved in strategy, organizational improvement or information technology offer process improvement services under the name of BPR, or related labels. In addition, many smaller firms have specialized in reengineering, often with a niche focus on specific industries. When considering the major firms worldwide, it can be concluded, that BPR market shares in percent are generally low (under 10%, except Andersen Consulting), which can be derived from the fact that most firms are offering multiple kinds of consulting services, e.g. accounting, tax auditing, strategy development, etc., or have been entering the BPR market relatively late.

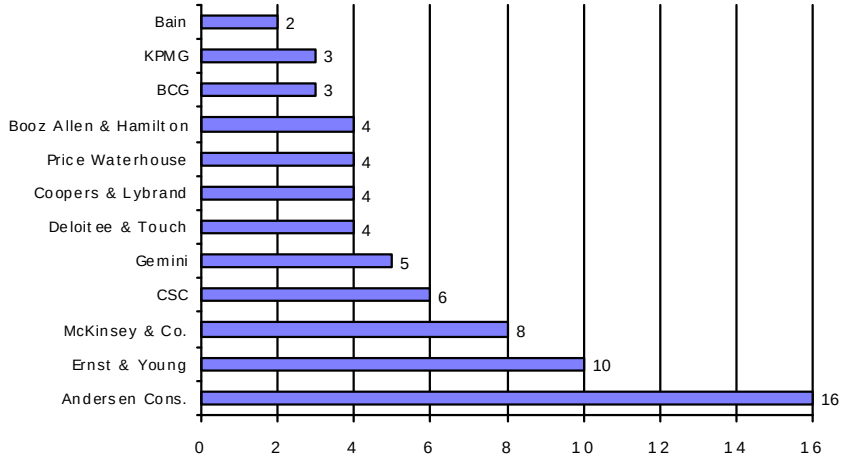


Chart 6.2: BPR market share (%), source: Industry data

The above chart can be complemented with the fact that other consulting firms hold a market share of about 31%, accounting for 1.1 bill. US$. This category consists of smaller, often regional firms, but includes even hardware and software vendors, providing BPR tools (Examples: IDS, SAP) and related services.

Reading the chart carefully, it can be concluded that the majority of leading BPR consultancies are traditional consultants, which especially holds true for the ”Big Six”. These firms have been offering various consulting services in the areas change management, systems development and strategy prior to the occurrence of BPR. This group of traditional firms holds a share of about 58% of the BPR market. Despite their market share, many of the firms have varying levels of dedication to BPR, which it depicted by the BPR share of their corporate revenues. The traditional consulting firms have a BPR share of corporate revenues of around 20% or lower, while firms with a higher level of specialization have a higher share. Having a BPR revenue share of more than 15-20% would indicate, that the firm has been active in the market at an early stage. In addition, it could be claimed that several of the previously existing consulting firms have embarked on the ”BPR-trend” by adapting their traditional services and methodologies to a process approach by adding steps for process analysis and design. Another measure for the success of a consulting firm is the revenue per professional figure. For the four firms described in the following - Andersen Consulting, Bain, BCG, McKinsey - the 1998 figures look like following.

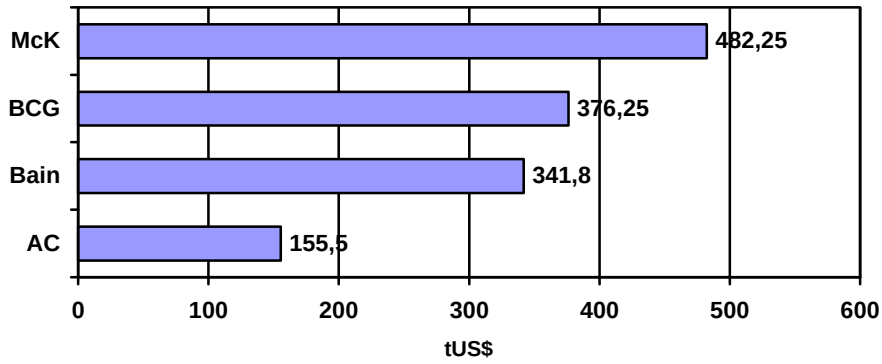


Chart 6.3: Revenues / consultant for four firms, year 1998 (source: Consulting News, 7/99)

6.4 Boston Consulting Group (BCG)

The BCG has a background in strategy consulting and considers itself as a major contributor to the strategy field. Several of the concepts being developed by BCG have, in fact, found their way into the general method portfolio of strategy development and strategic change. The most prominent one is the Boston Matrix (Boston Square), a qualitative technique for product life-cycle and product portfolio analysis.

The BCG employs a set of twelve guiding principles for reengineering. Even though they can not be considered as a formal method, they provide a basis for the analysis and design work being part of a process improvement initiative. The BCG approach has a clear focus on process cycle-time and has been promoted under the name of *Time Based Competition.* The publication of a book under the name of *Competing against Time: How time-based competition is reshaping global markets*, authored by BCG consultants George Stalk and Thomas Hout (1990), has been contributing to making BCG a player in the arena.

According to the principles of the BCG approach, time is the most important aspect of process improvement and constitutes a prerequisite and driver for improvements in other performance dimensions, such as cost and quality. The relation between the different dimensions can be described like following.

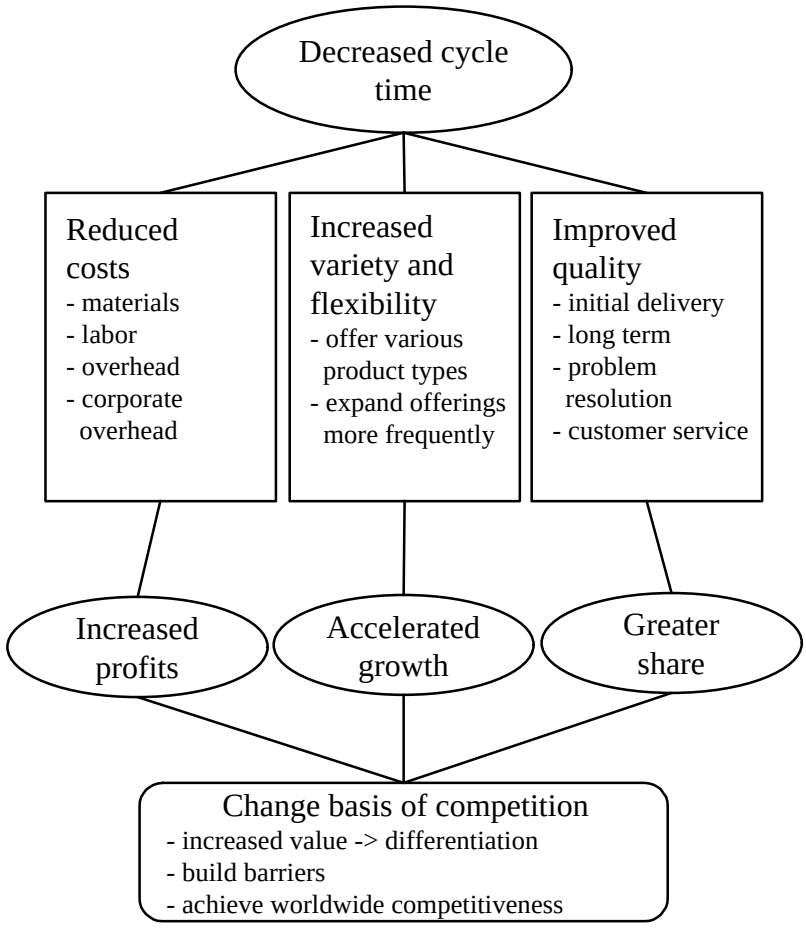


Figure 6.2: Time as primary improvement factor

6.4.1 The role of IT

The Boston Consulting Group does not offer IT products or services. Despite this fact, information technology is considered an important tool for reengineering efforts, if it is linked to business and organization strategy. Additionally, the positive impact of IT is linked to the requirement of customer value creation. In this area, BCG does not offer systems development assistance, but strategic guidance. IT development is done in-house by clients, or outsourced to specialized firms. However, as a result of the increasing importance of IT, e.g. e-commerce, BCG has rethought its own strategy and is now offering some IT services in the area of Web-site prototyping.

Information technology is considered as being value-adding, if it increases speed and accuracy to reduce cost, which often is achieved when whole functions or activities can be reduced or eliminated with the help of IT, or when core competencies are developed, i.e. that new strategic business opportunities are deployed, that have not been exploited by the company or any competitor. A third area for IT use is the support of information-rich processes, where IT can provide help in managing large amounts of information efficiently.

Using information technology for achieving competitive advantage includes a genuine understanding of how it can be deployed, and when this should be done, where the ”how” question is answered by line managers together with IT experts, and the ”when” question by top management, which has to plan and guide the implementation according to the firm’s strategic objectives.

6.4.2 The twelve principles of reengineering

BCG is using a set of 12 principles that are used as guiding principles, rather than imperatives for the change process. Taking its starting point in the role of senior management and strategy, these guidelines basically describe the critical success factors for a reengineering project. The following list summarizes the BCG principles and provides a short interpretation of their meaning.

- **Senior management must lead reengineering.** This means firstly, that senior management's role is to *lead* the change, but not to manage it. It is important to distinguish between these roles, where leading means facilitating, promoting and sponsoring, whereas managing means control and direct intervention. Secondly, senior management is responsible for "shaking the barrier", i.e. removing road-blocks set up within the organization by people opposing the change process.

- **Strategy must drive reengineering.** The foremost strategic objective is to create competitive advantage. However, competitive advantage is not solely depending from company internal structures and processes, but is basically created through delivering service to customers. Consequently, the underlying strategy supporting the reengineering effort must take into consideration external effects. In addition, strategy must be balanced again operational improvement,

i.e. changing the strategic direction must even result in sustainable bottom-line improvements.

- **Add value for customer.** BCG has the thumb rule, that for every dollar in margin improvements through cost reduction, at least two dollars can be added as increased customer value. This aspect clearly points out the difference between reengineering and cost-cutting approaches, which have been running under the label. Cost-cutting, or downsizing, is a means for improved efficiency, but does not necessarily elevate effectiveness.

- **Focus on process, not function.** The change team should contain people from all parts of the organization being concerned. However, it must be clear that the participation in the change team does not mean to represent a certain function and to serve as a sentry for its interests. Instead, all members of the team need to focus on the targeted processes. Also, people participating in a change team should be chosen upon their openness to radical change and ability to think "out-of-the-box".

- **Play to win.** Reengineering is not a ”do it in your spare time” job. It is necessary to assign the best available people to the project. Additionally, there must be clear incentives for participation in the effort, i.e. that career opportunities must exist for those who are dedicating themselves to the project.

- **Take a system view.** Processes need to be considered from an end-to-end perspective, i.e. that they are looked upon from customer need to the satisfaction of the need. The customer thus plays a double role in being the determining factor for the design of the process, as well as its customer. This view is substantially different from the means-end analysis often used in traditional change projects, where customers are considered as the receiver of the outcome of a push-process.

- **Preplan and learn as you go.** It is necessary to stake out the over-all direction of the project, but it could be fatal to create a route description, since it must be possible to make adjustments during the change process. This also means that a process view is taken at the change effort.

- **No ”one size fits all”.** There is no one best way to handle any occurring situation. This means that different approaches are required and that action being taken throughout the process is situated, rather than pre-determined. It also requires that metrics for performance measurement must be chosen accordingly, i.e. that simple quantity measures often are inadequate as for example when looking at knowledge intensive work, such as R&D.

- **Metrics matter.** Customer often perceive a firm in a way that differs significantly from the way the firm looks at itself. Therefore, a company should use the same measure as their customers in order to create a common ground for measuring and evaluating performance.

- **Care for the human dimension.** Reengineering success stands and falls with the people in the organization. It is therefore imperative to understand and anticipate individuals’ expectations, emotions, and behavior. This includes to manage fear and resistance to change. This aspect is also the one being most frequently neglected.

- **Reengineering is not a one-time thing.** Reengineering can not be seen as a one-time phenomenon, but must open the way for a cultural change that enables and encourages a climate of on-going change. In other words, the reengineering effort must prepare the fertile ground for organizational structures and processes that allow the company to continuously adapt to changing environmental conditions.

- **Communicate, communicate, communicate.** Communication is a crucial factor, and must include a communication plan that extends to all stakeholders – employees, owners, unions, press, communities, etc.

6.4.3 Reengineering approach

BCG uses a three stage process – preparation, transformation, consolidation – where each of the stages contains several steps. The actual redesign of business processes is considered as part of the transition management. Top management has a dual role in each of the steps, firstly setting directions and creating value, secondly to motivating individuals and creating commitment to change.

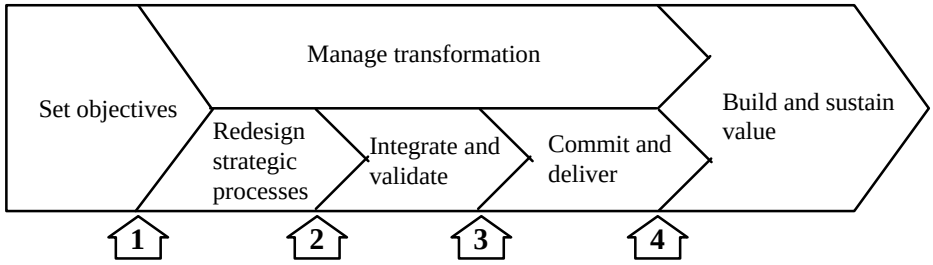


Figure 6.3; BCG reengineering approach

When taking the step between different phases, the project is checked against a set of conditions of satisfaction. These check-points, or toll-gates, exist to ensure that all necessary actions have been taken in the previous phases. The different aspects to be considered can be expressed in the form of questions or statements.[10]

Check-point 1

- **Rationale for change**. Is the rationale for the change initiative identified and communicated throughout the organization? The *Why?* and subsequently *How?* must be declared and communicated in a way that makes it understandable to all organizational members.

- **Senior management understanding and commitment.** Has senior management accepted its sponsor role and is prepared to support the effort by all necessary means? A large-scale process improvement has to be sponsored and facilitated by senior management, not only through words, but through action. This includes to back up the project organization and to actively promote the effort.

- **Selection of processes.** Have the process to be scrutinized been identified and have the right selection mechanisms been used? The selection of process should be based on the processes' value adding potential, i.e. that a limited number of high-potential process is selected first.

[10] In the list of check-points, bold text describes the check-point name given by BCG. The questions and additional text are comments by the author.

- **How much/long/fast?** What is the scope of the project in terms of intention level and time frame? *and* Have the necessary resources been allocated in terms of financial and intellectual resources? A common mistake is to allocate too limited resources to the change project in terms of people and time. Also, the project objectives must be clearly set, but must not be unachievable.

- **Organizational readiness.** Is the organization, i.e. the individuals working there, prepared for the effort and has it been communicated appropriately? When individuals are taken by surprise, they often react irrationally and defensive, i.e. that barriers are built, stakes are claimed and the considered threat then creates massive resistance.

- **Assign the best people.** Who are the people being assigned to the project? Is it ensured that they are knowledgeable, committed to the project and not acting watchdog for other parts of the organization? In many organizations, managers do not give away their best people, but those they consider as troublemakers or under-performers. In others, people are sent to change teams as representatives of the unit they come from and are expected to guard their unit's or department's interest, instead of committing themselves to the project.

Check-point 2

- **Assess existing processes.** What are the deficiencies of the current processes, i.e. where are the performance gaps in terms of time, quality, cost and service? This point assumes that there are identifiable process existent in the organization, that satisfy the characteristics outlined in chapter 5. Otherwise, this step also includes the identification of work activities that conceptually can be grouped into processes.

- **Customer input and competitive assessment.** How are customers perceiving the organization's ability to perform in terms of time, quality and service? *and* How is the organization positioned in relation to its competitors with regard to the critical performance measures that have been identified? This point includes the external assessment of the company's performance by its customers, but also the process of benchmarking it against its competitor's performance measures.

- **Magnitude of opportunities**. Which is the intended level of improvement that shall be achieved through the reengineering initiative and is it relevant and achievable? The objectives to be defined must satisfy the requirement of being ambitious with respect to the improvement's order of magnitude, without being unreachable. Stretch targets should only be used if the necessary elevation of the change process can be ensured.

- **New process vision.** How should the new process work, i.e. how should the business logic look like, what are the necessary resources and how can the process be designed with respect to low cycle-time and cost, without compromising the required quality level? The process vision must include a sketch of the contained activities, required resources and competencies. If applicable, it should also include a description of the technological components required. Developing the process vision is an iterative process, where design prototypes are evaluated and refined.

- **Determination of major changes required.** What are the gaps between the new process vision and the current process and what are the most important parts to be changed in order to establish the envisioned process? Mapping the existing process against the new process vision allows the identification of gaps and the required measures to be taken in order to establish the envisioned process.

- **Roadmap for change.** What actions must be taken in order to bring about the changes that have been identified and in what way should these actions be taken? As mentioned above in the description of BCG's reengineering principles, this roadmap is not a fixed path, but can be adapted over time, i.e. that it serves as guidance, rather than prescription.

Check-point 3

- **New process documentation and validation**. Is the new process valid and feasible and has it been documented? The new process design has to be finally determined and documented. At this stage, the connections with other process need to be identified and described, the chosen metrics defined and the required resources determined.

- **Key people's concerns addressed.** Have the comments of all people being relevant for implementation and the adequate performance of

the new process been gathered and considered? In order to ensure a smooth and friction-free implementation and deployment of the new process, the concerns of major stakeholders need to be taken into account.

- **Support systems consistent with new requirements.** Are the process' environmental conditions sufficiently examined and the results determined? The support systems of a process - performance metrics, measurement mechanisms, evaluation procedures, reward system, responsibility structure - need to be defined together with the process and are included in the description of the targeted future state.

- **Necessary investments funded.** Are the necessary funds for implementation and investments, e.g. in information technology, available? These consideration should also include slack resources for handling possible operational disruptions related to the change process, and must include costs for recruiting, training and education of staff, as well as for possible lay-offs.

- **Major barriers removed.** Are the concerns of people, resulting in possible resistance, taken into consideration and are the necessary organizational conditions available for the implementation and deployment phase? Barriers for change can emerge from insufficient organizational preconditions, lack of competence in change management and the use of information technology. However, the most important barrier can be found in the heads of individuals feeling threatened by the changes to come.

- **Road-map for action.** Have all the necessary preparation steps been taken and can the implementation phase be initiated? Are the necessary steps of the change process identified? Change management is crucial to the successful conduct of any process improvement initiative. At this point the actions to be performed during the implementation and sub-sequent deployment phase are defined and prepared.

Check-point 4

- **Positive customer reaction.** How are the transition process and resulting process and structures perceived by customers? The purpose of process improvements efforts is to deliver increased value to the

process' customer and consequently the outcome of the change effort must be checked again these expectations.

- **Evidence of customer-oriented focus.** Has the customer focus been considered and improved? There must be clear evidence that customer orientation has been imperative during the redesign effort and this premise must also hold for the implementation and outcome of the new process.

- **Improved decision making.** Are decisions made by the right people on the right level in the organization? In order to improve a business process' ability to deliver value, decisions must be taken as close to the customer as possible. This is achieved through empowerment of people working in the process, i.e. that decision power must be transferred to those being responsible for the process outcome.

- **Business plan aligned with new capabilities.** Has the business strategy and implementation plan been aligned with the organization's improved capabilities? No process oriented organization can be better than its overall business strategy. Consequently, strategy and capabilities must be constantly evaluated against each other in an iterative process. New capabilities make it possible to change strategy and changing strategies may require the development of new capabilities.

- **Evidence of improved responsiveness to market changes.** Is it evidential, i.e. can it be clearly shown, that new capabilities have been developed that contribute to improved environmental responsiveness? Adaptability to changing environmental conditions is one of the guiding principles in any process improvement effort. At the same time, an extreme focus on operational efficiency might hamper the organization's ability to respond to changes in the market place. Consequently, both factors must be considered and balanced against each other.

6.4.4 Top-down vs. bottom-up

In most of the BPR-related literature, reengineering is described as a top-down approach. Analysis and design starts with the assuring commitment from senior management, processes are analyzed and designed from an overarching level to more detailed levels. BCG follows this general

principle, but also points out the necessity of including a bottom-up approach. Both cycles are run as connected iterations.

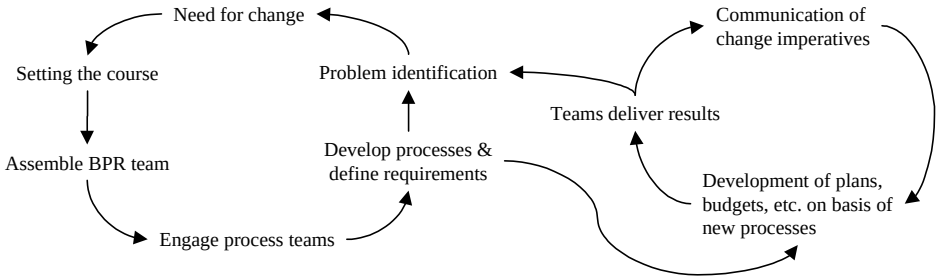


Figure 6.4: Connected change cycles

Cycle 1 - Top-down

- **Senior executive agreement on need for change.** Senior management agreement and commitment is not the only, but one of the most critical factors for success. Without this agreement on the need for change and sponsorship all sub-sequent steps can not gain the required creditability that is necessary for driving a project successfully.

- **Setting the course.** Course-setting means to decide upon the general goals and directions for the change effort, but does not include detailed plans and procedures.

- **Assemble reengineering team.** The reengineering team must be compiled on the basis of competence and is responsible and accountable for achieving the defined overall objectives. The reengineering team must include people with competencies in methods and tools, change management and organization, but not necessarily with in-depths knowledge about all operational areas covered by the project.

- **BPR team engages process teams.** Each process is scrutinized by a team assuming responsibility for a specific process. The process teams are staffed with people covering the different competence areas covered by the process.

Cycle 1 - Bottom-up

- **Design teams develop new processes and define requirements.** The process design teams are responsible for designing the general design of the new processes and to define the performance requirements and propose metrics to be used. The results are transferred to cycle 2 for the development of more detailed plans, budgets and metrics, but they also serve as input to the problem identification step of cycle 1.

- **Identification of problems needing attention.** The problem identification step is informed by the overall process development results in cycle 1 and the results from the results delivered by the teams being responsible for the detailed design of the processes' operational characteristics. Identified problems are delivered back to management for evaluation and, if considered necessary, adjustments of the current process design.

Cycle 2 - Top down

- **Communication of change imperatives and direction by management.** Communication is, besides commitment and sponsorship, the most important management contribution to project success. The imperative and direction of the change effort must be communicated throughout the organization in order to gain understanding and reduce potential resistance.

- **Development of plans, budgets, performance metrics etc. on the basis of new processes.** A new process design often makes the existing plans, budgets and performance metrics obsolete, since they often are designed to fit an hierarchical, functional organization. Consequently, they must be adapted to an organization based on processes. This development phase is informed by the general process design step in cycle 1 and the communicated needs and directions staked out by senior management.

Cycle 2 - Bottom-up

- **Teams deliver results.** The results of the development phase are documented and delivered. These results are used as the basis for further communication, but also to inform the problem identification step in cycle 1.

