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Medical device innovation

The integrated processes of invention, diffusion and deployment

Kerstin Roback

Center for Medical Technology Assessment
Department of Health and Society
Linköping University, Sweden

Linköping University
INSTITUTE OF TECHNOLOGY

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Cover picture: Tumor-ablation. The microwave-specific absorption rate in live tissue subjected to an anchor-shaped microwave source. Pictured by COMSOL Multiphysics modeling package. (With permission from COMSOL, inc.)
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To the memory of my parents, Anna-Lisa and Milton Carlsson. You showed me the good things in life. You taught me to relish the small joys present everywhere around us. You taught me confidence and persistence.

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ABSTRACT

An increased use of medical devices has been assumed to be a major cause of rising healthcare expenditures. Nations around the world are trying to keep costs down, but strong incentives still exist for the development and use of new devices. Innovation is, however, never exclusively good or bad and it is not easy to evaluate the net effect. Theories and empirical research on innovation have been produced for more than 100 years. In this, the diffusion of innovations has attracted the most interest, while other areas, such as the integration of technologies, have been less thoroughly researched.

This thesis presents a model of medical device innovation in hospitals – from the first idea and invention effort to regular use of a new technology. The suggested model is built on three fundaments: (1) academic innovation literature, (2) empirical studies, and (3) observations of on-going innovation processes. The model is a synthesis of the accumulated knowledge in different innovation research traditions, and of empirical studies of the Swedish healthcare system and the medical device industry. The aim is to give a comprehensive picture of the innovation process, and to provide a theoretical model, which can be used for studying and influencing the paths of medical device innovations into healthcare practice.

In order to achieve a balanced rate of change, with long-term societal benefits, an inter-disciplinary approach is necessary in the planning and regulation of medical device innovation. The new model combines academic views with political/entrepreneurial and healthcare views. Innovation, in this model, is suggested to occur in three integrated activity domains: invention, diffusion, and deployment. A great number of factors that influence these activities are investigated and described, and different roles and incentives are discussed. Deviations from traditional innovation theory are for example: (a) integration of invention activities as having an impact on later events; (b) inclusion of the inventor/developer as a main actor also in the diffusion and deployment domains; (c) increased focus of the concept of technology cluster innovation, and (d) the rationality of use and abandonment of knowledge as factors to be included in the estimation of consequences of innovation.

Finally, the thesis suggests a number of model and methodology improvements and policy implications for management of innovation in hospitals.

LIST OF PAPERS

Note: This thesis presents a model of medical device innovation as an integrated process, including invention, diffusion and deployment of medical devices. The produced papers do not cover all these aspects of innovation, but are intended to provide some illustrative examples of crucial activities in the innovation process. The papers are numbered in order of initiation of the underlying studies. A presentation of these studies is given in Chapter 5 and the papers are reprinted at the end of the book.

Paper I:

Roback K, Hass U, and Persson J, **Transfer of health care technology in university-industry research collaboration environment**, Engineering in Medicine and Biology Society. Proceedings of the 23rd Annual International Conference of the IEEE, 2001. Page(s): 3938- 3941 vol.4.

Paper II:

Roback K, Nelson N, Johansson A, Hass U, Strömberg T, **A New Fibre-Optical Respiratory Rate Monitor for the Neonatal Intensive Care Unit,** Pediatric Pulmonology, 2005; 39(2): 120-126.

Paper III:

Roback K and Herzog A, **Home informatics in healthcare: Assessment guidelines to keep up quality of care and avoid adverse effects**, Technology and Health Care, 2003; 11(3): 195-206.

Paper IV:

Roback K, Gäddlin PO, Nelson N, and Persson J, Adoption of medical devices – Perspectives of professionals in Swedish neonatal intensive care, 2006 (submitted manuscript).

INNOVATION TERMS AND CONCEPTS

This chapter displays delineations of commonly used innovation terms and concepts. The terms have been collected from several different authors and research traditions. I have tried to merge together different conceptions and also, in several cases, made useful extensions of the terms. Furthermore, in case of divergent conceptions of a term I have chosen the definition, which is the most practicable for describing innovation models, methodology, applications and research history.

Adopter: Individual or collective unit that has adopted an innovation. A *potential adopter* has not yet adopted, but is estimated by the investigator/author to be among those who may adopt the innovation later. In a social system there may also be some members who cannot be included in the group of potential adopters.

Adopting unit: Unit of adoption. The term is used when the adopter is a collective unit. Adopting units can be e.g. families, firms, organizations, counties, states, countries or even continents.

Adoption: Acceptance of an innovation. "Adoption is the primary mechanism by which an innovation is diffused" [Kelly *et al*., 1978]. It is a decision process resulting in the procurement of an innovation or the assimilation of new thoughts or actions into the adopter's immediate conceptual environment. See also *dis-adoption, non-adoption*, and *rejection*.

Adoption rate: "The rate of adoption is the relative speed with which an innovation is adopted by members of a social system" [Rogers, 2003].

Champion: A champion uses his/her personal influence to encourage the adoption of an innovation. Champions for health ideas are often mid-level officials in an organization [Goodman & Steckler, 1989].

Change agent: A change agent is an individual who influences adoption decisions. The change agent usually promotes innovations [Rogers, 2003].

Cluster: See *technology cluster*.

Communication channel: The means by which messages get from one individual to another. They can be divided into *Mass media channels* and *Interpersonal channels* [Rogers, 2003:18].

Communication network: See *Social network*.

Compatibility: In this thesis, compatibility refers to how well an innovation agrees with existing social norms and current work procedures, and also with the existing medical equipment and technical standards. This is a wider definition than Rogers used in his model. "The degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters" [Rogers, 2003:473].

Deployment: The organization of people or tools, so that they are in the right place and ready to be used. Deployment involves both successful implementation and reinforcement of the adoption decision.

Developer: The developer transforms inventions to innovations. The term is also defined in this thesis as a person who makes incremental (marginal) improvements and adaptations of the innovation, to enhance its benefits or make a better fit with the needs of the adopter. Such adaptations have also been called *re-inventions*.

Diffusion: The process by which an innovation is spread among potential adopters.

Diffusion curve: Adoption rate plotted on a cumulative basis over time. Many innovations have S-shaped diffusion curves. *The diffusion function* is the mathematical expression representing the diffusion curve.

Dis-adoption: Disuse after first having adopted the innovation and used it for some time. It is also called discontinuance.

Divisibility: See *Trialability*.

Engineering: The application of scientific knowledge in the invention, development, and maintenance of products.

Gatekeeper: The gatekeeper controls the flow of messages and has the power to allow or block an innovation. Chief physicians, consultants and managers may act as gatekeepers. They keep abreast of technological developments inside and outside of the organization and transmit (or withhold) pieces of information to their colleagues [Tornatzky & Fleischer, 1990:106; Rogers, 2003:155].

High-technology: A cutting-edge technology, i.e. a technology that is in the forefront of research and/or is produced by newly developed techniques. Thus, a technology cannot be permanently defined as high-tech, but the term

is often used to denote complex technologies that are based on a substantial body of research and engineering work.

HTA: Health technology assessment has been described as "the bridge between evidence and policy making" [Battista & Hodge, 1999]. It provides information for healthcare decision-makers who are involved in funding, planning, purchasing and investment decisions [OECD, 2005:20].

IDD: The Invention-Diffusion-Deployment model. An integrated model of innovation proposed in this thesis.

Implementation: The integration of an innovation into the routine practice of the adopter.

Inhibitor: In this thesis, the term inhibitor is used for a factor that makes the innovation process slower, more controllable, and/or causes it to stop. (This is in accordance with the use in chemistry, where inhibitor denotes an agent that slows or interferes with a chemical reaction.)

Innovation: Innovation can be seen either as an entity or as a process: (1) An innovation can be "an idea, practice, or project that is perceived as new by an individual or other unit of adoption" [Rogers, 2003:12] and (2) it can be the process of introducing an innovation into a given social environment. Innovation is "the situationally new development and introduction of knowledge-derived tools, artifacts, and devices by which people extend and interact with their environment" [Tornatzky & Fleischer, 1990:10]. (Compare *Technological change*.)

Innovation development: In this thesis, the term describes the process of transforming an invention into an innovation, to make the invention useful to the potential adopters.

Innovativeness: The degree to which an individual or other unit of adoption is receptive to innovation and willing to adopt new ideas.

Invention: An invention is (1) a novel solution, device, material, method or an idea, and (2) the process of invention. Invention is not the same as discovery. To make a discovery is to find something that was already there, but no one had known of it before.

Inventor: Someone who is the first to think of or develop something. An inventor is a person who creates an invention.

Non-adoption: Describes the situation when adoption is not considered, even though awareness of the innovation is present. The potential adopter has not actively decided for or against. (Compare *Rejection*.)

Observability: By observability is meant how visible the results of using an innovation are and the degree to which others can recognize the benefits of using it. Both patients and medical professionals are more likely to ask for the new technology if the advantages are highly visible.

Opinion leader: An individual who is able to influence other individuals' attitudes and make them change their behavior. It is a type of informal leadership, but the opinion leader often also has a high formal position or status in the system. Opinion leadership is earned and maintained by the individual's technical competence, social accessibility, and conformity to the system's norms [Rogers, 2003].

Performance gap: A performance gap is the difference between the actual performance of a practice and the performance desired by the user. This difference can be a strong initiating factor to invention activities and search for a solution.

Pro-innovation bias: The implication in diffusion research that an innovation should always be diffused rapidly to as many as possible. The conception that innovation is always good. A tendency to neglect possible undesirable effects and that benefits might be small to marginal adopters.

Re-invention: Re-invention is defined by Rogers [2003] as the degree to which an innovation is changed or modified by a user in the process of its adoption and implementation. This concept is here extended to also cover modifications and improvements made by the original inventor or, when referring to physical objects, by a manufacturer.

Rejection: The decision not to adopt an innovation.

Relative advantage: The degree to which an innovation is better than the practice it supersedes [Rogers, 2003]. The former practice may be an old technology, but it can also be the practice of doing nothing.

Science: The study of natural facts.

Social network: Interpersonal networks that link together different members of a social system. A *communication network* consists of interconnected individuals who are linked by patterned flows of information [Rogers, 2003].

Social system: A given social environment and its members.

Technological change: Technological change follows when an innovation is put into practice, but technological change may also occur back to a formerly used technology. It involves cessation of an existing practice in favor of another practice.

Technology: Application of science and/or inherited knowledge to a definite purpose. It can be the knowledge and skills needed to operate a tool, it can be the knowledge used to solve problems or the pedagogical tools to extend the knowledge of others [OTA, 1976; Kline, 1985].

Medical technology has been defined as "the set of techniques, drugs, equipment, and procedures used by healthcare professionals in delivering medical care to individuals and the systems within which such care is delivered" [OTA, 1976].

Health technology is defined, in this book, to also include technologies used by individuals for their own care, rehabilitation or health promotion.

Technology cluster: A set of interrelated innovations that complement one another in such a way that the adoption of one innovation might naturally lead to the adoption of one or more of the other innovations [Meyer, 2004].

Technology transfer: The transfer of technical or scientific information from one actor to another, or from one context to another.

Trialability: Trialability is the ease with which the innovation can be tried out by a potential adopter. This concept includes both *divisibility* and *irreversibility* [Zaltman *et al*., 1973]. If the innovation is divisible, the adoption decision concerns whether the new technology should complement the traditional healthcare alternative and, if so, to what extent. An irreversible technology, once implemented, cannot without great economic loss be replaced by an alternative method. Both divisibility and irreversibility are important factors influencing the riskiness of adoption.

1. INTRODUCTION

> "With the traditional explanation of inherited mental ability inadequate, what are the factors that have caused the great evolution of our culture from crude and simple beginnings to the magnificence it has now attained? The explanation lies in four factors: invention, accumulation, diffusion, and adjustment" [Ogburn, *Social change* 1922].

Innovation research has a long tradition that has grown out of several academic specialties and it has entrepreneurial and marketing, as well as political implications. Current innovation models and research methodologies has given a fairly good understanding of the processes of innovation, but the models are quite academic in character, with few immediate applications.

This thesis has been inspired by the many excellent contributions, to the current innovation theories, by a large number of authors. But I have also been challenged to think differently about innovation and to explore new roads. These new ideas will be outlined in the thesis and implications will be given for a more applied and practical hands-on innovation research in the area of medical device innovation.

What is innovation?

> "... technological innovation involves the situationally new development and introduction of knowledge-derived tools, artifacts, and devices by which people extend and interact with their environment" [Tornatzky & Fleischer, 1990:11].

> "A technological product innovation is the implementation/commercialization of a product with improved performance characteristics such as to deliver objectively new or improved services to the consumer" [OECD, "The Oslo Manual", 1995:9].

The concept of innovation has developed in two directions, as illustrated by the above definitions. The definitions are used in two different classes of literature, each with its own field of interest: (1) social change, and (2) economic development. The first field has a more general definition and the main interest in this literature lies in areas such as cultural heritage, social

interaction, communication and decision-making [See e.g. Wejnert, 2002; Rogers, 2003; Kincaid, 2004]. The second direction is almost exclusively occupied with industrial and enterprise competitiveness. Authors within this field are sometimes using the terms invention and innovation as synonyms, with the central meaning of "development of new products." The purpose of innovation, according to this literature, is to meet market needs and get an improved economy [See e.g. Curlee & Goel, 1989:5; Fagerberg, 2005:4].

Generally the "economic development" field has a more positive attitude to innovation and often claims that innovation is the driver of economic growth and prosperity. The "social change" field, though recognizing that innovation can be both good and bad, has so far been more interested in the process than in the consequences of innovation. And speaking "innovation language", the two fields have separate social networks, information sources, and communication channels. This is the reason why the two directions are increasingly divergent: One practically oriented and the other more academic in character.

In this thesis, innovation is thought of both as an entity and as the process by which this entity is conceived, developed, diffused and deployed. The terminology is most closely following the "social change" tradition, merely by practical reasons, because this terminology covers both fields better.

Innovation, as a process, may be seen as the act of getting a new technology into a given social environment [Tornatzky & Fleischer, 1990; Rogers, 2003]. In this sense innovation is almost the same as technological change. But while innovation implies a certain newness of the technology, technological change, theoretically, can occur back to an old technology, even if that seldom happens.

However, in the business and entrepreneurial field, innovation is seen only as one of three phases leading to technological change in the sequence: invention, innovation, and diffusion [Edquist, 1977; Eliashberg & Chatterjee, 1986; Hall, 2005]. In this tradition innovation is the refinement of inventions into practical technologies, useful to the society. Most often this is assumed to take place within firms and to result in new products or services to meet market needs. Much of this literature is, thus, focused on how to forecast which new products or services will succeed in the market and how to persuade consumers to purchase these products or services.

In this thesis, the first (the sociological) definition will be used, as it is predominantly used in contemporary academic research literature, for example in anthropology, history, and agricultural economics.

Innovation, as an entity, may be a new physical tool or product, but in a wider sense, innovations can also be new methods, practices, and even new ideas or new ways of making things. The criterion to be called an innovation is that it is perceived as new in the given adopter population [Rogers, 2003], which implies that a technology may be an innovation in one social system, while an old practice elsewhere.

Health technologies and medical devices

Technology can, like the concept of innovation, be so much more than a physical tool or product. It can be the knowledge and skills needed to operate a tool, it can be the knowledge used to solve problems or the pedagogical tools to extend the knowledge of others [OTA, 1976; Kline, 1985].

Medical technology can, therefore, have a correspondingly broad definition, like the one proposed by The Office of Technology Assessment (OTA), which definition will be used throughout this book.

> "Technology is defined as "science or knowledge applied to a definite purpose". Thus, medical technology includes all elements of medical practice that are knowledge-based, including hardware (e.g., equipment and facilities) and software (e.g., knowledge and skills). Medical technology is defined as the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals and the systems within which such care is delivered" [OTA, 1976].

Health technology is defined, in this book, to also include technologies, used by individuals for their own care, rehabilitation or health promotion.

Medical device has been defined in the European Medical Devices Directive from 1993, to be:

> "... any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means" [EU, 1993].

In this book I will sometimes also use the term *medical equipment*, meaning a sub-class of medical devices, which have a certain technical complexity and most often are power-operated, such as life-support systems and monitoring stations.

The changeable nature of the arena for medical device innovation

Technological change is generally considered responsible for rising healthcare expenditure [Gelijns & Rosenberg, 1994:28; OECD, 2005:31]. Improvements in treatment of a certain disease may reduce cost per patient, but this will frequently cause an increased demand that in turn generates an expanded indication for use and rising costs for the patient group as a whole. Healthcare innovations, however, can also be the driving force behind a country's improved productivity and economic growth. It is therefore desirable to achieve a balance between industry and healthcare goals that is beneficial from a societal, citizen, and patient perspective. Efforts to approach this must be multidisciplinary, with involvement of politicians, public authorities, health professionals, scientists, engineers, economists, and entrepreneurs.

The buyers of medical devices are predominantly hospitals and other healthcare organizations, and, even though, the healthcare organizations may be publicly operated, the purchase process can be characterized as a business-to-business trade, where the healthcare side is strongly influenced by political factors.

The producers of medical devices exist in a highly dynamic sector with small companies frequently entering and leaving the market. New medical insights, new technologies and new enterprise constellations may alter conditions for a manufacturer. Their product may become obsolete, or competing firms can

offer the same technology at a lower prize. The medical device industry can be described as knowledge intensive and niche specialized. There are a few large international enterprises, which dominates the market and it might be hard for small companies to survive. Purchases and fusions are therefore frequent among the mid-sized medical device companies [Sidén, 2003].

Introduction of new products is constrained by the actions of public authorities. The regulatory framework is a crucial aspect of the environment in which companies operate. It needs to be fine-tuned if firms should be able to develop their full innovative potential and if authorities, at the same time, should be able to control healthcare expenditures. This is perhaps a delicate task, but it has been shown that market regulations may have positive effects, on health and safety as well as on productivity and trade [Steg & Thumm, 2001].

Hospital adoption of medical devices is thus influenced by political fluctuations, changeable regulatory controls, an unpredictable device market, and frequent re-evaluations of the medical knowledge base. This makes adoption and diffusion patterns difficult to detect and presents the investigator with a multitude of different innovation diffusion "stories".

Innovation research: Time to innovate?

Through more than 100 years of innovation research, different research traditions have converged to a general methodology for studying innovation and diffusion which have developed very much out of practical reasons, because some research questions are easier to find answers to than others. Few authors have questioned this practice, although aware of the problem. In a methodology paper from 2004 Meyer states:

> "Advantages associated with efficiency of data collection, standardized surveys, large samples with high response rates, ease of data collection and analysis, and the ability to publish results in a relatively short amount of time have primarily been driven by pragmatic concerns. This common tradition is not to suggest that such decisions are inappropriate, irresponsible, or unethical in any way. They are not. In fact, given the research questions that have dominated diffusion studies, the established methodology makes perfect sense. Indeed, one might question the choice of alternative methodological decisions" [Meyer, 2004].

I agree with the author that "given the research questions" the methodology may be appropriate, but perhaps it is time to ask some new questions in innovation research.

Although the total accumulated mass of research on innovation exceeds most (perhaps all) other research areas, there are blanks in the knowledge and understanding of the process. This has been observed by several innovation researchers. Developments of the methodology have been suggested to fill in the gaps [See e.g. Warner, 1974; Rogers, 2003; and Meyer, 2004], but the innovativeness in practical innovation research has so far been limited. The vast majority of published studies can be ascribed the following features:

- based on quantitative data,
- investigating one single innovation,
- data collected after widespread diffusion of the innovation,
- data collected at a single point in time,
- data collected from adopters only, and
- consists almost exclusively of basic research, with no immediate practical applications

This thesis is an attempt to rebut some of this criticism by, for example, data collection from both adopters and rejecters, the use of qualitative research methods, and introduction of technology cluster innovation as a concept in the study of medical devices.

Aims of the thesis

The aim of this work is to describe the processes leading to technological change in the area of medical device utilization and to suggest measures to optimize diffusion and implementation of beneficial new technologies. But the aim is also to challenge old innovation research traditions with new ideas and perhaps arrive at more applicable theories. Innovation research, so far, has contributed little to the actual practices of health technology use and the presented theories have been difficult to apply in the efforts to promote use of effective and cost-effective technologies.

Previous innovation research on health technologies has almost exclusively been occupied with diffusion of large and highly visible investments, but, put together, the small investments may have as important policy implications as the big ones, from a healthcare and societal perspective [OECD, 2005:35]. An

intention was, therefore, to set focus on innovation activities coupled to relatively inexpensive medical devices. The ultimate aim, however, has been to arrive at generally applicable measures to optimize diffusion and implementation of beneficial health technologies.

The processes of technological change in the medical device field include idea generation, invention, development, spread of information, adoption, diffusion, implementation, and deployment of the new technology. It also often involves replacement of an obsolete or inefficient product or practice, which raises questions about disuse and abandonment of knowledge. All these activities have been the scope of the thesis.

A multitude of questions have been formulated during my investigation of these processes, of which the most fundamental may be compiled as follows:

- How are new ideas generated? Where and in which contexts do they emerge?
- How are ideas transformed into new technologies?
- What are the main features of technology development?
- At what stage is the technology considered a beneficial product, ready for the market?
- How is awareness of the innovation built up among the potential adopters?
- How is information and opinions about advantages/disadvantages communicated?
- What influences are important in adoption decisions and diffusion of devices? Can these influences be moderated?
- How are new technologies integrated into practical use? Why does implementation of adopted technologies sometimes fail?
- How evidence-based are the adoption of new technologies? And how evidence-based are the disuse of old technologies?
- Which consequences are considered in the adoption decision? Are there additional consequences that ought to be evaluated?
- Is there an optimal organizational innovativeness? Can innovativeness of organizations be influenced?

The intention to find answers to all these questions may not have been completely fulfilled, but the thesis has taken me a long way in my efforts and it has also revealed some useful directions for future studies.

Disposition of the thesis

The thesis is organized as follows. ***Chapter 1*** presents some central concepts, important for the following text, and it gives a short description of the arena for medical device innovation. The aim of the thesis is also described here. Furthermore, the chapter points out some deficiencies in the theoretical knowledge and research efforts in the field of innovation, which implies a need for further developments and an improved understanding of the process. This has been addressed in the thesis and the work has resulted in a proposal for a new innovation model. This model has been constructed with the purpose of depicting medical device innovation and it is built on three fundaments: (1) academic innovation literature, (2) empirical studies, and (3) observations of on-going innovation processes.

The knowledge base and perspectives of the author is presented in ***Chapter 2***. This chapter gives a compressed description of the research area and lists influential literature. It also points out the close connectedness of innovation and Health Technology Assessment (HTA). Furthermore, the applied social perspective is defined and the standpoint of the author is declared, regarding fundamental principles of technological change.

A description of the research methods follows in ***Chapter 3***. This includes both the overall method applied for construction of the new model and the methods used in the empirical studies. The material collected by observations of on-going innovation processes (fundament three in building the model) is also presented here. Fundaments one and two, however, are described in separate chapters, since they provide the most important contributions to the model.