6.5 McKinsey & Company

Also McKinsey uses a set of basic guiding principles, or prerequisites, which must be satisfied in order to achieve reengineering success. McKinsey, with its background in strategy, organizational change and rationalization, traditionally has a strong organizational scope, and emphasizes the consideration of organizational variables. The firm has developed its own reengineering flavor, going under the name of ”Core Process Redesign”. The focus of the McKinsey approach is on primary, customer value adding processes and the necessary changes of organizational variables to establish these processes.

Despite the fact that the Core Process Redesign approach is conceptually de-composed into three phases, McKinsey emphasizes the fact, that these three phases, applied to a reengineering project, can not be divided. Additionally it is pointed out, that the change process is highly iterative, i.e. that the application of the model, despite its graphical representation as a straightforward process, is not linear. The diagnostic phase is considered as being the key for the identification of performance improvement opportunities and obstacles.

6.5.1 The role of IT

Even though McKinsey recognizes the need for IT analysis in reengineering projects, there is no emphasis on that point, i.e. that IT analysis and design are not considered as main objectives of a reengineering effort. McKinsey identifies the role of IT during the different phases of the BPR exercise as following.

Diagnosis. During this stage, the fit of the IT architecture and organization with the needs implied by business is assessed. This is achieved through a simultaneous mapping of process and information flows, together with the identification of the architectural and organizational barriers to change.

Redesign. The different process design options are assessed with regard to the technological implications. This includes the consideration of investments required for technology development, implementation and deployment, the possible effects of IT-use on lead times and operational costs and the benefits from eliminating non value adding work.

Pilot test. When new processes are tested in pilot studies, the performance of the new IT systems is measured according to the capacity required to fulfill the process objectives. This business simulation phase investigates the functioning and co-functioning of the different technological components. Depending on the complexity of the targeted solution and the level of business criticality of technology, this simulation phase can be of high importance.

Generally, McKinsey accepts the fact, that IT often accounts for substantial improvements in the areas of cycle time and improved information flow. However, redesigning the IT core architecture must not necessarily be a part of the redesign effort. The replacement of IT with newer systems is no main objective, and not a goal in itself. Much IT value can be realized by improving information flow and access with innovative solutions within the existing infrastructure, keeping the need for IT investments on a moderate level.

Observing the increasing importance of IT for many business, McKinsey also reconsidered its service offering. Since 1998 an information technology practice, the Business Technology Office (BTO), has been established as a virtual organization with office locations in various places around the world. In order to extend the firms service offering into the electronic commerce market, McKinsey has also recently established a practice in this field under the name of @McKinsey.

6.5.2 Reengineering principles

McKinsey uses nine reengineering principles, which are divided into two time related categories. The first category contains prerequisites, i.e. factors to be addressed in advance of embarking on the improvement effort. The second category describes the aspects requiring attention during the project.

Before

- **Senior management readiness.** The ability of senior management of being open to organizational change, to understand its implications and possible outcomes, is crucial to the success of any improvement effort, but is also a major enabler of positive performance impact.
- **Strategy must drive reengineering.** Business strategy must be sound, well described and feasible in order to provide a context for

core process definitions and to allow the creation of processes being aligned with the business' objectives and performance requirements.

During

- **Cross functional participation.** The process redesign teams must include people from the relevant business functions, i.e. all functions being affected by the initiative. As part of the choice of team-members it must also considered that they are serving as members of the project team, not as stakeholders of the existing business functions.

- **Focus on performance metrics.** The selection and application of relevant performance metrics is critical to achieving success in high impact areas. Performance metrics must also fit the business objectives and it must be considered that metrics in a process-based organization are substantially different from those being used in a functional structure.

- **Analytical depth.** In order to create a balance between breath and depth of the analysis, the aspects of detail richness and holistic perspective must be considered. This includes to emphasize both the need to adopt an end-to-end process view, and the need for a quick identification of leverage points.

- **Solid diagnostic.** Of the two basic reengineering approaches, either starting with process design from a clean slate, or departing from the current processes, McKinsey proposes the latter one. A careful process diagnosis is advocated in order to create a redesign based on facts, which is considered more powerful than if current processes were disregarded, since improvement potentials and performance gaps might remain undetected.

- **Performance impact.** While a reengineering project as a whole is aiming at long-term improvements, it is essential that substantial benefits can be reaped already during the initial 6-12 months, in order to create positive examples and sustain a climate of success in the organization.

- **Creativity.** The ideas generated in the initial phase must be taken into account without constraints, i.e. that nothing is principally disregarded, while the feasibility is tested during a later stage. This

approach, similar to the idea collection phase in brainstorming sessions, prevents innovative ideas from being lost or abandoned.

- **Accountability.** The overall performance of a process must be referenced to a single point, i.e. that factors influencing process performance must be identifiable and measurable.

6.5.3 The reengineering approach

A reengineering effort guided by McKinsey typically involves three broad phases with different time frames – diagnostic, redesign, and implementation, each of them consisting of a number of partial steps and activities.

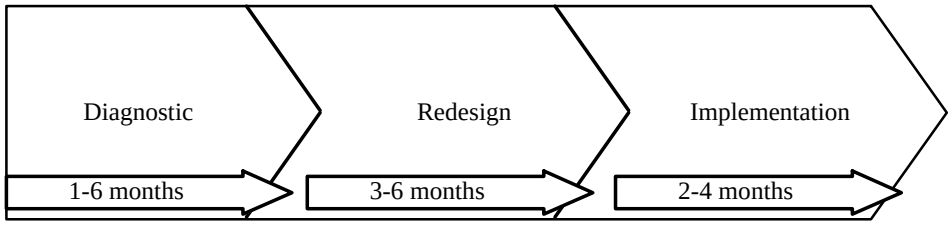


Figure 6.5: McKinsey's reengineering phases

Diagnostic - Steps

- **Definition of core process scope.** The initial step is to identify the organization's core processes - the processes being most important to the implementation of business strategy and with the highest value delivery. The scope refers to their organizational span, i.e. their range across business functions.

- **Quantification of performance gaps.** Performance gaps, i.e. the difference between targeted and current performance need to be identified in a way that makes them quantifiable and measurable during the diagnosis phase.

- **Diagnosis of existing processes.** The existing processes need to be scrutinized and the previously identified performance gaps diagnosed. The underlying causes are derived by analyzing the activities being part of the process in terms of speed, quality and cost. Additionally, the relations and interdependencies between activities are analyzed in order to identify wait-states and insufficient coordination and communication.

Diagnostic - Activities

- **Develop value driver understanding.** Business value is created by certain drivers, and these factors must be understood in order to identify and assess the value creating potential of organizational processes. Value drivers are those activities that make a process' output more valuable than its input.

- **Define 3-5 core processes.** For each organization, it should be possible to identify a limited set or core processes, i.e. processes where the primary value stream takes place and that have the highest contribution to business objective achievement.

- **Identify core processes with maximum performance impact.** In order to achieve substantial improvements fast, the core processes with the highest impact on organizational performance are selected and targeted as the initial objects. This does, however, not mean that the remaining processes can be neglected. The argument for selecting a sub-set of processes first follows the Pareto-principle, i.e. that a small number of processes account for the largest share of potential improvement.

- **Identify process activities.** Each process can be broken down into a number of activities. This de-composition process is iteratively continued until the level of desired remaining complexity has been reached, i.e. that the process is broken down into nearly de-composable sub-systems.

- **Set performance goals.** For each of the selected processes, a set of performance goals is developed. These goals are set upon the basis of an ideal process design and are used in order to identify the magnitude of the identified performance gaps.

- **Measure current performance and identify performance gaps.** For each of the processes chosen for investigation, the relevant performance variables are measured and related to the identified performance goals. The magnitude of performance gaps, i.e. the difference between desired and actual performance, is identified in the primary dimensions time, quality and cost.

- **Identify sources of pathologies.** While performance gaps are symptoms of pathologies, the underlying sources need to be revealed.

For this identification process, it is necessary to look beyond the boundaries of a specific process, since possible causes might be found in interdependencies with other processes.

- **Determine causes.** The process of determining the causes of pathologies includes the verification of possible causes that have been identified in the previous activity. It also means to divide direct and indirect causes and to track symptoms over multiple steps to the original generator.

Redesign - Steps

- **Definition of redesign vision.** The redesign phase starts with an overall description of the future objectives of the organization and the business processes existing within it. It also describes the new business process at an overall level and their primary sub-processes and interconnections.

- **Redesign of processes in detail.** In this phase, a detailed map of the processes' future design is developed, including all sub-processes, relations between activities being part of the processes, interrelations, process-teams, etc. The level of detail can vary significantly and is mainly depending from the desired complexity to remain and the amount of local decision making and design that is considered feasible.

- **Pilot test of new processes.** The new process design needs to be tested in order to verify the process logic. The test also includes the assessment of the resource allocation and the process' interconnections with other processes.

Redesign - Activities

- **Develop clean slate process design.** The design of the new process is following the clean-slate approach. Following this rationale means to develop a new process without taking departure from the existing one and to rearrange it. However, it does not mean to disregard the results of the analysis of the existing process. Learning from analysis during new process design means to consider the shortcomings of the existing process that have been identified.

- **Identify IT and organizational implications for new processes.** A new process design will possibly new opportunities and needs with

regard to IT-use and the organization being required for establishing the process. These implications need to be identified and described in order inform the change specification activity.

- **Generate redesign initiatives.** Process redesign activities need to be initiated from within the organization by gathering together people who bring their specific competencies and capabilities into the design process. It is crucial, that the design activity is initiated and conducted within the company, and not done by outsiders.

- **Specify changes required in practices, organizational structure and information systems.** Based on the process design scheme and the identified organizational and technological implications, the actual changes in work practices, organizational structures and technological systems are outlined. This process also includes cost estimations for the necessary changes, that are balanced against the targeted benefits from the new process.

- **Design process pilots and system prototype (if necessary), test pilots in an iterative way.** The new processes are developed as pilots, together with the technological support systems. Within a "process laboratory", the new process are tested and tuned iteratively.

Implementation - Steps

- **Define implementation plan.** The implementation plan consists of a road-map for the process implementation and roll-out. It contains descriptions of the implementation time-frame, resources, migration activities, training, and other related activities.

- **Roll out initiatives throughout the organization.** In the same way as process design, the roll-out of new processes must be driven internally. In many cases, the process design teams also take on responsibility for implementation.

Implementation - Activities

- **Identify required phasing, resource assignment and performance objectives.** The initial activity of the implementation phase contains the development of a master-plan for the new process introduction. In order to avoid inter-locks and mutual dependencies, it becomes necessary to develop a phasing model. Also, the resources being required for the implementation must be defined and assigned.

- **Designate change management leadership.** Change management can be facilitated, but not driven by external consultants. Consequently, selecting people that are determined and dedicated to the change effort is important to manage the actual change process. At the same time, change managers need a sound understanding of the organization and business in order to foresee and overcome barriers to change.

- **Develop actual organizational change management program.** The change management program is the detailed description of *how* the new processes, and the related organization and technology are to be introduced. A change management program includes time-plans, training programs, workshops, etc., but also resource allocations, feedback mechanisms and adverse events handling. Another important aspect is the migration plan, describing how changes can be introduced without disrupting ongoing operations.

- **Launch initiatives.** In order to sustain momentum, process implementations are normally conducted in parallel, i.e. that multiple processes are introduced simultaneously. To launch several implementation initiatives at the same time therefore requires high-level project management capabilities.

- **Manage to explicit performance objectives.** Although the new process designs have been tested and tuned as pilots in a lab-environment, the "real" processes need to be adjusted in order to ensure performance according to the defined objectives. This fine-tuning process is the final stage of implementation and has no clearly defined end. From here, process management and improvement is carried forward into a continuos improvement phase.

6.5.4 Final considerations

Typical McKinsey guided process improvement efforts have a strong focus on organizational issues, such as the reduction of levels in the structural organization, the re-organization of units and departments, and the development of organizational strategies. When considering the objective, approach, and scope used during reengineering efforts, the following picture emerges.

Objective	Approach	Scope
Reengineering is a	by reconfiguring	that are sufficiently

targeted effort to gain substantial improvements in business unit performance...	activities and information flows...	broad to comprise core processes.
• One time effort • Major bottom-line impact • Breakthrough performance goals • Simultaneous improvements • Phased impact (short/long term)	• Concurrent information and activity flow redesign • Focus on high leverage areas • Driven by fact base • Iterative design	• One of 3-5 activity/information flows required to deliver value • Cuts across organizational boundaries • Holistic process view

6.6 Bain & Co.

Bain uses five key success imperatives for BPR projects. The approach used by Bain & Co. also differs from the definition outlined by the early advocates Hammer & Champy.

Hammer & Champy's definition	**Bain's definition**
The radical redesign of business processes to achieve dramatic improvements in critical measures of performance, such as cost, quality, capital, service, and speed.	The holistic redesign and optimization of a business to achieve full potential and build strategic competitive advantage. This includes the radical redesign of core processes as well as the application of the entire Bain tool kit of performance enhancing

	techniques.

The definition of Hammer & Champy is focusing the aspect of business process performance improvement in quantitative terms. Conducting a BPR-project with this definition as starting-point, the targeted improvements would primarily be defined in terms of quality, cycle-time and cost efficiency. The Bain definition, on the other hand, takes a wider perspective and includes the aspect of strategic competitive advantage in an explicit way.

6.6.1 Reengineering principles

- **Top management sponsorship.** Senior management is obliged to provide an inspirational vision of the ultimate goal to be achieved. This includes the slaughter of ”sacred cows”, allowing the reengineering team to explore all opportunities, even those that might imply a re-consideration of the company's business scope and strategy. Also, there must be a clear and early commitment to the results that are developed during the initiative in order to give the necessary creditability to the effort.

- **Strategic foundation.** The business of the company must be clearly defined. Consequently, any business improvement effort must depart from a re-consideration of the organization's business scope, vision statement and overall strategy. The result of this initial phase must inform the identification of business processes and customer requirements.

- **Comprehensive change management.** The goals of the change initiative must be communicated extensively throughout the entire organization. The change effort, lead by the project team, has to show early achievements, that provide momentum to the overall effort.

- **Right and left-brained thinking.** Breakthrough ideas, and radical and creative design must be combined with a systematic, deliberate and conservative implementation of the designed processes, organizational structures and technological components.

- **Aligning organizational components through investments.** Information technology that supports the new processes is a necessary investment. The compensation and reward structure must be aligned

with the new organizational form, while training and education must be provided to enhance individual and organizational skills.

6.6.2 The role of IT

Even though Bain is not directly involved in systems development for clients, recent developments in e-business have not passed unnoticed. As a consequence, Bain has developed a model for evaluating start-up companies in the e-business sector and taken on the role of business incubator.

In its client projects, Bain considers technology as a medium that offers significant opportunities to enhance service, reduce costs, and achieve a differentiated breakthrough in the way a company develops and delivers its products, or services. The change team for BPR projects in which Bain is involved is typically staffed with experienced IT people from the client company and facilitated by a senior member of Bain's technology practice. This person is responsible for coordinating the IT-related activities within the project. Generally, Bain is not involved in developing IT solutions, leaving this part to partners specializing in this field. Appropriate partners are selected and recommended. The technological guidance is covered by a four stage approach, where each stage consists of a number of activities with varying Bain involvement. Bain runs the IT aspects of a process improvement project through a cycle similar to the one being used for the organizational and process elements.

Identification of potential breakthrough technology

In this initial phase of the IT improvement cycle, the involvement of Bain is relatively high. Either the activities are directly carried out by Bain personnel, or strong support is given to client personnel doing the work with regard to research, analysis and methodology.

- **In depth understanding of customers.** In order to identify technology opportunities, it is necessary to gain a sound understanding of the role and expectations of customers and their interfaces with the company. It also includes the consideration of the "electronic value chain" as a whole, instead of investigating and improving its elements individually.

- **Knowledge of leading edge technology and applications.** A high pace of development in the IT area constantly offers new technologies and application areas. The selection of cutting-edge, yet sustainable, technology solutions requires a deep knowledge of leading applications and emerging technologies.

- **BPR survey of comparable firms.** In order to explore the potential for gaining strategic advantage through IT, a survey or investigation of comparable firms is conducted and the results are benchmarked against the company. Comparable companies, in this context, does not only mean firms in the same industry, but can include organizations with similar processes or customers.

Detailed description of technological requirements

Also in this phase, the involvement of Bain personnel is high. The specifications are developed in the reengineering team, consisting of client personnel and consultants, where the consultants take responsibility for the methodological approach and the structuring of results.

- **Define detailed user requirements to satisfy customer needs.** Internal requirements for functionality and usability need to be considered together with the needs for customer oriented performance and the achievement of customer satisfaction.

- **Work closely with leading edge vendors.** In order to assure that recent and relevant technology is considered for inclusion in the project, contacts with leading vendors are taken at an early stage of the improvement initiative. However, that does not mean that a selection of a specific solution takes place.

- **Evaluate cost/benefit with respect to reengineering vision.** Investments in information technology must be in line with the defined vision of the reengineering effort and justified with improvements in customer service, process performance, or quality. In other words, the value added by technology must exceed the required investments and deployment costs.

Develop prototype

In the prototype development, the role of Bain is less prominent than in the previous phases. Since Bain does not take on the development of technological solutions, the involvement is limited to be guiding and

ensuring that the IT development is in line with the objectives of the overall initiative.

For this stage, three options are available, depending on the clients IT-sourcing strategy. The technical solution can be developed internally by the company, if the required resources and competencies are available. Alternatively, development can be sourced to the company's existing IT partner, or a partner recommended by Bain.

- **Prototype hardware and basic infrastructure.** The hardware specification defines the overall architecture of the technical system to be implemented with regard to network infrastructure, choice of hardware platform and required hardware performance. This also includes the determination of network protocols and operating systems.

- **Software/application design and development.** The necessary software in terms of applications and integration modules must be designed and developed in compliance with the objectives set out for the improvement initiative, but must also follow good practice in systems development, especially when business critical systems are part of the development. When off-the-shelf software is used, development does not take place, while the design effort remains the same.

- **Develop Alpha-version of integrated system.** With all components in place, a first prototype of the technology solution as a whole is developed. In the case of purchased system, this step includes the installation and initial customization.

- **Meet pre-pilot performance threshold.** For ensuring system performance in compliance with the objectives set out on process level, the alpha-version must be able to reach a threshold to be considered as feasible and valid. If tuning of the first version does not make it possible to reach this threshold, the solution must be reviewed and possibly replaced.

Pilot and Rollout

Once the pilot installation has met the performance threshold and has been approved for further development, the pilot installation and rollout is initiated. In this phase, Bain is operationally involved in determining

internal technology ownership, defining and designing training and education programs.

- **Alpha/Beta pilot sites with leading vendors.** In cooperation with the internal or external vendors being selected, the improved solution prototype is developed into a stable prototype that is installed at a number of pilot sites.
- **User training and feedback.** User training and the collection of feedback for further improvement is crucial for the successful rollout and deployment of the technological solution. The emphasis must be on training in technology use and the development of understanding the business and process benefits of technology.
- **Plan for needed revision and total rollout.** Based on the user feedback and system evaluation during the pilot phase, a plan for the required revisions and subsequent organization-wide installation and deployment is developed.

6.6.3 The reengineering approach

Bain comprises five stages into the BPR approach, each of them with different objectives, duration, and Bain involvement. The different may involve other companies, e.g. as part of the benchmarking process.

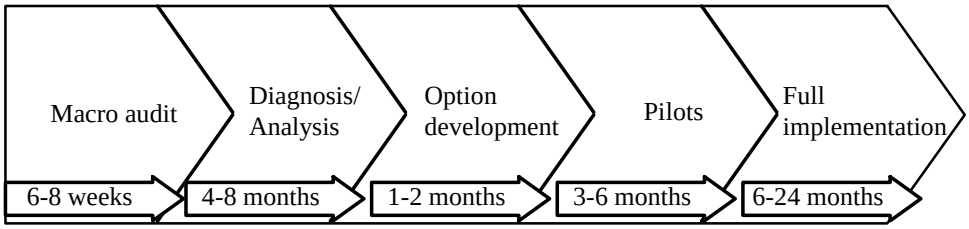


Figure 6.6: Bain reengineering approach

Macro audit

At this stage, Bain takes an active role and is involved in all activities. The overall steering group and teams for different improvement areas are actively supported.

- **Identify and prioritize target areas and opportunities.** In this phase, the overall objectives of the initiative are identified and

outlined. This includes the identification and prioritization of processes and organizational units to be targeted and the definition of the vision and intended outcome of the improvement effort.

- **Define scope and intended improvement level for each area.** For each of the targeted processes and organizational units, the scope of the improvement initiative is defined. Within this scope, the improvement objectives are described in terms of time, cost, quality and service level.

- **Build project teams.** For each area, a project team is assembled that is responsible and accountable for the improvement effort and achievement of the targeted goals. These teams are coordinated by an overall group.

- **Hunt for profit.** Any organizational and process improvement effort must result in bottom-line profit. In the final stage of the macro-audit, the defined improvement areas are investigated with regard to their ability to deliver added value and profits.

Diagnosis/Analysis

The consultants' involvement in this phase is high, but limited to high-priority areas. Typically, consultants are involved in the benchmarking activities and contribute with their experience from other companies and provide methodological support.

- **Fact base development.** For each area, a fact base is developed, including a detailed analysis of the current situation. For this purpose, the current processes and organizational structures are investigated and documented, and performance gaps are identified and scrutinized for the underlying causes.

- **Inclusion of benchmarks into evaluation.** The results of the benchmarking against external organizations can contribute to developing a more informed fact base and are included into the analysis. The benchmarking effort can include organizations in the same industry, but also companies with similar processes in different industries.

Option development

The development of possible change options is a concentrated effort with high involvement of consultants. However, the consultants primarily play a facilitating role.

- **Test limits of current approach.** The current organizational structures and processes are analyzed with regard to their ability to satisfy the performance requirements set out for the improvement initiative. The result of this analysis determines the required level of change in the different target areas.

- **Develop alternatives.** Depending on the level of change being required for achieving future performance goals, different process and organization alternatives are developed and evaluated against each other. This evaluation is includes the determination of resources and effort required for implementation of the new processes and structures and their potential for future change.

Pilots

The consultant participation in this phase is focused on the support of company internal work groups and the conceptual testing and evaluation of existing and new processes and organizational structures.

- **Prove and select ideas.** In selected areas, pilot implementations of new processes and organizational support structures are implemented and tested in order to prove and evaluate different approaches and concepts. The test, evaluation and selection phase is conducted in an iterative way and the evaluation of these pilot implementations is used for selecting the most feasible options.

- **Build commitment for rollout.** A fast and consistent rollout requires a broad commitment from various actors in the organization. Creating a genuine understanding of the new working principles, processes and organizational structures is a pre-requisite for ensuring a smooth and effective diffusion process.

- **Identify rollout support requirements.** A second requirement for making the rollout process work is the identification and assignment of resources and support for the diffusion process itself. The new process introduction must take place without disrupting operational efficiency and the old ways of working must be transformed fast and seamlessly.

Full implementation

It is common, but not necessary, that consultants are involved in the roll-out phase. In most cases, Bain personnel is supporting the implementation teams and assists them in the initial check-up phase.

- Rollout to organization. Depending on the assigned resources and the implementation strategy and capability, the roll-out phase can take between 6 and 24 months. A parallel introduction is more resource consuming and involves higher risk, whereas a step-by-step diffusion reduces these factors, but extends the project and postpones the initiation of the deployment.
- Install tracking system. In order to monitor the performance of the implemented processes and engage in a phase of continuos fine-tuning and improvement, a tracking system must be implemented. This measurement tool analyzes processes according to their performance metrics and in relation to the performance objectives being set out in the initiation phase of the improvement effort.

6.7 Andersen Consulting

Disregarding companies that offer both consulting and accounting services, Andersen Consulting is the world's largest consulting firm. The company offers a collection of integrated services, comprising strategy consulting, change and process management, and technology development. This integrated concept, named ”Business Integration”, has made AC to one of the major players on the reengineering market. The integration of IT services is also the main reason for many companies to choose Andersen Consulting for supporting their process improvement initiatives.

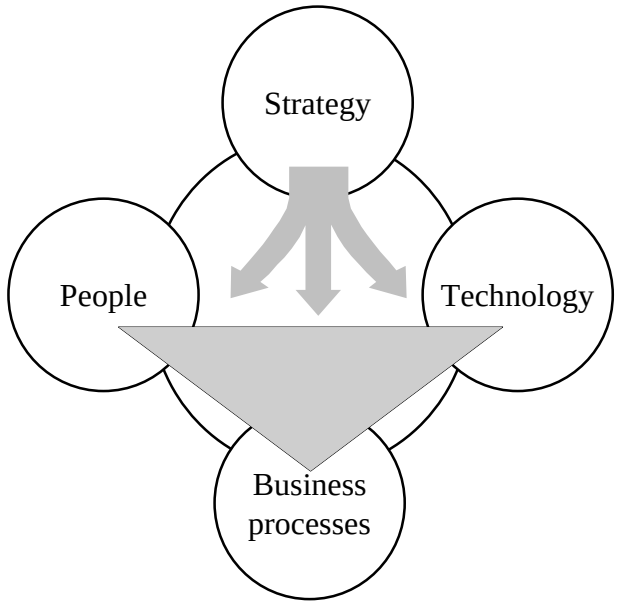


Figure 6.7: Andersen Consulting Business Integration

6.7.1 Reengineering principles

Andersen Consulting uses six basic principles for their engagements with clients.

- **Flexibility.** Given the complexity of problem situations that clients have to face, it is necessary to offer a wide range of integrated services. Together with the client, the necessary selections can be made in order to ensure that the right services are delivered.
- **Joint teaming.** Change can be facilitated, but not delivered, by consultants. Effective projects require joint teams and working closely with clients creates full-service partnerships and ensures long-term results and client relations.
- **Work toward strategic objectives.** Any improvement project must depart from the strategic objectives of the client company. The service offering from Andersen consulting should include all client needs, from strategy formulation, change management, IT solutions, and full-scale system implementation.
- **Knowledge management and transfer.** Knowledge must be transferred into the client organization and must be maintained and

developed. Project success is depending from fast delivery and a knowledge leverage process.

- **Willingness to assume an implementation and/or an advisory role.** Andersen Consulting can take on multiple roles in a project, including pure advisory, but also development and implementation of solutions. In addition, Andersen Consulting also offers outsourcing services on the IT-side.

- **Delivering value.** Results of change must be linked to client success, defined by measurable outcomes, such as increased profitability, shareholder value, ROI, and cost savings.

6.7.2 The role of IT

Andersen Consulting has a strong focus on IT issues, considering its own capabilities there as a competitive advantage for clients, as well as AC itself. Systems development, implementation and sourcing services are an integrated part of the Business Integration concept. In its process improvement projects, information technology is considered as an enabler and also driver of change and is considered as one out of four main target areas within the Business Integration approach. Technology is considered as being vital in the following areas:

- **Communication across organizational boundaries.** Taking a process view includes a re-consideration of the communication and interaction structures within the organization and between the organization and its external partners, such as customers and suppliers. Information Technology can significantly contribute to make these communications more efficient.

- **Information sharing.** Work consists of the execution of tasks and activities according to a plan and workflow, but includes also the instant and ad-hoc sharing of information. Information technology can enable and support both forms of work and interaction.

- **Support new ways of doing business.** IT can provide significant improvements in operational performance, but technology can also facilitate new ways of doing business, e.g. by short-circuiting supply chains and industry value systems, and it can allow companies to re-consider their business scope.

- **Elimination of clerical effort.** On an operational level, technological solutions can reduce manual work by creating electronic workflows and automating clerical routine tasks.

- **Support for knowledge workers.** When work becomes increasingly knowledge oriented and knowledge provisioning and management becomes more important than the physical flow of goods, information technology plays an important role for supporting knowledge workers by delivering information timely and accurately, but also by facilitating communities and networking.

6.7.3 The reengineering approach

Andersen Consulting's reengineering methodology, termed ”Value-driven reengineering”, consists of five sequential stages and support process for team management, change management and the development and introduction of a client specific adaptation of the overall Business Integration framework.

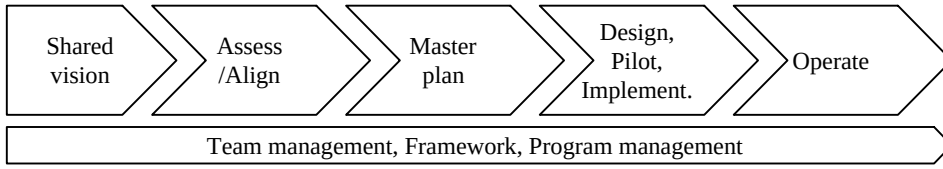


Figure 6.8: Andersen Consulting reengineering approach

Shared vision

The initial set-up phase is concerned with identifying and defining the scope of the initiative, based on a value assessment and the positioning of the company. This part is normally conducted by executive management, together with major stakeholders.

- **Define stakeholder value.** Any improvement effort must provide value for the organization's stakeholders in some way. In most cases, shareholder value if highly prioritized, but it is often achieved indirectly, by increasing value for other stakeholders, such as customers.

- **Define core competencies.** The identification of core competencies is an important measure to assess the current and possible future positioning of the company. The identification process includes

competencies within the own organization, but also those of competitors that have an impact on the competitive position.

- **Develop shared vision.** The future vision must be shared broadly among the company's stakeholders in order to create initial momentum and prepare for the necessary commitment in the organization.

- **Determine strategies and priorities.** Based on the future vision, strategies are developed in the areas business, organization/processes, technology and people. Within the areas, the most important improvement areas are targeted.

- **Develop operational vision.** Based on the overall vision and strategic priorities, an operational vision is developed, describing *how* the new organization is supposed to work.

Assess and align

- **Create next level process models.** The results of the initial phase are used as input for developing new process models, supporting organizational structures and sketches for IT solutions. The future process models are conceptually describing the future state of operations and structures, but defined by using a process approach and terminology.

- **Benchmark current operations against vision.** The new process models are now benchmarked against current operations with regard to performance in terms of time, cost, quality and service level. For this purpose, the models are run through a first business simulation, allowing an evaluation of their potential and limitations.

- **Analyze gaps.** Gaps are defined in terms of performance differences between current and future operations, as identified in the previous benchmarking process. The identified shortcomings, which are symptoms, are then analyzed in order to detect underlying causes.

- **Assess barriers to change.** Factors that can hamper organizational and technical change and development can be found in multiple areas. Strategic mis-positionings, lack of competencies, threatened power bases, etc. Most of the barriers are related to people aspects.

- **Identify quick hit initiatives.** In order to show results fast, a number of limited and targeted initiatives is defined that can be executed in a short-term perspective and with limited resources, but still can provide significant improvements within their scope.
- **Define major program initiatives.** The remaining areas are grouped into a number of major initiatives. Each of these initiative has a specific scope, based on the major business processes that have been identified.
- **Project benefits and costs.** In order to justify a project, it becomes necessary to run a sound and realistic cost/benefit analysis. The factors to be included are direct costs and benefits and alternative costs, i.e. the cost for not choosing a specific solution.

Master plan

- **Profile current operations.** Within the profiling phase, the current operations are considered with regard to their necessity and their value contribution. Non value-adding activities and multiple instances of the same activity can be removed, similar areas can be grouped and functionally streamlined.
- **Create top-down solutions.** Depending on the overall objectives that have been defined for the future operations, processes are designed in a top-down way, from a macro-level to a detailed map of activities.
- **Build bottom-up solutions.** A reverse design process, building on the integration of individual activities bottom-up is conducted in parallel to the top-down design phase.
- **Synthesize solutions.** The top-down and bottom-up design phases have resulted in two sets of process descriptions with different perspectives that must be taken into account. The synthesis brings together both approaches into one consistent image of the future process design.
- **Create master plan.** The master plan contains a detailed outline of the change program initiatives for each area. It synthesizes, synchronizes and coordinates the individual plans within each program area.

Design, pilot and implement

At this time, the overall initiative is split up into sub-areas, each of them targeting a specific area of improvement. Regularly, the division is made upon major business processes. A change management team, being responsible for design, pilot implementation and roll-out, is assigned to each program area.

- **Design.** The change team designs a local plan for organizational and, if necessary, technical development in compliance with the master plan. These plans include time-schedules for migration, training and education programs and a definition of working procedures .

- **Pilot implementation.** Within the different areas, the new processes are introduced as pilots and evaluated in a real-world environment. Where necessary, adjustments are made at process level if the overall process structure integrity is not compromised. Otherwise, the required adjustments are referred back to the overall integration team. The same procedure is, if applicable, performed for IT-systems.

- **Roll-out.** The finally approved process is introduced in full scale and the migration from current to future work procedures is initiated. At the same time, the finalized version of the technological support systems is implemented and put into production.

Operate

- **Balance sheet.** An opening balance sheet is set up for the new operational processes as a starting point for ongoing evaluation. At this stage, the new processes are brought into continuous improvement phase.

- **Scorecard.** Scorecard based models for measuring internal and external performance have proven to be powerful instruments for operating and improving processes. Scorecards are introduced at different levels, for individual processes and activities for managing individual processes, and aggregated in order to provide an overall image.

6.8 Common aspects and differences

6.8.1 General aspects

Generally, the different approaches considered here have relatively few differences on the conceptual level. They all contain the phases Initiation, Analysis, Design, Implementation and Deployment, but each firm adds specific elements to the general concept. Boston Consulting Group includes an in-depth preparation phase in which senior management is committed to the intended changes and results, and assesses the organizational readiness for change. Additionally, it is focused on the need for assigning the best available people to the reengineering effort. McKinsey recognizes the reengineering effort as a highly iterative process between the diagnostic and design phases. Both McKinsey and Bain use a pilot approach, where the new processes are tested in a laboratory environment before full implementation. This business simulation is used for verifying the process prototype against the defined performance objectives. If the new process design involves the deployment of technological solutions, these are included into the business simulation in order to ensure functional fit and usability. Andersen Consulting has a strong emphasis on technology from the diagnostic phase, i.e. that the current IT-infrastructure and the applications in use are analyzed concurrently to the business processes. The new process implementation is, where necessary, complemented with the introduction of a new technological solution.

Also, the methods and tools being used within the different methodological stages are basically identical and are based on the theoretical bedrock of the reengineering concept, as it has been described in the early articles and textbooks. They share the striving for order-of-magnitude improvements, the focus on business processes and their value adding capability, the aspect of cross-functionality and the enabling role of information technology.

In the strategy area, the strategy consulting firms (Bain, BCG, McKinsey) have a very solid base. Especially, the Boston Consulting Group has developed some concepts, such as the Boston-matrix, which are widely used within the area of strategy analysis and development. Andersen Consulting, on the other hand, has a very strong practice in the IT-field, including not only advisory on the strategic level, but also systems development and implementation.

The main differences can be derived from the consulting companies' traditions and core competencies. The Boston Consulting Group, Bain and McKinsey, with their roots in organization and strategy consulting, have a stricter focus on the strategic foundation of the reengineering effort, whereas Andersen Consulting, with its background and strong competence in the IT-field, seems to highlighten the impact and enabling capabilities of technology. The recent efforts of the strategy firms to develop their IT-practices has increased their capabilities in this field, but of the consulting firms investigated here, Andersen Consulting is the only one providing full-range IT-services.

When considering a number of basic principles, we can see the following picture emerge regarding common aspects and differences between the investigated process improvement approaches.

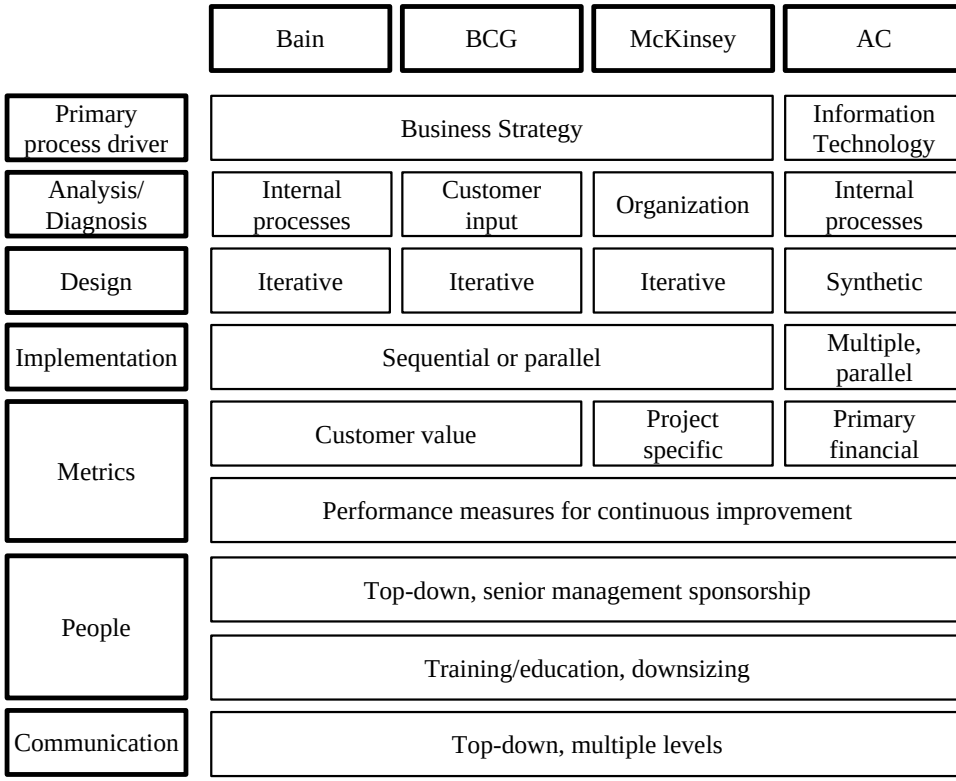


Figure 6.9: BPR principles, comparison[11]

[11] In his comments regarding the Andersen Consulting approach, Christer Mohlin, the responsible partner for the CANDELA project at Astra, stated that AC does not

An important aspect to note is that all approaches contain the design of new processes as a step, but that no concrete guidelines are offered with respect to the level of detail to be chosen, despite the fact that this issue is crucial to the acceptance and usability of the design. Naturally, there is no given level of specification that fits all organizations - the design of the loan management process in bank is substantially different from a process designed for pharmaceutical R&D - but the absence of any guidelines involves the risk of being too general or over-detailing a process design. A very general design leaves room for adaptation of work procedures and technology use on a local process level, which might compromise the overall performance of the process and result in negative consequences in sub-sequent sub-processes. A very detailed process, on the other hand, can limit individuals' creativity and result in strictly controlled processes that can not be easily adapted to specific demands, or it results in organizational work-arounds.

6.8.2 Scope of service offering

All four companies investigated consider themselves as full-service providers and engage in reengineering projects including the improvement of operational processes, as well as management and support functions. The following processes are explicitly included in all companies' service offerings and all companies have been involved in multiple client engagements where the improvement of these processes have been part of the initiative.

Operations

- **Customer relationships.** Customer Relationship Management (CRM) involves all customer related activities of a company, but can be divided into a number of areas: (1) Acquisition, i.e. the identification, attraction an retainment of target customers. (2) Cross-functional marketing, involving multiple parts of the organization in the marketing effort, instead of reducing it to a sales relation. (3) Customer support, the satisfaction of customers' on-going

consider IT as the primary process driver, but rather as an enabler. My interpretation is built on the strong focus that AC puts on technology solutions for solving business problems. Christer Mohlin also noted, that the AC strategy practice comprises several thousands of consultants (3-4000) and that a significant portion of the AC assignments include strategy work.

requirements and activities such as field service and other post-sales activities.

- **Product/service development.** The process by which a company determines what products and services that should be part of its value proposition to customers, the design and development of these products and the development of infrastructures to deliver it to their customers.
- **Supply Chain Management.** The SCM-process involves activities such as order processing, procurement, inventory management, physical distribution and replenishment and associated planning activities.

Management/Support

- **Finance/Accounting.** The financial area covers all activities being related to the organization's cash flow and financial transactions, such as accounts receivable, accounts payable and payroll management.
- **Human Resource Management.** HRM includes administrative activities, but also attracting, acquiring, developing, measuring, motivating and rewarding employees.
- **Information and Technology Management.** This process includes the determination of the organization's information needs and requirement, but also the development, maintenance and improvement of organizational and technological mechanisms for supporting the information flow.
- **Knowledge Management.** KM can be seen as a part of the ITM-process, but is very often considered as a separate process, involving elements of ITM and Human Resource Management.

6.8.3 IT involvement

All firms recognize information technology as a key enabler for organizational change, but have different levels of involvement and participation when IT issues are addressed and solved. These differences can be derived from the different backgrounds of the consulting firms. More recently however, this traditional image has also begun to change industry-wide. Many of the traditional strategy consulting firms have established practices in the IT-field, mainly e-commerce, but also

covering Enterprise Resource Planning, Customer relationship Planning and others. McKinsey & Co. Has established its @McKinsey e-commerce practice and the Business technology Office and BCG has started a prototyping lab for WWW-site development in the e-commerce field. Andersen Consulting, with its traditionally strong proficiency in the IT-field, on the other hand, has attempted to strengthen its profile in the strategy field. Bain is still maintaining its profile, but includes certain IT-aspects, such as the development of technology strategies and architectures, in its service offering.

High IT involvement

> **Andersen Consulting** has a core competency in the IT field, and considers this as a significant competitive advantage. The adoption of an integrated approach to solve clients' problems is intended to create a close link between organizational and IT issues.

Medium IT involvement

> **Bain** takes an active part in the development of technology strategies, including the determination of IT architecture and the development of data models. The technical design and development is normally outsourced. Participation in system implementation to ensure alignment with new business processes.

Minor IT involvement

> **BCG and McKinsey** have a focus on the strategic aspects of reengineering projects. Information technology is considered as another tool for achieving business process redesign. Involvement takes place at a high level of the IT requirements definition, while the IT element of the project normally is outsourced. IT is not conceived as a mandatory component of all reengineering efforts.

6.9 Working with a consulting firm - aspects to consider

Working with a consulting firm is not only a financial issue. The competence that consultants bring into a project, or the lack thereof, can contribute significantly to a project's success or failure. When considering the cooperation with a consulting firm, a company must consider several

aspects, of which the completeness of concept and the ability to execute are the most important ones. For many consulting clients, it is also difficult to find the appropriate selection criteria when consulting firms are brought into projects, since they lack experience in buying professional services. On the other hand, competence itself is not sufficient and personal chemistry play a role just as important as the formal competencies. The following aspects provide a compilation of factors that are relevant for the consultant selection process in the two categories concept and execution.

6.9.1 Completeness of concept

In order to be able to provide value-adding services to its clients, a consulting firm must use a comprehensive approach to solving clients' problems and improving their business. The approach, or concept, should contain guidelines and tools for developing and unfolding a process improvement initiative in the client's organization, but it must also be adaptable to the specific conditions and environment of each company.

- **Seamless execution tailored to industries.** While improvement efforts have several common characteristics, they also differ with regard to the industry sector in which they are taking place. The consulting firm's approach must consider these specific characteristics, e.g. the fact that companies in the area of pharmaceutical R&D have a significant share of highly educated employees, that require different communications, have a more critical perspective at the change initiative, and are more outspoken than people in other industry sectors.

- **Knowledge of how IT and organizational change can solve business problems.** The consultants need a sound understanding of the relation between IT and organizational change and these factors' capability to solve business problems and improve organizational performance. Whereas most of the larger firms can provide this expertise, smaller firms or consultancies with a focus on either IT or organizational issues might not have the required level of understanding.

- **Flexible approach to process improvement that can be tailored for specific customer needs.** In the same way as industry sectors have their specific characteristics, each company engaging in a change effort faces certain problems and has specific issues that need to be addressed. The consulting firm's approach must allow these aspects to be considered and

should not follow a template-based "one size fits all" principle, that is applied indifferently in every client organization.

- **Articles in business press publications.** The consulting firm should have a reputation for publishing its way of thinking to a wider audience where it can be criticized and discussed. Articles in various publications, such as business press, conference proceedings or journals, are a sound way of proving that the way of thinking is valid.

- **Quotations or references in trade publications.** The consulting firm's achievements should be mentioned in publications that are available also to the client organization. Successful, or even failed, projects in large firms are often mentioned in industry specific publications and can be used for analyzing the track record of the consulting firm.

- **Publication of acclaimed management literature**. Many consulting firms encourage their employees to publish their thoughts in books or other fora. Several acclaimed management books, such as *In Search of Excellence* (Peters and Waterman, 1982), have been written by consultants and demonstrating thought leadership in this way allows companies to get their own image of the consulting firm's capability.

- **Invitation to conferences.** Many consulting firms actively participate in professional and academic communities as part of their networking activities and invitations to academic or industry conferences can also demonstrate how a consulting firm develops and communicates its concepts and techniques and stays close to the theoretical and practical developments.

- **Working relationships with leading academic institutions.** Academic institutions around the world account for a significant portion of research in the management and IT-field. Cooperating with academia allows consulting firms to adopt current research and to improve their own methodologies and techniques.

- **Experience from multiple projects.** The consulting firm should possess considerable experience from similar projects and should be prepared to offer examples for how business problems have been approached and solved in previous client engagements. The experience should include all aspects and phases of the effort to be undertaken by the client organization.

6.9.2 Ability to execute

While sound concepts, methodologies, techniques and tools are necessary pre-requisites for successful change projects, they are not sufficient. A consulting firm also needs to be able to execute the task that it has been assigned and committed itself to deliver. The ability to execute is depending from various factors, but the most important one relates to the consultants' personalities and competence.

- **Senior management talent.** The senior management of a consulting firm is responsible for assignments of the firm and is supervising the activities of the younger associates. Consequently, the professional competence of the senior personnel is important to any project and client firms should be able to assess these capabilities.

- **Consultant’s quality.** It is not uncommon, that consulting firms use client engagements as training for their consultants. In these cases, senior consultants are maintaining contacts with the client's management, while young and often inexperienced consultants are carrying out the actual assignment. While this is not wrong per se, it should be clear to the client. In order to avoid these situations, many firms have started to request professional curricula for the consultants being involved in a project.