The first model building fundament is presented in ***Chapter 4***. It is a review of innovation theories found in the academic literature. This review describes the growth of innovation as a research area. It is also an investigation of the literature in different sub-areas of innovation and it points out differences in the prevailing theories as well as areas of insufficient understanding. The chapter provides a rationale for how my lines of thought have evolved.

The second model building fundament is presented in ***Chapter 5***. The chapter contains short descriptions of the work in the four studies (Papers I – IV), and how this work has contributed to my understanding of the innovation process.

Chapter 6 is a comprehensive description of the new model of medical device innovation. The model is called IDD after the three suggested activity domains: invention, diffusion and deployment. The chapter is constructed with the intent to provide a kind of "manual" to the IDD model. This makes it easy to look up what is said about single actors or events in the model. A drawback with this construct, however, is that the same thoughts may be expressed more than once in the text.

Chapter 6 has eight sections. The first section is an overview of the *innovation process*, as described by the IDD model. Then follows a section presenting the *actors* and three sections presenting the three *activity domains*. The possibilities to *measure innovation* are pointed out in the next section and this is followed up by a display of the factors in the model, the *facilitators and inhibitors*. Finally, in the last section, it is emphasized that innovation and technological change have a variety of *consequences*, in different phases of the process, of which most are difficult to predict.

In ***Chapter 7*** the model is discussed against the background of the literature and it is placed within the context of earlier innovation and assessment research. The mechanisms of the *factors* are discussed here as well as the challenge of *measurements*. Important sections of the chapter are the *discussion points* of the model and its *deviations from traditional theories*. The *role of HTA* is likewise an essential part, as assessment of consequences is an important aspect of innovation, and this is followed by a discussion of the *usefulness of innovation models*.

Chapter 8 contains the conclusions of the work. It starts with a section where I present some *new insights* in the process. The following sections suggest *improvements in the methodology* and *policy implications* for management of innovation in hospitals. Finally, the chapter ends with some thoughts about innovation research in general and its possible future path and an appreciation of the early scholars and their valuable insights.

2. KNOWLEDGE BASE AND PERSPECTIVES

Innovation concepts and models on which this thesis is based have been collected from widely different research traditions and from a multitude of disciplines and sub-disciplines. The expression "Frames of reference" is consequently not a relevant graphical description of the knowledge base of my work. On the contrary, I have taken on the privilege to escape outside of frames and discovered unlimited possibilities to collect small pieces of knowledge here and there, which I could tie together to form a spider's web, with ties to the outer environment, rather than a picture that fits into a frame.

Innovation research providing background knowledge

The conceptual approach of this thesis is, more than anything else, interdisciplinary. It all started with a short synthesis of innovation literature 2001, providing background for Paper I. A more thorough literature review was performed 2003 [Roback *et al*. 2003], which was conducted as a point of departure for a study of diffusion and implementation of medical devices in the Swedish healthcare system. Already at that point, there was an aspiration to illuminate the research area from several different perspectives and to use sources from different research traditions, different geographical and societal cultures, and from industry and healthcare as well as from their regulatory environment. The preparatory literature study synthesized information from six separate fields: (1) medical devices, (2) general innovation processes, (3) healthcare innovation, (4) healthcare decision-making, (5) health technology assessment, and (6) regulation and legislation.

A number of databases were used to find relevant literature, but, considering the large volume of research that exists in the field of innovation, I had to trust my intuition and just choose some works for closer examination. Thus, the preparatory literature study was based on a diverse collection of sources of differing scientific value. Of these works, I would like to mention the following literature, which I have found valuable in my continued studies: Usher [1954], Coleman *et al*. [1957], Edquist [1977], Kelly *et al*. [1978], Rogers [1983], Elliott [1986], von Hippel [1988], Battista [1989], Tornatzky & Fleischer

[1990], Walsh-Sukys *et al*. [1994], Finkelstein *et al*. [1995], Bonair & Persson [1996], Witkin [1997], Poulsen [1999], and Battista & Hodge [1999].

Reference lists in the most relevant sources, together with database searches for recent literature, have provided a solid base of literature in the six fields mentioned above. Some works have been particularly important in the innovation research field, as historical milestones and/or as theory-builders. It all started with de Tarde [1890] and the social behavior of innovators and imitators. Then the spread of innovations, as a field of research, came up with Ryan and Gross [1943] and their diffusion study of an agricultural innovation. This investigation provided the basic framework for Rogers' diffusion model [1962] in which he established a new paradigm for diffusion research and defined a lot of concepts in the sociological strain of innovation research. In the economic field, and among the politically aiming authors, the theories of Schumpeter [1934], Arrow [1962], and Rosenberg [1974] became influential, as well as the empirical research by Griliches [1957]. Studies of innovation processes in healthcare started with Coleman *et al*. [1957] and their study on the spread of a new practice among doctors, in this case, the prescription of a new drug. Theories in this field have been further developed by Greer [1977], Stocking [1985], Banta [1990], and Blume [1992], which authors have been great sources of inspiration in my work.

A large proportion of my sources will be cited in the review of past and present theories (Chapter 4), which is also a summary of my understanding of the academic knowledge in the field of innovation. Finally, among the most important works, not yet mentioned in this section, are also: Ogburn [1922], Menzel & Katz [1955], Zaltman *et al*. [1973], Warner [1974], Utterback [1974], Pierce & Delbecq [1977], Kimberly & Evanisko [1981], Kamien & Schwartz [1982], Nelson & Winter [1982], Fineberg [1985], Eliashberg & Chatterjee [1986], Carlsson [1987], Dosi *et al*. [1988], Van de Ven [1991], Grover & Goslar [1993], Gelijns & Rosenberg [1994], Ziman [2000], Wejnert [2002], Fagerberg [2005], and Greenhalgh *et al*. [2005].

Perspectives

An *overall social perspective* is applied in this thesis on innovation and technological change. The perspective is not entrepreneurial, not economic, and not political, but I consider all these aspects to be important parts of an interdisciplinary social study. My definition of a social perspective is that it is

people-centered and that it includes both measurable social aspects and aspects that cannot be measured or quantified. The unmeasurable aspects are often called intangibles in the economic literature. Economists and business people have most often recognized the unmeasurable and unquantifiable nature of intangibles, but are nevertheless frequently trying to quantify them, which I do not intend to do (at least not in this thesis). However, application of a social perspective also involves analysis and promotion of social justice and fair distribution of the common good, which actually implies that intangibles must be ascribed a value, so that central social elements may be included in social policies and key policy instruments.

A central activity in the making of policy instruments is also the valuation of consequences of a changed behavior. The consequences of medical device innovations are, for instance, treatment benefits and increased costs, which constitutes the main territory of *Health Technology Assessment (HTA)*. This is the main reason why HTA is so closely related to innovation and, in particular, diffusion of innovations. It is important to show that the changed behavior is better that the current practice.

My overall perspective has two main components. The first component is the conceptualization of *innovation as an evolutionary process* [Nelson & Winter, 1982; Nelson, 1987; Ziman, 2000]. My perception is that genuine breakthrough innovations are extremely rare, since an innovation that departs too far from existing norms has little chance of surviving cultural and regulatory inhibitors on its way. I also strongly believe that events and choices are influenced by earlier events and "paths" taken in other processes of change [David, 1975; Arthur *et al*., 1987 and 1994].

The other component encompasses the members of the social system of innovation. In my view, *non-adopters and adopters are equally important* in the innovation process. In fact, all actors take part in the initiation, pursuit, promotion, or hampering of activities that may lead to technological change. Consequently, the two components are working together in a way that implies that the people (the actors) are building the framework of norms, regulations, and laws, within which innovations evolve.

3. MATERIAL AND METHODS

The study object in this thesis is the process of medical device innovation, including all its sub-processes, from idea generation through adoption and use to disuse. I have studied innovation activities and influences in several different environments representing different functions and activities such as: R&D, clinical testing, decision-making, and care giving. Data collection is mainly performed through literature surveys, interviews, and observations. Four studies (Papers I – IV) have contributed to the overall results together with on-going studies of the literature and observations of current innovation processes and innovation strategies. Qualitative data and research methods have been used in Papers I, III and IV and in the overall work of the thesis. Quantitative measurements and statistical analysis have been employed in Paper II.

Research strategies

The work in this thesis has been planned and conducted with the intention to combine several different methodologies and sources of knowledge, which has enabled a multifaceted illumination of the study object. The collected data (units of information) originates from academic literature, conducted studies, entrepreneurial and political information material, and observations. The main analysis principle has been to merge together data from these sources and find common structures, contrasts, differences, and patterns of relationships that can be used to explain different features of the innovation process.

The overall research strategy applied in the thesis is interpretivism. Data has thus been collected and analyzed in the light of the theoretical understanding of the researcher and the conceptual orientation of the time and location for data collection.

The theoretical methodology chosen for the overall study is best described as a dynamic structuralism, i.e. the strategy combines process-like features, which continuously change, with features that remain stable in a series of interactions. The dynamic part comprises, for instance, the evolvement of technologies and how technology utilization changes over time in the health

care system. The structuralistic part consists of the examination of connected structures and relations, and merging together the different components to build a comprehensive picture of the studied phenomenon. The main focus has been on the dynamic processes, but these are considered in relationship to structures that are more or less fixed. The purpose of the dynamic structuralism strategy is also to show if, when, and how structures emerge out of dynamic processes, and how they in turn may influence these processes.

The applied methodology is based mainly on the following works: Ely, 1991; Denzin & Lincoln, 1994; Huberman & Miles, 1994; Miles & Huberman, 1994; Starrin & Svensson, 1994; Coffey & Atkinson, 1996; Strauss & Corbin, 1998.

Data collection

Data elements in the overall work of the thesis are the "units of information" that have been collected and stored. The data originates from academic literature, the four studies, entrepreneurial and political information material, mass media, and observations. Data collection in the four studies has mainly been performed through literature surveys and interviews. One clinical trial has been conducted (Paper II), in which data was collected through measurements. Furthermore, notes have been taken on the observations and these have been stored and analyzed together with other data elements.

Literature searches constitute a substantial part of the data collection, as the work in this thesis, to a great extent, is based on literature surveys. The following databases have been used to find relevant literature on innovation and specifically on medical device innovation: the Cochrane Library, Medline, CINAHL, Libris[1], Sciences Citation Index, Science Direct, and Internet (World Wide Web). Database searches has been performed to find literature addressing certain aspects of innovation and to find recent innovation research literature. However, the vast body of literature providing the knowledge base of this thesis has been found by a "snowball method," i.e. the exploration of references of references to track earlier influential literature, and I have also used electronic citation tracking via the Internet to find more recent works.

[1] A department at "The National Library of Sweden." Among the undertakings of LIBRIS is the maintenance of a national union catalogue and interlibrary loan service.

Innovation research literature has been studied in a number of different fields. The academic literature will be presented in Chapter 4. The studied literature includes, however, not only academic works, but also sources containing information about innovation strategies in business and politics. This strain of literature is available mostly in the form of information brochures and booklets, but a main source of information, in my research, has been the "European Innovation" (formerly "Innovation & Technology Transfer"), a magazine that covers development and innovation policy in the European Union. It is published by the Communication and Information Unit of the European Commission. There is also a corresponding portal on the Internet, which is maintained by the Community Research & Development Information Service [CORDIS, 2006]. An informative Internet site is also provided by the Center for Devices and Radiological Health (CDRH), which is a center under the US Food and Drug Administration [CDRH, 2006]. This site contains, among other things, information on marketing procedures, guidance documents, databases, and notifications of recent approvals and recalls of devices.

Paper III is a pure literature survey of the use of information technologies and computers in home healthcare, including the risks and potential adverse events associated with this. All four studies have, however, substantial elements of literature search.

Interviews have been used as the means of data collection in Papers I and IV. Paper I investigates the research work in eleven biomedical engineering projects, aiming at invention of new medical devices. Paper IV is an adoption study. It investigates the views of medical professionals on adoption and use of medical devices for neonatal intensive care.

In both studies semi-structured interviews were used. An iterative method was applied where interviews and analysis were performed alternately. The interview questions were constructed to cover the research questions as fully as possible and the initial sets of questions were tested and adapted after analysis in order to enhance focus on the essential aspects of the investigation. This research method is described in Paper IV.

Field studies and observations have also been conducted in connection with the studies. In the breathing sensor study (Paper II) I had the opportunity to do some field studying of product development and prototype testing in clinical environments. This gave some insight in the work and contextual situation of a start-up medical device company.

Information on the entrepreneurial and political side of innovation has also been obtained by following mass media reports of medical device enterprises and emerging products over time; and by attending meetings on biomedical engineering.

The breathing sensor study (Paper II) is the only quantitative study. In this study the respiration of preterm neonates was measured by a new respiratory rate monitor and compared to well-established measurement methods. This work has indirectly contributed to the thesis through the observations made on prototype development and clinical testing of the new device and on the function of established technologies in routine care.

Conceptualization and analysis methods

Conceptualization in innovation studies is complicated by the conflicting needs of mapping structures and following processes that constantly change these structures, i.e. we need a map of the arena for adoption of devices and at the same time investigate technological change that strongly impacts this arena. Considering these features of the studied phenomenon, a generally accepted qualitative method, using alternately performed analytic work and data exposure, has been regarded as the best alternative for conceptualization and analysis.

The main analysis method in the overall innovation study is best described as "text-analysis", as data from the different sources has been stored as texts (notes and citations). The units of information has been collected, categorized (coded) and stored for easy access and analysis. Data retrievals and displays have been used to illuminate specific events or elements of the innovation process. This has been conducted iteratively during the research work and the data displays have driven the data collection and analysis forward through exposing areas of insufficient understanding or posing new questions. This analysis method, by which data collection, coding and reduction, display, and analysis are performed iteratively, has been described by Miles and Huberman [1994]. The initial set of coding categories was chosen on basis of the researcher's prior theoretical understanding and the framework for analysis evolved with the study. Categories were continuously added, splitted or merged after each examination of the material.

Data displays are the compilation of data (units of information) that relate to a particular category (a specific event or element) or to categories with common or contrasting features. It is a kind of sampling of the stored data, which is performed either with an exploratory or confirmatory purpose. This has been a key element of the analysis.

In the two interview studies (Papers I and IV), data storage and retrieval was managed with the qualitative research softwares QRS Nvivo and QRS NUD*IST [QRS, 2005]. Raw data from the interviews were stored as "text-units" that was coded and analyzed as described above. The applied coding technique is described by e.g. Coffey and Atkinson [1996:26-53] and the techniques of data reduction and of iterative data displays are to be found in Miles and Huberman [1994:10-11; 1994:90-142].

The qualitative research software QRS NUD*IST [QRS, 2005] was also used in the literature survey (Paper III). The QRS software is not originally intended for this kind of data, but proved suitable for data management and analysis also in studies that are more text-analytic in character.

Paper II is a traditional clinical trial, where analysis has been performed by statistical methods.

4. HEALTHCARE INNOVATION – A REVIEW OF PAST AND PRESENT THEORIES

The purpose of this overview of healthcare innovation is (1) to give a comprehensive, but not too detailed, picture of the innovation process and (2) to sum up where innovation research stands today. This overview will also provide a basis to relate to in the following chapters.

There is a continuously growing research interest in hospital innovation and technological change in the medical field. However, there are few descriptive works giving a comprehensive overview of these processes. Most of the research is case studies giving pieces of information on innovation in very specific settings. In this review, innovation research from a variety of disciplines has been explored, sieved and adapted to the healthcare area, in order to get a more complete picture, and non-medical examples have also been used to illustrate innovation processes. The chapter starts with a short review of the growth of innovation theories. The following sections are covering past and present views on how innovations are conceived, developed, diffused and deployed. A deficiency in the current literature is pointed out: The lack of texts covering integration, use and disuse of innovations, and the consequences that innovation might bring about. And finally, a short summary of prevailing theories is provided.

The framework of this chapter has been built on a large number of sources. In the field of the literature, specifically dealing with healthcare innovation, the following works should be mentioned: Greer [1977], Kimberly & Evanisko [1981], Carlsson [1987], Battista [1989], Andreasen [1990], Bonair [1990], Blume [1992], Bonair & Persson [1996], Poulsen [1999], Fleuren *et al*. [2004], Stanton [2002], Berwick [2003], and Greenhalgh *et al*. [2004].

Healthcare innovation and diffusion may be influenced in many different ways. Consequently, in the following, a number of terms will be used denoting factors that facilitate or inhibit innovation. I have chosen the terms *facilitators* and *inhibitors*[2] for use in this thesis, but commonly used terms are

[2] Inhibitor is used here (in accordance with the use in chemistry) to denote an agent that slows or interferes with the innovation process (the chemical reaction).

also incentives and barriers[3], which may be defined as: *incentives* – promotive factors that will make innovation possible or speed up the process, and *barriers* – restrictive factors that will slow down or stop the process, or make start of an innovation process impossible.

Development of innovation theories

The theories of innovation have grown out of a long tradition of research and philosophic work. To get a good understanding of the field we have to look at two strains of literature: *diffusion of innovations* and *entrepreneurial innovation*. Here follows a very brief summary of this literature. For a more detailed description of the development of innovation theories, I suggest the following two works: *Diffusion of Innovations* [Rogers, 2003] and *The Theory of Innovation* [Sundbo, 1998].

As a point of departure, in the diffusion strain, theories by the French sociologist and criminologist Gabriel de Tarde may be chosen. In his book, *The laws of imitation*, [de Tarde, 1890] he hypothesized that small psychological interactions among individuals are the basic explanation of social change. Inventions are picked up by the venturesome innovators, who then will pave the way for the more cautious imitators. He showed that the diffusion of inventions in a society could be presented graphically as an S-shaped curve when plotted as a function of the cumulative number of users (adopters) over time. He also found that diffusion has a geographical center from which habits spread like rings on water. His theory of innovators and imitators can be traced in almost all diffusion literature of today.

After 40 years of scientific discontinuance in diffusion research, a frequently cited study by Ryan and Gross [1943] came to be considered the next milestone in this field. The authors found that the diffusion of hybrid corn among Iowa farmers followed the typical S-shaped pattern. They argued that non-economic factors must work to explain this seemingly irrational adoption of a proven beneficial technology. A usable theory appeared in *The People's Choice*, 1944, [Lazarsfeld *et al*., 1965] in which Paul F. Lazarsfeld and colleagues presented their theory of the "Two-step flow of communications." The aim was to explain the spread of political ideas, but this theory was picked up by

[3] Many authors also use the term dis-incentive instead of barrier and inhibitor.

Elihu Katz [1957] and adapted to diffusion of innovations. The main message in this theory is that news about an innovation flows first to opinion leaders who then transmit information to the general population.

A limitation in this line of theory building is that it does not include invention activities. Even though de Tarde suggested that invention is initiated by frequent social interactions and communication, this strain of literature has not been particularly interested in the making of innovations, at least not until 1962, when Rogers proposed the first general model that also included initiation of the innovation process. This model was built on different earlier theories and in his book, *Diffusion of Innovations*, Rogers argued for its use among various research traditions. The model have been refined to meet some 30 years of criticism and proposed developments, and in the 4th edition of the book [1995] the theory seemed to have found its final form.

However, to get an understanding of entrepreneurial activities and innovation within firms we have to turn to a different strain of literature. Many health technologies are manufactured products or depend on the use of such products. That is why this "other side of the coin" is so important. Market structure and market incentives are markedly involved in health technology innovation.

Among the first theory builders, on the entrepreneurial side, was the Austrian-American economist Joseph Schumpeter. Like de Tarde, he found that diffusion of innovations followed a logistic curve (the S-shape), but while de Tarde concentrated on personal interactions as the means of social change, Schumpeter saw innovation as the means of economic development [*The Theory of Economic Development*, 1934]. He also saw the individual entrepreneur as the main dynamic factor. According to this theory, the entrepreneur was the innovator sensing the customers' needs and acting creatively to find solutions to the benefit of both producer and consumer and the economy in large. During a period of fordism and keynesianism,[4] that followed, Schumpeter's theories were forgotten. However, they were brought to the scene again in the 1970s and 1980s when they proved useful to explain the stagnation of the economy that occurred in several countries [Sundbo, 1998]. This started an "innovation economics" theory, which has had a lot of followers and developers [See e.g. Freeman, 1982; Rosenberg, 1974; and Dosi *et al.*, 1988]. An

[4] Domestic mass production, state regulation of the economy, and stimulation of consumption are characteristics of this period.

opposing view was represented by William F. Ogburn [*Social Change*, first ed. 1922] and the breakthrough of "the technological innovation paradigm" in sociology [Sundbo, 1998]. In this theory, the technological development is the driving force in social change, not individual entrepreneurs.

Vernon W. Ruttan [Ruttan, 1997 and 2002] has distinguished three models of technological change: *induced change, evolutionary theory*, and *path dependence*. He argues that each of the three theories, if used alone, is approaching a dead end. Only if they are regarded as separate components and put together could they build a more general theory.

In the "induced change" approach major attention is focused on changes in demand and in relative factor prices. The "demand-pull – supply-push" controversy has its roots in this tradition, while both an increased market demand and knowledge accumulation may induce advances in technology. The agricultural economist, Zvi Griliches, found that demand factors could be important drivers of innovation. In his well-known study of the invention and diffusion of hybrid maize [Griliches, 1957], he demonstrated that the hybrid seed industry modified the seeds to suit the customers in close relation to the spread of the innovation to different farming districts. Nathan Rosenberg [1974], on the other hand, argues that demand factors are of little importance and that inventions is determined by what is technically possible and profitable to do, depending on the current levels of skill and scientific knowledge.

> "… After all, the demand for higher levels of food consumption, greater life expectancy, the elimination of infectious disease, and the reduction of pain and discomfort, have presumably existed indefinitely in the past, but they have been abundantly satisfied only in comparatively recent times" [Rosenberg, 1974:107].

In the 1970s and early 1980s the renewed interest in Schumpeter's theories caused a shift in focus from "induced change" to "evolutionary" innovation models. Richard R. Nelson, Sidney G. Winter, and John Ziman are representatives of this theory [Nelson and Winter, 1982; Nelson, 1987; Ziman, 2000]. These models claim that technological change occurs in small steps (incremental innovations) rather than in revolutionary changes. During the 1980s the seemingly related "path dependence" model of technical change entered the scene. Bryan Arthur and colleagues [Arthur *et al*., 1987; Arthur *et al*., 1994] advocated this approach [Ruttan, 2002]. It is related to the "evolutionary model" in that it claims that small historical or probabilistic events may give one of several technologies an initial advantage. The main

difference is the thought that turns taken in the past will determine the future fate of an invention. This may cause a "technological lock in" with a technology that is inferior in the long run [David, 1975 and 1985].

An author, who is difficult to sort in any of the above theories, is James M. Utterback [1971 and 1974]. His works definitely have the entrepreneurial and industry perspective, but in a wider sense that makes his thoughts easy to transfer to other settings. In a simple model of innovation, used to explain the process, he proposes three phases: (1) generation of an idea, (2) problem solving or development, and (3) implementation and diffusion. He states that innovation starts with an idea generation and that this includes synthesis of diverse information and background knowledge.

The above theories are providing the theoretical basis for studies of healthcare innovations. However, few authors in the medical field have considered both invention and diffusion processes in their works, but two books covering idea generation, development, and diffusion of medical devices may be recommended to the interested reader: *Insight and Industry* by Stuart S. Blume [1992] and *Sources of medical technology: universities and industry* edited by Annetine Gelijns and Nathan Rosenberg [1995].