- **Tools used.** The analysis and design tools being used by the consulting firm must be up-to-date and feasible for the project. In addition, the consultants must be able to master the tools they are applying. The client should therefore ask about the tool-kit of the consulting firm, where it has been developed, how it is applied and how the use of the specific tools benefit the project. Typical examples here are tools for process design and modeling.

- **Innovation ability to assist clients to develop out-of-the-box thinking.** While it is essential to master the tools being used in the project, process improvement efforts also require the ability to find and develop new and innovative solutions. The question for a client firm is, in what way the consulting firm is able to assist in this process. In this instance, there is also a potential conflict with the application of standardized methods and tools, which might provide a structured approach at the expense of out-of-the-box thinking.

- **Integration of implementation stages.** Pilots and roll-outs of organizational and technological solutions must be coordinated and different stages of the implementation process must be integrated in order to minimize time and effort. The consulting firm should be able to demonstrate implementation competence.

- **Change management in complex environments.** The client organization should ensure that the consulting firm is capable of taking on engagements involving change management in complex environments. This aspect is especially important when it comes to organizations and processes with complex workflows, structures, high knowledge content, or multiple and strong cultures. Pharmaceutical R&D is a typical example for a complex and knowledge intensive work process that requires high competence for managing change successfully.

- **Successful integration of IT.** Most process improvement initiatives include organizational, as well as technological aspects. For many companies, the implementation and deployment of IT-systems has become a business criticality. The consulting firm must therefore have a proven track-record in integrating IT in their methodology and problem-solving process.

- **References.** A consulting firm should be able to provide client references for previously conducted projects. References are a good complement to publications and quotations and prospective clients should be able to validate statements from the consulting firm through contacts with other companies.

- **Investment in R&D and training.** The client firm should require to receive information about the internal knowledge development efforts and investments in research and the development of methods and techniques. Also, the time and resources spent on staff development can provide information about the consulting firm's interest and capability to bring knowledge into the client firm, rather than using client assignments for internal development purposes.

- **Client learning.** Knowledge transfer from the consulting firm is vital to ensure long-tem sustainability of results. The consulting firm should be able to show how the knowledge transfer is supposed to take place.

- **Ability to integrate different methods and tools.** The consulting firm should not be limited to certain methods and tools, but possess a wide range of knowledge about different approaches. The focus on specific tools can reveal knowledge limitations in other areas and result in a sub-optimization of project results.
- **Focus on client’s needs instead of consultancy’s competence.** The primary focus of the consulting firm's work must be to serve the client's need, rather than promoting the own areas of competence. The client firm must investigate, how well the consulting firm's competence fits the business problems being investigated during the change initiative.

7 Process improvement in the pharmaceutical industry

7.1 The industry stage

Historically, after World War II, the pharmaceutical industry developed into one of the most profitable business sectors. The discovery of new drugs against so far intractable diseases, with about 1.000 new products in the 1950s alone, resulted in the emergence of large-scale pharmaceutical companies, often with a heritage in the chemical industry. The industry has been characterized by its dependency on blockbuster products and their patent depending life cycles, a strong vertical integration from basic research to marketing, and sales driven market behavior with a rather peripheral role in the health system it is supplying.

However, the end of the millennium has represented for the pharmaceutical industry a period of substantial change. The current wave of mergers and acquisitions is an obvious indicator of a changing sector. The creations of giants, such as Novartis, Pharmacia & Upjohn and AstraZeneca, through horizontal integration have put a focus on that business in the pharma-industry is no longer what it used to be.

Instead of pursuing a strategy of organic growth, which has been the predominant approach, many companies are now aiming for deploying economy-of-scale. In addition, some are also pursuing vertical integration strategies, as shown by the examples Merck-Medco, SmithKline Beecham-DPS (Diversified Pharmaceutical Services) and Eli Lilly-PCS. This strategy is not primarily aiming at growth within the same segment of the industry value system, may it be through mergers or acquisitions, but tries to increase the span the company covers in the industry value system, e.g. by purchasing a supplier or value-added reseller of their products. The vertical integration strategies chosen also differ between different companies. While some are attempting to integrate backwards, or up-stream, in order to purchase specialized R&D firms with a high discovery potential, others might follow a forward, or down-stream,

strategy, aiming at getting closer to the consumer and exploiting the potential margins in the reseller segment of the industry system.[12]

In 1997, more than 400 mergers or acquisitions involving life sciences (pharmaceuticals and bio-technology) companies took place worldwide (PWC global market and deal survey for 1997, 1998), with the following geographical distribution. Considering the period from 1988-97, the number of deals involving pharmaceutical companies has increased with a factor of 8.5, from 50 to 426.

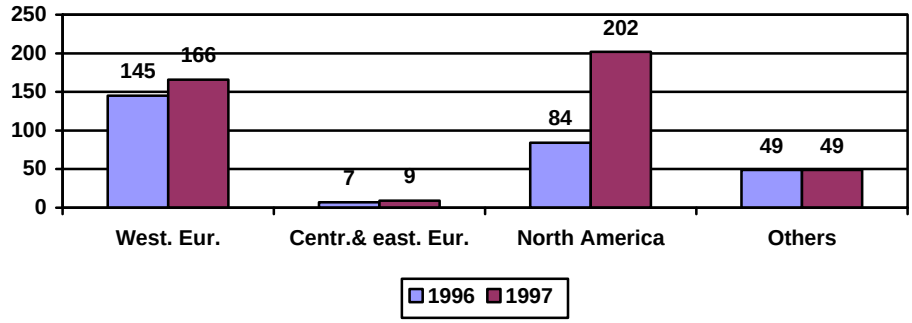


Chart 7.1: Deals in the life sciences industry

These figures indicate, that the large mergers and acquisitions, despite their publicity, only represent a fraction of all transactions taking place in the industry. The reasons for this development can be found in several areas. The most obvious is a striving for economy-of-scale and the attempt to develop stronger research pipelines and to develop capabilities for leveraging R&D results.

The pharmaceutical market structure is also very different from consumer good markets. It has been a highly regulated oligopoly with high profits due to branding and patent protection. In addition, the huge investments in R&D required for developing and testing new drugs could be passed on to patients, government health care programs and insurance companies. At the same time, the dependency on a small number of high-volume selling products makes it difficult to sustain long-term

[12] The terms forward/downstream and backward/upstream might appear confusing, since they use different "directions" for describing the same phenomenon. The reason for this terminological confusionis the existence of different ways of graphically describing industry systems, where one uses a vertical, and the other a horizontal angle.

competitive advantage and patent expirations could reverse the situation even for highly successful companies. The conflict between required investments in long-term research programs and the demand for increased short-term profits and shareholder-value is another tension creating factor, as expectations from investors are high after a period in the 1990s when the pharma-industry delivered an average of +11% in annual earnings, outperforming the S&P 500 index by 90%.

During the past few years, significant changes have taken place in the pharmaceutical industry and the future is expected to require even more radical adaptation, breaking with the paradigm of today. This means leaving the concept of organizational integration from basic R&D to marketing and creating alliances with small and medium-sized specialized companies; reducing the development of drugs for large populations and instead focusing on specialized drugs for smaller communities; embracing new information technology for managing bio-informatics and high-throughput screening.

Also, new drug indications and niche products, in combination with higher demands for documentation and drug safety[13] by regulatory organizations (US Food and Drug Administration (FDA) and its correspondents in other countries), have increased development costs and resulted in longer development cycles. The increasing costs for health care, in many countries consuming 12-15% of national spending, and the following governmental regulations regarding price setting and drug prescription have further reduced profitability. Despite the fact that profits still are high, these developments have forced pharmaceutical companies to rethink their business and to redesign their way of developing, testing and marketing products.

Similarly, industry studies conducted by consulting firms[14] urge pharmaceutical companies to overhaul their competitive focus. They commonly identify several factors that will have a considerable impact on

[13] The sleeping pill Thalomide, developed by Merrill in 1962, caused serious side effects such as birth deformities resulting from women taking the drug during pregnancy. This event was the starting point for increasing documentation requests, and resulted in drug safety becoming a priority among customers as well as drug approval authorities.

[14] Industry reports from the following consulting firms have been investigated: The Boston Consulting Group, McKinsey & Co., PriceWaterhouseCoopers, Andersen Consulting.

the pharmaceutical industry over the next years. When taking a closer look at the most important factors influencing the pharmaceutical industry in the future, we can identify the following most prominent ones.

- **Discovery.** The number of New Chemical Entities (NCEs) has been relatively low during the 1990s. A study conducted by Andersen Consulting (1997) states, that the large pharmaceutical companies have brought forward less than 1 NCE per firm during the period 1990-94. On the other hand, new mechanisms and an increasing understanding of the genetic base is expected to boost discovery in the next few years. An industry study conducted by the Boston Consulting Group (1999) projects a significant increase of NCEs in next decade, as a result of developments in pharmagenomics and technology.

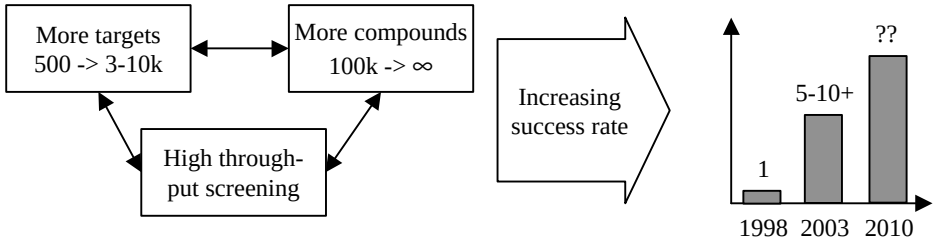


Figure 7.1: Projection of developments in discovery[15]

However, while these figures apply to large pharma-firms, a large number of NCEs will also be developed in small bio-technology firms.

- **New indications and patient community segmentation.** The result of genomic research and a better understanding of molecular intervention will allow a higher segmentation of patient communities, i.e. that drugs can be developed for highly specified indications.

- **Information technology.** Information technology has, traditionally, been considered as being a tool for improving organizational performance, e.g. in clinical trials. In fact, many firms managed to realize substantial cycle-time reductions in clinical R&D by deploying IT efficiently. New simulation models, more efficient data

[15] Analysis applies to large pharma-companies and is based on a BCG evaluation of analyst estimates.

management and the emerging field of bio-informatics promise a high level of data re-usability. The simulation of trial outcomes can also obliterate the conduct of "real-world" studies, not only saving companies high costs, but resulting in more informed decisions about research directions and prioritization.

- **Networks and alliances.** In addition to the already mentioned mergers and acquisitions, the number of alliances and partnerships, primarily between traditional pharmaceutical companies and bio-technology firms, has been increasing significantly over the past years. Also, the number of contract research organizations (CROs) has been growing and exceeded the number of 800 in 1998. Besides the out-sourcing of operational activities, such as clinical trials, pharmaceutical companies are looking for new ways of acquiring promising compounds, a process for which several strategies can be chosen: Discovery stimulation, idea acquisition, or product acquisition. (McKinsey, 1999)

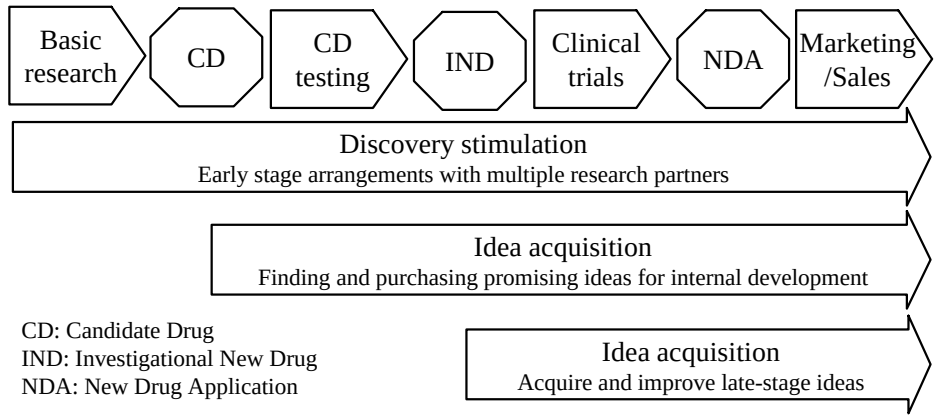


Figure 7.2: Networking and alliancing strategies

- **Requirements from authorities.** The requirements for documentation have increased dramatically over the last years. Some decades ago, clinical trials involved a handful of patients and New Drug Applications were short documents. Today, clinical research regularly involves several thousands patients and has become a lengthy and costly process, constituting a considerable investment also for large firms.

- **Blockbuster dependency.** Most large pharmaceutical companies gain a considerable share of their revenues from a small number of successful products developed in the 1970s and 80s. As patient protection for many of these products run out in the next few years, it becomes important to develop and market new products.

- **Long and short term requirements.** With a time-to-market of 15-20 years, pharmaceutical R&D requires a long-term investment perspective. In fact, most of today's blockbuster drugs, such as AstraZeneca's Omeprazole, stem from decisions made in the 1970s and 80s. On the other hand, the shareholder value concept has found its way also into the pharmaceutical industry and stock owners demand increasing short-term pay-off.

7.1.1 New challenges for pharmaceutical R&D

The return on R&D has been traditionally high in the pharmaceutical industry, but the potential is far from being fully exploited. In 1997, the market share of follower drugs among the top 100 products was 47%, thus leaving 53% of a total sales volume of 85 billion US$ to the first-to-patent company. Blocking new market entrants and increasing the own market share is therefore an important strategy for first-to-patent companies. The importance of this choice is supported by the fact that overall R&D returns are generally expected to decline not only because of cannibalizing generic products, but also due to managed care programs and excess costs for new product development.

Trying to achieve economy-of-scale and R&D synergy, drug-makers have had to downsize, consolidate, and reorganize during the past years. In an industry, where a product’s life cycle rarely lasts more than a dozen years, and profits are no longer guaranteed, efficiency suddenly has taken on a new urgency. In their striving for productivity and an accelerated pace of innovation, many pharmaceutical companies have initiated large-scale change initiatives in order to implement new organizational and technical infrastructures.

Considering that every day lost in the development of a drug equates up to $ 1 million, it is easy to understand why pharmaceutical companies are prepared to invest heavily in organizational change programs, business process re-engineering initiatives and technological solutions promising

to squeeze out time of R&D. After all, the potential return of these change initiatives is immense .

The integration of functional activities and removal of departmental barriers in the chain from pre-clinical research over clinical testing, to production and marketing, are frequently used measures. New technology for remote data collection, study management and bio-informatics is brought in place and as a result of these combined efforts, many companies have actually achieved significant cycle-time reduction in R&D. The most advanced firms today manage to run the clinical part of the overall R&D process in about 4 years, as opposed to the 8-12 years being common a decade ago.

7.2 Company setting

The research documented in this case study was conducted mainly during the period 1995-98. After the merger of Astra and Zeneca, the situation has changed significantly. A brief description of the current organization will be given later on in this chapter. However, in order to give the reader an impression of the company during the research period, the following description refers to year 1995.

AstraZeneca R&D in Mölndal is a research site within the AstraZeneca group. Prior to the mergers of Swedish Astra group and British Zeneca, the organization was, under the name of Astra Hässle, a research company within Astra. The research focus of AstraZeneca Mölndal lies on the development of pharmaceuticals for cardiovascular and gastro-intestinal diseases.

Before the AstraZeneca merger, when having its own company status, Astra Hässle employed about 1.400 people at three locations: Mölndal and Umeå in Sweden, and Boston (MA) in the United States. The company had a line/staff organizational structure, consisting of four operational and four staff units. The organizational structure depicted in Figure 7.3derives from a major restructuring project in 1994.

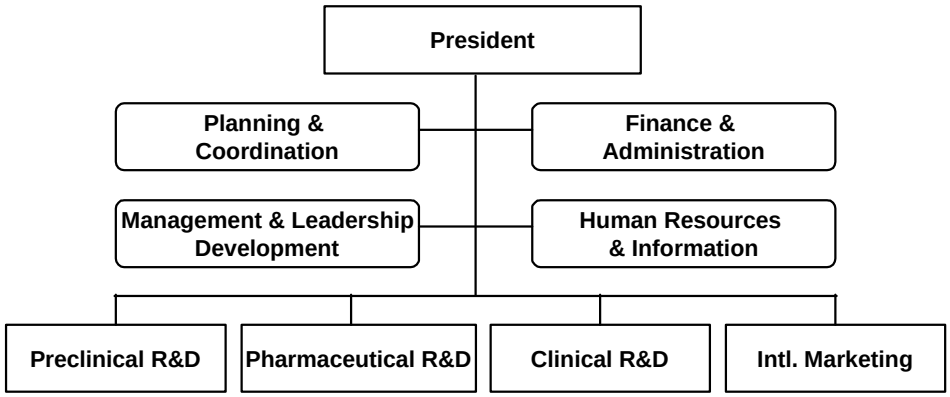


Figure 7.3: Astra Hässle's organizational structure 1994

While the organizational chart provides the image of a clear and simple structure, the real picture is more complex than that. In fact, Astra Hässle appeared to be a line/project matrix organization, with elements of local, unofficial initiatives, ad-hoc teams solving self-assigned tasks and elaborate network structures throughout the organization.

In 1997 the Astra group achieved a total sales volume of 44,9 billion SEK. For 1998 a 27% increase was accounted, raising total to 57,2 billion SEK. Products originating from Astra Hässle accounted for more than 80% of total sales. The Astra group's main product, Omeprazole (Losec©), accounted for about half of the group's sales, including licensed products, thus making it the best selling drug world-wide, but also creating a significant dependency on a single product.

The core competencies of Astra Hässle have traditionally developed and sustained in four areas–medicine, biology, pharmacology and chemistry– with a focus on technical knowledge within these disciplines. Today, these four core areas spread over a wide variety of sub-disciplines, and new competencies have been added as a result of technical development, extended research, documentation requirements and trends in society. Especially the use of information technology has begun to play a major role in pharmaceutical research, used for communication of research results, data collection and analysis of data in clinical trials, and cooperation and coordination purposes within and between research groups. The employment of IT is also industry-wide considered as a major enabling factor for successfully elevating performance, finding new indications and more efficient ways of conducting clinical trials, thus

reducing the time and resources required for testing new drugs and contributing to an increased return-on-investment and shareholder value.

In order to sustain their competitive position, virtually all pharmaceuticals companies have embarked on large-scale improvement projects. Also Astra Hässle, a research company in the Swedish Astra group, has found itself in the position of needing to elevate its organizational processes and to find new ways of employing information technology. The company has a strong record, the products developed at Astra Hässle include blockbuster substances Selocen and Omeprazole, the latter one being the world's best selling drug since 1996. Nevertheless, a considerable number of improvement projects was initiated and conducted since the early 1990s.

After several limited structural modifications, a large-scale re-organization took place in 1994, resulting in a new organizational infrastructure, consisting of four major operational units and four support areas. This new structure succeeded in delivering some operational improvement and a more efficient functional organization, but was considered as inappropriate for achieving the radical improvements the company was aiming at. Management became increasingly aware that a general overhaul of the company's business processes would be required in order to meet the goals being set in terms of cycle-time reduction, quality improvement and cost reduction. Consequently, a large-scale reengineering-style project was initiated in 1995 under the name of FASTRAC - *Fastest and Smartest to Registration and Commercialization*. The project was also considered as a major leap forward to achieve the strategic goals of the company that are to be realized by the year 2000. They comprise three new, original drugs, a total of 20 new registration applications, the establishment of a new research area and the establishment of a research unit outside Sweden. Accordingly, he new research area, biochemistry, has been established and a research facility in Boston has been opened. However, the ambitious goal for product development and registration could not be achieved with the organizational and technical infrastructure in place and the FASTRAC project was seen as the most important effort to bring the company forward in its striving for improved efficiency and effectiveness in clinical R&D.

7.2.1 Product development in the pharmaceutical industry

The conduct of clinical trials, used for investigating the effect of a drug on humans, is the final stage in the product development process. The development process as a whole consists of three sequential sub-processes. Traditionally, the three phases within the clinical trial period have also been conducted in sequence, and a major aim of the change initiatives was to parallel the planning, conduct and analysis of multiple trials within the same study.

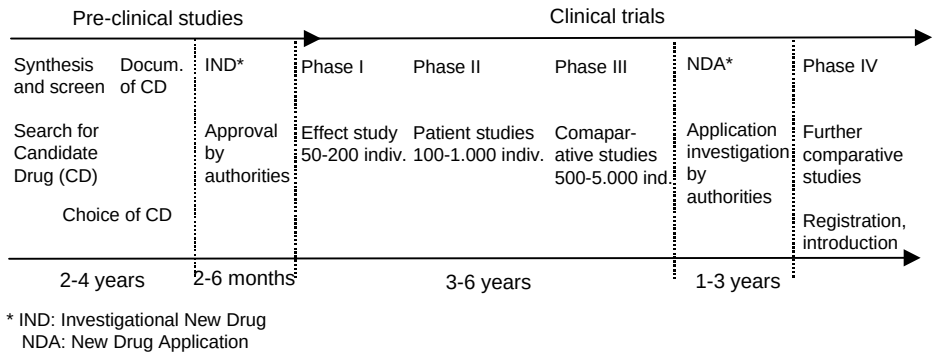


Figure 7.4: The drug development process

During chemical synthesis, different chemical substances are synthesized with regard to their usability as components in drugs. The biological testing and evaluation results in a number of substances possibly usable as drug components. These "candidate drugs" are further investigated through scientific and patent literature studies. For prospective candidate drugs, a patent application is submitted. The patent protection for a new drug begins after patent protection has been approved. All further activities are reducing the patent protection time, thus reducing the return-on-investment (ROI).

The pharmaceutical research process investigates various delivery mechanisms for candidate drugs (pill, injection, aerosol, etc.). The delivery mechanism promising the most effective absorption of the drug in the human body is developed and tested.

Clinical trials comprise a series of steps, where a new drug is tested on different patient groups. The purpose of these studies is to find the optimum dose, detect side effects, and evaluate the drugs treating effect.

These investigations are conducted at different clinics in various countries. The results of the clinical trial phase, extensively documented and analyzed, is the basis for the application for approval to the respective authorities in different countries. After approval, the product is handed over to a production unit within the Astra group, and marketed by local market organizations in various countries. In addition, further comparative studies are conducted and the use and results of the drug are monitored for control and further improvement.

7.3 FASTRAC - Reengineering à la Astra Hässle

The re-organization of Astra Hässle in general, and the clinical R&D unit in particular, did not only provide some operational improvement. It also had the purpose of preparing the organization for a general overhaul of the clinical R&D process. Consequently, in the spring of 1995, a steering group, consisting of the department managers within clinical R&D, was formed for setting up a re-engineering project for clinical R&D. The project was named FASTRAC - Fastest And Smartest To Registration And Commercialization.

Looking at the industry situation at this time, the FASTRAC project was clearly a response to the initiatives that already had been initiated in other companies. Several of these were regarded as successful BPR-style projects and the Astra Hässle senior management reasoned that, despite the current success of the company, preparations had to be made for the future. Also the fact that several patents for the Hässle blockbuster drug Losec would run out in the first years of the next decade was a contributing factor. With this reasoning, the FASTRAC initiative can be seen as a forecast reengineering project. But, when looking at the characteristics of FASTRAC, it was a mixture of the two categories crisis and forecast reengineering (see Table 5.1, page 93)

The following organizational vision, together with two mission statements, was defined for the clinical unit:

> ***Vision:*** *To be considered as the leading company in clinical research and the development of innovative therapies.*

- **Mission statement 1:** To create knowledge in the clinical area for the development, adequate use, and support for commercialization of our products during their entire life-cycle.
- **Mission statement 2:** To create medical and methodological knowledge to achieve our primary mission and to actively contribute to Astra Hässle's strategy.

Looking at these statements we can conclude that they are relevant and valid, but hardly revolutionary. Similar statements can be found in virtually all companies and leadership, best-in-practice and innovation are frequently occurring terms in corporate visions and missions.[16] However, for the members of the clinical R&D department it was an important experience to be able to define the statements and to implement them. They were also considered as being a valuable common point of reference for the FASTRAC project. During an internal meeting of the project team it was obvious, that many participants considered the vision as a source of inspiration for their contribution to the project.

The FASTRAC project was inspired by successful BPR-style projects in other pharmaceutical companies, which had been managing to reduce time-to-market significantly by introducing new business processes and organizational and technical infrastructures for supporting R&D. Early adopters of process oriented change methodologies had proven that cycle-time reductions of 30-50% within R&D could been achieved without compromising quality and safety, but with substantial cost savings. Glaxo Wellcome, considered as a main competitor to Astra, had already initiated a similar initiative and many other companies were in the preparation or starting phase of re-engineering projects.

The FASTRAC project took off by identifying three major processes to be scrutinized: Drug acquisition, clinical trials and Market support & Safety. Of these, the clinical trial process attracted most attention, since it was considered to be the most resource consuming, but also the one that

[16] **Novartis:** *Novartis is a global leader in the life sciences, committed to improving health and well-being through innovative products and services.* **Glaxo Wellcome:** *Glaxo Wellcome is a research-based company whose people are committed to fighting disease by bringing innovative medicines and services to patients throughout the world and to the healthcare providers who serve them.*

contained the highest improvement potential due to its major impact on overall R&D cycle time.

The objective and strategic intent of the initiative was clearly defined: Reduction of cycle time from *Investigational New Drug* to *New Drug Application* by at least 50%, from an average of +8 to 4 years. Since drug development is not only a lengthy, but also considerably expensive process with an average cost of $ 60-250 million, also financial aspects played an important role and the project team considered the achievable benefits of cutting time and cost in clinical trials as significant and important for sustained and improved competitive advantage.

The analysis of the clinical trial process focused on three major areas - planning and reporting, data handling, and operating values. After that vision, mission, major processes and focus areas had been identified, these initial results were presented to all members of the clinical R&D group during June 1995. From this point on, the project was transferred to the clinical unit and all further project activities were performed by people from this unit, including selection of project management and process teams.

For each of the identified areas, a project group with members from the involved departments of the clinical unit was assembled. Membership in the project groups was voluntary, since it was considered important that all members of the project team would be highly committed to the project. Of the more than 100 organizational members volunteering for participation in the project, about 30 were chosen and assigned to the three groups. The selection criteria were based on the requirement that all parts of the clinical unit should be represented and that a high number of competence areas should be covered. The latter requirement, however, only referred to the clinical area and did not include knowledge in the areas of organization or change management, since this knowledge and experience was not present in the organization.

The three main project groups, now broken up into nine smaller groups, started their work during the summer of 1995 and were supposed to deliver their analysis of the current process and their conclusions and recommendations by the beginning of 1996.

To support the groups in their work, third party assistance was contracted. A team of five consultants from AT Kearney was assigned to the project and their task was to support the project from a

methodological perspective and to perform some of the analytical work, since none of the Astra project members had more than limited theoretical knowledge and no practical experience of any kind regarding process improvements projects. While it was obvious that external guidance from consultants would be necessary to run the project successfully, the criteria for which firm that should be selected were more diffuse. A formal list of requirement or competencies for the consultants did not exist and the choice was finally made upon the basis of personal chemistry between Astra Hässle's senior management and AT Kearney's representatives. The argument was that personal fit was more important than formal aspects and that their were no substantial differences between the methodological approaches being offered by different consulting firms. This claim could actually be supported by the descriptions and comparison of process improvement approaches in chapter 6.

Members of the Astra organization, on the other hand, frequently expressed dissatisfaction with the work the management consultants delivered. However, as discussions with Astra employees reveal, this was not primarily a critique of the consulting firm in question, but an expression of the general skepticism against consultants that could, and still can, be found in the Astra Hässle organization. The consultants from McKinsey and Andersen Consulting, participating in the corporate-wide BPR-project CANDELA, were met with the same skepticism and in personal discussions, many employees at Astra claim to be "tired" of consultants. In order to draw scientifically valid general conclusions from this phenomenon it would be necessary to conduct studies in more organizations, but the Astra case could indicate that there is a correlation between the level of education and knowledge in an organization and the attitude its members have towards consultants. The AstraZeneca Mölndal site is a R&D organization with hundreds of advanced degree holders - professors, MDs, PhDs - and for many people it can be considerably difficult to accept that external consultants, without knowledge of the company, tell them "how to do things around here". This observation was also made by Christer Mohlin, who was the responsible partner at Andersen Consulting for the CANDELA project.

The project group members were assigned to the project with 20% of their working time, while group leaders were assigned with 50%. Despite the intention of reducing day-to-day workload many project participants, especially group leaders, considered themselves as being overwhelmed

with additional tasks. In reality, the regular work of the people participating in the project wasn't reduced with the 20%, respectively 50% or working time, that had been assigned to the reengineering effort. In November 1995, the work-overload had become critical to the time plan of the project and in order to maintain the original schedule, measures had to be taken. In the project master plan, a period of 6 months had been foreseen for delivering feasible proposals for improvement, and the group leaders were now allowed to dedicate 100% of their time to the project.

Lack of time, and consequently effort, that can be invested into a change effort is a critical success factor. Being unable to dedicate themselves to the initiative, people might reduce their commitment and the early momentum gains might be lost. In the Astra case, a variant of slack resources, in accordance with the design strategies proposed by Galbraith (1977) that have been discussed previously in chapter 3.1.2, were used in order to resolve this problem, in addition to the self-containment of tasks that had been achieved through the division of the project groups into nine task forces. However, it is interesting to note that this decision was taken on an intuitive basis by the FASTRAC steering group, rather than following Galbraith's strategies deliberately.

The reporting date was set for February 1 and the teams for the different sub-projects actually managed to finalize their work and presented their results according to schedule. The following 10-week period, from early February to the middle of April was dedicated to developing a project implementation plan. For this purpose, a group under the name of FIST - Fastrac Implementation Steering Team - was formed and given the task to develop an implementation plan to be realized until fall 1997. The implementation team started its work by developing time schedules for the implementation of the new overall process structure and its different parts. An important aspect of this process is to manage the transition, without loosing efficiency in the currently on-going operational activities. The company had several important projects in the research pipeline and it was made clear, that these projects could not be disrupted in any way in order to keep the market introduction schedule. This issue, however, never had to be resolved. Senior management at corporate level decided to initiate a group-wide reengineering effort, CANDELA, and the implementation of other change measures was put on hold in order to

await the CANDELA results, which were expected to contain general organizational structures and standardized processes and IT-portfolios.

7.3.1 Summary of FASTRAC outcome

The project group delivered its report on time in February 1996. In accordance with the project directives, the report contained a description and analysis of the current clinical trial processes, a new process design proposal and recommendations for infrastructure deployment. The report indicated nine areas for potential improvement of the clinical trial process, falling into three main categories: managerial, organizational and cultural. In addition, a set of actions for achieving the change was defined. The use of more advanced IT-infrastructures, especially for data collection, was identified as one of the major enablers for improvement, but no direct suggestions were made regarding specific technologies, or how they should be developed, implemented and deployed and consequently, different solutions had to be explored.

Management and control. In order to focus the available, yet limited, R&D resources on the most promising areas, adequate mechanisms for project planning, assessment and prioritization were considered critical and had to be developed and adopted. So far, too many projects had been conducted with highest priority, resulting in internal competition for resources. While this problem was experienced throughout the organization, the FASTRAC team could not easily propose measures to address it. Project priority decisions were, and are, taken at senior management level and the mandate of the project did not include the propositions of solutions outside the clinical unit. Consequently, the observation was passed on to senior management for further consideration. This phenomenon also points at the problems that are associated with driving process improvement projects within limited parts of the organization, instead of addressing the entire organization. Problems, or solutions, that are related to other organizational parts can not be easily addressed, or resolved.

Another important issue was the management of documents throughout the clinical process. While clinical R&D very often is perceived as a primarily research oriented process, document management is, in fact, critical to its efficiency. In order to shorten the drug approval time required by regulatory authorities, the preparation, compilation and

management of drug documentation can be an important area for focused improvement efforts.

A third aspect that was conceived crucial was the application of common standards and coordination mechanisms. Due to the highly decentralized structure of the Astra group, a wide variety of terms, systems, standards and protocols have been in use for different purposes. The coordination of different activities and processes enabled and facilitated by the use of common standards and terminology can contribute to a more efficient coordination within and among different parts of the organization. Also here, the problem with global aspects of local improvement efforts became evident. The terminology issue not only affects the clinical unit within Astra Hässle, but involves the other local units, but also other parts of the Astra organization that are involved in clinical R&D, such as the market companies. In order to make the development of a common terminology relevant and useful, compliance from all units would be required and achieving it is a matter of negotiation.

Structures and processes. The clinical trial process, with its average cycle-time of more than eight years, was generally considered as being too time-intensive. Paralleling work, improving coordination and cooperation between line and project were identified as the major organizational factors for time reduction, optimized resource allocation and training and competence development for study participants.

Also, the conduct of various work processes, especially phase I-III studies, was primarily sequential, awaiting completed results before initiating the sub-sequent process. Using a parallel approach to planning and conduct allows non-critical activities to overlap and thus reduce wait-states in the process (see Figure 7.5, page 172).

The implementation and deployment of a new IT-infrastructure was considered as a pre-requisite for achieving the targeted improvements of processes and the underlying organization.

Culture and values. The spirit and informal ways of doing things, considered as an important part of the organizational culture, plays an important role as informal guidelines. It can be effectively used as replacements for formalized chains of commands and bureaucratic structures, and thus reduce the need for managerial control. The re-establishment of Astra Hässle's operating values, which had become less prominent during the period of rapid growth, was therefore seen as an

important instrument for facilitating direct communication and an information sharing environment. These values and beliefs, which had a significant importance for making Astra Hässle a successful R&D company, should also be shared by temporary employees and consultants, which are used in a variety of areas, from medical research to systems development, helpdesk and systems maintenance. Incorporating temporary members of the organization into the social context of work can improve work satisfaction as well as enhance cooperation between permanent and temporary staff.

Action for change. Within the areas that were targeted for improvement, a set of measures was identified in order to assess their potential and define concrete actions which could be initiated and performed under coordination of the implementation steering committee. These actions comprised technical solutions, operational process improvements and structural changes, as well as guidelines for the re-establishment of the organizational value system. Following the steps of the clinical trial process, project planning and documentation were the first areas to be changed. The action to be taken included the introduction of clear targets for project prioritization, funding and resource allocation, as well as the development of a master plan for all activities from the investigation of a new drug (IND) to final product. Additional steps should be taken to align project documentation with requirements imposed by regulatory authorities. For making internal and external document and data management as efficient as possible, new IT-infrastructures had to be explored and introduced. Special attention was paid to remote data capture (RDC) within clinical trials and all clinical projects were urged to initiate RDC projects.

The sequential way of performing clinical R&D activities was perceived as a major time-consumer and in the new process design, it was attempted to overcome this performance limitation. Rather than running project activities in sequence, sub-processes should be conducted in parallel, thus reducing wait-states and waste of time between different activities. In addition, all clinical R&D activities were supposed to be concentrated within clinical research projects. Instead of conducting small-scale clinical studies, comparable to Phase I studies, in pre-clinical research projects, all field trials were moved into the clinical phase and conducted in accordance with the new process design. The idea behind this measure was to increase efficiency by running all clinical R&D

activities within the same organization, using a standardized process design.

Together with new business process and organizational structure, a process of cultural re-establishment was initiated. As the FASTRAC report stated, the cultural awareness initiative was promoting

> *respect for each others competence and work, clear goals, and leadership that facilitates the implementation and acceptance of the process.*

While these goals must be seen as important for the success of the change initiative, it was not clear how the actual awareness creating process should look like and what activities it should include. Due to the urge for improved operational effectiveness, the cultural issues were not actually paid a high level of attention in the implementation phase and the FIST-team did not develop an action plan within that area. Nevertheless, many employees at Astra in Mölndal have declared that the FASTRAC project actually influenced their cultural perception and opened their eyes for the need of change.

As part of its outcome, the FASTRAC project also proposed a complete overhaul of the clinical trial process to be initiated as soon as possible, including the introduction of a new set of business processes as the basis for the future organizational and technical infrastructure. In the spirit of Business Process Reengineering, which was the encompassing approach for the FASTRAC project, a strict focus on processes, cycle-time reduction and radical change was applied. Consequently, in order to monitor projects' performance and their impact on overall R&D efficiency, a set of quantitative measures, aligned with the new process, was introduced. The continuous evaluation of projects conducted in accordance with the new process design are used to inform the change team and prepare for further improvement.

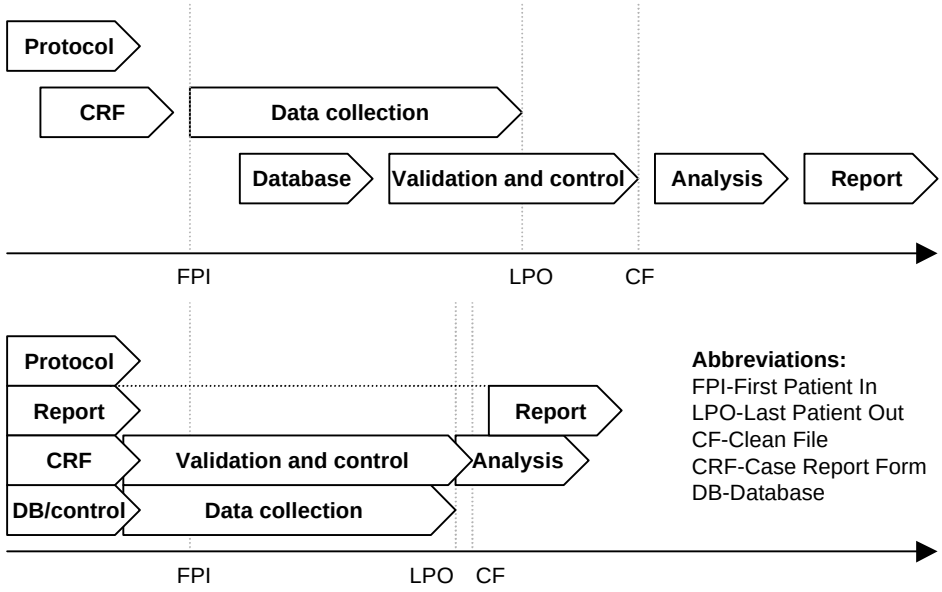


Figure 7.5: Old and new process design for clinical studies

As mentioned above, information technology was conceived as one of the major enablers of a new, streamlined and time-compressed clinical trial process. Special attention was paid to Remote Data Capture (RDC) as a technological infrastructure component that would allow a faster, more accurate handling of clinical trials. The target was set to 24 hours for the data flow from patient to the national project coordinators in each country. At the same time each department was urged to initiate an IT-project for developing a technical infrastructure for RDC and six projects were started, employing different technologies.

7.4 CANDELA - The corporate BPR upscale

While the Astra Hässle reengineering project was in progress, the urge for efficiency, time-to-market reduction and improved R&D performance had reached Astra's corporate headquarters in Södertälje. Sponsored by Håkan Mogren, President and CEO of the company, a corporate wide R&D improvement effort was launched under the name of CANDELA - Clinical Appraisal New Design Engaging Large Areas - in spring 1996.

CANDELA was promoted internally as "the key to our vision" and as the "project to take Astra into the next millenium" and ambitious goals were

set and communicated throughout the Astra organization when the project was presented:

> *The objective of the project is to position Astra as one of the top three pharmaceutical companies, as measured by speed of product development, adherence to goals, efficient use of resources, methodology and quality of clinical documentation.*

Together with the vision, a set of objectives and principles was developed and announced. These additional statements were aimed at clarifying additional project objectives and means to achieve them.

- **Objective 1: Optimizing key clinical R&D processes.** The key processes for clinical research and development were under scrutiny also in the CANDELA project. For these processes, a standard design and operating model was to be developed and implemented in all Astra research companies.

- **Objective 2: Maximizing return on marketing investment.** Marketing investments are considerable for new product introductions in the pharmaceutical industry. Increasing ROI in marketing was seen as an important measure for improving the financial performance of Astra.

- **Objective 3: Prolonging the protected time of products.** Extending patent protection can be achieved in two ways, (1) by shortening time from IND to NDA and (2) by developing improved versions of a product, e.g. by changing delivery mechanism or prolonging other patents than those for the chemical entity itself. The CANDELA project, with its focus on process improvement, had the first option on its target list, whereas the second one was considered as being an issue for pre-clinical R&D.

- **Principle 1: Clarity in all processes.** In order to avoid mis-interpretations of how work should be conducted, all processes must be described in an unambiguous way. This includes not only operating procedures and workflow, but also clear lines of authority and decision making.

- **Principle 2: Simple solutions to complex problems.** For most problems, solutions with varying levels of complexity can be found.

For the CANDELA project, simplicity was an outspoken goal. This aim included straightforward process descriptions, decision taking mechanisms and execution of tasks.

- **Principle 3: Individual responsibility for implementing continuous improvement.** While large-scale and radical process elevation, such as targeted in the CANDELA project, continuous and incremental improvement of daily operations was considered as being an individual responsibility for all employees.

- **Principle 4: Transparency in prioritization, allocation of resources, and decision making.** In order to direct peoples' efforts into the most important directions, it was seen as necessary to make the basis for project prioritization and the subsequent allocation of resources clear and transparent.

A project organization, consisting of the project sponsor Håkan Mogren, a steering committee comprising representatives from all product companies and senior executives, and 9 project area managers for key R&D and support processes was formed. An overall project plan with a total time frame of 3 years (1996-1998) for the project was developed.

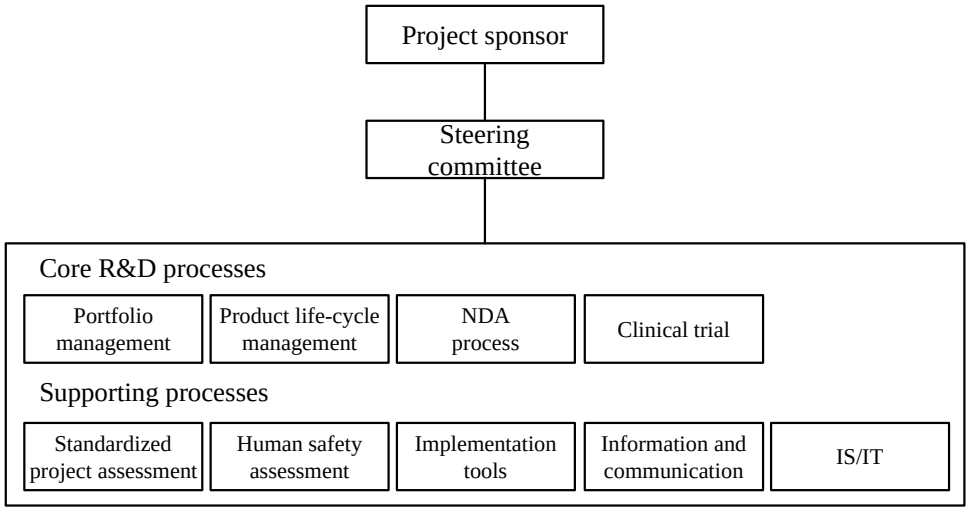


Figure 7.6: CANDELA project organization

The methodological approach for the CANDELA project followed the traditional model for BPR-projects, with an initial analysis and assessment of the current operations and their performance, followed by a

design phase, and concluded by an implementation phase with re-assessment, fine-tuning and continuous improvement. At an early stage, several critical success factors for change programs were identified and also communicated in the Astra organization.

- **Poor communication.** It was early realized, that poor communication constitutes a serious threat to the buy-in of all members of the organization. Frequent communication was therefore considered as a high-priority took place via information over the intranet, and a news-bulletin.

- **Poor implementation of change.** The CANDELA team also realized, that change programs are not only a matter of sound analysis and consistent and good design of solutions. Implementing the designed processes, organizational structures and IT solutions is actually as important as design itself.

- **Inadequate resources.** In the FASTRAC project, the initial lack of time resources jeopardized the project time schedule until this problem was resolved by additional time assigned to the project. Intending to avoid this situation, and others that could be referred back to lack of resources, the CANDELA project was well financed. Another reason for the generous resource provisioning was the fact that CANDELA was considered as the Astra-group's flagship change project and that a lot of prestige had been invested in it.

- **Poor follow-up.** A change initiative does not end with implementation. The introduction and roll-out of new processes must be followed by an on-going evaluation of results and a program for continuous improvement.

It was also pointed out that the CANDELA project was proactive and future oriented and not intended to be a fix to current problems. As a counter-example to CANDELA, the FTTM (Faster Time To Market) project at Ciba-Geigy (now Novartis) was used. The Ciba project realized a 63% increase of productivity in clinical development and a significant cycle-time reduction was achieved. If, it was argued, Ciba could achieve these dramatic results despite the shortcomings of the project set-up and conduct, it should be possible to realize even higher gains through CANDELA, which was described as being superior in terms of approach and project set-up and management. Especially it was pointed out that

CANDELA used a bottom-up approach as opposed to the top-down analysis and design employed in the Ciba case.

The Ciba-Geigy case has also been described briefly in a report from consulting firm Coopers & Lybrand (PriceWaterhouseCoopers, 1997), that had been involved in the project. Despite the fact that the provided description must be seen as a marketing instrument, it still reveals some interesting aspects of the Ciba project. The FTTM-project was clearly intended to be a time and cost control initiative and did not have the primary ambition to be a full scale BPR-project. The goal was to reduce annual R&D expenditure with 10% and to establish a management control structure for the R&D process. The employed methods, activity analysis and financial analysis, are typical top-down approaches. Considering the different levels of ambition and scope of FTTM and CANDELA, it was clear that the methods being used by Ciba-Geigy could not be used at Astra and the comparison was therefore somewhat irrelevant. On the other hand, it provided an instrument for pointing at the superiority of CANDELA and boosting motivation in the Astra organization.

The CANDELA project continued with the development of a high-level process map, showing the core and support processes and their sequence on a general level. This overall sketch was submitted to the steering committee and approved as the basis for analysis and solution development. The sub-sequent work was assigned to sub-process task forces and coordinated by a project management team.