How health technologies evolve

Many health technologies require three different players to evolve: academy, industry, and healthcare. High-technology firms are producing medical technologies such as pharmaceuticals, devices (instruments), and information processing. Such technologies are, to a great extent, based on academic research findings. These findings are refined to innovations by research and development (R&D) activities within the firm. Finally, testing and further refinement will be conducted in the hospital setting.

Blume has described these processes in his book *Insight and Industry* [1992] and proposes that the making of medical technologies occur in five stages: (1) exploration, (2) development, (3) diffusion and accommodation, (4) assessment, and (5) feedback. Blume gives a detailed and illuminating description of the events that transform an idea to a mature medical technology and how these events are influenced by manufacturers, medical professionals, and patients.

Discoveries underlying invention and product development

> "Our understanding of inventive activity (and perhaps of social change generally) is excessively rooted in success stories. We study the history of successful inventions but devote little attention to inventions that were not made. Yet it is highly relevant to ask why it took so long to do certain things, and why inventions failed for so long at some inventive efforts while they succeeded quickly at others" [Rosenberg, 1974:106].

Invention does not happen out of nothing. Invention is the utilization of accumulated knowledge and skills in order to produce an innovation. Successful inventions are often ascribed to individual inventors. However, the embedded knowledge, on which the invention is built, the many contributions by earlier research and discoveries, are often forgotten. We have learnt that Thomas Edison invented the light bulb. But did he invent the glass technology for manufacture of the bulb? Did he discover electricity?

In the same line of thought, medical breakthroughs could be traced to a multitude of underlying inventions and discoveries. Comroe and Dripps [1976] used statistical methods to investigate what kind of research that led to the methods for diagnosis and treatment of cardiovascular and pulmonary disease used in the 1970s. The background was a questioning of the value of basic research and a shift in funding principles to the benefit of clinically oriented research. With the help of clinical experts, the authors identified the ten most important advances in cardiovascular-pulmonary medicine. These ten advances could be traced to 137 "essential bodies of knowledge." By scanning the literature (4000 items), the authors found the roots of this knowledge and could determine what kind of research activities that led to important steps in the development process, what they called "key research articles." Of the key articles, 61.7% could be classified as basic research, 21.2% as other research (e.g. clinical), 15.3% as development articles, and 1.8 as review articles or data syntheses. The authors also found that 41% of the articles described research work that was not clinically oriented at the time it was performed and their conclusion was:

> "Our data show that clinical advance requires different types of research and development and not one to the exclusion of another. Thus the problem is not either-or, but a question of how much support to one type and how much to another. Our data compel us to conclude (i) that a generous portion of the nation's biomedical research dollars should be used to identify and then to provide long-term support for creative scientists whose main goal is to learn how living organisms function, without regard to the immediate relation to

> their research to specific human diseases, and (ii) that basic research, as we have defined it, pays off in terms of key discoveries almost twice as handsomely as other types of research and development combined" [Comroe & Dripps, 1976:111].

Applied research and development

Comroe and Dripps showed that medical innovation is dependent on different types of academic research. Health technologies are often manufactured products or depend on the use of such products. Industrial innovation and innovation within firms may thus also be derived from academic research activities. Two studies in this field were conducted to find out how, and to what extent, new industrial products and processes were based on academic research [Mansfield, 1995]. Among seven industry sectors (76 firms) the drug industry was most dependent on academic research and petroleum industry the least. Academic research often provided theoretical and empirical findings, while invention activities most often occurred within the firm. Top management, in a random sample of 70 firms, were asked to cite about five academic researchers that had contributed to the firm's new products and processes in the 1980s. Usable data in the study was provided from 66 firms and results showed that there were 321 cited researchers. For most industries a relation was found between frequency of citations and quality of the cited researcher's faculty, as measured by an established quality index. The scale of the university's R&D activities seemed also to be important, as did the geographical position. High academic productivity in the relevant area of research and proximity to the firms were positively related to the frequency of citations. More than 80% of the cited researchers were also financially supported by industry, but the greater parts of their research budgets were government funded. However, several of the cited researchers reported a shift during the 1980s from government to industrial funding. Many of the researchers felt that government-funded work was more fundamental than their industry-funded work. The more close to applied R&D, the higher interest in cooperation was expressed by the firm. Geographical proximity seemed also to be more important to the firm when applied R&D was at issue [Mansfield, 1995].

Proximity and/or availability to clinical research facilities and patients, for tests and development, are also important factors for the health technology industry. There is an extensive regulatory framework, which the innovating

firm has to consider, and there are also coverage, and reimbursement requirements to be met for each new technology. The first pre-marketing tests are foremost concerned with efficacy[5] and safety, while later tests are effectiveness[6] studies. In the OECD countries, nearly 20% of gross sales are spent on R&D, of which some 30% go toward pre-marketing and post-marketing clinical trials [OECD, 2005].

Initiation of innovation - Unmet needs or produced desires?

A generally accepted theory is that innovation is initiated by either of two kinds of forces – *demand-pull* and *technology-push*. In diffusion research these forces are also frequently called demand-side and supply-side factors [See e.g. Rosenberg, 1974; Kamien & Schwartz, 1982; and Curlee & Goel, 1989]. Demand-driven innovation starts as a response to a performance gap identified by the innovator, while technology-push is initiated by the supply side and the possibilities created by developments in science and engineering. Rosenberg has argued that demand factors are of limited explanatory value and that supply side factors are the main drivers of innovation. Opposed to this view is a working paper from the Stockholm School of Economics [Goldfarb *et al*., 2001]. The paper compares the different structures for commercialization of academic research findings in the United States and Sweden[7]. The authors classified the Swedish exploitation of research findings as supply-driven and opposed to the demand-driven market of the United States. They concluded, "…the technocratic, supply-driven nature of attempts to exploit academic output in Sweden has been markedly less successful…" [Goldfarb *et al*., 2001: abstract] and that Swedish transfer of technologies, "…when it does occur, does not lead to the establishment of dynamic, fast growing technology-based firms" [Goldfarb *et al*., 2001:2].

The truth is perhaps that technology-push and demand-pull are coexisting mechanisms, which was proposed by Kamien and Schwartz [1982].

[5] With 'efficacy' is meant the extent to which a technology produces beneficial results under ideal conditions.

[6] With 'effectiveness' is meant that the intended health benefits will be produced, also when the technology is deployed in the field under routine circumstances.

[7] An odd fact is that Rosenberg is also one of the co-authors of this paper, which opposes his own arguments.

Technology-push can be seen as a long-run theory and demand-pull as a short-run theory.

> "All in all, the evidence suggests that technological opportunity does influence the pace and direction of technical advance in a broad sense and especially in the long run. Indeed, it would be rather surprising if it did not. Also, technological opportunity may have a strong impact on activities within an industry and on the growth of some industries and the decline of others. Yet when one gets down to the level of specific inventions, it becomes apparent that it is economic opportunity that is essential. In fact, of course technological opportunity and economic opportunity are complementary influences on the course of invention" [Kamien & Schwartz, 1982:64].

However, it seems as if the general perception has changed over to the "demand-side" theory, which claims that demand-pull is more important to overall technological change than technology-push [Curlee & Goel, 1989].

A similar theory, regarding organizational initiation of innovation, is that of innovation imperative. There exists two schools of thought that either advocates the *technological imperative* or the *organizational imperative*, depending on which causal agent is seen as the most influential. With this approach, either technology factors or organizational factors are seen as the main drivers of innovation [See e.g. Davis *et al*., 1984]. In a study of organizational adoption of telecommunication technologies, Grover and Goslar found that, for these innovation processes, the organizational imperative seemed to make the best fit [Grover & Goslar, 1993].

In the 1980s there was a debate on the technological imperative in healthcare [Wolf & Berle, 1981; Hofmann, 2002]. The concept in this debate drifted away somewhat from the original definition and the issue came to be about the observation that technology use in healthcare seemed to be determined by what was technically possible and that technology development had, more or less, a life of its own. This is sometimes also called the imperative of possibility. "What is possible to do has to be done." The doctor is expected to try everything possible to help his patient. The possibilities provided by new technology have to be tried out if there is the least chance of improvements in the treatment. Medical professionals today are technological experts, who are used to solving health problems with complex technology. In rescue medicine and intensive care, a wide range of medical equipment is deployed to save lives. It may be a difficult decision to not use available technology and it is undoubtedly hard for decision-makers to say no to the introduction of a promising new technology. Today, however, this debate has almost faded

away. The end of the imperative of possibility came probably when accelerating healthcare costs forced us into a more selective technology use.

Diffusion of innovations

In this section I will describe the prevailing theories of diffusion, as applied to the healthcare area, and illustrate some of the hypotheses with relevant research findings.

Case studies of the diffusion of health technologies have been conducted for a wide range of diseases and treatments: end stage renal disease [Stocking, 1988], myocardial infarction [Cook *et al*., 2004], benign prostate cancer [Sennfält, 2005], antidepressants [Berndt *et al*., 2002], laparoscopic techniques [Dirksen *et al*., 1996], and information technologies [Andersson *et al*., 1983], to mention a few. Some studies are merely interested in measuring the extent or rate of diffusion, while others are trying to relate the diffusion pattern to theories of social change or decision-making. Yet a third class of studies is carried out for modeling purposes in an attempt to predict the diffusion of new technologies.

Diffusion is the mechanism by which innovations spread to potential users. The area has attracted an enormous interest among researchers from different disciplines. This review will only present the reader with small pieces of the vast literature, which exists in this field. Recommended sources for a more comprehensive description of the process and the literature are Rogers [2003], Greenhalgh *et al*. [2004; 2005] and Hall [2005]. Other sources used in this chapter are Greer [1977], Banta [1990], Tornatzky & Fleischer [1990], Blume [1992] and Bonair & Persson [1996].

The overview will start with a section on different research traditions. This will be followed by three sections on the main sets of influences on diffusion, as identified by Bonair and Persson [1996]: (1) *actors in the process*, (2) *characteristics of innovations*, and (3) *structure and environment*. In the first set of influences I will include characteristics of adopters as well as of other main actors in the process. The adoption decision and the influence of communication networks will also be described here. The second set focuses on the nature of the innovation and the third set on environmental factors, such as politics, regulatory frameworks, and commercial market.

Finally, in the last sub-section, construction and use of diffusion models will be described.

Diffusion research traditions

In accordance with research traditions of the innovation process as a whole, diffusion research also has its academic and its entrepreneurial strain, exemplified below by the authors Everett M. Rogers and Bronwyn H. Hall:

> "The diffusion of innovations model (DIM) is concerned with how innovations, defined as ideas or practices that are perceived as new, are spread. Diffusion is the process through which an innovation spreads via communication channels over time among the members of a social system. This is a social sciences definition of diffusion, one that is not to be confused with the thermodynamic definition of diffusion. Diffusion occurs in complex systems where networks connecting system members are overlapping, multiple, and complex" [Rogers *et al*., 2005:3].[8]

> "Understanding the diffusion process is the key to understanding how conscious innovative activities conducted by firms and governmental institutions (activities such as funding research and development, transferring technology, launching new products or creating new processes) produce the improvements in economic and social welfare that are usually the end goal of these activities" [Hall-05, 2005:460].

Social and technological change as a field of research has its origin in the nineteenth century [E.g. de Tarde, 1890]. Most theories and thoughts of today can be found in their embryonic forms in sociological, economic and political literature from that time. The early works were almost exclusively theoretical and even somewhat later, in the 1920s and 1930s, there were only few empirical studies [Kinnunen, 1996]. Diffusion of innovations, as the main interest of empirical studies, gained popularity after Ryan and Gross' well known study on the spread of hybrid corn among Iowa farmers [1943]. A growing interest followed and the 27 diffusion studies made until 1941 had risen to 423 in 1959 [Katz *et al*., 1963].

[8] This reference, "Complex Adaptive Systems and the Diffusion of Innovations," was published posthumously. Everett M. Rogers died on October 31, 2004.

Different academic disciplines developed their own innovation research traditions during this time. Greenhalgh *et al*. [2004] identified four main research traditions in early diffusion research: Rural sociology, Medical sociology, Communication studies, and Marketing. Researchers were unaware that they in fact explored the same idea and around 1960 the field was divided into two independent traditions, one sociological and one economic. Each had its own terminology, definitions and objects of research. The *economic tradition* has primarily defined the innovation process as the activities that bring a product into the market. Diffusion is seen as the spread of the product among potential buyers and the ultimate aim of innovation and diffusion is economic development. The *sociological definition* of the innovation process is wider and could include invention and marketing as well as diffusion. In this tradition the objects of innovation are not always physical in character, but could also be an idea, a procedure or a piece of news [Bonair & Persson, 1996].

After 1962, when Rogers had presented his more general innovation model, academic innovation research became more and more interdisciplinary. The terminology used by Rogers became more or less standard and the methodology of Ryan and Gross was used as a template in a variety of disciplines. But outside of the academic world, in the entrepreneurial field, businessmen, marketers, and politicians have developed their own definitions and methods of investigation.

The interest in innovation and diffusion as an academic field of research has exploded since the 1960s. Much of the credit for this growing interest must be ascribed to Rogers and his work *Diffusion of Innovations*, which is the most cited work in innovation research. Before his book appeared there were 405 identified diffusion publications. Twenty years later there were more than 3000 publications [Rogers, 2003: preface] and in 2004 it had exceeded 5000 [Rogers, 2004].

The first diffusion study in the area of health appeared 1957 when Coleman, Katz and Menzel presented their study of diffusion of a new drug, in which they found that prescription of new drugs depended very much on networks and physician-opinion leaders. This work became a template for later studies. Diffusion research in the medical field was long dominated by studies of pharmaceuticals [Bonair & Persson, 1996], perhaps because a medicine is a more manageable study object than a device, which is often a "moving target" that develops in parallel with the diffusion. Diffusion of devices starts before the innovation has found its final form. Incremental changes often occur when the device is deployed in regular use. A studied device is, therefore, not the

same innovation after the diffusion study as it was on initiation of the study. However, today devices are more common as study objects. There are plenty of examples in the literature, especially from the two last decades. The vast majority of these studies are investigations of so-called "big-ticket" technologies, which have highly visible structural and economic implications.

A L Greer has written a very useful review of studies in the medical field up to the 1970s [Greer, 1977]. Greer sorted the reviewed studies into three categories: (1) reception and adoption of innovations in an organization, (2) aspects of organizations that inhibit or facilitate the adoption or implementation of innovations, and (3) interests and values relevant to innovation and their representation in organizations.

Another recommended work in this field is a chapter by David Banta in the book *Life-cycles of Medical Technologies*. This chapter picks out the most important landmarks of diffusion research in the area of health technology [Banta, 1990].

The efforts in diffusion research have been more and more interdisciplinary in character and most works of today seem to be influenced by Rogers' general *Diffusion of innovations* (DOI) model from 1962 [Rogers, 2003]. The model was not, however, developed to suit organizational innovation, and therefore not immediately applicable to diffusion of health technologies. Several attempts have been made to adapt the theories to the healthcare setting and Rogers argues, as late as 2004, for the generalizability of his diffusion model.

> "New applications of the diffusion model are constantly occurring, with yet newer innovations becoming available to study. My main conclusion is that the diffusion process displays consistent patterns and regularities, across a range of conditions, innovations, and cultures. Thus it seems there is indeed a general diffusion model" [Rogers, 2004:19].

Rogers is the overwhelmingly most cited author in diffusion research and I will here give an outline of the main traits of his diffusion model. Rogers suggested four important elements of diffusion: the *innovation*, *communication channels*, *time* and the *social system*.

> "*Diffusion* is the process in which an innovation is communicated through certain channels over time among the members of a social system. It is a special type of communication, in that the messages are concerned with new ideas. Communication is a process in which participants create and share information with one another in order to reach a mutual understanding" [Rogers, 2003:5].

The main actors involved in this process are the *adopters*, the *change agents*, the *opinion leaders*, the *champions* and the *gatekeepers*, which roles are not static but may vary depending on the nature of the innovation. Rogers also distinguished three main sets of influences on diffusion: *perceived characteristics of the innovation, characteristics of the adopters*, and *diffusion networks* [Rogers, 2003]. He gives quite a few examples of diffusion in the medical field and it has a section on organizational innovation. Rogers also acknowledged that invention and development activities might influence later diffusion of the innovation. However, he did not devote much attention to these thoughts in his book.

Greenhalgh *et al*., suggest six broad categories within which influences and activities in organizational diffusion may be sorted: "(1) the innovation itself; (2) the adoption/assimilation process; (3) communication and influence (diffusion and dissemination, including social networks, opinion leadership, champions, and change agents); (4) the inner (organizational) context, including both antecedents for innovation in general and readiness for particular innovations; (5) the outer (interorganizational) context, including the impact of environmental variables, policy incentives and mandates, and interorganizational norms and networking; and (6) the implementation process" [Greenhalgh *et al*., 2004:585]. The authors do not agree with Rogers that diffusion patterns can be explained by adopter and innovation characteristics. Instead, they argue that it is the interaction among the innovation, the intended adopters, and the particular context that determine the rate and extent of diffusion.

The work by Greenhalgh *et al*., *Diffusion of Innovations in Health Service Organizations,* is an extensive systematic literature review of the diffusion of innovations in service organizations [2004]. The aim was to find theories to support spread and sustained use of innovations in health service delivery and organization. For this purpose they scanned more than 6000 titles/abstracts and appraised 1024 full text papers and book chapters, of which 495 sources were included in the final report. The sample consisted of 213 empirical and 282 non-empirical works. This systematic review gives a very detailed picture of diffusion research until today and the authors have arrived at their own model of diffusion in the course of the analysis.

Tornatzky *et al*., have a somewhat different focus in the book, *The Processes of Technological Innovation.* It describes technological change within firms or

organizations. Change is supposed to be influenced by the nature of the technology, characteristics of users, characteristics of deployers[9], boundaries between users and deployers, and characteristics of communication and transaction mechanisms [Tornatzky & Fleischer, 1990:127-143]. They call this a *Context-based approach* and concepts often referred to in this book are: the innovation, the knowledge base, and the social context.

The actors and the process

Diffusion of an innovation follows of individual adopters' decisions to change their practices in favor of a new technology. Rogers diffusion model suggests this process to occur in five stages: *knowledge* (awareness of an innovation), *persuasion* (attitude formation), *decision* (to adopt or reject), *implementation* (putting the new idea into use), and *confirmation* (reinforcement of the decision) [Rogers, 2003:169]. In this thesis, the first three stages are referred to as the diffusion process, while implementation and confirmation are considered parts of a deployment process, which is dealt with separately.

The knowledge of an innovation might also be the result of an active search. Sometimes a search for solutions is initiated by the perception of a performance gap and a need for improvements [Zaltman *et al*., 1973]. Rogers have defined a performance gap as the discrepancy between an organization's expectations and its actual performance [Rogers, 2003], but a performance gap may also be a task-related discrepancy perceived by individuals in their personal activities.

This section will follow the adopters in their identification of a performance gap and search for solutions, through awareness and attitude formation, to the decision to adopt or reject an innovation. Characteristics of the main actors will be outlined as well as their roles and incentives in the diffusion process.

The adoption decision

"Adoption is the primary mechanism by which an innovation is diffused" [Kelly *et al*., 1978]. An adoption decision results in adoption or rejection of the

[9] By deployer, in this context, is meant the person or organization, which forwards the innovation to the end-users and sustains its use.

innovation. However, neither adoption nor rejection is a final decision, but can be reconsidered and reversed. In this thesis, a reversed adoption decision will be called *dis-adoption*, and, in case neither adoption nor rejection has been actively considered, the term *non-adoption* will be used.

Diffusion of health technologies occurs mainly among healthcare organizations, which implies that the adopters are adopting units, for example hospitals or ward units. Consequently, the decisions about innovations are often authority decisions or collective decisions, and the decision may also be dependent on decisions made by others in the organization. However, individual adoption decisions about health technologies also occur.

According to Greenhalgh *et al*. [2004], the adoption decision in organizations is better described as a process than as an event. To explain the stages in this process they suggest the use of the *Concerns Based Adoption Model*, initially developed for innovation in schools. This model distinguishes three stages of concerns in the adoption decision, which can be seen as different levels of knowledge about the innovation. In the first stage (preadoption) awareness of the innovation arises and the adopter gathers sufficient knowledge about what it does and how to use it, and about its benefits and costs. In the second stage (early use) the adoption is fitted to the adopter's routines and involves further information, training, and support. The third stage (established use) concern knowledge about consequences of the adoption and of possible adaptations and improvements of the innovation to better fit the needs of the adopter.

However, I find it more useful in this overview to divide the process in stages of *awareness*, *attitude formation*, and *decision*. These three stages are sometimes also preceded by definition of a problem or identification of a *performance gap*. During this preceding stage the adopter gets a deeper understanding of the problem and its context, gains insight to different approaches, and come up with innovative solutions. Rogers [2003] called this the agenda-setting stage of organizational innovation. This stage has so far not attracted much interest in diffusion research and March, who studied organizational innovation, stated that "... changes often seem to be driven less by problems than by solutions" [March, 1981]. This could be true for most healthcare innovations of today, however, through times, medicine has plenty of examples of truly problem-driven innovations.

At the *awareness* stage the potential adopter hear about the innovation, but knowledge about it and its possible benefits is rather fragmentary. A certain degree of conscious evaluation of the pieces of information is required to get

full awareness of an innovation. In order to arouse this interest, it is also important that the information comes from a trusted source. Manning and Denson [1979 and 1980] investigated the use of information sources among medical professionals. In two survey studies they asked physicians what information sources they used in different stages of their learning about new technologies. The surveys pointed out medical journals as the most popular source of information in all stages of learning. Other identified sources were continuing medical educational programs, meetings and conferences, newsletters and recommendations (Medical Letter), company representatives, discussions with colleagues, courses, and hospital rounds.

Attitude formation occurs as the potential adopter becomes interested in the benefits of the innovation and seeks additional information about it. This stage involves evaluation of the innovation and its application to the present or future situation of the adopter, i.e. how well the technology will suit the need of the adopter. It also involves estimation of advantages, disadvantages and costs associated with the innovation. This estimation is performed more or less formally and sometimes with a minimum of information available. The process may lead to a decision to try out the innovation, if that is possible, and collection of further information by means of trials. At this stage the opinions of colleagues are important influences in healthcare innovation [Coleman *et al*., 1957].

The *adoption or rejection decision* is the last step in this process. Adoption results in procurement of an innovation or the assimilation of new thoughts or actions into the adopter's immediate conceptual environment. Rejection is the decision not to adopt the innovation or not to adopt on grounds of the present knowledge. A cautious adopter might find it worthwhile to wait for better evidence of possible benefits and information on other consequences.