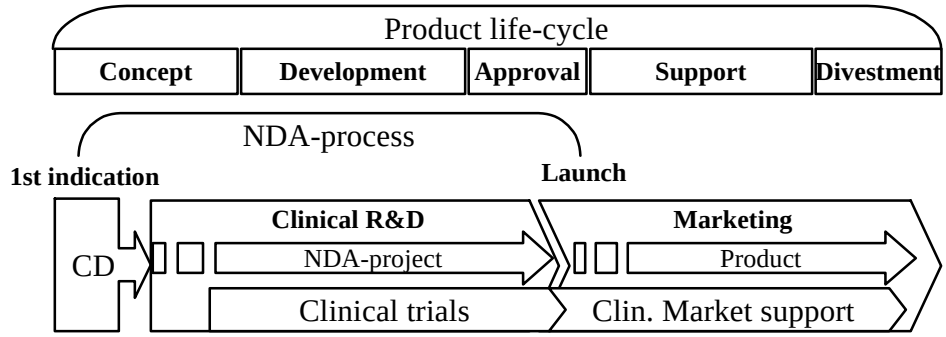


Figure 7.7: CANDELA overall scheme for clinical R&D[17]

At that point, a consulting team from McKinsey & Co. was brought into the project in order to assist the internal project management team. Individual consultants had been participating in the project since its beginning, but the McKinsey team was assigned in order to provide methodological support for the development and implementation of a master plan for the implementation of change measures and to provide administrative assistance to the CANDELA management team with regard to planning, co-ordination of the sub-teams and the identification of resource requirements. It was rather clear, that the external consultants would play an assisting role, but not being the ones driving the project forward.

The McKinsey team conducted its work in compliance with the methodological approach described previously in chapter 6.5. Initially, the existing processes were mapped and described with regard to their shortcomings. In the next step, the existing processes were integrated with new design ideas and a projection of potential benefits and problems was developed. In several iterations, alternative process designs were developed, rejected, or modified, until a final design was agreed upon and approved by the CANDELA management team and steering committee.

On the basis of the new process design, a list of the prioritized changes was compiled and also this list had to pass the approval process. Once the list had been approved, a master plan for implementing the change action was developed, including a sequential description of the different steps to be conducted in order to ensure a migration to the new processes without

[17] The schema presented here is a sub-set of the original image, covering only the aspects being relevant to this thesis.

disrupting the current operations. The master plan also included a set of tollgates and mechanisms for measuring implementation progress, based on the delivery plan and critical path.

7.4.1 The NDA-process

One of the most important processes within clinical R&D is the New Drug Application. The NDA contains all documentation of the new drug, including a description of its chemical composition, its indication, and the results and analysis of the clinical trials. Since regulatory authorities take their decisions regarding the approval of a new product mainly based on this application document and the supporting documentation, the NDA is the critical delivery within the clinical R&D process.

When CANDELA was initiated, Astra was considered as being an "average performer" with regard to managing time efficiently in the process from Candidate Drug to New Drug Application. The average Astra project had a total lead-time of 8.8 years, with an industry average of 8.7 years and this was far too much for a place in the top-performer list of the industry. The CANDELA steering committee approved a proposal comprising three main areas.

- **Process analysis and description.** The analysis and description part of the project should focus on the description of an overall NDA-process and its sub-process, including definitions and terminology, optimum lead-times, risk assessment and management and critical success factors and milestones.

- **Toolbox.** The toolbox part was supposed to develop a common set of tools and principles for managing the NDA-process efficiently, including measurements and measure points, monitoring mechanisms and performance data collection.

- **Roles and competencies.** The third and last part of the NDA improvement initiative was investigating the required competencies and roles for managing the NDA process and its continuous improvement.

The task groups for these areas worked with a common set of long-term objectives for the new NDA-process, of which the time-related one was most important. Other goals referred to performance criteria and requirements for efficient process management and continuous

improvement. The NDA project team also identified and outlined a set of critical success factors for the timely delivery of New Drug Applications. These factors involved not only the clinical organization, but stretched over a variety of areas within and outside the company as a cross-functional process.

Adequate planning of the entire NDA-process was considered as the primary success factor. Planning, in this context, does not only mean that the content and sequence of activities are pre-defined, but that a target date for the finalization of the NDA is set upon initiation of the NDA-process after authority approval of a Candidate Drug. Proactivity towards regulatory authorities was another aspect being taken into consideration.

IND- (Investigational New Drug) and NDA-files had been following a standardized pattern, often resulting in "over-delivery" of documentation, i.e. that more documentation than required was submitted together with the application for approval. Since the authorities could neither reject, nor ignore, the additional information, its evaluation extended the cycle-time for authority approval. A pro-active attitude towards regulatory authorities was considered as an effective instrument for preventing this form of ineffective behavior. Engaging in a dialogue with regulatory authorities could reduce the volume of documentation submitted, thus lowering the workload for Astra, as well as for the authorities and resulting in a faster handling of the NDA.

It was also understood, that the planning and conduct of the NDA-process is not only a matter for R&D functions, but affecting a variety of units within the company and cooperation partners, such as contracting organizations for clinical trials, chemical and pharmaceutical units and the marketing organization in various countries. As a consequence, all these entities being involved in the process were be considered in the planning phase in order to run the process in an integrated environment and paralleling activities when possible.

Early participation of other part of the Astra organization, such as Health Economics, Quality of Life, Epidemiology and Marketing was not only seen as a way of improving the quality of clinical studies, but as a means for ensuring that product pricing and reimbursement strategies could be taken into account already in the planning phase of clinical R&D. In order to enable this cooperation across organizational borders within the organization and with regard to external partners, it was necessary to

develop a common terminology, that would cover all aspects of clinical R&D and that would become a part of the process model, common tools and standard operating procedures that comprised all activities within the process.

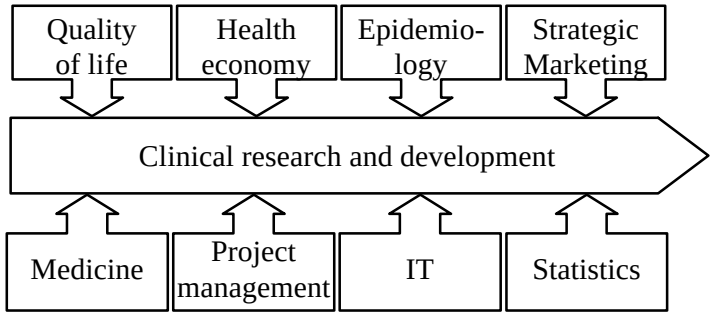


Figure 7.8: Competencies needed in clinical R&D

All these requirements imposed on a new NDA made it imperative to have an elaborate and consistent model for planning and running the process. The planning model must include aspects such as the availability of internal and external resources, a funding model being independent from the annual budgeting of the functional organization and roles, responsibilities and accountability for project progress. In addition, it must contain milestones and delivery and decision points. In order to bring all these aspects together, a task force was formed to develop a project management model that would allow to run and control the NDA-process efficiently, without hampering flexibility and problem solving.

We can also conclude, that CANDELA affected more parts of the organization than R&D functions and that the project became a truly global initiative not only in terms of the corporate-wide implementation of its results within R&D, but also with regard to its impact on different functional parts of the organization.

7.4.2 Clinical trials

Since clinical trials are the most time-consuming part of clinical R&D, this area was considered as being the most promising one with respect to cycle-time reduction. For the new clinical trial process, an average cycle-time of 235 days, excluding authority approval was assumed to be an achievable objective. The investigation was conducted in seven task groups, each being responsible for one area.

- **Process description,** being responsible for developing a new model and description of the new clinical trial process. The new model should take into account the CANDELA objectives, but also be built on the best practices to be identified within Astra and other companies.

- **Planning, monitoring and reviewing** emphasized the planning aspects of clinical trial management and had to develop tools and procedures for setting up, monitoring and following up trials.

- **Performance management** focused efficiency aspects of clinical trial management and had the task of identifying performance measures and benchmarks and mechanisms for implementing them in the process.

- **Protocol and report approval** looked at procedures and tools for designing case report forms and study protocols. In addition, tasks, roles and responsibilities for approval of these documents were investigated.

- **Recruitment.** Clinical trials involve the recruitment of investigators and patients. Since patient recruitment usually consumes a considerable portion of overall trial time, fast recruitment and the avoidance of over-recruiting was considered as a high-prospect time saver. The task of this group included the design of recruiting principles and performance measurement for recruitment by investigators.

- **Remote Data Capture** (RDC) was analyzing how information technology could be used for reducing the time and effort required for patient data collection and transfer from the study center into the Astra information systems. The task of the group also included the assessment of the value-adding potential of RDC technology and the investigation of commercially available systems.

- **Data management** is the process of handling data from clinical trials for analysis and report writing. The working group was given the assignment to develop new procedures for data management, including clean-file.

The different working groups were supposed to deliver a result report within a few months, in order to allow the implementation of the new

clinical trial process for all new R&D project under 1999. The aggregated results were used as a basis for a new process design and documentation, which was used as input for the overall design and integration by the management team.

7.5 IT-aspects of FASTRAC and CANDELA

In both projects, information technology was considered as a key to improving business process performance in two ways. (1) Information technology could accelerate process performance by reducing transaction cost and time and (2) it could enable process designs that were impossible to consider without IT. This reciprocal relationship was a red thread in both projects, but was more prominent in the late phase of FASTRAC, whereas CANDELA had a stronger focus on the supportive functions of IT.

7.5.1 IT aspects of FASTRAC

It was obvious to the FASTRAC team, that the employment of current and relevant IT could deliver a major leap forward for implementation of the proposed change agenda. Consequently, serious efforts were made to investigate possible IT infrastructures for providing support to clinical trial projects. As a measure to improve performance in clinical data handling, special attention was put on RDC (Remote Data Capture), i.e. the collection and transfer of clinical data by means of technology. The use of RDC based technological infrastructures was seen as a way of satisfying organizational and technological needs of the new process design. As the result of the identified need to improve data collection and management, six projects employing different technologies were initiated. Of the technological solutions being chosen, some were based on packaged solutions, that were adapted to fit the clinical project in which they were supposed to be used, whereas other solutions were in-house developed systems.

- **Apple Newton.** For a quality-of-life study, a system for data entry by patients was developed and implemented on 130 Newton PDAs (Personal Digital Assistants). The PDAs were distributed to the investigators in the study, but data entry was actually conducted by the patients in the study. The data collection was based on multiple choice lists and ticking boxes and was well received by the users.

Since the study involved patients with a wide age variety, it is notable that mainly positive comments were received from users.

- **Internet.** Using the Internet as carrier for remotely collected data is currently explored, and a first trial application has been in use since April 1998 with promising results. Medical personnel at the test center enter the clinical data directly into the central database at Astra Hässle through a Web-interface. This RDC-system, termed COOL (Clinical Operations On-Line) uses the in-house developed AMOS-system for data management and is basically a WWW-technology based data entry interface.

- **Bedside continuous data collection.** Collecting data directly from bedside medical equipment is a way to collect highly accurate patient data without interfering with the treatment of the patient. It also makes the manual collection and transfer of data obsolete, but is only feasible for a limited category of patients. For trials with patient not being stationary treated in a hospital, this technology is not feasible.

- **Datafax/OCR (Optical Character Recognition).** For studies with low reporting frequency and standardized measures, i.e. handwritten notes are not used, the transfer of data via fax with subsequent optical character recognition is a low-cost, yet sufficiently efficient, way of collecting data.

- **AMOS C/S client/server) on WAN (Wide Area Network).** AMOS is a study and data management system developed internally by Astra Hässle. In its client/server version it consists of a proprietary client for data entry and access and a database. The AMOS system had been in use at Astra Hässle for some time and its proprietary interface was commonly used for data entry in most clinical projects where paper CRFs (Case Report Forms) were entered into the system at Astra Hässle. It was considered technically possible to provide investigators or local marketing companies in other countries with a client-version of the software for direct data entry into the AMOS-system, but the concept never reached full-scale implementation.

- **SCODA: Semi-RDC.** The SCODA system used a 2-tier client/server architecture for data entry and storage. The client module contained an electronic version of the paper CRF, being able to save and handle multiple records. The transfer between client and server module is

achieved through a modem-connection to a private network. This system is conceptually close to the AMOS C/S solution, but included the possibility to store patient records locally in the client module.

The solutions being investigated for managing data collection in clinical trials more efficiently ranged from traditional forms of data capture, over client/server based architectures to Internet-based RDC. In parallel to the development of the various technological infrastructures, a new process for clinical trials was developed in the FASTRAC-project. The strategic intent of the reengineering initiative was, of course, to align the business process and its procedures with the use of an IT-infrastructure for data collection. However, the in-depth analysis of the deployment process of one of the technical solutions, SCODA, indicated that there was a discrepancy between the globally designed business process and the procedures for working and technology deployment developed at the local level.

7.5.2 IT aspects of CANDELA

As the CANDELA project was aiming at redesigning R&D at corporate level, a very wide perspective was taken with regard to the technical support systems. For the IT-aspects of CANDELA, a team from Andersen Consulting was brought into the project. The task of the consultants was to assist the project management team in the selection and assessment of products that could be considered for the global IT-portfolio and to test and evaluate the different portfolio options in a business simulation.

The build-vs.-buy-vs.-partner debate was extensive in the project and from within the Astra organization, many comments regarding this issue were received by the CANDELA team. It was decided at an early stage of the project, that packaged solutions should be considered in the first place, rather than looking into the possibility of developing systems in-house, or partnering with an external vendor of systems development services.

This decision was justified with the argument that is was essential to free resources from developing basic systems in-house to concentrate instead on systems that have more specific functionality and provide more benefit to the R&D process. According to the management team, this would not mean to compromise with functionality and usability of the systems to be selected. Furthermore, it was pointed out that this policy

would not apply to all existing systems, but primarily to new ones and those that had to be replaced at the end of their life-cycle.

With regard to the relation between the local and global project it can be concluded that the CANDELA goal to use packaged solutions was not totally in line with the intentions of FASTRAC, where no such limitation was found. The technology options of FASTRAC included the internal systems that were already in use within Astra Hässle and did not exclude the possibility of developing in-house systems, since many of the standard system available on the market were considered as being insufficient in terms of functionality and long-term deployment.

Another issue that was raised during the project was the competitive advantage that technology could provide. It was argued, that the same packaged solutions and portfolio could be purchased by any competitor to Astra and that it would be impossible to realize advantages relative to Astra's competition, if the system portfolio was based on standard solutions. The project management team responded to this issue with the following clarification.

> *This* (the replacement policy) *does not mean that...*
>
> *...we blindly select packages and sacrifice functionality that is necessary for our business. The objective therefore, is to free scarce resources to work on solutions that will radically change the way we do business and not just core functionality which may already be available in packaged solutions.*
>
> *...we immediately replace all custom built systems that exist within Astra today. When these custom systems reach the end of their life, they will be replaced where possible by package solutions.*

It was also concluded that the benefit of IT would not come from technology itself, but from the support it could provide to standardized business processes that were used throughout the organization.

The CANDELA-team developed several portfolio options, comprising different combinations of standard products. The portfolios included systems for supporting multiple aspects of clinical R&D: Analysis & Reporting (A&R), Data Management, Electronic (Remote) Data Capture

(EDC/RDC), Product Life Cycle Management, Project Management, Safety and Study Management.

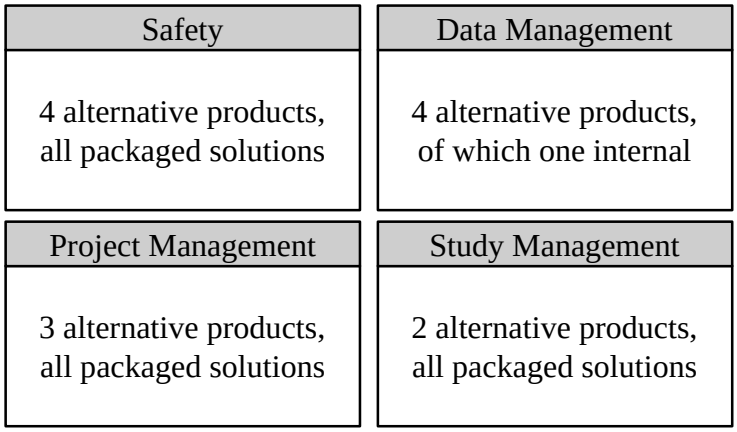


Figure 7.9: Alternatives for the product portfolio[18]

The products to be included into the portfolio options were selected upon a set of weighted measures, where strategic fit, product quality and supplier quality were the main evaluation criteria. After some further discussions in the project management group, however, these original criteria were complemented with some additional measures - functional fit, product integration and cost - in order to better reflect purchasing and deployment aspects. Of all evaluation criteria, functional fit was considered as being the most important one, with a relative weight of 32%.

The products being considered for the corporate standard portfolio were then analyzed with regard to their functionality and ability to be used together in projects. This selection process resulted in the final selection of a subset of the products being included in the first list. Among the remaining products, clear preference was given to one alternative in the areas Safety and Study Management and of the three options for Project Management, only one remained after the first evaluation round. The final recommendation included four alternative portfolios, of which two were considered as preferred choices.

[18] Product names have been removed due to confidentiality reasons.

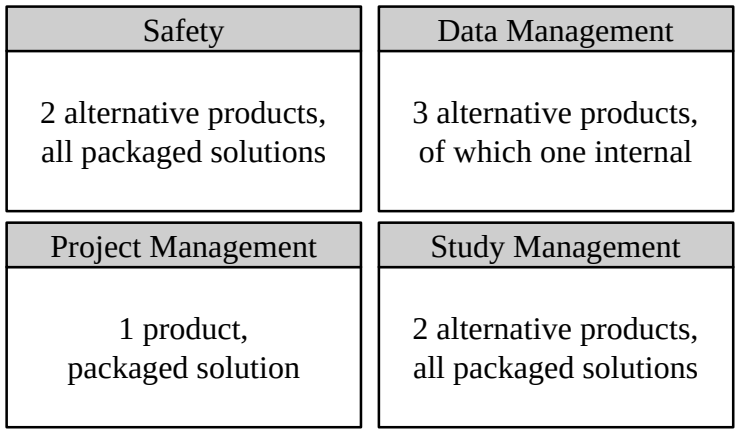


Figure 7.10: Final selections for the product portfolio

In parallel, the different products were analyzed with regard to their costs and benefits. The cost analysis included software purchase, configuration and maintenance, required internal and external implementation resources, data conversion, training and system support. Direct costs for software licenses were gathered from the respective vendors, whereas additional costs were estimated upon the experience from the internal IT-department and the Andersen Consultants. The benefits were estimated indirectly by calculating the projected time-savings and opportunity costs. The first estimation, resulted in a total cost of 170-290 MSEK, depending on the chosen products and including software, training, implementation and data conversion. Additional 11-21 MSEK cost for maintenance on an annual basis were added.

The recommended portfolio options were developed in early 1998. For the business simulation phase, a period of six months was projected in order to implement and test the different solutions. This time plan was aligned with the overall schedule for CANDELA, in which the final decisions regarding the new process design were projected for the end of 1998. With a beginning in early 1999, the implementation and roll-out phase was supposed to be initiated.

The CANDELA project was discontinued in January 1999 as a result of the merger between Astra and Zeneca.

8 A closer look at SCODA

The FASTRAC and CANDELA projects both included an overhaul of the data collection process in clinical trials. Considering that clinical trials regularly involve thousands of patients and that they are conducted on an international basis, it is obvious that managing patient data accurately and efficiently has a substantial impact on overall performance of the clinical trial process. The options for Remote Data Capture (RDC) technology that had been considered in the FASTRAC project included SCODA[19], a 2-tier client/server system, developed and marketed by an independent software company.

The SCODA-system was, on the other side, not a part of the product portfolio options being developed within CANDELA. However, since the systems being investigated there were similar to SCODA in terms of functionality and technical architecture, SCODA can be said to be representative for the basic approach to RDC in CANDELA. We have therefore chosen the SCODA-system for a more detailed study and analysis of the data collection process and the relation between organizational and technological aspects in the deployment process of a business process and an IT-infrastructure.

The implementation and deployment process of SCODA was studied during a period of one year. During this period, a series of interviews was conducted in Sweden, Germany, Spain and the United States. The interviewees were study monitors in these countries and data managers and study managers at Astra Hässle in Mölndal. In addition, a close dialogue with the Clinical IT and Data Management department within the clinical unit at Astra Hässle was maintained. The clinical project that we have followed during the research project was a relatively large study, conducted at 500 centers in 12 countries, and comprising 4.000 patients and can therefore be considered as being representative for clinical projects in general.

It was obvious from the beginning of the study, that the implementation and deployment of an IT-infrastructure is not an organizational and technological issue alone and that these aspects cannot be investigated

[19] SCODA was the Astra-internal name of the product.

and considered independent from each other. An important role is played by the dynamics between these factors; dynamics resulting in tension between global and local aspects of the company's organization and processes. Consequently, we have chosen to focus our analysis on the tension between global and local organizational procedures and technological flexibility.

As the project revealed, the actual outcome of the deployment process is different from the anticipated use of technology and the globally designed organizational procedures are subjected to modifications and work-arounds. The infrastructure in use is, in fact, the result of the interaction between business processes and the use of information technology, rather than a result of a deliberate planning process and management control mechanisms. The case study also shows, that the design and introduction of global standardized processes and technologies certainly contains a significant improvement potential, but that disregarding the aspect of local adaptation puts limits to the understanding and deployment of the infrastructure in use.

8.1 The SCODA-system

SCODA is a data capture application for collecting and entering patient data in clinical studies. It is part of a product suite offered by the vending firm, comprising components for study design, data entry and management, communication and data analysis. The technical solution is based on a client/server system, consisting of a data entry support application running on a laptop-computer, and a central server component for data aggregation and analysis. The connection between clients and server is established through modem links over a commercial global network.

The SCODA application interface represents a digital version of the traditional paper-based case report form (CRF), that is used by the investigators for the first step of the data collection process. The study monitors, being responsible for data entry, use this electronic CRF for transferring patient data into the computer-based system. Most of the collected data consists of numbers, describing the status of various medical variables, such as blood pressure, etc. If additional information regarding the patient or the treatment is annotated by the doctor, the monitor can open normally hidden fields in the electronic form with a simple mouse-click and enter the supporting information.

At a first glance, the interface gives a user-friendly impression, but it lacks of some fundamental functions that are crucial for supporting a clinical study as a whole. It is basically the reproduction of the paper folders, i.e. it does not provide support for study management, which is the other important tasks of monitors. The monitors can not easily access the state of work, the status of recruitment for the study and for individual study centers. The study management capability is basically limited to individual patient records, but doesn't include the collation of results. Editing and monitoring is limited to one patient record at a time. Upon submitting CRFs via modem to Astra Hässle, requests for further specifications or error notifications can be received in return. In this case, the problem is checked locally by the monitor, eventually corrected and the record re-submitted to the central database. The work process for using the system is strictly sequential – data entry cannot take place disregarding the structure and sequence of data entry fields pre-scribed by the electronic case report form – and empty fields are not accepted by the system.

The data handling at Astra Hässle took place in the in-in-house developed AMOS database system. The AMOS-system is basically a relational database system that was developed locally, with the help of an IT-consulting firm, by Astra Hässle, resulting from the lack of a corporate-wide portfolio and the limitations of packaged solutions that were considered as being insufficient for supporting the needs and requirements for clinical R&D at Astra Hässle. Other R&D units within the Astra group had chosen other solutions, either self-developed or standard packages, but AMOS could match most of these systems in terms of functionality and was also considered for the global IT portfolio during the CANDELA project's portfolio selection.

8.2 The data collection process

The choice of the new organization and technological infrastructure was based on the rationale of supporting clinical studies with a time-saving tool for data collection and transfer into the central database for data analysis and the development of supportive documentation for the New Drug Application. It was also anticipated, that data quality would increase due to shorter feedback cycles between study monitor and the investigating and documenting personnel, doctors and study nurses, at the study centers. Since data cleaning, i.e. the consistency check and

validation of clinical data, has a considerable impact on the time being required for the clean-file procedure, i.e. the correction or removal of errors in the database, further time savings were anticipated for the overall clinical trial process.

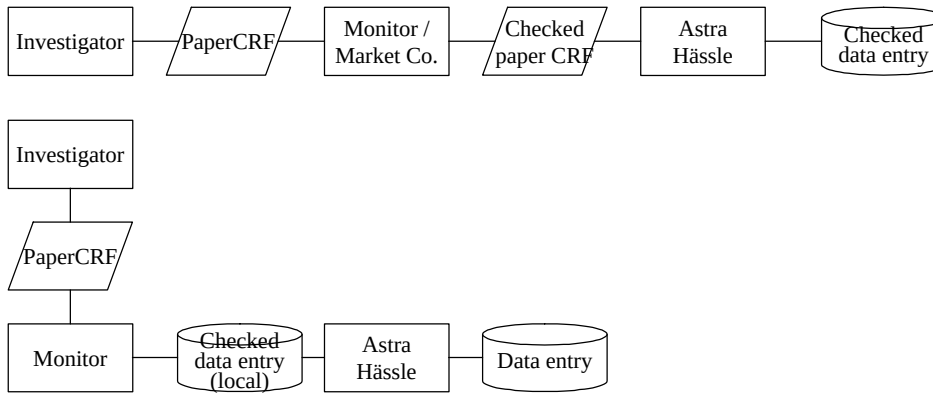


Figure 8.1: Old and SCODA data collection process

The new process was aiming at bringing data collection and quality control together at the study center and for this purpose, the traditional roles and responsibilities in clinical studies were modified. In most previous studies, data collection was conducted by investigators on paper-based CRFs, that upon completition were sent to a central data entry facility, in most cases AstraZeneca in Mölndal, that maintained a special group of people being occupied with keying clinical data into the database systems for cleaning and analysis. For this clinical project, this process was changed in the way that investigators still would collect data on paper CRFs, but data entry into the electronic system became a task for the study monitors.

Study monitors are a group of well-educated specialists being occupied with supporting investigators during the studies and managing clinical projects locally in their countries. In order to realize the intention of reducing the time needed for data cleaning and the handling of clarifications, the role of monitors was changed. From primarily being concerned with data cleaning and local study management, the content of their work spanned over a wider part of the process, including the actual data entry into the computer system that is considerably time-consuming.

The monitors reacted in a differentiated way to this change of their work. While they realized that there was a potential time-saving that could be

exploited by moving data entry to the study sites, they had two basic objections. Firstly, monitors consider themselves as being primarily local study managers and not data entry personnel. The new process was thus to some extent conflicting with the professional pride that monitors have in their work and competence. Secondly, several practical factors were mentioned that would hamper the actual implementation of the process in the form it was designed.

8.3 SCODA case analysis

The final report resulting from the FASTRAC initiative contained an analysis of the existing organizational and technical clinical trial infrastructure and recommendations for a new process design and other areas for improvement. However, the project outcome did not include a specific recommendation with regard to technological solutions or implementation strategies for either new organizational or technological infrastructures. While it was stated that Remote Data Capture would have a significant potential for reducing cycle-time in the data collection process, no concrete decisions were taken regarding which solutions that should be chosen and implemented and consequently, clinical project leaders were facing the responsibility for introducing project-specific RDC-infrastructures. This phenomenon was also observed in other projects and the development of organizational and technical infrastructures specifically for each project can be said to be the typical, yet undeliberately chosen, strategy for setting up and conducting clinical R&D projects.

The technology to be used for facilitating remote data collection was chosen locally for each clinical project, based on knowledge about available systems in the Clinical IT department, where several alternatives had been initially investigated for future consideration in clinical projects. At the same time, the clinical IT department did not have the mandate to propose and develop a common systems portfolio that could be used in all clinical projects within Astra Hässle and therefore, the decisions regarding choice and implementation of RDC-systems had to be taken by clinical project managers.

Also in the SCODA project, the system selection followed the same rationale. The system was chosen as the result of discussions between the project leader and the Clinical IT department. It had been developed by a small development company that specializes in systems supporting RDC.

Moreover, it had recently been purchased and implemented at large scale by another pharmaceutical company, Glaxo Wellcome, and was therefore considered as a safe choice.

However, the system was not originally developed for being used by study monitors, but for data entry by investigators, and the data entry process embedded in the system followed this design rationale. Accordingly, the system was highly functional for data collection, but lacked substantial functionality for monitors' main task: study management. The lack of functionality in the study management area was also mentioned as the major source of dissatisfaction by all monitors that were interviewed during the research project.

8.3.1 System implementation and training

The SCODA system was used for a study of considerable size, 4000 patients in several hundred centers located in 12 countries. Implementing and deploying organizational and technological infrastructures for large scale studies on a global basis is neither simple nor intuitive. This lesson had been learned by Astra Hässle during previous projects and consequently, the SCODA implementation process was planned thoroughly.

The RDC-software, used as the technological component of the new infrastructure, had not previously been used within Astra Hässle. It was also employed for the first time for use by study monitors in a combination of data entry and study management, instead of being used for data entry by investigators only, for which the system had been developed originally. In this way, the deployment at Astra Hässle also differed from the use of the system at Glaxo Wellcome, where the use of SCODA had been limited to data collection by investigators, whereas study management was conducted with the help of a different technological solution.

Due to the limited experience with the software within Astra Hässle and its intended use by study monitors, training was considered as an important issue for successful deployment of the new technology. All study monitors received a 2-day hands-on training. Despite these efforts, the training period was considered insufficient due to several reasons.

- The training was actually based on a beta version of the product that was not fully functional.

- Some specific new functions, required by Astra Hässle in order to adapt the system to the use by monitors instead of investigators, were not part of the version used for training.
- When the system was delivered in its final version, the monitors had to adapt to this version before it could be put into production.

8.3.2 Work procedures

Together with the new technological infrastructure, the organizational procedures for clinical trials were overhauled in order to fit with the new way of technology deployment. Instead of collecting paper copies of medical records, which then would be shipped to Astra Hässle for data entry, monitors were supposed to stay on-site at the study center and enter the clinical data into the SCODA system. According to the new process, some pre-cleaning of the clinical data should take place in conjunction with the data entry and the monitors were supposed to discuss unclear data on the paper-based CRF and other problems with the investigator directly on-site, and then transcribe the data into the SCODA system for transfer into the central AMOS database at Astra Hässle. However, interviews and discussions with monitors being involved in the project revealed, that the actual process in use deviated from the theoretical design and several reasons were given.

- **Time limitation:** Depending on the number of test centers for monitoring, their geographical distribution throughout the country and the time required for study management and data entry, excessive travel could be required in order to follow the procedure.
- **Budget constraints:** The project budget is negotiated between Astra Hässle and the local market companies in each country in advance of the project. Consequently, when more traveling than anticipated is required, the result is a conflict between the requirements imposed by the global process design and budget constraints.
- **Inadequate facilities:** The study centers were not considered during the process design and were often unprepared for hosting monitors. They were often unable to provide the necessary physical office space and investigators were not prepared to spend the necessary time with the monitors.

As a result of these tensions between the global process design and the locally imposed constraints, several varying instances of the process could be found in the different countries that participated in the clinical study. In these cases, the monitors tinkered the process in order to manage the contingent requirements. A typical situation is that monitors obtained a copy of the paper-based CRF and did data entry at home or in their own office at the local Astra subsidiary, rather than spending time at the study center.

8.3.3 Project management and "serious adverse events"

As mentioned, the SCODA-system was originally designed for supporting investigators at local study centers in their data entry. The main focus of the system was therefore to enable a structured and sequential data entry process. Considering the work of study monitors, we find that process and content are rather different. Data is entered at different times and in varying sequences, and data entry and study management are interwoven activities. However, the monitors were expected to comply with the rather strict and sequential process design developed around the use of the SCODA system.

In order to reduce the time required for data entry and cleaning, i.e. the checking of data for consistency and completeness, the procedure requires monitors to stay at study centers. The rationale behind this design is the opportunity to discuss eventual problems directly an immediately with the responsible investigator. However, in practice it is impossible to interrupt the investigator's ordinary work for every occurring question. Alternatively, the monitor might enter all data without interruption and then discuss deviations and problems with the investigator. This alternative procedure is not facilitated by the system.

Study monitors also maintain responsibility for study management at local level. In order to facilitate effective study management, a computer system would need to contain additional functionality, such as accumulated recruitment figures and patient status information. The system does not fulfil these requirements and monitors had to use an inductive procedure through the CRFs for obtaining study management information.

An important aspect of clinical studies is the handling of so-called *serious adverse events*, e.g. side effects of the investigated drug or other unexpected events, such as suddenly increasing mortality of patients in

the study. When these events occur, regulatory authorities require that the are to be reported to the study management within 24 hours. Due to the asynchronicity of the system, i.e. data is collected and delivered with delay and not immediately available at Astra Hässle, it is impossible to include the handling of serious adverse events into the system. As a consequence a manual procedure, based on phone and fax communication, has to be set-up in parallel with the computer based data collection process.

A second aspect related to system asynchronicity, and common for all client/server systems with local data storage and manipulation, is that information is not available centrally before it has been transferred from the client application to the server. Considering the complexity of the architecture and the movement of the client system between different sites, it is obviously difficult to ensure a smooth and continuous data flow. Also, data may be stocked in client applications, e.g. as a result of technical problems, which might result in over-recruitation of patients into the study. Consequently, central study management and data analysis at Astra Hässle is heavily depending on the functioning of local client systems.

8.3.4 System choice and implementation

During the SCODA project, a considerable discrepancy emerged between the needs being experienced and expressed by the study monitors and the organizational and technological support provided to them. This was not clear and obvious from the beginning of the study, but emerged during the roll-out of the technical solution and the implementation of the organizational procedures. The main source for dissatisfaction was found in the job enlargement of the study monitors, that was not accompanied by appropriate organizational and technological support.

Data collection is, in most pharmaceutical companies, not a task that normally is conducted by study monitors, but by specialized personnel. In the SCODA project, monitors were expected to handle their regular tasks - local study management and providing assistance to the investigators at study centers - but also data collection was included. The work of monitors has also been characterized by different timely and spatial constraints that are imposed by the design of a clinical research project, the goals being set for local market companies and the resources being assigned to the study.

Obviously, the objectives and performance of these tasks are partially in conflict with each other and this tension is influencing the organizational and technical infrastructure of the project. The infrastructure deployed in the SCODA project was primarily chosen to support and increase performance in the data collection activity. The rationale and design idea was that the use of a common computerized platform, used for data cleaning with help of the investigators and digital transmission, would enable a faster, more accurate collection of all data required for analysis and the sub-sequent drug registration. Following the intentions of the FASTRAC project, driven as a typical BPR-project, time reduction was the dominant implication for choosing the SCODA system, as time consumption in clinical trials was identified as one of the most important factors for long time-to-market.

As a result of this strict time focus, other aspects of data collection and study management, such as a user friendly administration of study centers, had to stand back. The need for supporting effective local study management by monitors, their timely constraints and the lack of space at study centers were considered as subordinated factors in relation to the time savings that could be achieved by a fast deployment of the RDC-system without major adaptations. As a result, the tension between the different rationales governing the SCODA project at different levels had a considerable impact on the infrastructure deployment, i.e. the way of using the system and complying with the organizational procedures that were designed around it. Understanding the different rationales and intentions of the project at global and local level and the tension that was resulting from them is therefore imperative for improving the performance of future projects.

Looking back at the outcome of FASTRAC, it was obvious that momentum was too important to be lost in long-term evaluations of different options and the development of a set of business processes and a standardized IT-portfolio that would support and improve all aspects of clinical trials. Including the previous re-organization of the Astra Hässle organization, almost four years had been spent on organization and process analysis and visible results were needed for justifying the project and maintaining confidence in the capabilities of the company. Within the Astra Hässle organization, the project advertisement had also created a sense of urgency and expectation and many employees were anticipating considerable changes and improvement. In this sense, the

SCODA project was not a failure. Despite the shortcomings of the technical component, the deployment of SCODA and the other RDC-infrastructures was well in line with the FASTRAC results contributed to developing a change awareness in the organization.

The initiation of the six RDC-projects can, at least partly, be seen as the consequence of these expectations and the requirements for improvement. Clinical project leaders realized situations where they felt obliged to chose FASTRAC compliant technological and organizational infrastructures for their projects, but also to conduct the clinical tests within given time and budget frames. Since FASTRAC did not include detailed selection or implementation guidelines, the systems were chosen and implemented in accordance with decisions taken by clinical project leaders or the technical responsible in the projects. In the case of SCODA, the system was purchased from an external software company, that took care of implementing the software as well as system maintenance. The system provider was also furnishing the network supporting the data transfer.

Consequently, a division of competencies for project support to monitors took place. Technical aspects were taken care of by the software company, and content or study related problems by Astra Hässle's project helpdesk. Several monitors, however, expressed doubts about this division, since the borderline between technical and content related problems was not clear to them, or to the help-desk staff. Before contacting the help-desk, the monitors had to determine whether the encountered problem is related to the study itself or to the technology employed, a question that often was considered as difficult to answer. Moreover, simple technical problems, that could have been fixed easily by the local IT support staff, had to be solved by the system provider in the Netherlands. A monitor in the USA described a situation where the laptop-computer had to be sent to the system provider in Europe for repair and re-installation and configuration of the RDC-client software. This proceeding was part of the contractual agreement between Astra Hässle and the software provider and related to warranty issues, but the monitors experienced this situation as time-consuming and frustrating.

Summarizing the results of the analysis, the SCODA deployment reveals the presence of different, and partially conflicting, rationales behind the decisions governing the selection, implementation and deployment of the RDC-infrastructure. On one hand, providing an appropriate infrastructure

to support monitors' work was considered as important for improving overall performance in the clinical trial process. On the other hand, the chosen solutions had to be simultaneously compliant with the FASTRAC recommendations, i.e. to reduce cycle-time in the clinical trial process, which caused a dilemma when systems had to be selected. The monitors' working situation and experienced problems, related to local conditions in the countries participating in the study, are highlighting issues that can't be solved by implementing a system and process that primarily follows the rationale of cutting time and does not take into account the local circumstances under which it is used.

Considering the implemented solutions for all clinical projects, and the different rationales governing the underlying decisions, one can conclude that there was a significant amount of patchwork in the system selection and implementation process. While the performance and outcome of most studies was not affected by these aspects, the SCODA project experience has shown revealed several factors that need to be taken into consideration.

The system was chosen and implemented to reduce cycle-time in data collection, while monitors' expectations included functionality for study management. In addition, the system came bundled with a process design and organizational procedures, i.e. that the project infrastructure for SCODA was a combination of information technology and organizational elements, partly conflicting with local objectives and environmental constraints. Consequently, the monitors were tinkering the infrastructure they had been provided with in order to adapt it to their local conditions, while still complying with the objectives of the SCODA project.

8.4 SCODA as an infrastructure

In the SCODA project, the underlying foundation has been the design and use of a global business process, supported by high-end, standardized technology. The aim of this infrastructure, which actually can be considered as a bundle of a computerized system and organizational procedures, has been to achieve compliance with the strategic intent of the FASTRAC project.

Consequently, the selection of the SCODA infrastructure was not the result of cultivation (Dahlbom and Janlert 1996) or evolutionary processes in the organization, but stemmed from a single point of

reference: The FASTRAC recommendations. Considering the span of FASTRAC, including new business process design and organizational change as well as cultural aspects, the SCODA project not only concerned the implementation of a computer system, but implicitly addresses the problem of interaction between technology and organization.

8.4.1 Change and drift

When analyzing the design and use of infrastructures, especially in large and multi-national organizations, it is crucial to understand the dynamics that occur as a result of the change process. Firstly, we have to consider the interplay between technology and the organizational structures and processes that surround it. Secondly, the tension between global and local, between design and inscription on the one hand, and local use and adaptation on the other hand, need to be considered. Distinguishing between global and local aspects also allows us to refer to the magnitude of the change process. Change at infrastructure level does not only concern new forms of performing certain organizational tasks. It actually means to redefine their underlying foundation, the skeleton around which operational activities are built.

The FASTRAC project at Astra Hässle was conceptually based on the idea of radical and disruptive change and followed the steps being required for change initiatives under the label of Business Process Reengineering. The implementation of new technical infrastructures is a standard element of BPR efforts and in this sense, the SCODA project is not different from other initiatives. The BPR literature frequently pinpoints the mutual relationship between processes and technology and IT is considered as a supporter, as well as enabler of new organizational forms and procedures. However, when looking at the BPR-approaches presented in chapter 6 and considering the conduct of BPR projects, the enabling concept often falls short. Instead, an in-depth analysis and detailed design of business processes is used as the point of departure for the IT-related aspects of the initiative, resulting in customized support systems for new process designs.

A perspective of the relation between IT and organization being similar to the one advocated in the BPR literature, though from an academic and more theoretical perspective, is promoted in the Strategic Alignment Model (SAM) (Henderson and Venkatraman, 1993). The SAM is pushing

the idea of matching organizational structure and information technology to achieve an inherently dynamic fit between external and internal domains, comprising business strategy, IT-strategy, organizational infrastructure and processes, and IT-infrastructure and processes (Henderson and Venkatraman, 1993). The role of infrastructure is generally regarded as being an enabler for new pre-defined organizational forms and procedures. The SAM model's attempt to bring together multiple facets of the organization is, however, a difficult undertaking as, Charles O'Reilly, professor at Stanford University has noted:

> *When we say organization what we mean is an alignment, and one of the reasons changing an organization is hard to do is that they are aligned in multiple dimensions and just getting one or two dimensions newly aligned doesn't work.* (Source: Consulting Magazine, issue 4, 2000)

Both approaches are based on the assumption, that organizational and process change initiatives and the implementation of infrastructural changes are fully plannable and predictable in their outcome. However, the study of SCODA suggests something different, namely that changes processes are dynamic and not fully predictable and that the implementation of new organizational procedures and IT-infrastructures are an inseparable element of this processes. Consequently, the outcome of the implementation of a new infrastructure is not fully predictable and the *infrastructure in use* is different from the ex-ante design.

Ciborra (2000) refers to this process as drifting, but does not necessarily consider it as being negative. On the contrary, drifting can be a way of balancing the bounded rationality of top-level decision makers, which are unaware of the aspects that influence the local units of the organization. In the SCODA case, this top level is represented by the process and systems designers at Astra Hässle, whereas the monitors are representing the local organizations that drift in their use of the centrally designed procedures and technology support.

A similar argumentation lies behind the use of divisionalized organizational structures, as described in chapter 0. The bounded rationality, i.e. the cognitive limits, within top management, a concept that has been introduced in chapter 3, is balanced by the introduction of operational divisions. Williamson (1975) has pointed out, that the decentralization of decision making that comes along with this

organizational form also contributes to balancing the opportunistic behavior of middle management, since it facilitates a stronger identification with corporate objectives and reduces the favorization of local goals at the expense of the central ones.

In the context of SCODA, it was clear that the local adaptations of the global process and the resulting work-arounds were opportunistic, but not necessarily in the sense that global goals were disregarded. The opportunistic behavior of monitors can rather be considered as a way of maintaining focus on the global goals under the limitations being imposed by local circumstances. Consequently, we might be able to speak about this behavior in terms of altruistic opportunism.

8.4.2 The global and the local

The change management and infrastructure literature uses several assumptions that, at a first glance, are rather clear and obvious. However, when taking a closer look, they appear to be somewhat simplified. A typical claim is that introducing new IT in institutionalized organizational procedures will enable strategically defined positive externalities. This claim is expressed for example by Broadbent, Weill & Clair (1995), but is also part of the strategic alignment concept and other proposals for business renewal, such Tapscott and Caston's (1993). In these contexts, the role of IT-infrastructure is clearly defined. It is an engine for business globalization and standardization of procedures throughout the global enterprise.

The analytical model normally employed in projects aiming at strategic change and following the reengineering and alignment philosophy is based on a description of business processes, the rational evaluation of change options, and the identification and implementation of the best innovative technologies and procedures to improve organizational performance from a given and well-defined point of departure. The position of infrastructure in this context is to enable and accelerate the defined business processes on a global level, where it is implicit that global means uniform. Shared databases and common sets of organizational procedures, often combined with workflow technology, are frequently proposed as measures to cope with diversity, which is considered as a disturbing factor in the process of creating a global organization and implementing standardized business processes.

Consequently, the role of the infrastructure becomes more complex. Instead of being a means for supporting and improving business performance, it also becomes an engine for reducing variation and diversity in organizational processes. As Lévy (1996) puts it: The organization is striving for ”universality with totality”. Following this argumentation, globalization is not perceived as the process of organizing and doing business worldwide, but as a way of constituting a global institution, and thus to a large extent a process of *standardization*. Through standardization, local characteristics are homogenized to the global, predefined ones. The result is thus uniformity rather then globalization.

A major imperative for the implementation of change based on the concept of standardization is the alignment of organizational structure and processes on one hand, and IT-infrastructure and its deployment on the other hand. Each form of misalignment or variation in the adoption process is considered as an organizational pathology, rather than an effect of local adaptation in the implementation process, and must consequently be removed or re-aligned in accordance to the pre-defined business process or action plan.

The SCODA case reveals, that local adaptation of the globally defined infrastructure, variations in organizational procedures, and differences in the use of IT are characteristic elements of infrastructure implementation and deployment processes. Otherwise, globalization would be nothing more than the upscale of a local implementation process, and the global organization a larger extension of the local one. In this case, the process of globalization that many companies are struggling with would be relatively simple. To organize world-wide, however, means to deal with local circumstances and dynamics, without loosing perspective on the common goals of the global organization.

Summarizing the result of the case study we can conclude, that infrastructure implementation and deployment is highly situated. Situadedness derives from specific organizational needs, but is also strongly influenced by the dynamics of the change process, such as global and local organizational politics and power games. Instead of creating a single infrastructure, alternative systems were implemented to comply with the FASTRAC recommendations, partly for investigating different technological threads, partly due to a heterogeneous image of the planned change. Analyzing the specific infrastructure used in the SCODA project.

we have found an approach to change based on different levels of tinkering and improvisation, rather than reengineering and strategic alignment. (Ciborra 1997)

8.5 Organization and technology: reciprocal inscriptions

The relation between global and local aspects of an infrastructure, which we have found to be an endogenous element of its implementation and deployment process, can be analyzed through the concept of inscription (Akrich 1992). Using this approach, we can describe the world as being defined by the reciprocal interaction between objects and subjects. ”Objects are defined by subjects and subjects by objects” (ibid., p 222), i.e. that the world is inscribed in the object and the object is described in its placement.

This concept of reciprocity in the relationship between two phenomena lies at the core of the analysis of the relation between technological and organizational inscription with regard to local and global dynamics in infrastructure implementation. Taking this point of departure, we can describe how inscription occurs at technology and organizational level and what impact it has on the relation between IT and organization.