Adoption decisions in healthcare organizations are influenced by a large number of factors. The understanding of the key influences on medical professionals and other players is not complete. Three common explanations for adoption of medical technologies can be distinguished in the literature: the *profit maximization model*, the *technological preeminence model* (the wish to be a technology leader), and the *strategic-institutional model* (clinical excellence) [See e.g. Teplensky *et al*., 1995; and Greenberg *et al*, 2005]. Another approach may be represented by Anderson and Steinberg [1994], who coupled the incentives in hospital adoption behavior to different models of competition: models of *price competition*, *technology competition*, and *utility competition*. The price competition model is based on traditional economic theory and assumes that

demand and financial profit determine which innovations the hospital will adopt. The technology competition model can be derived from three theories: hospitals want to be the largest, hospitals want to be technologically advanced, and hospitals choose technologies that will maximize physician income. Finally, in the utility competition model, the innovations are evaluated against the benefits they will bring to the hospital and are adopted in an effort to maximize resource utilization.

The larger part of these models of hospital adoption is probably less valid in a financial context where competition among hospitals is less pronounced. In that environment, societal utility and patient preferences may be as strong influences as price, technology, and hospital utility, and even in competitive environments there is always a wish to improve the treatments of patients. This is in line with the evidence-based model of adoption of health technologies. It has been put forward that the publication of key research results and evidence-based guidance and guidelines are increasingly important in hospital adoption behavior [Gosling *et al*., 2004; Cook *et al*. 2004], while others state that evidence-based practices have generally not been accepted [Freeman & Sweeney, 2001; Lam *et al*., 2004].

Adopter characteristics

Characteristics of adopters have always been regarded as important determinants in adoption and diffusion of innovations. Researchers have investigated factors such as socioeconomic status, education, habits of information seeking, extent of media exposure, various forms of network contact, and the size of networks (volume and extension). There is also a set of characteristics that are psychologically related. Greenhalgh *et al*. [2004] identified a large literature, relevant to this field, in cognitive and social psychology research. They found that psychological factors influencing adoption behavior could be either personal or context specific. Factors at the individual level are determining the willingness to try out innovations (e.g., tolerance of ambiguity, intellectual ability, motivation, values, and learning style). Contextual psychological factors include overall values and goals, which motivate adopters to try out new ideas.

Another factor in this field is the perception of risk, associated with the innovation, and several diffusion researchers have pointed out that the risk behavior of adopters is an important determinant in the diffusion process [See e.g. Slade & Anderson, 2001; and Marra *et al*, 2003].

In Rogers' Diffusion of innovations theory [Rogers, 2003] the adopters are divided into five categories, or ideal types: (1) innovators – the more venturesome, more educated, those with more extended information networks, (2) early adopters – the social leaders, who are influential and respectable, (3) early majority – the followers, (4) late majority – the skeptical, cautious followers, and (5) laggards – the traditional, unwilling followers.

These adopter categories can be coupled to adopter innovativeness, i.e. "the degree to which an individual or other unit of adoption is relatively earlier in adopting new ideas than other members of a social system" [Rogers, 2003]. This categorization of adopters is based on a function of the time from introduction of an innovation to its adoption by individual adopters. Rogers assumed that the time (t), in this function, was normal distributed and he used the mean (m) and standard deviation (sd) to categorize the adopters. The first 2.5% ($t \leq m-2sd$) of the individuals in a system to adopt an innovation are called innovators. The innovators are more interested in new ideas and more cosmopolite in their social relationships. Early adopters are the next 13.5% ($m-2sd < t \leq m-sd$) individuals to adopt the innovation. Rogers defined them to be more integrated in the local system than the innovators and claimed that this category, more than any other, has the highest degree of opinion leadership. Potential adopters look to early adopters for advice and information about an innovation. The early majority is the next 34% ($m-sd < t \leq m$) and the late majority the following next 34% ($m < t \leq m+sd$). Finally, the laggards are the last 16% ($t > m+sd$) of the individuals in a system to adopt the innovation. According to this theory the later adopters will only accept a new idea when they are surrounded by peers who already have adopted and who are satisfied with the new idea.

Rogers' adopter categories have been widely cited, but opinions differ regarding their practical use. Among the skeptics are for example Greenhalgh *et al*., who expressed the following in a systematic review of literature on innovations in service organizations:

> "People are not passive recipients of innovations. Rather (and to a greater or lesser extent in different persons), they seek innovations, experiment with them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, "work around" them, gain experience with them, modify them to fit particular tasks, and try to improve or redesign them – often through dialogue with other users. This diverse list of actions and feelings highlights the complex nature of adoption as a process and contrasts markedly with the widely cited "adopter categories" ("early adopter,"

> "laggard") that have been extensively misapplied as explanatory variables. There is little empirical support for these stereotypical and value-laden terms, which fail to acknowledge the adopter as an actor who interacts purposefully and creatively with a complex innovation" [Greenhalgh *et al*., 2004].

Change agents

The change agent communicates innovations to others in the society of potential adopters. He or she will influence adoption decisions in a certain direction, usually in favor of a new technology, but a change agent may also attempt to prevent the adoption of an innovation considered undesirable by a change agency.

> "Many different occupations fit our definition of change agent: teachers, consultants, public health workers, agricultural extension agents, development workers, and salespeople. All of these change agents provide a communication link between a resource system with some kind of expertise and a client system. One main role of the change agent is to facilitate the flow of innovations from a change agency to an audience of clients. For this type of communication to be effective, the innovations must be selected to match clients' needs. Feedback from the client system must flow through the change agent to the change agency so that it appropriately adjusts its intervention programs to fit the changing needs to clients" [Rogers, 2003:368].

A change agent has best chance of succeeding in his/her mission if the communicated message is clearly understood and perceived as reasonable by the adopters. It is thus important that the change agent creates a relation to the clients of trust and confidence. In order to achieve this, the change agency may recruit key persons, which are more similar to clients within the system, to act as aides. Rogers (2003) describes the situation like this:

> "Change agents are usually professionals with a university degree in a technical field. This professional training, and the social status that goes with it, usually means that change agents are heterophilous from their typical clients, thus posing problems for effective communication about the innovations they are promoting. Many change agencies employ change agent aides. An aide is a less than fully professional change agent who intensively contacts clients to influence their innovation-decisions. Aides are usually homophilous with the average client and thus provide one means of bridging the heterophily gap between professional change agents and their client audience" [Rogers, 2003:28].

The use of change agents to support diffusion in healthcare has been suggested in several cases. One example is the automated external defibrillator, which has been adopted by emergency service staff as a first-line intervention in the management of out-of-hospital cardiac arrest. The practice of using it within hospitals, however, has been sporadic and isolated, even though it is strongly recommended. This has been suggested to be due, at least in part, to the absence of change agents within the hospitals [Laws *et al*., 2004]. In another case informatics nurse specialist have been suggested as primary change agents regarding clinical information systems. With their knowledge about the work situation, and problems and needs in nursing, they are in a key position to facilitate implementation of innovations in the healthcare setting [Hilz, 2000].

A change agent may also use opinion leaders within a given social system to enhance his/her influence. Opinion leaders are influential persons within a given social system. The opinion leaders have large interpersonal networks that allow him or her to serve as a social model, whose innovative behavior is imitated by other members of the system. The influence and respect with which the opinion leader is held can be lost, however, as when an opinion leader deviates too far from the norms of his or her system [Rogers, 2003].

Opinion leaders

Opinion leaders are members of the social system in which the innovation diffuses. Sometimes they are professionals who represent change agencies outside of the system. The opinion leaders are able to influence other adopters' behavior and attitudes by providing information and advice about innovations to many in the system. They are at the center of interpersonal communication networks in the community of adopters and thus more influential. The opinion leaders may promote new ideas or they may oppose change. The position taken does often reflect the norms of the social system of potential adopters [Rogers, 2003]. In healthcare the innovativeness of the units is partly dependent on these norms and on the actions of opinion leaders.

Opinion leaders are found to have somewhat higher social status within the group of adopters, but opinion leadership is not a function of formal position, it is earned and maintained by the individual's competence, social accessibility, and conformity to the norms of the system. The opinion leader can be influential in certain areas, while less influential regarding other areas.

He or she is "empowered" to exert opinion leadership by other members of the group [Katz, 1957; Rogers, 2003].

Opinion leaders are also supposed to be more cosmopolite and more exposed to all forms of external communication. However, in spite of their greater exposure to the media many opinion leaders report that they in turn are influenced by other people. Most opinion leaders are primarily affected by interpersonal contacts and not by the communication media [Katz, 1957].

Later adopters turn to early adopters for advice and information about an innovation. Early adopters in healthcare are usually also opinion leaders. Introduction of innovations through opinion leaders will thus speed up the diffusion process. Coleman *et al*. found that adoption of new drugs depended very much on physician-opinion leaders [Coleman *et al*., 1957]. This has also been proven by Rogers [2002] (preventive innovations) and in a randomized controlled experiment by Lomas *et al*. [1991] (implementation of clinical guidelines).

Change agents often use opinion leaders in diffusion campaigns. By intervening directly with the opinion leaders, the lag time between introduction and widespread diffusion can be considerably reduced [Valente & Davis, 1999].

Champions and gatekeepers

As soon as an innovation is subject to adoption considerations many people may be for or against it. The most active and influential individuals in this process have been termed champions (or product champions) and gatekeepers [Rogers, 2003; and Stocking, 1985].

The *champion* facilitates diffusion of an innovation. He (or she) communicates information about the innovation to potential adopters and sells the idea to superior colleges and authorities to obtain resources and otherwise accelerate acquisition of the innovation. Champions may be of great value. Finkelstein *et al*. described this actor as "… an effective tool for bridging the gap between engineers and clinicians", but he also observed that there is "…a tendency of visionary champions … to trust their own clinical and technological intuition above that of all others" [Finkelstein *et al*., 1995]. Which indicates that very active champions may ignore ideas and suggestions emanating from others.

A champion is not always present in the adoption process, but a technology has a greater chance of success if it has a champion that facilitates its passage through committees and gatekeeping activities [Stocking, 1985].

The gatekeeper has the power to allow or block innovation. Chief physicians, consultants and managers may act as gatekeepers [Stocking, 1985]. They may withhold or reshape information so that they can control what flows into the organization. Both gatekeepers and product champions keep abreast of technological developments inside and outside of the organization and transmit (or withhold) pieces of information to their colleagues, but while the product champion acts in favor of the innovation, the gatekeeper may act for or against it.

The industrial and entrepreneurial perspective gives a similar but somewhat different description of the gatekeeper. The idea is that most information comes into the organization from outside and that a few individuals, namely the gatekeepers, who have more contact with outside influences, bring this information into the firm. These influences are, for example, colleagues outside the firm and technical literature [Utterback, 1974]. Three different gatekeeper roles have been defined within this perspective: the technical, the market, and the manufacturing gatekeeper. The technical, or scientific, gatekeeper is the one who stays abreast of technological developments inside and outside of the organization and transmits information to colleagues. The market, or product gatekeeper, is sensing the needs of customers, and suggests R&D in response to changes in requirements. The manufacturing, or process gatekeeper, is sensing the needs of production departments within the organization and couples this with practices used elsewhere [Dosi *et al*., 1988; Tornatzky & Fleischer, 1990].

Characteristics of innovations

The characteristics of the innovation that influence diffusion are not the ones objectively determined after long time use of the innovation. Instead, it is the adopter's perception of innovation characteristics before adoption that is crucial. Such characteristics are for instance the five suggested by Rogers, relative advantage, compatibility, complexity, trialability, and observability [Rogers, 2003:265-266]. He called these characteristics *innovation attributes*.

Relative advantage is the degree to which an innovation is perceived as better than the practice it supersedes.

Compatibility is the degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters.

Complexity is the degree to which an innovation is perceived as relatively difficult to understand and to use.

Trialability is the degree to which an innovation may be experimented with on a limited basis.

Observability is the degree to which the results of an innovation are visible to others.

Rogers' attributes of innovations have been used as a template in diffusion research since the first edition of his book *Diffusion of Innovations* [1962], and authors, who have tried different systems of categorization, do often refer to these five innovation characteristics. They have been recognized in one form or another by numerous researchers in the past. However, the attributes may appear under different names and are often somewhat rearranged and completed with more attributes.

> "... one can derive a list of factors that might be expected to influence the diffusion of innovations. These can be classified into four main groups, those that affect the benefits received, those that affect the costs of adoption, those related to the industry or social environment, and those due to uncertainty and information problems. Alternatively, using the classification system of Rogers, one can identify the first and second as combining to yield relative advantage and complexity, the third as compatibility, and the fourth as being determined by trialability and observability" [Hall, 2005:469].

Lund suggested that the following additional factors should be used together with Rogers' classical list when investigating health technologies. The first two of these are innovation attributes, while the rest are general influences of organization and environment [Lund, 1990:16-18].

Distinctivity: By this the author mean the degree of influence by status-consequences on the decisions to adopt or reject an innovation in a professional healthcare context, and he claims that this is particularly important in choosing between an established medical procedure and a new technology, including all the risks associated with this.

Controversiality: This factor relates the rate of diffusion to the conflict potential of a medical innovation.

Organizational structure: In this, the author includes organizational size, institutionalization, and specialization.

Organizational culture: This is, according to the author, how norms and myths of professionals and laymen influence the transfer of medical technology.

Public and private policies: This factor includes management strategies and governmental regulation of innovation diffusion in healthcare settings.

Another aspect, often regarded as a separate set of attributes influencing the relative advantage of an innovation, is the *costs* of adoption and use. This includes not only the price of acquisition, but also the cost of complementary investment and learning required to make use of the technology. It may include training of nurses as well as the purchase of necessary operational and maintenance services. The innovation might even require reorganization of the work process in the intended user organization. If these combined costs are high, the perceived benefits will be considered too costly and rejection will occur [See e.g. Teplensky, 1995 and Hall, 2005].

Different authors have suggested numerous important attributes of innovations. The attributes are sometimes approaching larger numbers. One example is a study by Kearns, in which he identified 25 innovation characteristics relevant for the evaluation of management innovations [Kearns, 1992]. However, the practical value of a complicated model might be limited, and Rogers' five characteristics have been proven useful as explanatory factors and cover some of the most important innovation attributes in the adoption process.

Technology Cluster Innovations

An important, but sometimes forgotten, characteristic of technical innovations is that they often form bundles or clusters of innovations [Silverman & Bailey, 1961; Prescott & Van Slyke, 1997; Rogers, 2003]. Innovations are typically studied individually, but technologies may be complementary related and they may share a common platform, which is necessary to obtain the full potential of the innovation.

Silverman and Bailey [1961] demonstrated that, sometimes, it is necessary to study a whole set of related technologies. He found that farmers who adopted thicker planting of corn, but not the related innovations of hybrid seed and fertilization, got lower corn yields than if they had continued their old practice. This made them more likely to later dis-adopt the innovation.

Three types of cluster formation were identified by Prescott and Van Slyke [1997]: clusters that address a *similar function* (e.g. different Internet browsers), clusters that share a *common platform* (e.g. browsers, gophers, and the web, which share the Internet communications backbone). A third class of clusters is provided by technologies that share an *overall common function*, though each may have widely different functions, individually. Examples of such cluster technologies are air bags and anti-lock brakes in cars, which both are related to vehicle safety. A person, who is interested in vehicle safety, will most probably adopt both. Adopting one technology in a cluster makes adoption of others in the cluster easier. The authors indicated in their study that diffusion of the Internet had been dramatically affected by the development of related innovations that improved its usefulness.

Structure and environment

Adopters of innovations are located within a country's national innovation system. Such systems of innovation strongly influence the diffusion process. This has been addressed by for example Edquist [1977; 2005] and Wolcott *et al*. [2001]. There may also be regional and local systems of innovation providing incentives and barriers to innovation. Systems of innovation constitute the outer environment, in which the adopting unit operates. These systems have structures, which determine the influence on adoption and diffusion. There are, of course, also internal structures of healthcare organizations that are important in this respect, but these will be referred to later as organizational adopter characteristics.

Structure and environment, in the healthcare innovation process, comprise the health service organization, the commercial market (including product development structures), and the political and societal climate in which they are working. These environmental factors are constantly changing, but relevant factors have to be identified and their impact on adoption decisions evaluated, in order to get a clear picture of the diffusion process.

The influence of structure and environment on healthcare innovation has so far not been extensively explored, but four areas may be distinguished that are exerting substantial influence on this process: (1) *reimbursement system and funding*, (2) *competition*, (3) *legislation and regulation*, and (4) the *political and societal climate*, including cultural determinants.

Reimbursement system

One important factor in healthcare innovation is the reimbursement system. Slade and Anderson [2001] investigated reimbursement incentives and disincentives to the adoption and use of new and expensive technologies. In their study they found that the block grant financing system does not encourage innovation adoption. Adopting new technologies usually go together with increased costs and the block grant system does not automatically reward quality improvements. Another common reimbursement system is the fee-for-service system. In this system incentives are present for innovations generating additional services. Quality improvement innovations, however, are not always generating measurable additional amounts of healthcare and may be valued less in this system.

Romeo *et al*. [1984], National Health Policy Forum [1998], and Selder [2005] are recommended for an overview of the effects of reimbursement systems on the diffusion of innovation.

Competition

Competition is present in two different dimensions: competition between hospitals and competition on the commercial market for health technologies.

Market structure, which determines the competition on the commercial market of health technologies, may influence adoption decisions. Producers of medical devices often act as oligopolies. These are able to alter adoption prerequisites by offering sponsored products to gain market shares. Market structure affects the adoption of innovations in two different ways: via seller behavior and via buyer behavior [Hall, 2005].

Competition, among technology producers, to build market share, may induce a faster than optimal adoption rate in hospitals. The medical device industry, as one example, is quite oligopolistic and if two (or more) producers are offering different standards, they may compete with prices below the actual

cost of producing the new technology, which will induce a rapid adoption rate [Farrell & Saloner, 1986]. In healthcare, this may lead to overuse of an immature technology, and, in the worst scenario, cause unnecessary suffering to patients.

Gelijns and Rosenberg [1994] point out that competition can be a strong incentive affecting the diffusion of medical technology. The authors claim that hospitals consider technology a way to stay competitive. It attracts patients and physicians. The number and distribution of hospitals is, therefore, an important determinant of technology use. A large number of competing hospitals in close proximity will thus lead to a higher rate of diffusion of new technologies.

Legislation and regulation

Technology legislation and regulation may slow down adoption rate in some areas, while other areas might benefit from the relatively stable technological standard, which is provided by a general regulatory environment. The presence of technological standards is strongly influencing healthcare innovation. A technology standard may lead to exclusion from the market of products using another technological solution, even if that technology would be beneficial in the long run. An advantage, however, is that standards increase the compatibility of products [Katz & Shapiro, 1985]. Farrell and Saloner [1986] suggest that compatibility benefits the adopter in three different ways: interchangeability of complementary products, ease of communication, and cost savings. Transferred to the hospital setting these benefits are primarily a reduction in time and cost spent on education and training, and that inter-hospital movement of staff is facilitated.

Political and societal climate

The political and societal climate may favor healthcare innovation, but can also impose constraints on innovativeness in hospitals. There is also, of course, a set of moral and ethical norms valid for working with human subjects, which will constrain the possibility of experimenting with innovations of which the benefits and side effects are not known.

Cultural attitudes towards changes and risk-taking may vary among geographical areas, religious communities, rural and urban environments,

organizations, genders, and among target groups for different innovations. The *norms of a social system* have been defined as the established behavior patterns of its members [Rogers, 2003]. A system's norms can inhibit changes that would seem rational from the view of an outside observer. Rogers points out some examples of seemingly irrational religious roles about foods and about resistance to family-planning methods in certain cultures. Similarly, cultural variables seem to influence the diffusion of consumer durables in European countries. In a study on this, Tellis *et al*. investigated economic and communication variables, as well as the cultural variables such as uncertainty avoidance, masculinity, need for achievement, and industriousness. The authors found that the probability of early adoption increased with higher need for achievement and industriousness and decreased with uncertainty avoidance. They also found that the take-off time for these products was half as long in Scandinavian countries (4 years) as in Mediterranean countries (7.4 years) [Tellis *et al*., 2002].

Diffusion models

Two theories are basic in the attempts to explain the mechanics of diffusion: The Two-step hypothesis of communication [Lazarsfeld *et al*., 1944; see also Katz, 1957; and Robinson, 1976] and the Diffusion of innovations theory [Rogers 2003].

The main feature of the *Two-step hypothesis* is that news about an innovation flows first to opinion leaders, who then transmit the information to the general population. This theory has its origin in de Tarde's ideas from 1890 about innovators and imitators, in which information and acceptance of ideas spread via a social elite to other members of the society [Kinnunen, 1996]. This theory is also the fundament of the Bass model, which has been constructed to give information about the diffusion of consumer durables [Bass, 1969 and 1986].

Rogers' *Diffusion of innovations theory* focuses on innovation attributes, the innovativeness of adopters, and how the innovation is communicated in the social system of potential adopters. His model includes the following five sets of variables that determine the rate of adoption: (1) perceived attributes of innovations, (2) type of innovation-decision, (3) communication channels, (4) nature of the social system, and (5) extent of change agents' promotion efforts [Rogers, 2003:222]. Rogers also pointed out that the extent of the required behavioral change and the size of the investment are important explanatory

factors, and that the return on the investment must be considered, in the case of industrial products.

Many attempts have been made to predict diffusion patterns of innovations. Predictive models of diffusion have been of great value in marketing science to describe patterns of sales and to predict timing and levels of adoption [See e.g. Eliashberg & Chatterjee, 1986], but generally, the models have added little to the understanding of the actual decision process. Theories behind the models often neglect to include interaction among actors, contextual factors and the influence of information accumulation.

The many factors involved in diffusion processes have encouraged the use of regression models to test the explanatory power of different diffusion variables [See e.g. Gatsonis *et al*., 1995; Teplensky *et al*., 1995; McWilliams *et al*., 1998; and Grilli & Taroni, 2004]. However, there are numerous hurdles to pass in order to arrive at a useful regression model. Each variable in the model must be measured, or at least ascribed a value, and, to take but one example: The degree of relative advantage (from Rogers' five attributes of innovations) contains several sub-measures. When applied to health technologies one must consider for example treatment outcome, different costs, social prestige, work convenience, and patient satisfaction.

Prediction of the adoption of innovative products

People respond to new ideas or products in different ways. The adoption of a new technology can be analyzed using different predictive diffusion models. Understandably, this has been of great interest in marketing science and to producers of new products. Numerous attempts have been made to predict the acceptance of new products, but forecasting accuracy of most models is low due to the large number of factors involved.

A common approach is to construct complicated regression models [See e.g. Teplensky *et al*., 1995], but the problem is to find a model that is valid for a broad range of innovations and for different types of healthcare organizations. Another approach is to involve chance or probability in the models. Innovation diffusion models have often ignored the stochastic property of diffusion, but consumer preferences and competitive activities change rapidly and so do the environmental conditions outside of the social system, which may influence adoption behavior [Eliashberg & Chatterjee, 1986]. These changes are often seemingly irrational and appear to happen by chance.

Utterback [1974] also recognized the difficulties in modeling adoption behavior, but outlined the following model criteria: The probability that a given adopter will accept an innovation is (1) an increasing function of the proportion of adopters already using it and of the benefits of doing so; and (2) a decreasing function of the size of the investment. With the industrial market in mind, Utterback suggested that relative advantage is the primary determinant of adoption. Relative advantage, to the firm, is the result of a change in either process or product range. Process innovations may make the production more effective and a product innovation may increase sales, and both have a potential to reduce the average total cost of production per unit.

A well-known method of predicting innovative behavior is the above-mentioned *Bass model*, which estimates adoption probability [Bass, 1969; Wilton & Pessemier, 1981; and Sillup, 1992]. The Bass model gives information about the timing of initial purchase of new products by consumers, but has also been suggested for prediction of medical device adoption [Sillup, 1992]. The model was constructed as a market prediction for consumer durables. It yields an S-shaped cumulative adoption curve that has a high proven empirical fit with retrospectively collected adoption data for a wide range of products.

The model is built on a conditional probability that a consumer will purchase the new product at a certain time, given that an adoption has not yet occurred. Some consumers are innovators, who are more apt to try out new things, but the larger part is imitators, who are more influenced by other adopters. Thus the sales at a certain point in time is described in the Bass model by a function that is modified by two parameters, which are called the coefficient of innovation and the coefficient of imitation. The effect of innovators will be greater at first but will diminish monotonically with time, while the effect of imitators will increase with time. Bass' model is thus consistent with the theories of de Tarde and Lazarsfeld [Lazarsfeld et al., 1944; Kinnunen, 1996] about innovators and imitators. This is a logic that is applicable in medical device adoption of durable products. However, Bass did not include repurchasing in his model, each adopter is supposed to buy only one item of the product. However, though simple in its form, the Bass model is probably the most useful at present for consumer durables.

Implementation of adoption decisions

Implementation is defined, in this book, as the integration of an innovation into routine practice of the adopter. This has long been a neglected area in diffusion research, but has attracted increased interest in recent literature.

Rogers [2003] stated that the implementation stage might continue for a long time, depending on the nature of the innovation. It stops at a point where the innovation becomes institutionalized as an integrated part of the adopter's operations. Re-inventions, defined by Rogers as the degree to which an innovation is changed or modified by the user, are especially likely to occur during the implementation stage.

An overview of innovation and integration of health technologies, and a review of the literature on this topic, is provided in the OECD report *Health technologies and decision-making* [OECD, 2005]. According to this report, institutional and financial factors are major influences in the implementation of decisions. They found that additional funding and flexibility between budgets are important facilitators for successful implementation. A key factor is also the level of trust in the evidence of the benefits of the innovation and in the systems that produce the evidence. The importance of the implementation process is emphasized in this report and the authors conclude: "Health system characteristics, including provider payment mechanisms, can create strong disincentives to efficient decision making, leading to potential under-use of cost-effective technologies."

Organizational innovation processes

The diffusion of medical technologies is the result of organizational adoption, which means that several individuals within the adopting units are involved in the decisions. Healthcare innovation is most often an organizational process. Parallels can be drawn to innovation processes within firms and much of the research in that area can be applied to technological change in hospitals.

In a book by Zaltman *et al*., *Innovations & Organizations* [1973], it was pointed out that organizational innovation had to be seen as a process with distinctive aspects that should be treated differently from traditional diffusion theories, in which the adopters were for example individual farmers, families or doctors.

This insight has been followed up with a large number of theoretical and empirical studies [See e.g. Pierce & Delbecq, 1977; Van de Ven, 1991; Grover & Goslar, 1993; and McManus, 2003].

Organizational innovation has been described as a three-stage process: *initiation, adoption*, and *implementation* [Pierce & Delbecq, 1977; Grover & Goslar, 1993; Rogers, 2003]. In another dimension, adoption and implementation in organizations also occur at two different levels: the organizational and the individual level [Prescott and Van Slyke, 1997]. An organization may implement an innovation, but individuals within the organization may not choose to use it. Prescott and Van Slyke [1997] found that the opposite situation could also be true. In their study of diffusion of Internet Web browsing in different organizations, they saw that some individuals used the Internet in their job before their employers adopted it.

Five sets of factors may be recognized as important to adoption of innovation: *adopter characteristics, innovation characteristics, task-related factors, structural factors*, and *environmental factors*. In a study of organizational adoption of telecommunications technologies Grover and Goslar [1993] picked out structural and environmental factors as the most influential in an organizational context. However, task-related factors may be crucial in the choice of innovations to integrate into the organization. If the innovation is relevant to work performance and if it improves relevant tasks, adoption will be more likely to occur. Likewise, if it is feasible, workable, and easy to use, it will be adopted more easily. However, there is limited evidence that efforts to enhance task relevance improve the chances of successful adoption [Greenhalgh *et al*., 2004].

Utterback [1971], who investigated innovation processes within firms, found that the effectiveness in initiating, developing, and implementing innovations was mainly dependent on characteristics of the firm's environment and information flows between the firm and its environment. But he also pointed out that internal characteristics of the firm itself could be important determinants of innovation.

Organizational adopter characteristics

As adoption decisions on medical technologies are made both on the organizational and at the individual level, the adopter characteristics of

healthcare organizations are also the characteristics of individual physicians. The individual level will not be treated here, but the reader is recommended to turn to a book chapter by Fendrick and Schwarz [1994] for a thorough understanding of this topic and a discussion around physicians' decisions regarding acquisition of health technologies.

The adopting unit, in a healthcare organization, is the national or regional healthcare provider, a hospital or other healthcare service provider, a ward unit, or an individual, for instance a chief physician. The adopting unit is represented by medical professionals, administrators, and economists, who sometimes need political and management authorization in their adoption decisions. It is not clear which factors are the most influential in this adopter group, but a suggestion recently put forward is that publication of key research results, and evidence-based guidelines are influences, which are gaining importance [Cook *et al*., 2004; Packer *et al*., 2004]. Earlier innovation research in the medical field has also emphasized professional networks, education and personal contacts as important influences [Menzel & Katz, 1955; Coleman *et al*., 1957; Manning & Denson, 1979; Manning *et al*., 1986; Blume, 1992]. When the evidence-level of a treatment technology is low, professional networks are even more important. This was a conclusion drawn by Coleman *et al*., who studied the prescription of a new drug. In this study, the authors found that, in uncertain situations, colleagues influenced physicians' adoption behavior more [Coleman et al., 1957].

A general set of organizational characteristics is proposed by Grover and Goslar [1993]. They pointed out *organizational size, specialization, centralization*, and *formalization* as major variables for organizational innovativeness. The characteristics most often investigated in healthcare diffusion studies are hospital size (often determined as the number of hospital beds), hospital age, centralization, specialization, degree of research activity (university hospital and/or clinical tests within the hospital), and degree of teaching activity (university training or other education) [See e.g. Moch & Morse, 1977; Stocking, 1985; and Teplensky *et al*., 1995].

Kimberly and Evanisko [1981] investigated the influence of environmental and organizational factors on hospital adoption of innovations. They found that hospital age, competition between hospitals, size of the organization, and size of the city, are important predictors of the adoption of technological innovations. All these factors are positively related to the innovativeness of the adopting units. Others have also recognized that larger hospitals and specialized hospitals are earlier adopters. Banta [1990], for example, found that

larger hospitals, university hospitals and specialized hospitals tend to be the first adopters of new medical technologies. Further conclusions in this work were that specialists generally are more interested in new technologies than generalists, and that younger physicians tend to be earlier adopters than older physicians. Banta also pointed out the importance of influences from outside the hospital and that early adopters seemed "to have a more cosmopolitan outlook."

The positive relationship between city size and adoption may be due to the fact that a larger city has a hospital serving more patients, which justifies acquisition of innovations for treatment of relatively rare conditions. The large hospital is also less risk-averse and can afford to try out an innovation early in the technology life cycle. Further, a positive relationship between hospital age and innovation has been explained by older hospitals having a well-defined resource base and a high survival potential. But early adoption of innovations may also be a way of insuring their status in the community [Kimberley & Evanisko, 1981].

Initiation, adoption, and implementation

> "An organization adopts an innovation when it decides to commit resources to it. The implementation stage includes development and installation activities that take place as the organization begins to use the innovation" [Grover & Goslar, 1993].

According to Grover and Goslar [1993], the initiation stage involves a pressure to change, but also the gathering and evaluation of information, while the adoption stage is merely the decision to commit resources to the innovation. Similar thoughts can be found in Rogers' *Diffusion of innovations* [2003]. The initiation stage involves identification of a performance gap and a search for possible solutions. Rogers called these activities for agenda-setting and matching. In his model, the matching stage includes information accumulation and evaluation of the innovation, while the adoption decision is assumed to be an instant transformation from potential adopter to adopter, after which the implementation stage follows.

A more analytical description is provided by Zaltman *et al*. [1973] in *Innovations & Organizations*. Zaltman divides the initiation stage into three sub-stages: knowledge-awareness, attitude formation, and decision. He also pictures the decision-making as a process with separate elements and

proposes the following sequence, citing Taylor [1965]: "(a) the generation of some subset of alternative courses of action available; (b) a set of consequences is attached to each alternative; (c) there is some preference ordering (utility function) in an attempt to rank the consequences of various alternative; (d) the decision-makers select the first alternative that meets some minimum standard of satisfaction with respect to each of the utilities that are being sought." Zaltman claims further that initiation of innovation occurs as an identification of a performance gap and suggests several different causes leading to the perception of a performance gap. He does not, however, recognize that initiation of innovation can occur as a result of technology-push.

The implementation process, in Rogers' model, consists of three stages [Rogers, 2003:420]: (1) redefining/restructuring, (2) clarifying, and (3) routinizing. With this he meant that the innovation is first modified to fit the need of the organization; then the relationship between the organization and the innovation will be clearly defined; and finally it is integrated into the routines of the organization.

A quite different picture of organizational innovation is provided by Van de Ven [1991], who studied three examples of successful adoption of innovations in hospitals. The starting point in his writing is Rogers's basic diffusion model, but he soon states that revisions are needed:

> "Although this model is robust in explaining the adoption of innovations by individuals, it must be revised to incorporate the complexities exemplified in our three hospital cases and often observed when the organization is the locus of adoption" [Van de Ven, 1991].

The reasons for such revisions, according to the findings in Van de Ven's studies, are: (a) a more extended initiation stage in organizational innovation and involvement of many different participants, (b) direct personal confrontation with needs or problems resulting in "shocks" that trigger action for innovation, (c) adoption activities does not unfold in a simple linear sequence of stages and sub-stages, (d) setbacks and mistakes are frequently encountered during the innovation process, (e) reinvention of innovations developed elsewhere is facilitated by modifications of the innovation to fit the local organizational situations, where top management was extensively involved, and (f) adoption processes vary to fit the specific contingencies of the innovation.

Van de Ven continues to conclude that knowledge about the innovation process provides the management with a tool to increase the odds of

innovation success. It will, however, not ensure success. All innovation is a "leap into the unknown" and the author suggests that managerial control may need to be decreased to enable successful innovation.

> "A number of practical consequences follow if innovation success is recognized to be a probabilistic process. First, innovation success or failure would more often be attributed to factors beyond the control of innovators. This, in turn, will decrease the likelihood that the careers of innovation managers will be stigmatized if their innovation fails, and increase the likelihood that they will be given another chance to manage future innovations. After all, one cannot become a master or professional at anything if only one trial is permitted" [Van de Ven, 1991].

Technology adoption under risk and uncertainty

When looking at diffusion of innovations in organizations, it is important to remember that the decision to reject an innovation at any point in time is seldom a final decision, but a choice to postpone the decision until more information and evidence of benefits are available. Early adoption always involves uncertainty and risk, as the available knowledge is never sufficient to predict future consequences of the decision. There might be an option value of waiting. When the degree of irreversibility of the investment is high, it might be wise to let others do the mistakes in case of a wrong decision [Arrow & Fischer, 1974; Marra *et al*, 2003]. However, in a competitive environment, to be a late adopter may also have negative implications.

The adopting units may vary in their risk preferences and their perceptions of an innovation's riskiness and advantages. Every adoption decision has a certain degree of associated risk dependent of the absolute cost of the innovation, its cost relative to the resources of the organization, and the ability and willingness to absorb the cost of a wrong decision [Utterback, 1974].

The implications for risk and uncertainty in innovation have attracted much interest in different kinds of innovation and diffusion research, see e.g. Arrow & Fisher [1974], Saha *et al*. [1994], Gelijns *et al*. [2001], and Coburn [2005].

Information, learning and imitation

The fundamental piece of information about an innovation is knowledge about its existence. The next step is information about how suitable it is to the potential adopter's particular need. And the last step is information about the net benefits, i.e. advantages, disadvantages and costs connected to the innovation. The first two steps in the information chain do in many cases reach the potential adopter in the form of advertising, while the last step, in most cases, contains information exchange and discussions among members in the social system in which the innovation is introduced. This stage may also involve persuasion and feelings as determinants in the formation of an attitude towards the innovation [Rogers, 2003].

The importance of personal experience and experimentation in the adoption process is emphasized in several fields of innovation research [Warner, 1974; Foster & Rosenzweig, 1995; Lam, 2002; Rogers, 2003; and Marra *et al*, 2003]. Warner concludes that learning and imitation are central concepts in the diffusion process and that the value of learning-by-doing lies both in the reduction of uncertainty and in an improved efficiency, which accompany learning. His interpretation of the S-shaped diffusion curve is that potential adopters initially are reluctant, as they lack experience and knowledge about the innovation.

This is also relevant in the healthcare setting. Before the adoption or rejection decision, medical professionals seek information on the advantages and disadvantages of the innovation, first from clinical trials and experiments, then from other users' experience, and last from their own use. As more information is gathered, the uncertainty will decrease and knowledge from using the innovation will make it possible to benefit from its full potential. A basic argument in Warner's theory [1974] of imitation and learning-by-doing is that the efficiency in the use of the innovation will increase [See also Tsur *et al*., 1990].

Diffusion and then...?

Technological change is generally held to be the primary driving force behind improved productivity and economic growth. This is particularly pronounced in the political and entrepreneurial strains of the innovation literature. In this view the consequences of innovation are all desirable effects such as economic

growth, international competitiveness, and high employment [See e.g. Lundvall & Borras, 2005]. However, benefits and increased welfare in one area might cause undesirable effects somewhere else, in a different activity or at a different time. Technological change makes it possible to produce a desired output with a smaller volume of inputs in labor or money, but the undesired effects that spill over in the society, at large, are most often forgotten when calculating net benefits of innovation.

In the case of technological change in medicine, one important negative effect is rising healthcare costs, which force us to prioritize between healthcare and other social utilities, such as education, employment, and welfare. However, contingencies, between innovation and the growth and decline in different areas of social utilities, have not been extensively explored. It might as well be a win-win situation, in which healthcare innovation, industry, and social welfare all prosper, but we do not know. Research on the consequences of innovation is strikingly absent, even though many have recognized this deficiency [See e.g. Bonair & Carlsson, 1987; and Rogers, 2003]. Rogers devotes a chapter to this topic in the book *Diffusion of Innovations*. He suggests a classification of different types of consequences and gives illustrative examples of innovation in the different classes. However, the essence of his reasoning is that diffusion research has to change focus and that we must strive to find answers to what the effects are of diffusion of innovations.

Consequences of technological change in healthcare

Social consequences of healthcare innovation is a sparsely investigated research field and there is a lack of empirical research. The topic attracted some interest in the 1980s and the innovation researcher and sociologist A L Greer among others wrote papers on this in the journal *Research in the Sociology of Health Care*, which devoted a whole issue to adoption and social consequences of medical technologies [Roth & Ruzek, 1986]. A decade later the topic was resumed by for example Newhouse [1992], Paltiel & Kaplan [1993], and Gelijns & Rosenberg [1994]. The focus in this literature was still on medical expenditures and welfare. Today, however, the concern seems to be mostly about what impacts medicine and technology have on us, as human beings: cloning, mechanical spare parts, plastic surgery, transplantation of personality determining parts and organs, genetic selection and so on [See e.g. Ellis, 2004].

It is certainly true that healthcare innovation might bring about undesirable and unanticipated consequences to patients, medical professionals, hospitals, and to healthcare itself. Such effects are likewise sparsely investigated, even though this apparently is a task for researchers interested in health technology assessment (HTA), in which it is often claimed that, for instance, ethical and social consequences are vital parts.

Summary of the review

The interest in innovation as a research field arose around 1900 when de Tarde's theory of *innovators and imitators* was presented [1890]. He hypothesized that small psychological interactions among individuals are the basic explanation of social change and that the diffusion of inventions could be presented graphically as an S-shaped curve. This theory of innovators and imitators can be traced in the "Two-step flow of communications" [Lazarsfeld *et al*., 1944] and in the Bass model, which has been constructed to predict the diffusion of consumer durables [Bass, 1969].

Another early theory was proposed by Ogburn [1922], in which he claims that technological development is the driving force in social change. His model of social change, with the stages *invention, accumulation, diffusion, and adjustment,* may still be valid and useful. Alongside with this Schumpeter developed his economic theories of social change [1934]. He saw innovation as the means of economic development and pointed out the individual entrepreneur as the main dynamic factor.

Ryan & Gross [1943] made decisive contributions in the empirical diffusion research. They found that diffusion of an agricultural innovation followed the earlier suggested S-shaped pattern, and they argued that non-economic factors must work to explain this. Agricultural economics and innovation was further explored by Griliches [1957], who found that demand factors could be important drivers of innovation. This has, however, been strongly opposed by other scholars, and e.g. Rosenberg [1974] argues that demand factors are of little importance and that innovations depend on the current levels of skill and scientific knowledge.

The first diffusion study in the healthcare area appeared in 1957, when Coleman *et al.* presented a diffusion study, in which they found that

prescription of a new drug depended very much on networks and physician-opinion leaders.

A few years later a general model of innovation was proposed by Rogers [Diffusion of Innovations, 1962]. This model was built on different earlier theories and was refined by the author until 1995, when it seemed to have found its final form. Rogers' model was the starting point for a more interdisciplinary innovation research and the interest in this field has virtually exploded since the 1960s. The terminology used by Rogers became standard and the methodology of Ryan and Gross was used as a template for empirical studies (See pp. 42-45).

Zaltman *et al*. [1973] were among the first to recognize that organizational innovation had to be seen as a process with distinctive features. This insight has been followed up with a large number of theoretical and empirical studies that have been useful in understanding innovation in hospitals.

Evolutionary innovation models were advocated in the 1980s [Nelson and Winter, 1982; Nelson, 1987] and the theory has its followers [See e.g. Ziman, 2000]. These models claim that technological change occurs in small steps rather than in revolutionary changes. During the same period the related "path dependence" model entered the scene [Arthur et al., 1987; David, 1975 and 1985; Ruttan, 2002]. The main trait of this theory is that turns taken in the past will determine the fates of future innovations.

5. FOUR STUDIES AND THEIR CONTRIBUTIONS TO THE THESIS

The produced papers are based on four studies, which are presented in this chapter. These studies have substantially contributed to my understanding of the innovation process and to the model presented in Chapter 6. Several aspects of innovation are covered by the four studies and they provide some illustrative examples of crucial activities in the innovation process.

I: Technology transfer and research collaboration

Roback K, Hass U, and Persson J, **Transfer of health care technology in university-industry research collaboration environment**, Engineering in Medicine and Biology Society. Proceedings of the 23rd Annual International Conference of the IEEE, 2001. Page(s): 3938- 3941 vol. 4.

Paper I describes innovation activities and university-industry research collaboration in eleven projects. Most of these projects had also a cooperating clinical department at a university hospital. The aim of the study was to investigate how this research work was carried out and, if possible, identify facilitators and impediments to project progress. The activities in the projects could be classified as applied biomedical research or invention, sometimes close to product development, and the ultimate goals of the collaboration projects were commercially marketable medical devices.

Data collection in this study was performed by semi-structured interviews. A literature search was performed prior to the interviews, and relevant literature provided a basis for the interview questions. The respondents were senior researchers in charge of the projects. A follow up questionnaire was sent to the respondents a year after the interviews to check on the progress and identify major changes in work practices or cooperation structure. This resulted in a data set that pictured the project work from the academic perspective. The collected data was stored and managed by a qualitative research software [QRS NUD*IST, 2005].

Paper I has contributed to the thesis by observations on innovation initiation, and on invention and development work. The collaboration with industry was perceived as a facilitator to research progress, even though the industry partner was usually not practically involved in the research work. The main contribution from industry seemed to be knowledge, preferably about market demand and production possibilities. The facilitating mechanism is thus probably increased communication. The healthcare partner, on the other hand, was more actively involved in the work in some of the projects. However, the most important outcome of this type of three-party collaboration seemed to be the facilitated communication between university, industry, and healthcare.

An observation made in Study I was the apparent need for technology assessment in this early phase of innovation. Assessments ought to be performed already in the initiating phase, both of the need for the emerging technology and of its possible health benefits and negative side effects. Furthermore, this ought to include assessment of the probability that any kind of useful results (knowledge or products) would come out of the project.

II: Development and clinical testing of an optical breathing sensor

Roback K, Nelson N, Johansson A, Hass U, Strömberg T, **A New Fibre-Optical Respiratory Rate Monitor for the Neonatal Intensive Care Unit,** Pediatric Pulmonology, 2005; 39(2): 120-126.

Paper II describes a clinical trial of an optical breathing sensor for preterm neonates. In this study, I also followed the development work and prototype testing that was carried out before the trial. I took part in the planning and setting up of the trial and made some of the data collection in the neonatal ward.

When the project started, the optical measurement technology was already utilized in a breathing sensor for adults, which was available on the market. The inventor/developer (who was also the entrepreneur) wanted to introduce the sensor for neonatal intensive care and a prototype was ready for a first test in the clinical setting. The prototype was first tested on healthy term babies. However, the nasal adapter needed improvements, as it was easily displaced when the babies moved. It also had to be reshaped and scaled down in size to suit the preterm neonates. This work went on for more than a year. After

several alternating tests and improvements it was finally decided that the clinical trial could be carried through.

The trial was planned and conducted without involvement of the entrepreneur or the manufacturing firm. The respiratory rate was measured simultaneously by the optical sensor and a standard method (transthoracic impedance) for respiration monitoring. Furthermore, experienced nurses counted the breaths manually and this was used as a reference method. Video recordings were used for estimation of body movement of the neonates and of nurse interaction that could interfere with the sensor registrations. Results of this trial showed that the optical sensors as well as the standard method had low accordance with manual counting. The main conclusion was, therefore, that the accuracy of the new sensor was not sufficient and that improvements were still needed. However, an important point was also that the reliability of the standard method was unsatisfactory.

This study has provided a close-up of a development process, which has been of great value for my understanding of the invention and development stages. The study has contributed to the thesis by observations on for example prototype development, collaboration with clinical departments, and the situation for small and emerging medical device enterprises. It also provided an opportunity to follow the work in a technology-intensive clinical department, the neonatal intensive care unit.

III: Diffusion of devices into the private sphere of the patient

Roback K and Herzog A, **Home informatics in healthcare: Assessment guidelines to keep up quality of care and avoid adverse effects**, Technology and Health Care, 2003; 11(3): 195-206.

This study was initiated within a cooperative project engaging three university disciplines: health technology assessment, computer and information science, and biomedical engineering. The aim of the project was to investigate healthcare applications of home informatics. Three studies were projected, of which two resulted in journal publications, Paper III in this thesis and an additional paper suggesting improvements in network solutions for home healthcare [Herzog & Lind, 2003].