- **Technology inscription** can be defined as the rigidity of the technology in constraining the users in the way they are related to the technical object. In other words, it refers to the way technological systems can be used within or outside their design and which forms of work-arounds the system allows or prevents.

- **Organizational inscription**, on the other hand, reflects the level of freedom or rigidity in organizational procedures or, in other words, the extent to which organizational agents are allowed to reshape the ways in which the technical object are used with respect to organizational rules.

As a consequence of this relationship, organization and technology interact and reciprocally shape the organizational context that is resulting from their interaction. Technology is providing a platform for performing organizational activities, and the way of using the technology in the organization "situates" technology itself. Consequently, organization and technology can not be considered as separate entities, but must be seen as

"flip-sides" of the same coin. Looking at organizational improvement initiatives, the reciprocal relation between IT and organization leads us to the conclusion, that it is impossible to isolate and improve either of these aspects without taking into account the other one.

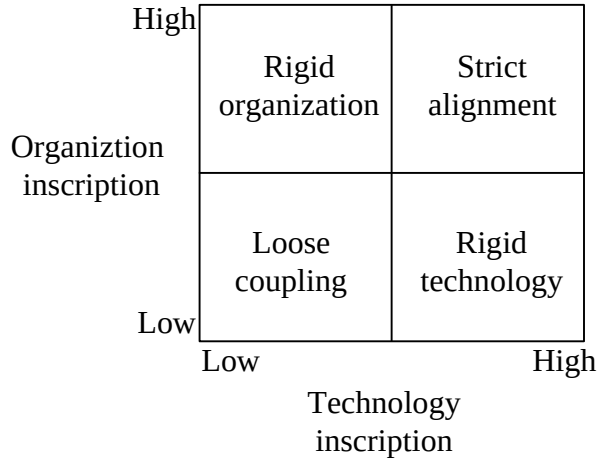


Figure 8.2: The framework for analysis

The two-entry schema provides a combination of alternative scenarios based on different inscription levels in its two dimensions - organization and technology - and allows to characterize different ways of conceiving infrastructure and its deployment. The entries in the table represent four alternative infrastructure implementation contexts.

Strict alignment. In this case, the design of organizational procedures leaves no room for local adaptation. At the same time, technology is rigid: There is no option for use outside the defined context. Standardization of technology and organizational procedures and strict alignment between these elements typically characterize the infrastructure. In most process improvement initiatives, the aim is to develop and implement a strictly aligned organizational and technical infrastructure, following a pre-defined process design and using information systems that are supporting this design efficiently. Both improvement initiatives at Astra that have been investigated here also had this intention.

Rigid Technology. Organizational procedures are open for local adaptation, while technology does not permit changes in use. Infrastructure is characterized by tensions between global and local

organization procedures aiming at satisfying the same objectives, but differing in the means for their achievement. Despite the original intention to develop a strictly aligned infrastructure, the SCODA case falls into this context. The reason can be found in the lack of control that was exercised with regard to process compliance. It was assumed that all monitors would comply with the globally designed process and senior management was not aware of the local adaptations that took place.

Loose coupling. Organizational procedures and technology use can be redefined and adapted locally. The infrastructure allows adaptation to internal and environmental dynamics and is typical of knowledge intensive organizations. During the FASTRAC project, some voices already claimed that the company should aim at developing an infrastructure that would allow local adaptations and combine standardization with flexibility. During 1998, some middle managers in the clinical unit started to develop a framework that was less rigid than the BPR-track that had been followed in the FASTRAC project and also governed the CANDELA initiative. At that time, also some senior managers had adopted a more open view and advocated a loosely coupled infrastructure concept. However, the concept was never actually implemented, since the merger with Zeneca stopped all local initiatives of this kind.

Rigid organization. In this context, organizational procedures are strictly defined at global level, while technology is open for modifications. The infrastructure is characterized by tensions between different technologies adopted at local level, or local variations in technology use. This context is typical for a post-merger situation, where the merging firms are aiming at developing a common and standardized set of organizational procedures, but maintain their individual technical infrastructures. The AstraZeneca organization can here serve as an example.

Obviously, the four contexts presented here can not serve as a prescriptive model for selecting the best possible infrastructure for a given organizational setting, or for optimizing an organization using a specific technology. Rather, they can be considered as an explanatory model to understand possible interactions between organization and technology and to outline the characteristics of the infrastructure in use in these two dimensions.

8.6 SCODA - a rigid technology example

The infrastructure adoption process at local level can define or redefine the infrastructure in use. When this redefinition takes place, the actually deployed infrastructure differs from the globally defined organizational procedures, or prescriptions regarding the use of technology.

In the case of Astra Hässle, the infrastructure in use in the SCODA project, is resulting from different local organizational adaptations due to the low level of organizational inscription. The monitors use different procedures, developed on the basis of a local organizational context, to fulfill their task, e.g. data entry is not always done on-site in the study center, as prescribed in the global process design. At the same time, technology inscription is high, the IT-system does not allow a local customization.

While standardized technology can be used for achieving a high inscription in the technology dimension, local factors can have a considerable influence on the implementation of organizational procedures and therefore, subsequently, on the infrastructure in use. In the Astra Hässle case, the different local adaptations of the global organizational process are creating local, modified instances of the globally defined infrastructure and are therefore affecting and re-shaping the global infrastructure and the way globalization is achieved.

Following the argumentation in chapter 8.5, the SCODA infrastructure is not only constituted by the used technology and its highly inscribed characteristics, but is a result of the reciprocal relation and interaction between two dimensions, the organizational and technological. Limiting the analysis of infrastructure to either one of these dimensions, without taking into account the other, would provide an image of reality that is considerably different from what has been found in the case study.

The analysis of the technological dimension alone would lead to the conclusion that the infrastructure in fact is standardizing organizational procedures and resulting in globalization in terms of uniformity. Looking solely at the organizational dimension, we would find a non-articulated and uncoordinated puzzle of locally defined activities. In order to understand the scenario in which the organization is situated, as well as its implications for the infrastructure in use, it is thus important to take into account the organizational and technological dimensions and their level of inscription.

9 Conclusions

9.1 Conclusions from the SCODA case

The analysis of the case study at Astra Hässle allows us to identify some critical factors for the introduction and implementation of a new infrastructure for the clinical trial process within the AstraZeneca organization. Even though the lessons learned stem from a specific case, they can be applied in a wide variety of organizations.

It was observed that there is a divergence between the originally designed and anticipated way of working and the actual local work procedures being applied in the project. At the same time, the study of the technological infrastructure being employed for data collection and entry has revealed two major shortcomings. (1) The technology only supports a sub-set of the tasks to be conducted by monitors in the project. (2) The technology in its organizational context does not facilitate organizational processes to be fully compliant with the recommendations of the FASTRAC change initiative. The infrastructure in use is thus the result of a deliberate planning process regarding the design of organizational procedures and the selection, implementation and use of information technology, intertwined with dynamic and unpredictable elements due to non-anticipated local adaptations.

In order to comply with legal and other requirements, clinical trial processes require certain rigidity, and thus a minimal general level of specification. As shown in the case study, a process definition and general rules for IT-use have been introduced through the FASTRAC framework: the global level of organizational inscription. However, IT-use was characterized by adaptation into its local organizational context: users actions took place at local level. Consequently, global design and inscription are only one element in the infrastructure adoption processes. Local adaptation and the unfolding of local inscription are other factors that influence the emerging work process and infrastructure use. In this case, the traditional managerial approach to study infrastructure deployment is not fully sufficient to describe and understand the *infrastructure in use* and the global and local dynamics influencing it.

Soh et. al. (2000) have identified four resolution strategies for handling the misfit been organizational and technological aspects. Their work is concerned with the implementation and deployment packages, but the strategies they outline are generally valid.

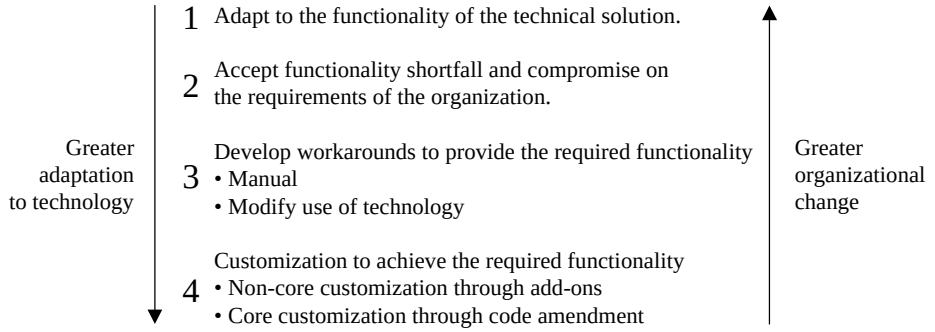


Figure 9.1: Misfit resolution strategies

The analysis provided by Soh et. al (ibid.) do not explicitly discuss global and local aspects of implementation and deployment, but they address the issue of implementing "best-practice" processes together with the technical solution, that do not fit the organizational requirements of the user organization. A similar point has been made by Brynjolfsson (1993). He used the term *productivity paradox* to describe the phenomenon that increasing investments in IT often only provide marginal performance improvements. and identified the lack of congruence between organizational requirements and IT-functionality as an important reason. The research results being presented by Soh et. Al. And Brynjolfsson, even though stemming from a different technology application area, are congruent with the results of the study presented here and leads to the following conclusion.

Infrastructure deployment has to be considered as the outcome of the interaction between global design and inscription and local adoption, rather than as the result of a deliberate and straightforward planning and implementation process. Local adoption processes regularly result in adaptation of global specifications and the development of locally situated technological use and organizational procedures. Different contexts of interaction can be identified, depending on the selected organization and technology: rigid organization; rigid technology; strict alignment; loose coupling.

9.2 Consequences for process improvement initiatives and approaches

The process improvement initiatives conducted locally at Astra Hässle (FASTRAC) and corporate-wide (CANDELA) both followed the Business Process Reengineering concept. BPR, in virtually all of its incarnations, is based on the idea of designing global business processes, supported by standardized IT-solutions that are adapted to fit and follow the process design.

The approaches to process improvement being used in practice, of which four have been described and compared in chapter 6, also support this interpretation of how BPR initiatives are actually implemented. The more theoretically oriented methodology descriptions, such as the one presented in chapter 5.7.1, provide an equivalent image: Organizational processes can be designed in a rational way, the best technology can be chosen and a global and standardized infrastructure, consisting of a set of business processes and IT-solutions, can be implemented and deployed. All deviations from the standardized design are considered as pathologies that must be removed and the process re-aligned with the original design.

Also in the SCODA project, which was part of the FASTRAC initiative at Astra Hässle, the same rationale was governing the development of the clinical trial process and the technological support system. However, the local instances of the global process showed deviations from the ex-ante design. These differences were the result of local process adaptations that were not anticipated by the designers. However, this phenomenon of "drift" (Ciborra, 2000) in the use of IT and the compliance with organizational process definitions did not emerge as a result of insubordination, but as an attempt to handle the incompatibility of globally defined goals and locally imposed constraints. This goal incongruence is similar to the phenomenon described in chapter 4.4.5, where processes are shared between several super-processes.

When looking at the process improvement approaches that have been described in chapter 6 we can conclude, that this issue is not explicitly addressed. Instead, the idea of top-down design is governing the methodologies, assuming that local deviations and adaptations can be avoided by inscribing certain behavior into the process. However, the results of the case study suggest, that the aspects of global and local should be included into the methodological framework for process

improvement in order to capture and address the dynamics that influence the organizational and technological adoption process.

9.3 Towards a new model for clinical R&D

The traditional hierarchical models for organizing have been proven to be inadequate for coping with the challenges the pharmaceutical industry is facing. The need for shorter product development cycles and new discovery and development strategies require other organizational structures than those imposed by the bureaucratic paradigm of the early industrial era, which was targeted at the mass production of standardized goods.

In order to adapt their organizations, processes and IT-solutions to the changing environment and competitive situation, many pharmaceutical companies have embarked on large-scale improvement efforts, following the dominating change approach of the 1990s, Business Process Reengineering. However, as the descriptions of four BPR-methods in chapter 6 and the results of the Astra Hässle case study have shown, that the BPR concept, as described in the literature and applied in practice, does not include the consideration of local implementation and adaptation issues in a way that allows to address them in a satisfying manner. Also, the rigid way of considering infrastructures and deviations from the pre-defined design does not seem to fit the clinical trial process at Astra Hässle. Consequently, it became necessary to develop a new organizational model that would allow the local adaptation of business processes and technology use, without compromising operational efficiency. Together with members of the Astra Hässle organization, a model based on three building blocks - process, project, center of excellence - has been developed.

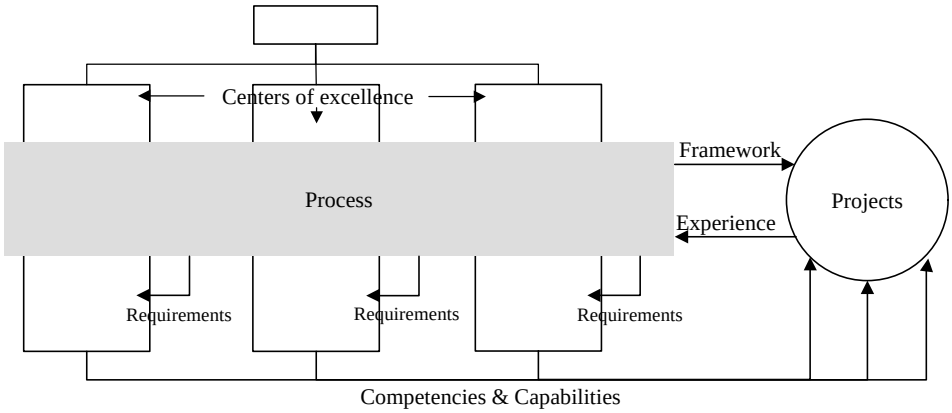


Figure 9.2: New model for clinical R&D

The application of this model, as simple as it might appear, allows the company to establish clear responsibilities for each of the components and relationships between them and to overcome the deficiencies of the previously used models - hierarchy and business processes with a high level of specification and prescription of behavior.

Process. The process represents a conceptual framework for clinical projects. It contains a collection of the practices, methods and tools being required for conducting clinical research in an efficient way. The process is developed and managed by a process owner, i.e. a person being responsible for the improvement of the elements being part of the process, such as organizational procedures and IT-infrastructure. Process development, in this context, means to include the experience and knowledge gained from previous projects, but also to consider external developments, such as emerging technologies and developments in other firms. The content of the process also describes the competencies and capabilities to be provisioned from the competence areas to the clinical projects. While the concept of process ownership is similar to the one proposed in the business process improvement literature and methodologies, the term *process* has a different meaning. Instead of being a detailed prescription of work procedures, it must be seen as a collection of good practices, recommendations and experience, supported by Standard Operating Procedures only where they are required by regulatory authorities. For non-regulated activities, the process leaves room for local adaptation and improvement in the clinical projects.

Projects. Today, clinical R&D is generally performed in project form, rather than by combining the activities of functional units within the line organization. A project is the instance of a process, where the methods and tools are deployed in a "real-world" setting, i.e. it contains the clinical research for an actual substance. Within a project, the framework provided by the process is used together with the competencies and capabilities provided by the organizational competence areas. The provisioning of services from competence areas to projects takes place on the basis of a market model. From the projects, experience gained is brought back into the process, which can be improved continuously according to the feedback provided. Projects are run by a project manager, who is assigned on a temporary basis for the duration of the project.

Centers of excellence. Competencies and capabilities are provisioned to projects from centers of excellence or competence areas, which are based on the functional units of the "traditional" organization. Competence areas can also be described as defined communities of practice within their functional areas. In this setting, the role of functional managers changes from supervisor to coach. In the coaching role, the continuous development of functional expertise plays an important role and must be matched against process requirements, as described in chapter 4.4.7-4.4.9.

9.3.1 Clinical Operations On-Line

In order to facilitate an organizational model that does not use detailed organizational structures or highly specified business processes, it becomes necessary to develop IT-systems that can be deployed independent from organizational structures and processes. A first step into this direction was taken through the development and use of COOL (Clinical Operations On-Line), an Internet-based system for clinical data collection. The COOL-system does not require that specific peoples or roles - investigators, monitors, study nurses - are entering the data. Instead, this activity can be performed by any person that has authority to log on to the system. In addition, the COOL-system uses the AMOS clinical database system directly, i.e. that data is entered directly into the central system, without intermediate storage in a client system. The use of COOL resulted in a substantial reduction of cycle-time in data collection, going far beyond what could be achieved through the process

improvement initiatives and the associated infrastructures for clinical data collection that followed the pre-designed business process.

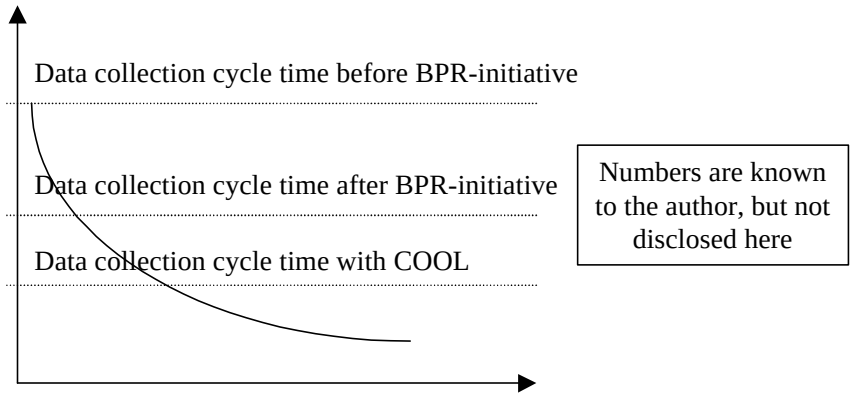


Figure 9.3: Time reduction for data collection in clinical trials

The development of COOL was the result of a local initiative in Mölndal, taken by some developers and the head of the clinical IT department. In its current form, COOL is primarily a tool for data collection, but it also represents a different idea about how clinical R&D should be organized. Following the model described in Figure 9.2 (page 213), COOL is a part of the process element of the organization, but it does not include a process prescription and leaves the form of its use to the project in which it is used. In this sense, COOL represents an example for the "loose coupling" infrastructure implementation context (see chapter 8.5).

COOL, as an application, is also only a first step towards the development and implementation of an infrastructure that ties together all relevant stakeholders in clinical R&D - investigators, monitors, project managers, data managers, regulatory authorities, patient communities - through one single entrance point. This common information space, or clinical R&D information portal, allows the instant delivery and exchange of information in clinical R&D projects and provides accurate and timely information to its users. Besides further improvements of clinical trial management, for example through on-line availability of patient recruitment status information and on-line monitoring of Case Report Forms (CRFs), the portal also facilitates cooperation within and between different communities that are participating in the research project, or have other interests in it, such as patient organizations and regulatory authorities.

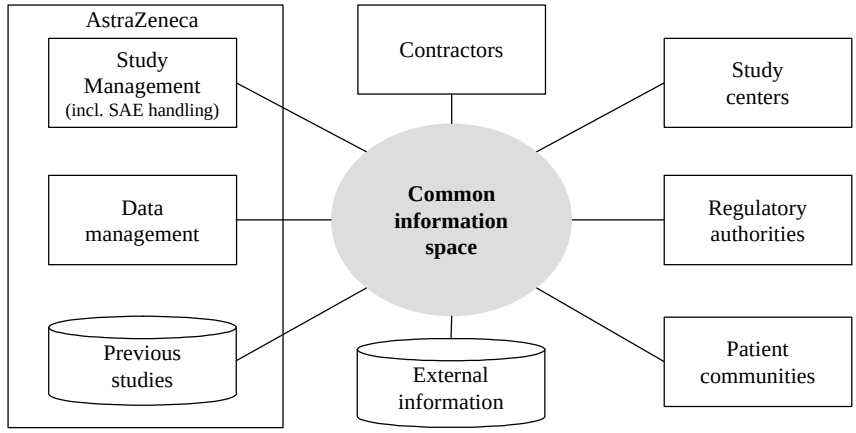


Figure 9.4: The Common Information Space concept

The current version of COOL has a simple form of cooperation functionality, but does not allow the categorization of users in different communities. Introducing discussion areas for different stakeholder communities is a way of providing added value to users, but also to create loyalty among investigators, who can engage in research oriented discourses and "chat" with other participants on a global basis. Also, the handling of SAEs (serious adverse events) can be improved significantly. In the current version of COOL, there is some functionality for publishing announcements and notifications, while the actual SAE handling still is based on a manual side-process. Within the portal, SAE-related information can be distributed instantly and, if desired, regulatory authorities can be linked directly into the SAE-process.

9.4 Final remarks

In this thesis, a history of the change initiatives that have been taken at Astra Hässle (now AstraZeneca) and the impact of these initiatives on clinical research & development has been provided. In order to provide the reader with a framework for the reasoning in this thesis, a review of the history of organization theory, from classic theory to process-based organizations, has been offered and the described theories have been discussed and briefly criticized.

The concept of process-based organizations and Business Process Reengineering has been taken into special consideration, since it governed the change initiatives at Astra Hässle, and a detailed description

of process improvement approaches being used by different consulting firms, has been included. Two of these firms have been actively involved in the projects at Astra.

During the case study it became evident, that global and local issues played an important role in the implementation of organizational and technological infrastructures. The tension between globally designed processes and IT-tools and their local deployment was found to re-shape the designed infrastructure in ways that were not anticipated. This issue was discussed as part of the analysis of a project-specific infrastructure for remote data collection and a model for identifying different infrastructure implementation issues was developed.

Finally, a new organizational model for considering clinical R&D, developed by the researcher and AstraZeneca personnel, has been outlined. This model, currently in an initial and tentative form, offers a more suitable rationale for designing clinical R&D at AstraZeneca. Future research will be dedicated to developing this model and following its use.

The new organizational model also required a new concept for the design of IT-infrastructures that does not prescribe or require certain organizational structures or processes. The common information space, or clinical R&D information portal, based on the COOL-system that was developed at Astra, seems to be a feasible solution to the issue of handling the relationship between organizational and technical aspects of the clinical R&D infrastructure and global and local aspects of the implementation and deployment process.

Summarizing the results being presented in this thesis in brief, we can compile the following list:

- The process improvement approaches being used by management consulting firms are similar with respect to scope and methodological steps. Consequently, the sub-sequent discussion of the FASTRAC and CANDELA initiatives is not specifically related to one specific way of conducting BPR-projects.

- Conducting BPR-style change initiatives, following the general methodological approach to BPR, in a company such as Astra Hässle is not the most efficient way to improvement, since aspects that are

crucial to the efficient implementation and deployment of organizational infrastructures are not taken into consideration.

- The fit, or mis-fit of organizational and technical aspects is a critical success factor for corporate change initiatives. High levels of organizational and/or technical inscription may result in work-arounds that modify the global design of processes and IT-use and re-shape the infrastructure in use.
- New organizational approaches and forms of technological support are required to improve operational performance in clinical R&D at Astra. A first step into this direction, proposing process, projects and centers of excellence as organizational building blocks, has been taken and a first version of an on-line system for clinical trials has been developed and successfully deployed.

10 References and exhibits

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