Paper III is a literature review. The aim was to identify risks and adverse events associated with the use of information technologies in home healthcare and to produce some useful assessment guidelines for implementation of such home healthcare applications. The research methodology was an attempt to find a way to produce useful results in a short period of time. This methodology was developed and tested in the study. The development part of the study has not been followed up, since the intended methodology in many respects is analogous to the one developed by Greenhalgh *et al*. [2004 and 2005]. A useful experience was, however, the feasibility of using a qualitative research software for storage and retrieval of text-unit data in literature studies [QRS NUD*IST, 2005].

Contributions to the thesis from Paper III are the following observations:

Concurrent assessment. Extension of the diffusion area of medical devices to patients' homes poses an assessment challenge. A concurrent assessment of technology, patient and the immediate environment must be advocated. Probably, this ought to be the case for all healthcare innovations, but private homes provide a highly heterogeneous environment and the test environment may be radically different from the home of the end-user.

Follow-up assessments. Proper training and education of the users must, of course, be provided. However, this must also later be followed up by assessment of the knowledge, skill, and motivation of the users. This is a matter that is relevant for all medical devices that are used by patients outside of the hospital.

Involvement of users. Opinions from end-users and different staff categories are important in the planning and implementation of home healthcare applications. Involvement of users seems to increase the chance of successful integration of devices.

User support. It is important, in the home as well as in the hospital, to have a highly available and useful technical support. Neglected support will inevitably lead to loss of confidence and sometimes to disuse of the technology.

User attitudes. The users' attitudes towards the innovation are crucial for whether the full potential of the innovation is realized or not. Increased acceptability of medical devices may be obtained by more handsome and user-friendly products.

IV: Opinions on adoption and use of devices

Roback K, Gäddlin PO, Nelson N, and Persson J, **Adoption of medical devices – Perspectives of professionals in Swedish neonatal intensive care,** 2006 (submitted manuscript).

The objective of this study was to investigate the processes leading to adoption or rejection of medical devices and their integration into regular healthcare practices. Data was collected through semi-structured interviews. Questions were formulated on the basis of findings from an earlier literature review [Roback, 2003] and the initial set of questions was tested in a pilot study. The questions covered several areas such as: innovation and adopter characteristics; influences on adoption and diffusion; managerial and organizational characteristics and contexts; information sources and communication channels; and assimilation of innovations into regular use.

An iterative analysis method was applied where data collection and analysis were alternately performed. This method is described in Paper IV and in Chapter 3 [See also Miles & Huberman, 1994; and Coffey & Atkinson, 1996]. Data storage and retrieval was managed with the qualitative research software QRS NVivo [QRS, 2005].

Respondents were recruited among healthcare professionals and clinical engineers working with devices for neonatal intensive care in Swedish hospitals. Hospitals at the regional/university level as well as at the district/local level were included in the study. Furthermore, as most previous studies of health technology adoption have focused on large and highly visible investments, the intention was also to throw some light on the adoption of inexpensive medical devices.

The study has in many respects contributed to the innovation model suggested in this thesis. Some areas that offered new insights are pictured in the following:

Integration gap. The study revealed the existence of a discrepancy between the degree of diffusion and the actual deployment of some devices. The adopters may choose not to make full use of a device for many different reasons. One such example, found in this study, was competing or overlapping technologies. Devices with overlapping functions were in use in the wards, which implies some freedom of choice within the treatments. This made it possible for trends to arise in favor of one or the other device. Other

reasons were insufficient training or low motivation to use devices that were perceived as unsafe or labor intensive.

Product development. Replacement of worn-out and defective products often implies a certain degree of innovation. The study showed that replacement devices often had been equipped with new functions and were altered in a way that forced the users to up-date their knowledge and skills. The purpose with these developments was to make the product more competitive, and modifications seemed necessary in order to not lose market shares, but these were not always perceived as improvements by the end-users. Several of the respondents mentioned that it could be hard to find good and easily integrated replacement products.

Conformity. Devices should preferably be both compatible and have the same user interface as earlier models and brands. This conformity to a specified standard was regarded to be an important factor contributing to high quality care and a good work environment. However, this goal is in conflict with the wish to avoid dependency on a monopoly vendor.

Long-time follow-up. Several measures were brought about to implement adopted devices into the routines of the wards. Information, education and training were provided to the staff and necessary adjustments of either the innovation or of work routines were made. Full integration was, however, not always achieved, and long-time follow-up of functionality and work integration was not performed routinely in the wards. Several respondents reported that they sometimes felt uneasy using the new devices and opinions were put forward that follow-up of devices was an area of potential quality improvements.

New technology load. Innovation in hospitals has many positive aspects, but the burden of change on the staff in the organization, a phenomenon called "new technology load," has to be kept within limits. Excessive change creates a poor working climate and may inhibit implementation. The ability of an organization to adapt to innovation is influenced by the speed at which new skills can be established to match the demands of the new technologies. However, a moderate challenge of skills and competences is often positively related to professional prestige and job satisfaction.

Health technology assessment (HTA). The use of scientific evidence seemed to be dependent of the size of the investment. High cost investments like cerebral function monitoring (CFM) and devices for inhaled nitric oxide (iNO) were evidence based, while for instance photo therapeutic devices were adopted in

a more preference based manner. This might be caused by the HTA agencies weak interest in low-cost devices, but there are probably also weak points in the transfer of assessments into healthcare use.

6. AN INTEGRATED MODEL OF MEDICAL DEVICE INNOVATION

This chapter will give an interdisciplinary description of the innovation process, with a special focus on medical device innovations – from idea to regular use and disuse. The full picture has grown slowly from melting together different innovation research traditions and filtering the brew through my own meshwork of experience. The integrated model is built on a large number of works in a variety of investigational fields, of which an essential part is presented in Chapters 2 and 4: *Knowledge base and perspectives* and *Healthcare innovation – A review of past and present theories*. This literature has, together with empirical studies and observations, contributed to my understanding of innovation and to my model. However, to keep this presentation distinct and comprehensible, I have chosen to limit the number of expositions and parallels to former theories in this chapter, and to give a minimum of references to my sources. The studied literature has indeed provided templates for my lines of thought, but the reader will find plenty of rearrangements, extensions and divergences. A discussion of these divergences, with respect to former theories, is therefore provided in Chapter 7.

The proposed model of innovation is a conceptualization of innovation as an integrated process and of technological change as the ultimate consequence of this process. *Invention, Diffusion and Deployment (IDD)* are its main elements. Technological change will only happen if all three elements are present: (1) a new idea – invention, (2) spread of the idea – diffusion and, (3) practical use of the idea – deployment (Figure 1). All the activities that are involved in this occur in *domains* connected to these three elements.

The model has been constructed with the intention to explain medical device innovation in an organizational context. It is, however, not difficult to extend the thoughts to also include other health technologies. In many respects, the model is general and thus also valid for healthcare innovations intended for individual adopters' own care, rehabilitation or health promotion.

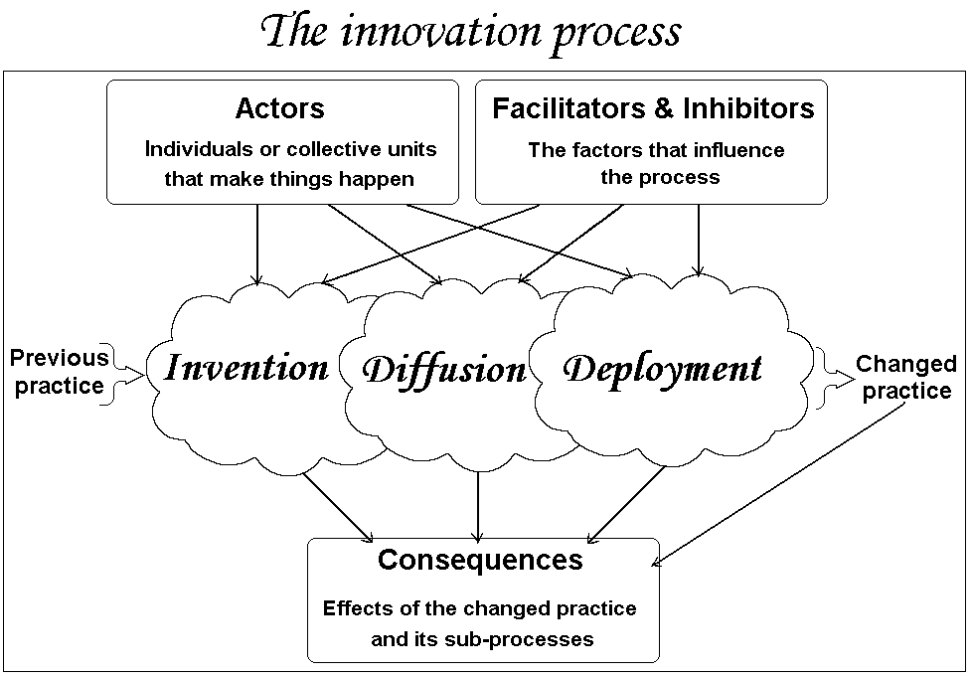

Figure 1 The IDD model of innovation.

Table 1 Actors in the process. Most of the actors are active in all three innovation domains.

Invention	Diffusion	Deployment
Discoverers	Adopters	Adopters
Inventors	Change agents	Change agents
Developers	Gatekeepers	Gatekeepers
Payers	Developers	Developers
Organizers	Opinion leaders	Opinion leaders
Regulators	Champions	Champions
	Payers	Payers
	Organizers	Organizers
	Regulators	Regulators

Table 2 Sets of facilitators and inhibitors, which may influence activities in the three innovation domains. Influences in the model are categorized into eleven sets of factors.

	Sets of facilitators and inhibitors
1.	Perceived need
2.	Knowledge accumulation
3.	Information flow
4.	Risk
5.	Incentives
6.	Competition
7.	Regulatory frames
8.	Actor characteristics
9.	Innovation characteristics
10.	Perception of benefits
11.	Promotion of the innovation

Table 3 A selection of consequences. Consequences of innovative activities may occur at all stages of the innovation process.

A selection of consequences
Productivity growth
Increased competitiveness
Social status
Increased welfare
Health gain
Labor-savings
Increased costs
Involuntary use of innovations
Disuse of older technology
Abandonment of knowledge
Path-dependency*

* By path-dependency is meant the impact of innovation on later innovation processes.

In the following sections of this chapter, the model and its different components will be outlined in detail. The linearity of the process is, however, somewhat exaggerated in this description. This is merely of practical reasons and in the real process the center of activity in the model is moving back and forth between the three domains.

The process – an overview of the model

This section is an overview of the IDD model. A more detailed description of the model is provided in the subsequent sections.

Technological change is the result of innovation activities, which can be sorted into three major domains: (1) *invention*, (2) *diffusion* and (3) *deployment*. These three groups of activities are sequential but overlapping. Events in one domain may also influence later events in other domains. The *actors* are individuals or collective units that make things happen; the *facilitators and inhibitors* are the factors that influence the process; and *consequences* are the effects of the changed practice and the sub-processes leading to technological change (See Figure 1 and Tables 1 - 3).

Initiation of the process occurs in the *invention domain*. The very first initiating step in this process is a discovery, and this can be either of two kinds: (1) a discovery of a possibility to do something that was not possible before or (2) a discovery of a need. The *possibility-discovery* is the result of knowledge accumulation, by means of basic and applied research (episteme) or by means of practical experience, craft and art (techne). The *needs-discovery* is related to the demand-pull concept. It is the result of a perceived performance gap[10], a perceived inequity, or simply a wish for change. The *discoverer* is the actor who discovers the possibility or the need, he/she may also be an *inventor*, but it is often in the encounter between the discoverer and an inventor that innovations are conceived.

An invention is a novel solution, device, material, method or an idea. However, an invention in its original form is seldom useful to many. This is the point where the *developer* comes in. The developer transforms the invention

[10] A performance gap is the difference between the actual performance of a practice and the performance desired by the user.

embryo into an innovation, ready to be diffused in a system of potential adopters.

Both invention and development are influenced by surrounding economic, organizational, and regulatory factors, i.e. the frames that determine what is possible to do. The *payer* provides the financial possibility. In the beginning of the process, the payer may be a research grants program or a university, and later on the payer is usually a manufacturing firm. The *organizer* ensures that time and resources are in place, so that the inventor and the developer can work on the invention. This actor might be a university, a firm, or even a family, in cases where the invention activities take place in the private sphere of a start-up entrepreneur. The *regulators* are often legislative bodies, government agencies, and other authorities, which are building regulatory structures to ensure that the newborn innovation fits into the norms of the society, for example effectiveness and safety norms. These regulations, imposed by authorities, do often also reflect other less formalized norms, such as moral and equity values. In this model, norms and values are included among the regulations as they sometimes have an equally strong regulating effect on innovation. In the internal arena, the regulator may thus be a person in a key position within an organization or organizational unit, upholding the norms and values of his/her organization.

In the *diffusion domain*, the innovation will spread to *adopters* outside of the inventor's and developer's immediate environment. If the innovation is an artifact this is only possible if a producer has adopted the "innovation of producing" it. The producer is then to be regarded as an organizer in the overall innovation process, i.e. the one who ensures that the innovation artifact is in place for adoption. In this domain the potential adopter becomes aware of the innovation, forms an attitude for or against it, and makes a decision to adopt or reject it. The awareness is most often effected by a change agent or a gatekeeper. The *change agent* is working for a change agency, which might be a producer or other unit that has an interest in a high rate of diffusion. He may have a variety of professional and/or social functions. He can for instance be a sales representative, but also, in a different context, a politician trying to diffuse an opinion. The task is to persuade potential adopters to adopt the innovation and to sustain the use of it. To succeed in this, the change agent often tries to identify *opinion leaders* and make them adopt the innovation first. Opinion leaders are persons (or units of adoption), who have substantial influence and whose practices are readily imitated by other adopters.

The *gatekeeper* is working on the behalf of the system of potential adopters or an organization. He is scanning the horizon for useful ideas, practices, and products. He looks out for changes in values and demands. The information is processed and evaluated and finally transmitted to other members of the society or to his colleagues. The gatekeeper transmits chosen parts of the information in a way that he thinks will favor the society or organization and in this he may promote or oppose an innovation.

The *payer* role, in the diffusion domain, is only relevant for products or services (not for example for political ideas or care practices, which not involve use of new artifacts or increased human resources). The payers, in the diffusion domain, are often the adopters themselves, but regarding health technologies a variety of payment systems exist. Someone must consider it favorable to pay for the possible utilities of the innovation, and without a payer – no diffusion of medical devices.

The roles of the *organizers* and the *regulators* in diffusion are similar to their roles in the invention domain. The organizer make diffusion possible by ensuring that resources are in place and the regulator sets the limits for what and how much of it that gets into the system. The payer, the organizer and the regulator may be influenced, to some extent, by a *champion*, i.e. a person who takes a special interest in a particular innovation and facilitates its diffusion by exerting his influence on other actors.

It is, however, not until the innovation starts to spread that its usefulness to the adopter society is really tested. Adaptations might be required to improve the usefulness, and consequently the *developer* again has an important role. This is frequently not the same developer as before. It might be, but it is often an adopter who makes small adjustments, or the adopter/developer and the first developer that jointly come up with a solution. Furthermore, an adopter/developer may improve the usefulness of an innovation by extending the scope of its use, as for instance when doctors prescribe a drug for conditions, for which it was not initially intended.

In the *deployment domain*, the innovation is integrated into the routines of the adopters. Deployment involves both successful implementation and reinforcement of the adoption decision from other adopters. The *organizers*, the *regulators*, and the *payers* do all exert their influence in this domain. They may facilitate or inhibit successful deployment.

Many change agencies withdraw their "forces" when diffusion begins to slow down, but the *change agent's* efforts are as important in the deployment as in

the diffusion domain.[11] The adopters need support in their learning of the new practice. Furthermore, the deployment phase provides an opportunity for the change agency to create a trusting relation to the adopter population that might be useful in later diffusion processes. The deployment of an innovation is thus more likely to succeed if some change agent activity goes on, and, in case of unfavorable organizational and regulatory structures, an innovation *champion* might be useful [Stocking, 1985]. The *developer* does also have a role here, as "use" and "routine use" are not the same, and further adaptations may be necessary to obtain full integration of an innovation.

There are four measures of innovation that can be used together with this model: (1) extent, (2) quantity, (3) speed, and (4) probability. *Extent* is a spatial measure of the spread of the innovation among potential adopters. *Quantity* is a utilization measure that tells us how much or how often the innovation is used. The third measure, *speed*, may be measured as the time it takes from one point to another in the model, for example from market introduction to 60% spread in an estimated adopter population; or the time for the whole process to occur, from first discovery of a need to routine use of an innovation that satisfies that need. *Probability* is the likelihood that innovation occurs, for instance whether the innovation will come into being, if it will be spread to some extent and/or gain some quantity of use, or that this will occur at a certain speed. Measurement is, however, a delicate task, which always requires sharp demarcations of the objects of measurement, and an innovation is not a solid body that is easy to define and neither is the population of potential adopters. Innovations undergo modifications during the diffusion and deployment stages and the population of potential adopters may grow together with the usefulness of the innovation and is thus not a fixed and solid number [Fineberg, 1985]. A problem is also to decide when modifications are just modifications and actually not new inventions that should be regarded to have separate innovation processes. I will discuss this further in Chapter 7.

Factors determining innovation extent, quantity, speed, and probability are denoted *facilitators and inhibitors* (Table 2, p. 83). The different actors, with their special actions and characteristics, constitute the innovation environment; consequently there are no separate environmental factors in this model. There are, however, facilitators and inhibitors that are not entirely determined by the actors' actions and characteristics, such as for example the need and the relative advantage of the innovation.

[11] This is based on observation made in connection with the work in Study II and Study IV.

We have, so far, looked at the *actors in the process* and the *facilitators and inhibitors*. An important part of the model is also the *consequences of innovation activity*, which is intended to induce reflections on whether the investigated innovation has been good or bad, a sort of evaluation of the overall utility of the innovation in the light of history. All actions that initiate or sustain an innovation process have consequences for the actors and for other individuals or organizational units inside (and sometimes also outside) the social system. Consequences occur at all stages of the process and they influence the actors and later events in the process. The consequences of one innovation process may also determine the "path" for later innovations, so that one technological change will follow the other in a seemingly unbreakable chain.

The actors

The actors in the process (Table 1, p. 82) are individuals or units that take part in the initiation, development, and pursuit of activities, which lead to technological change. It is the people (the actors), who are building the framework of norms, regulations, and laws, within which the evolution of innovations is confined. Adopters, non-adopters and rejecters[12] are equally important in this process, as all actors work together to shape characteristic innovation and diffusion patterns for each innovation. In the following I will refer to the actors as if they were male persons, they might however as well be women or collective actors, such as for instance organizations.

Discoverers

The discoverer is the actor (person or organizational unit), who discovers a possibility to innovate or a need for innovation. The discoverer may also invent a novel artifact or idea, which is a desired and logical consequence of the discovery. The making of inventions requires, however, often interaction between a discoverer and an inventor or several inventors.

Inventors

The inventor is the actor, who comes up with a novel solution, artifact, or an idea. Personal traits often associated with inventors are genius, insight, and

[12] A rejecter has actively decided to reject the innovation, while the non-adopter may not have decided for or against it. The non-adopter might simply not be aware of the existence of the innovation or he has not yet formed an attitude about it.

creativity. Inventors see things differently and they may have the ability to interpret information in several different ways, but the creativity lies in the inventor's ability to insert different pieces of information into a structure that gives them a new meaning.

Invention in the late eighteenth and early nineteenth centuries was very much a work of individual inventors. They sometimes worked in larger enterprises, but the inventive activity was individualistic [Bruland, 1989]. Today, invention is more of a teamwork, but creative individuals will always be crucial for the invention process.

Incentives for inventors are probably often the prospect of financial profit. Medical device innovation is frequently initiated by a possibility-discovery and only after consideration of the profitability. However, there is also a mix of utility incentives involved and the prospect of helping people to a healthier life.

Developers

The developers work to adapt inventions and innovations so that they will better suit the adopters' needs and thereby increase their usefulness. In the invention domain, the developer transforms the invention embryo into an innovation, ready to be diffused in a society of potential adopters. However, it is not until the innovation spreads that its usefulness to the adopters will show. The presence of a developer might thus be important at any point in the innovation process. An adopter sometimes takes on this role and makes small adjustments of the innovation, while more extensive modifications are referred back to the manufacturer and a developer within a firm's R&D department.

Payers[13]

The payers make innovation financially possible. In the invention domain, this could be obtained by means of for example a research grant, a professional position at a university, or R&D in a manufacturing firm.

In the diffusion and deployment domains, payers are the ones that buy innovations (products or services) and pay for their use and maintenance. The payer may also be the adopter, but in healthcare this is often not the case. Regarding medical devices, the payer is particularly important and different

[13] For innovations that are not purchased, for example the use of a new fashion expression or a political idea, this actor is not relevant.

systems of funding and reimbursement are decisively influential in all four innovation and diffusion measures: extent, quantity, speed, and probability.

Organizers

The organizer is often a work place: a university, a hospital, or a firm. This actor ensures that time and resources are in place, so that the inventor and the developer can work efficiently to invent and transform inventions to innovations. The organizer may also provide the discoverer with resources, so that he can detect possibilities and needs more efficiently. These resources may for instance be effective information channels and slack time that admits the discoverer to think about things that have little immediate or apparent relevance for the organizational assignment.

The organizer is also important in the diffusion and deployment domains. For medical devices, diffusion probability and speed are unquestionably dependent on how resources are organized. Deployment of medical devices is likewise dependent on the organization of resources, for example education and training of staff and maintenance of products.

Regulators

Regulators are important in all three domains of the innovation process. They are often legislative bodies, government agencies, or other authorities, which are building regulatory structures to ensure that innovations fit into the norms of the society. Such structures, important for medical device innovations, are for example effectiveness and safety norms. Laws and regulations, imposed by authorities, do often also reflect other less formalized norms, such as cultural, religious, and historical values. Therefore, in this model, norms and values are regarded as less formalized regulations. Consequently, the actors (individuals or collective units) who protect these norms and values are regarded as regulators. This kind of regulators may be present within organizations or in social systems and groups of people, upholding the norms and values of their immediate environment. It was, for instance, during the 1960s, not much freedom of choice of techniques for delivery and pain relief in childbirth. If the birth was progressing normally, a standard delivery bed was used, with no possibilities to conduct the delivery in alternative positions or to move about during labor. This came out of healthcare tradition and professional norms, more than anything else, even though practical reasons also influenced this practice. No clinical studies existed that showed the advantages of this standard method. The norms and values of the profession did not allow alternative ideas in childbirth. The laboring woman was regarded as a helpless

patient, and the obstetrician and the birth attendant was the ones who "delivered the baby." The norms were gradually changed from the mid 1970s and today the birth giving woman often makes an active choice and a variety of methods are available, such as the bean bag chair, squatting, and water births [DeVries, 1983; and Eberhard & Geissbuhler, 2000].

Among the regulators are also those who have vested interests in the current social and financial structures. A supplier of a competing device may take actions for conservation of the current practices, and professionals may want to preserve status quo, if they feel that the innovation is threatening their social status.

Adopters

Adopters are individuals or collective units that have decided to change their behavior in favor of an innovation, i.e. to adopt it. A potential adopter has not yet adopted, but is estimated by some investigator/author to be among those who are inclined to do so later. There are often some members of a social system, who cannot be included in the group of potential adopters. It is seldom the fact that all individuals or units will benefit from the innovation.

Adoption is the means by which the innovation will spread to people outside of the inventor's and developer's immediate environment. If the innovation is an artifact this is only possible if a producer has adopted the "innovation of producing" it and a vendor the "innovation of selling" it. These producers and vendors are to be regarded as organizers in the diffusion domain, i.e. they see to it that the innovation is in place for adoption. This approach is especially useful when considering diffusion of medical devices, as the roles of the actors as sellers (producers, vendors) and buyers (healthcare, hospitals) are not distinct in this process and interactions between industry and healthcare are complicated.

Furthermore, the adopter role is not just the task of adopting innovations. Adopters, non-adopters and rejecters also influence each other. Interaction among adopters occurs at all stages of diffusion and deployment, and information about the innovation is spread from one adopter to another. This is important, as successful implementation requires promotion of the innovation from users and the users need reinforcement of the adoption decision from other adopters.

Change agents

The change agent may be a sales representative, but also, in a different context, a politician trying to diffuse an opinion. He is working for a change agency, which might be a producer, seller or other unit that has an interest in a high rate of diffusion. The task is to persuade potential adopters to adopt the innovation and to sustain the use of it. However, the perhaps most important assignments of the change agent is to make adopters aware of the innovation and to make them enough interested to seek more knowledge about it on their own. To succeed in their tasks, the change agents often try to identify opinion leaders (See below) and make them adopt the innovation first.

Change agents in healthcare are often company representatives who work to promote the company's products. A possible scenario in this setting is also a combined organizer and change agent, when e.g. the top management acts to establish a climate for innovation through decisions on capital commitments and organizational opportunities.

The change agent is important for successful diffusion of an innovation, but the role is equally important in the deployment domain. The adopters need support in their learning of the new practice and the probability that an innovation will be successfully integrated increases if the change agent's efforts continue.

Gatekeepers

A gatekeeper is often active in organizational adoption. He is working on the behalf of the system of potential adopters or the organization. His task is to search for useful ideas, practices, and products and to keep track of values and needs within the system. He processes the information and transmits chosen pieces of information to other members of the society or to his colleagues. This processing and selection of innovation is intended to favor the system or organization, even though this will be from the subjective perspective of the gatekeeper himself. Anyway, a true gatekeeper does not work for his own good. An actor, who strives for personal favors or economic gain through, what seems like gatekeeping activities, is actually a change agent working for his own personal change agency. The gatekeeper has always the interest of the organization in mind and he may promote or oppose an innovation in this pursuit, but he may of course be rewarded for this if the organization finds it useful. The gatekeeper role might, however, be informal and far from all gatekeeping activities are beneficial to the organization in the long run.

Knowledge about innovations is often conveyed to the adopters through gatekeepers and/or change agents, but it also happens that adopters come across an innovation by chance. Active search for innovations by an adopter, however, often implies that the adopter has taken on the role of the gatekeeper.

Opinion leaders
An opinion leader is a person (or unit of adoption), whose practices are readily imitated by other adopters. He has the power to influence other individuals' attitudes and make them change their behavior. Opinion leaders are members of a social system of potential adopters, but they sometimes represent change agencies outside of the system. They may promote or oppose new ideas.

Opinion leadership is a type of informal leadership, but the opinion leader also usually has a high formal position or status in the system. He is at the center of interpersonal communication networks and thus in the position to influence many in the system [Rogers, 2003]. The opinion leader also has a high conformity to the norms of the social system, which implies that he will oppose the most radical innovations that should bring about extensive changes.

Champions
A champion uses his personal influence to encourage the adoption of an innovation. Champions for medical innovations are often mid-level officials in healthcare [Goodman & Steckler, 1989]. They facilitate diffusion by promotion of the innovation in committees and to authorities in the organization. A champion is particularly useful if an unfavorable organizational and regulatory environment is working against the innovation [Stocking, 1985].

Invention

Invention is the first domain in the innovation process. It involves conception of an idea, the shaping of an invention, and transformation of the invention to an innovation that is useful in a system of potential adopters. In a general sense, an invention can be a novel solution, device, material, method or an idea. It may, for instance, be the use of a word in a new meaning. Technical terms and fashion words are such inventions. They come up, sometimes by chance and sometimes by means of an active search for a suitable word, and they become defined. The definition, in this example, is the transformation

from invention to innovation. When others learn the new meaning, and see that they can make use of the new term, the innovation starts to spread. This chain of events is general and the overall process is the same when it comes to medical devices.

The first step in the initiation stage is a discovery. There are two kinds of initiating discoveries: (1) possibility-discovery and (2) needs-discovery. The first kind is a discovery of a possibility to do something that was not possible before. It is the result of knowledge accumulation, by means of basic and applied research (episteme) or by means of practical experience, craft and art (techne). Development in the medical field depends to a large extent on the accumulation of knowledge and skills [Comroe & Dripps, 1976]. Basic research has often initiated inventions in medicine and, for example, radiography (x-ray) and electrocardiography (ECG) have been invented as a result of interactions between medicine and general science.

The needs-discovery is the result of a perceived performance gap, need, inequity, or simply a wish for change. This kind of discovery has also initiated many innovation processes in medicine. In organizational innovation, a needs-discovery is often the identification of a performance gap. The perception of this performance gap is gradually evolving and during that time the discoverer gains a deeper understanding of the problem. Alone or together with an inventor he then seeks information about different approaches and different solutions. This active search for solutions may eventually result in an invention or the assimilation of an old technology in a new application. For instance pharmaceuticals are developed and designed to mitigate particular symptoms. These symptoms can be described as performance gaps in the effort to produce healthier patients. Another example of invention, as a response to a need, is the dialysis machine, which is the result of many targeted inventions, first to make patients survive transitory kidney disease and later to treat end-stage renal disease. The discoverer is often a medical professional and he/she may also be the inventor, but many innovative solutions are the results of cooperation between discoverers and inventors in healthcare, academy, and industry.

The making of inventions also requires funding and organization of work and resources. Funding of the initial research work may come from different sources, e.g. associations or agencies on national, regional or organizational level, but much of this work is supported and organized by academy or industry.

In the next step, it is necessary to refine the invention to suit the needs of an audience of potential adopters. This is most often done in industry, but the relation between industry and healthcare is complex and the image of a buyer and seller relation is probably not true. This has been pointed out by Blume [1992], who also gives a detailed description of interactions and activities associated with medical device innovation. Blume suggests that we should look at those activities as occurring in an inter-organizational field.

There are many high-technology firms producing medical technologies, such as pharmaceuticals, devices (instruments/equipment), and information processing. Such technologies are to a great extent based on academic research, which has been refined to innovations by R&D activities within firms. Testing and further refinement will then be conducted in the hospital setting. It has been shown that firms chose to cooperate with universities in the geographical proximity and that this seemed to be more important for applied research than for basic research [Mansfield, 1995]. An explanation for this is that personal interaction and hands-on work with instruments and patients are more important at the development stage.

Four players are thus necessary for medical devices to evolve: academy, industry, healthcare, and a funding agency (payer). When an innovation is approaching a marketable product the development work is increasingly funded and organized within a firm. At this point innovative activities are very much occurring at the firm level and there are actually three types of innovation processes going on: (1) the process of transforming an idea to a useful medical device for use by medical professionals in their daily routines, (2) the process of integrating a new article in the product range of the firm, and (3) the process of inventing a technically feasible production process to manufacture the new product. A conclusion drawn from this is that without the innovating firm, the innovation will never reach the intended user. An essential ingredient in medical device innovation is thus that someone considers the innovation a potentially marketable and profitable product.

Diffusion

Diffusion is the result of many individual adopters' decisions to change their practices in favor of a new technology. Diffusion starts when people outside of the inventor's and developer's sphere have become aware of the innovation and want to assimilate (adopt) it into their own practices. Diffusion occurs in a

system of potential adopters. This adopter population is, however, not fixed in extent and number, but can grow or shrink in response to innovation adaptations and perceptions of the usefulness and in response to changes in the scope of the innovation [Fineberg, 1985; Finkelstein *et al*., 1995]. Diffusion occurs over time. It often yields an S-shaped curve when plotted as a function of the cumulative number of adopters over time. This pattern of diffusion is in analogy with diffusion of a contagious disease, which implies that some people are more receptive to innovation than others. You may not adopt an innovation the first time you hear about it, but after several encounters with a "contagious" innovation you perhaps cannot resist it. Consequently, innovativeness can be seen as the degree of receptiveness to innovation.

Adoption is the process of assimilating innovations. This process can be divided in three main stages: *awareness, attitude formation,* and *decision*. The decision has three outcomes: adoption, rejection, or postponement. A rejection is seldom a final decision and both rejection and adoption may be reversed when the innovation begins to show its true qualities through the practical use among early adopters. Postponement occurs when the adopter considers the basis for decision unsatisfactory or when he expects better evidence to be available soon.

Almost all of the actors in the innovation model (See Table 1, p. 82) have important roles in the diffusion domain. The *change agent* and the *gatekeeper* try to influence potential adopters in their decisions. The *champion* paves the way for the innovation. He argues for its use and exerts his influence on other actors. The *opinion leader* shows that adoption is an accepted behavior in the adopter system. The *developer* makes adjustments of the environment, the innovation, or its scope, so that the value of adoption is amplified. The *payer* makes adoption financially possible. The *organizers* arrange that time, resources, and innovation are in place, so that adoption can occur. The *regulators* define the limits for what comes in into the system and how much of it.

Diffusion of medical devices often starts before the innovation has found its final form and a lot of adaptations occur before the device can be deployed in regular use. A device is also more integrated with the user skill and environment and thereby influenced by more factors in the diffusion process than for instance a medicine. Diffusion of medical devices occurs above all to hospitals and is thus an organizational innovation process. Consequently, the decisions about devices are often authority decisions or collective decisions, but individual adoption decisions also occur. The adopting units are

frequently hospitals or ward units, and the innovation processes have a lot in common with innovation within firms. Decisions are thus most often dependent on the decisions made by others inside and outside of the organization and on the scope of the production, i.e. the demand of the customers or patients.

In organizational innovation, awareness of an innovation may be preceded by definition of a problem (identification of a performance gap) and an active search for solutions. This is, however, regarded as a needs-discovery and referred to in the invention domain of this model, and even though the search may result in assimilation of an innovation (product or process), which is already diffused, it is quite probable that the use of it in the new context is an invention.

Awareness

Awareness of an innovation might be the result of an active search, but most often a *change agent* or *gatekeeper* relays information to the potential adopters. The change agent relays information about innovations because he is paid to do so, or he has something else to gain from a high rate of adoption. The gatekeeper, on the other hand, is scanning the horizon for useful ideas, practices, and products on the behalf of the society of potential adopters or the organization. He processes the information and will relay positive reports about innovations only if he believes that it will favor the society or organization.

The first knowledge about the innovation and its possible benefits is thus rather biased and fragmentary. Someone in the system of adopters may, however, be interested enough to remember that the innovation exists and after some time more pieces of information could be connected to it. A certain degree of conscious evaluation is required to gain full awareness of the innovation, and this is the result of merging together information from different sources and discussions with others in the system.

Attitude formation

As the potential adopters become interested to know more about the innovation, they start to form an attitude for or against it. Attitude formation has two components:

1. Estimation of need. This involves evaluation of the innovation and its application to the present or future situation of the adopter, i.e. how well the technology will suit the need of the adopter.

2. Estimation of benefits and costs. The adopter wants to know about the advantages and disadvantages associated with adoption of the innovation. Advantages in this respect may not only be those connected with application of the innovation in a particular activity. It may as well be for example higher status in the adopter society or reinforcement of social ties.

Estimation of need is best done in communication with other adopters and non-adopters. However, in order to get a full picture it is also important to know more exactly what the innovation can do. A change agent or a gatekeeper may provide such information, but their information may be inconsistent, which result in confusion and a variety of opinions about the value of the innovation. The attitude formation at this point is influenced most by informants that have a trusting relation and/or social ties to the potential adopter. As knowledge accumulates over the adoption process the variability of opinions will become less, but opposing opinions may still be present. The information can, however, also be in agreement but erroneous and lead the whole adopter population astray [Fineberg, 1995].

Later in the process of attitude formation, personal experience will become more important. This will, however, not guarantee conformity of opinions. Valuation of benefits is still dependent on subjective evaluations. For example, echocardiography was developed with the purpose of improving cardiac imaging, but image quality is highly dependent on the perception of individuals, and clinicians found it difficult to point out what was good or bad about an image [Finkelstein *et al*., 1995].

When and if the potential adopter decides that the innovation would be a useful tool, he starts evaluating and weighing the benefits against the costs associated with the innovation. This evaluation is performed more or less formally and sometimes with a minimum of information available. In hospital adoption, health technology assessment (HTA) can be an aid, but it is the potential adopter's own subjective processing of the information that leads to

an individual perception of the value of the innovation and this perception may change as more information is acquired.

Information about *medical device* innovations is initially provided by the manufacturer, either at an exhibition or a medical conference, or by a sales representative visiting the hospital. Information about its value, however, is sought from close colleagues. Adopters and non-adopters interact with each other and their subjective evaluations is probably the most influential factor in attitude formation. Common external information sources among medical professionals are for example medical journals, educational programs, meetings, and conferences, but external sources and networks are primarily used by opinion leaders and early adopters.

Decision

After the attitude formation comes the adoption decision. It can be either positive or negative, i.e. processing of the available information can result in either *adoption or rejection* of the innovation, or it can be a decision to wait for better evidence of the value of the innovation. A decision to reject is often also reconsidered after some time and the innovation will be adopted at a later stage, when other adopters' experiences show that it has a value as a tool in the intended application.

The adoption decision is not an instant transformation from potential adopter to adopter (or rejecter). It is a *process*, in which the perceived value of the innovation is applied to the potential adopter's own need, resource capacity (both human and financial), risk capacity, risk tolerance, and societal function. This process may lead to a decision to try out the innovation, if that is possible, and collection of further information by means of trials. Reports from earlier adopters and from trusted informants are often crucial in the adoption decision, but the own experience from practical use of the innovation is valued highest in the decision-making process [Paper IV].

There are three explanations for the perceived need for innovation in hospitals: resource utilization, patient need, and competition.[14] In *resource*

[14] This is a conclusion drawn from merging together information from several sources, for example Teplensky *et al*., 1995; Cook *et al*. 2004; Greenberg *et al*, 2005; Anderson & Steinberg, 1994; and Study IV.

utilization innovations are evaluated against the net benefits they will bring to the hospital in the form of labor savings and cost-effectiveness of treatments. Perceived *patient need* is grounded in the wish to improve health for many and for those with the most severe conditions. Cost-effectiveness is not a prime argument in this. *Competition* has three components: hospitals wish to be high-performing, they wish to have clinical excellence, and they wish to be technology leaders (most technically advanced). However, the information about innovations, presented to hospitals, does seldom take all these aspects into account.

Adoption results in procurement of an innovation or the assimilation of new thoughts or actions into the adopter's immediate conceptual environment. Procurement of *medical devices* is organizational adoption decisions, i.e. the decisions are collective, authoritative, and/or contingent on other decisions. A hospital's potential for innovation is a function of its environment, including economic, social, and political factors, but also the internal structure and management, which have a decisive influence on the hospital's capacity to "absorb" innovations. Among the internal factors are risk capacity, risk sharing, and learning capacity. A larger hospital generally has a better capacity to reverse a wrong decision, but risk sharing is an important aspect in this, and adopting units will be more risk-averse if the consequences of a wrong adoption will fall on a few decision-makers.[15]

Adoption of cluster innovations

Technology cluster innovations may be defined as "a set of interrelated innovations that complement one another in such a way that the adoption of one innovation might naturally lead to the adoption of one or more of the other innovations" [Meyer, 2004]. The concept has also been discussed by Rogers [2003], who suggests that cluster innovations are to be seen as an interrelated bundle of new ideas. The adoption of one innovation in the cluster may trigger the adoption of several others.

Adopting one of the cluster innovations may also make adoption of other innovations in the cluster much easier and sometimes cluster innovations have

[15] These thoughts originate from merging together several sources. See e.g. Utterback, 1974; Van de Ven, 1991; Greenhalgh *et al*., 2004; and OECD, 2005.

to be adopted in a certain order. One or more of the technologies included in a cluster may be necessary in order to achieve the anticipated advantages of adoption. It is thus necessary to study all innovations in a cluster and their reciprocal relations and context in order to get a true picture of the adoption process.

Three types of clusters have been identified: technologies that address a similar function, technologies that share a common platform, and technologies that share an overall common purpose, but may have different functions individually [Prescott and Van Slyke, 1997].

Medical devices for family planning such as condoms, contraceptive coils, and anti spermicidal foam are parts of the "family planning cluster." A couple that has adopted the idea of family planning will probably in a short time adopt one or more of these devices. Another technology cluster that has been the focus of diffusion research is computer equipment, which includes for instance processors, monitors, printers, and scanners. No one buys a scanner without having a computer. This has high relevance for innovation adoption in hospitals, as similar contingences are often the case in adoption of medical devices. Screening for cervical cancer, the pap smear test, the colposcope,[16] and the cervical imaging system[17] are technologies in the "cervix cancer prevention cluster." These four technologies are preferably adopted in the above order. The cervical imaging system, however, seems to have a potential to replace the colposcope.

Deployment

After a positive adoption decision the innovation process enters the *deployment domain*.[18] In this domain the innovation is integrated into the routines of the adopter. Technological change will not occur if the innovation is not deployed.

[16] The colposcope is an instrument that illuminates the cervix and gives a magnified view of it.

[17] The cervical imaging system analyzes how different areas of the cervix respond to a certain light source. It distinguishes between healthy and abnormal tissues and produces a color map that is intended to guide the doctor in the decision where to take biopsies [CDRH, 2006].

[18] The concept of deployment is related to the term institutionalization used in organizational theory, where it has been defined as "long-term viability and integration of innovations in organizations" [Goodman & Steckler, 1989].

For non-artifact innovations such as political ideas, services, or habits (e.g. the non-smoking habit) the transition from the diffusion to the deployment domain is not distinct and the deployment phase has often been neglected in earlier innovation research. However, medical devices are artifacts and as such they are sometimes diffused but not used. Integration occurs over time, but not all diffused devices are rationally deployed.

Deployment involves both successful implementation and reinforcement of the adoption decision from other adopters. The *organizers*, the *regulators*, and the *payers* do all exert their influence in this domain and may facilitate or inhibit successful deployment. An innovation *champion* might pave the way for an innovation through unfavorable organizational and regulatory structures, and his efforts are equally important in the deployment as in the diffusion domain.

Hospital management is the main organizer in deployment of health technologies. Proper education and on-going learning must be provided and incentives are sometimes necessary to overcome mental barriers to innovation. These early stages of the deployment process are crucial in shaping a favorable climate for the new technology, but even if this phase is carefully carried through, it will sometimes show that the innovation does not fully fit in with routine practices. This is where the developer comes in with valuable ideas to increase the usefulness of the innovation.

Innovation adaptations[19] are especially likely to occur in the deployment domain. It is when the innovation is put into use that its true qualities will show and adaptations is often required to integrate it into the routines of the adopters. These adaptations may be of three different kinds:

1. *The innovation is altered* so that it suits the intended need and can be integrated in existing practices. A medical device example of this is the heart valve prosthesis. Several adaptations to the original innovation have been carried out to obtain a valve with good wear properties and to minimize thrombosis and calcification.

2. *Practices are altered* so that the innovation can be integrated in the work or other activities of the adopter. Hemodialysis belongs to this group. Treatment of end-stage renal disease did not only require special facilities, it caused

[19] Innovation adaptation is often called re-invention in the diffusion research literature.

reorganizations of medical specialties and it was the start of a more integrated role of the clinical engineers into the work practices of hospitals.

3. *The scope of use is altered* so that the innovation is deployed in activities where its potential will be best exploited. This can be either an extended or a narrower scope. Pharmaceuticals represent numerous examples of extended use, but also some recent examples of narrowing of the scope, for instance the strive in some countries to reduce the use of antibiotics and direct the use to areas where it produces the largest net benefit.

The decision to adopt a medical device innovation can be reconsidered at any point during the deployment process, which is often the case if the expected benefits of the innovation will not show. It is thus in the interest of the change agent to see to it that the adopted innovation is properly deployed. Many change agencies assume erroneously that the change agent's efforts are not needed after the product is sold to the costumer, but the adopters may need support in their learning of the new practice. Furthermore, if the innovation is not deployed in the best way it will not show its full potential and this will put both innovation and change agency in unfavorable light in the adopter system.

Deployment is the last step in technological change. Successful deployment of an innovation means its integration in the practices of the adopters, but this may occur partially in a given adopter system. Some adopters may not succeed in making rational use of the innovation. If the innovation is widely diffused *and* deployed in the adopter system, technological change can be considered complete. This is, however, not a distinct point in time or in the process.

Rationality of the extent and quantity of use

Deployment may be more or less rational and irrational use of devices may be classified as *underuse, overuse,* or *misuse*. The worst degree of underuse is apparently to buy a new device and then not make use of it. This might, however, be a rational behavior in the case where the first use revealed that the innovation did not suit the intended need. It is however often carelessness and low incentives behind underuse. The first use may have been tricky and incentives to learn how to use the device may have been low. After the first few attempts it will be used more seldom and soon you will forget that you have it. The cell-phone calculator is a widespread example of underuse. When

a calculator is needed many of us do not remember that we have one in the phone.

Healthcare innovation shows similar patterns of irrational use of technologies and useful medical devices adopted in hospitals are sometimes not exploited to their full potential [See Paper IV].

Overuse can occur in two different ways, over-adoption and over-utilization. Over-adoption is the situation where diffusion has occurred in an adopter group that does not benefit from the innovation. It might be difficult to correctly evaluate precision technologies in medicine, and their apparent attractiveness may therefore exceed their true value. In the over-utilization situation, on the other hand, the value of the innovation is established, but the adopter tend to use it repeatedly in situations where no added value is gained. This is sometimes the case for useful diagnostic technologies. The extra CT-scan may, for instance, not add anything to the diagnosis.

Overuse and misuse are related concepts, but while over-utilization is unnecessary use of the innovation, misuse is application of the innovation to the wrong problem. Hitting the nail with the hammer a couple of times extra is over-utilization, while hitting a screw with a hammer is misuse.

End of the innovation life cycle

Deployment of an innovation often also implies disuse of an older technology. Discarding obsolete or useless technologies seldom pose any difficulties, but adoption of medical device innovations in hospitals often occurs before the current technology is worn out and/or useless. The products may simply be replaced by functionally better technology. This is an established part of the technology life cycle, but opinions about the value of the new versus the older technology are often divergent and there is always a resistance to change when it comes to discarding technologies that have been in use for a long time.

For a period of time old and new technologies may exist in parallel, but in order to obtain full integration of a technology it is important to discard the "old competitor." However, a lot of knowledge and skills may be invested in the old technology – knowledge and skills that can be hard to restore if adoption of the new technology should turn out to be a wrong decision. The risk involved in adoption is thus not only dependent on the innovation, but also on the old technology, which it is intended to replace.

Measures and variables

This innovation model is not primarily intended for measurements. It might, however, be useful to have some measures that enable comparisons between different innovation processes. I have identified four quantitative measures of innovation that can be used to describe the process:

1. *Extent* is a spatial measure of the spread of the innovation among potential adopters. This measure is the most commonly used in diffusion research. The extent may, however, reach a steady state while utilization of the innovation is still increasing.

2. *Quantity* is a utilization measure that tells us how much or how often the innovation is used. This is relevant for e.g. hemodialysis, phototherapy, monitoring equipment, and pharmaceuticals.

3. *Speed* may be measured as the time it takes from one point to another in the model, for example from market introduction to 60% spread in an estimated adopter population; or the time for the whole process to occur, from first discovery of a need to routine use of an innovation that satisfies that need.

4. *Probability* is the likelihood that innovation occurs. It is an estimation that may be performed at different points in the process: at the invention stage to predict the possibility that an invention will lead to technological change; or before diffusion to predict how it will be received by the adopters. It may also be described as the likelihood for a certain extent, quantity of use, or speed of innovation.

The above-described measures are *dependent* variables, which can be explained by *independent* variables such as: characteristics of adopters, characteristics of the innovation, context, information channels, communication, and networks. In this model the independent variables are called *facilitators and inhibitors*. The variables are, however, not easily quantified. In Paper IV the most important variables to explain adoption of medical devices in hospitals were found to be: (a) the subjective estimated value of the device, (b) the level of information and learning,[20] and (c) the innovativeness of the adopting unit. Obviously, this will pose substantial measurement problems.

[20] This is the essence of knowledge accumulation. When the information and learning process has reach a certain stage of maturity, the adopting unit is prepared to make a decision.

A fifth dimension of innovation is the *degree of change* it will bring about, which is an ordinal categorical variable. It can for instance be categorized as minor, small, substantial, extensive, and revolutionary, or it may be subjectively indicated on a scale from incremental to revolutionary change.

Facilitators and inhibitors

The independent variables in this model are called facilitators and inhibitors (Table 2, p. 83 and Table 4, below.). These variables are determining innovation extent, quantity, speed, and probability. A multitude of variables interact in the different innovation processes and the list provided here would not pretend to be complete. The emphasis has been focused on factors in organizational innovation of medical devices. Many of these factors are, however, general for all innovation processes and will therefore also apply to non-medical examples.

A certain grouping of variables is necessary in order to obtain an understanding of their interdependencies and interactions. This presentation will follow the list of facilitator and inhibitor sets provided in Table 2 (p. 83). Several of the facilitators and inhibitors are influential in more than one way and could be assigned to more than one set. I have, however, tried to avoid repeated occurrence of the same factor. It is also important to remember that all factors are not present in every innovation process, and when applying the model it is necessary to sort out the most dominant factors, in order to get a manageable model.

Table 4 Facilitators and inhibitors. Identified factors with considerable influence on medical devices innovation. Their mechanisms, main influences and domains.

Facilitators & inhibitors	Mechanism	Main influence	Domains
1. Perceived need			
Performance gap	Need for higher efficiency.	Initiates invention and adoption.	Invention, diffusion
Inequity	Societal striving for equity.	Initiates invention and adoption.	Invention, diffusion
Wish for change, fashion	Inherent wish for renewal. Changes in demand.	Initiates invention and adoption. Facilitates diffusion and deployment.	Invention, diffusion, deployment

(Table 4, continued)

2. Knowledge accumulation			
Academic research	Provides a structured knowledge base.	Initiates invention.	Invention
Clinical trials and/or HTA (positive results)	Provides positive information and learning possibilities.	Facilitates diffusion and deployment.	Diffusion, deployment
Personal experience	Provides information, learning and experience. Skill improvements.	Facilitates diffusion and deployment.	Diffusion, deployment
Networks	Extended, vertical and diverse networks provide a broader knowledge base.	Initiates invention and adoption	Invention, diffusion
Absorption	Ability to link new and old knowledge together.	Initiates invention and adoption. Facilitates deployment.	Invention, diffusion, deployment
3. Information flow			
Availability of information	High quantity, weight and number of sources. Encounters with the innovation.	Facilitates diffusion.	Diffusion
Networks	Knowledge and information transferred more easily.	Initiates invention and adoption. Facilitates deployment.	Invention, diffusion, deployment
Separation, geographical	Long distances between network members.	Inhibits invention, diffusion, and deployment.	Invention, diffusion, deployment
Separation, conceptual	Different definitions of concepts.	Inhibits invention, diffusion, and deployment.	Invention, diffusion, deployment
Change agent	Active transfer of positive information. Support to adopters.	Facilitates diffusion and deployment.	Diffusion, deployment
Gatekeeper (positive)	Working actively to disseminate positive information.	Facilitates diffusion.	Diffusion
Linkage	Active links between developers, producers and users.	Initiates invention and adoption. Facilitates deployment.	Invention, diffusion, deployment
Communication barriers	The two factors of separation above are also communication barriers. Other communication barriers are to be found among the actor and regulatory factors. (See group 7 and 8.)		

(Table 4, continued)

4. Risk and uncertainty			
Quality of information	High evidence-level of knowledge and information.	Facilitates diffusion and deployment. Decreased risk factor.	Diffusion, deployment
Origin of information	A trusted source with network and/or social ties to the adopter.	Facilitates diffusion and deployment. Decreased risk factor.	Diffusion, deployment
Cost of clinical trial (high)	Large investment needed to show positive effects.	Inhibits invention and diffusion. Increased risk factor.	Invention, diffusion
Observability (high, positive)	Visibility of effects and benefits.	Facilitates diffusion. Decreased risk factor.	Diffusion
Compatibility	Agreement with existing social norms and current work procedures.	Facilitates invention and diffusion. Decreased risk factor.	Invention, diffusion
Degree of change (high)	Radicalness of the innovation, high degree of departure from previous practice.	Inhibits diffusion and deployment. Increased risk factor.	Diffusion, deployment
Reversibility (high)	The ease (and degree) with which status quo ante can be restored. Trialability.	Facilitates diffusion. Decreased risk factor.	Diffusion
Divisibility (high)	Partial adoption possible. Trialability.	Facilitates diffusion. Decreased risk factor.	Diffusion
Changing regulatory frames	Frequent changes in the regulatory environment.	Inhibits invention and diffusion. Increased risk factor.	Invention, diffusion
Risk-sharing mechanisms	Effects of wrong decisions falling on several organizations/departments/ individuals.	Facilitates invention and diffusion. Decreased risk factor.	Invention, diffusion
5. Incentives			
Financial profit	Economic gain (inventors, producers, adopters)	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment
Utility, organization	Better process, labor-savings, cost-savings.	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment
Utility, patients	Better treatment, less discomfort, increased health and quality of life.	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment

(Table 4, continued)

Status, prestige	Professional recognition, scientific publications.	Facilitates invention and diffusion.	Invention, diffusion
Funding and reimbursement system	Low incentive system, e.g. fixed sectoral budgets (costs on hospital budget and benefits on society).	Inhibits invention, diffusion and deployment.	Invention, diffusion, deployment
Subsidies from vendors	Reduced price, free training, and/or trial devices.	Facilitates diffusion.	Diffusion
6. Competition			
Competition among hospitals	Hospitals struggling to be high-performing and the most advanced in a geographical area or a medical field.	Facilitates diffusion and deployment.	Diffusion, deployment
Competition among producers	Competition for market shares.	Facilitates invention and diffusion.	Invention, diffusion
Competition among professionals	Competition for professional recognition and scientific status.	Facilitates invention and diffusion.	Invention, diffusion
Competition for higher status	Struggle for higher social status within the organization and/or network.	Facilitates diffusion and deployment.	Diffusion, deployment
Conservation of social status and protection of vested interests	Protection of financial, political or self-interest in the current structure and practices.	Inhibits diffusion and deployment.	Diffusion, deployment
7. Regulatory frames			
Basic frames of reference	Narrow social norms.	Inhibits invention and diffusion.	Invention, diffusion
Organizational culture and management	Permitting morale.	Facilitates invention and diffusion.	Invention, diffusion
Stable laws and regulations	Stable definitions of rules and standards.	Facilitates invention and diffusion.	Invention, diffusion
Complicated laws and regulations	Difficult to get a clear picture of which rules are applied and in what way.	Inhibits invention and diffusion.	Invention, diffusion
8. Actor characteristics			
Risk capacity (organization)	Capacity to absorb a wrong decision. Large size and maturity of the organization.	Facilitates invention and diffusion.	Invention, diffusion

(Table 4, continued)

Personal characteristics	High coping capacity and a positive attitude toward change.	Facilitates invention and diffusion.	Invention, diffusion
Attitude toward change, identity as innovator	Management and staff having a positive attitude toward change.	Facilitates diffusion and deployment.	Diffusion, deployment
Communication behavior in organization	Extended, vertical and diverse communication behavior facilitates flow of information.	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment
Internal organizational structure	Functional differentiation, specialization, decentralized decision-making	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment
Management	Leadership skills in allocation of financial and human resources.	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment
Adaptation potential of the organization	The ease with which it can be reorganized to suit the innovation.	Facilitates diffusion and deployment.	Diffusion, deployment
Adaptation potential of staff and workplace	The ease with which work routines can be changed to suit the innovation.	Facilitates diffusion and deployment.	Diffusion, deployment
Knowledge and skill	Broad professional experience.	Facilitates invention, diffusion, and deployment.	Invention, diffusion, deployment
Slack resources	Slack resources to channel into new projects; facilitate trials; provide a climate for experimentation.	Facilitates invention and diffusion.	Invention, diffusion
Social ties	Strong social ties imply confinement to the norms of one or more social systems.	Inhibits invention. Inhibits initiation of diffusion.	Invention, diffusion
9. Innovation characteristics			
Net benefits (positive)	Health benefits and/or care-giving benefits (process) exceed costs. High efficacy/effectiveness.	Facilitates diffusion and deployment.	Diffusion, deployment
Returns to investment	Economic gain exceeds investment and running costs.	Facilitates diffusion and deployment.	Diffusion, deployment
Safety	Not imposing high risks of injuries to patients or staff.	Facilitates diffusion and deployment.	Diffusion, deployment
Usability	Easy to use.	Facilitates diffusion and deployment.	Diffusion, deployment

(Table 4, continued)

Complexity	Hard to understand and/or to use.	Inhibits diffusion and deployment.	Diffusion, deployment
Adaptation potential of the innovation	The ease with which it can be changed to suit the adopter.	Facilitates diffusion and deployment.	Diffusion, deployment
Adaptation need	High degree of adaptation needed.	Inhibits diffusion and deployment.	Diffusion, deployment
Compatibility	Agreement with existing social norms and current work procedures.	Facilitates invention and diffusion.	Invention, diffusion
Cluster innovations	Relevant cluster innovations already adopted.	Facilitates diffusion and deployment.	Diffusion, deployment
Additional education needed	Knowledge and skill to use the innovation is insufficient.	Inhibits diffusion and deployment.	Diffusion, deployment
Reorganization need	Reorganizations needed to deploy the innovation.	Inhibits diffusion.	Diffusion
Obsolescence	New generation of the innovation on its way.	Inhibits diffusion.	Diffusion
10. Perception of benefits			
Personal experience	Knowledge and skill from using the innovation or similar practices.	Facilitates diffusion and deployment. Benefits easy to detect.	Diffusion, deployment
Change agent activity	Transfer of positive information. Support to adopters.	Facilitates diffusion and deployment. Benefits emphasized.	Diffusion, deployment
Opinion leader (has adopted)	An opinion leader is already using the innovation. Ensures social acceptability.	Facilitates diffusion and deployment. Benefits added.	Diffusion, deployment
Gatekeeper (positive)	Working actively to disseminate positive information.	Facilitates diffusion. Benefits emphasized.	Diffusion
Origin of innovation	Innovation invented and developed nearby/ internally/within network	Facilitates diffusion and deployment. Benefits added.	Diffusion, deployment
Immediacy (low)	Long time lag between treatment and effect.	Inhibits diffusion and deployment. Benefits hard to detect.	Diffusion, deployment
Degree of change (high)	Radicalness of the innovation, degree of departure from previous practice.	Inhibits diffusion and deployment. Benefits hard to detect.	Diffusion, deployment

(Table 4, continued)

Unfamiliarity	Outside the normal range of experience and knowledge	Inhibits diffusion and deployment. Benefits hard to detect.	Diffusion, deployment
11. Promotion of the innovation			
Availability of the innovation	Many encounters with the innovation. Support in purchase procedures.	Facilitates diffusion.	Diffusion
Change agent	Promotion efforts, networking, and support.	Facilitates diffusion and deployment.	Diffusion, deployment
Champion (positive)	Promotion efforts in committees and by decision-makers.	Facilitates diffusion and deployment.	Diffusion, deployment
Allocation of resources	Adequate and continuing allocation of resources.	Facilitates deployment.	Deployment
Involvement	Involvement of staff at all levels. Promotion of positive attitudes.	Facilitates diffusion and deployment.	Diffusion, deployment
HTA (positive results)	Evaluation of health benefits (and social impact).	Facilitates diffusion and deployment. Promotive of "good" innovations.	Diffusion, deployment

The different actors, their actions, and their characteristics, are constituting the innovation environment; consequently there are no separate environmental factors in this model, but set 7, *Regulatory frames*, contains many environmental aspects. Neither have I found it necessary to divide determinants in internal and external factors, and for instance laws and regulations as well as internal organizational norms are to be found in set 7.

Main influences may differ from one innovation domain to another. In the invention domain, factors such as knowledge accumulation, network contact, economic incentives, and organizational and management principles are influential. These factors are also influential in the diffusion domain, but regarding *hospital adoption of medical devices*, three factors may be distinguished as particularly important: (a) the subjective estimated value of the device, (b) the level of information and learning and, (c) the innovativeness of the adopting unit [Paper IV]. The *subjective estimated value* is the difference between anticipated positive effects and anticipated negative effects, as perceived by the unit of adoption. On the positive side are benefits to the patients, staff and organization and on the negative side are costs, risks and undesirable side effects. Costs include purchasing, operating and maintenance

costs, as well as costs of information, education, and possible reorganizations. Among the risks are both those involved in the medical treatment and those connected with the investment, for instance in money and staff education.

The subjective estimated value is built of several factors, mainly by the *characteristics* of the innovation and of factors influencing the *perception of its benefits and costs* (See sets 9 and 10 in the model and Table 1, p. 106). Furthermore, this perception of benefits and costs is not static, but is related to the knowledge accumulation, which is an *information and learning process*. The perceived risk is gradually reduced as knowledge about the innovation increases. Whether this process will be slow or fast is to a high degree depending on the perceived uncertainty in the available information. In order to arrive at a decision to adopt, it is also important that the information is of high quality and that it comes from a trusted source.

The *innovativeness of the unit* is very much dependent on the ability to cope with risk and uncertainty, but also on the adopting unit's capacity to absorb a wrong decision and whether it has an identity as an innovator. Finally, in the deployment domain, *promotion of the innovation* is crucial and again the organizational and management principles are important facilitators or inhibitors.

Table 4 (p. 106) provides a list of facilitators and inhibitors that have been identified as influential in medical device innovation. Only short indications of their mechanisms and impacts are given in the table and the factors will therefore be more thoroughly discussed in Chapter 7 (p. 117).

Consequences of innovative activities

With the wider definition of technology (as an applied knowledge or tool) and with innovation defined as technological change, the purpose of innovation is always to improve the lives of the innovation adopters and/or the members of the social system, within which the innovation is diffused. The anticipated improvements may be labor-savings, increased welfare, higher social status or economic gain to the adopters. The total consequences of innovation are, however, difficult to predict. The deployment of the combustion engine, as one example, has led to extensive air-pollution and has been a substantial inhibitor in the development of electric vehicles. The consequences of this, e.g. respiratory disorders among people living in cities and the barriers to the

electric car, could not have been predicted in the early days of the combustion engine. Another example is the organic pesticide DDT, for which the Swiss chemist Paul Müller was awarded the Nobel Prize 1948. Its high rate of diffusion was close to disastrous to nature and to the whole human society.

Consequences of innovations may be classified as: (1) desirable or undesirable, (2) anticipated or unanticipated, and (3) direct or indirect [Rogers, 2003], of which the undesirable consequences are often both unanticipated and indirect. Consequences can also be classified as (4) private or public [Wejnert, 2002]. Public consequences, in this respect, refer to the impact of an innovation on others than the adopters themselves. If diffusion of an innovation imposes consequences on non-adopters and rejecters, these are categorized as public consequences. (For instance, one person's adoption of the smoking habit has undesirable public consequences for his/her family members and other people subjected to passive smoking.) A fifth classification, finally, are (5) short-term or long-term consequences.

Total utility of innovation must thus be regarded, as the sum of all five types of consequences and innovation is never entirely good or bad. On the contrary, different consequences are often conflicting, like the short-term and long-term consequences in the well-known DDT example. It certainly did kill the malaria mosquitoes, but in the long run might have killed all living organisms.

The adopters most often attach less importance to long-term consequences. Diffusion may thus be unduly facilitated or inhibited because short-term consequences are valued higher. For example preventive measures may be affected by this. The time period from adoption until visible consequences is usually longer for preventive technologies than for therapeutic technologies. This implies that incentives for producing preventive technologies are low, both in industry and healthcare. Surgery for treatment of obesity is thus more popular than obesity prevention programs in the struggle against obesity-related disease.

Two often neglected consequences of innovation are (1) path-dependency and (2) abandonment of knowledge. The first category is the dependency of innovations on earlier events and innovations, for which I will use the term *path-dependency* [David, 1975, Arthur *et al*., 1987]. New needs may be discovered as a consequence of innovative activities, and new technologies pave the way for other innovations. The way we build our societies is in large path-dependent on lots of earlier innovations. The separation of activities,

such as for instance the partition of cities in working, living, and shopping areas, would not have been possible without cars, to once again mention the consequences of the combustion engine.

The second category, *abandonment of knowledge*, occurs when old technologies are discarded and with them the knowledge and skills of using them. In case of unfavorable innovation decisions, one might pose the question: Can the abandoned knowledge be restored? Perhaps it is possible by means of careful documentation, but far from all knowledge and information is documented in this way. For example, correspondence between scientists was earlier in the form of handwritten letters that were often archived and that provided a source of knowledge and understanding of the progress of the discoveries. In a time when e-mail and telephone are primarily used for informal communication, this source of knowledge is gone. And who has the energy to go through the fragmentary correspondence, among thousands of spams, in the e-mail of today's scientists?

7. DISCUSSION

The applied theoretical model in this thesis is built of several different components. Four salient features of the theory are the following: (1) technological change is an evolutionary process; (2) opportunities more than demand initiates innovation; (3) innovation can be both good and bad; and (4) hospitals are producing the "goods" of health and knowledge, and thus have a lot in common with innovation within firms.

These things, among others, will be discussed below. The first section is, however, devoted to the examination of independent variables in the model and their mechanisms and impacts. When reading this, it is important to remember that innovation can be either good or bad. A high degree of innovation may not always be the best alternative. Facilitators and inhibitors are thus equally useful, and the desired state of being, in a social system, is a manageable rate of change and the diffusion of beneficial innovations.

Mechanisms of facilitators and inhibitors

The facilitators and inhibitors are not equally important in all of the three innovation domains (invention, diffusion, and deployment), even though many of them are present in all three domains. There are also substantial differences in impact on different types of innovations. Below are, however, the mechanisms and impacts discussed in more general terms. The sets of factors are numbered in accordance with Table 2 (p. 83) and Table 4 (p. 106), which are also recommended for an overview of the factors and the sets of factors.

1. Perceived need

Perceived need is one of the two initiators of technological change: needs-discovery and possibility-discovery. (See *Invention* p. 93 and *Knowledge accumulation* below.) Initiation of the innovation process occurs when the needs-discovery is discussed with an inventor. And if sufficient incentives are present the process will take off.

A **performance gap** is the perceived need for e.g. higher efficiency. This kind of needs-discovery, in the hospital setting, is typically made by medical professionals in their work practices. The identified performance gap may be the lack of satisfactory treatment of a certain condition or it can be a procedure that is working inefficiently. The transformation of a needs-discovery, first to an invention and later on to an innovation, has also financial implications, but it may be practical to treat the presence of a performance gap as a factor separated from the financial incentive.

Innovations in the form of new products, new treatments, or processes (changed practices) are often adopted as a response to productivity requirements [See e.g. Zaltman *et al*., 1973], which implies that identification of a performance gap may be initiated by changes in the regulatory frames or in the competitive environment.

A needs-discovery may also follow a perception of **inequity**. There is an inherent striving for equity within our social systems. This may seem altruistic but in order to benefit from the common good it is necessary to work for the good of others. Ogburn [1922] has discussed this and suggested that the development of social controls, such as social norms, directives, and laws, has occurred out of the "social necessity of curbing egotism and selfishness."

The implication of this, with respect to healthcare, is that we wish to do something for those with the most severe conditions and that we wish to distribute life-years so that each young person has a chance of a fair amount. Innovations in treatment of children's diseases are thus more likely to be diffused than other health technologies.

There is also an inherent **wish for change** that sometimes manifests itself as trends or fashions. This is opposed by social controls and the workability of traditions and familiar habits, but renewal seems to have a value in itself, even if the new practice is not superior over the old one. It has for example been shown that organizational program innovations have to adapt and become renewed to attain sustained use [Goodman & Steckler, 1989].

2. Knowledge accumulation

Knowledge accumulation represents the possibility-discovery initiation of technological change. It is sometimes also called technology-push, but this will direct the thoughts to science and engineering skills; and knowledge initiation of innovation may be of many different kinds, far from what we generally call

science. Accumulation of knowledge has an impact in all three innovation domains: in invention as a source of ideas, in diffusion as a means in decision-making, and in deployment as a learning process that makes it possible to make the best use of the innovation.

Invention and development may occur in the academy, industry, or in the private sphere of the inventor. But wherever this work is done, the basis for invention and development of medical devices is **academic research** [Comroe & Dripps, 1976]. The possibility to do something that was not done before may be discovered when studying the academic knowledge base or when experimenting with academic theories, but academic research is often also the basis for trying to find a solution to a needs-discovery. Comroe and Dripps argued for publicly funded support of academic research. I agree with the authors mainly for three reasons: It facilitates linkage to people who will develop the science and technology further; it provides open sources, available to innovators (also to industrial users); and it makes it possible to invest in research that is expected to have no immediate applications, but will produce social utility in the long-run.

Clinical trials and **health technology assessment (HTA)** provides evidence of benefits and disadvantages of the innovation. This knowledge is a support in adoption decisions and may facilitate or inhibit diffusion and deployment depending on the nature of the results. However, while clinical trials and HTA undoubtedly add to the knowledge base this is no guarantee for an evidence-based diffusion of devices. The adopter's perception of benefits is also dependent on how the results are disseminated and if they are used in the adoption decision.

Another problem is that the trials might be of low quality, which yields unreliable results. Tests that suit one type of innovations might not be right for another type. But it is often convenient to use familiar methods, and it makes it easier to communicate the results to potential adopters, even if a new test design ought to be used for the innovation in question [Arfalk *et al*., 1999].

Personal experience is likewise a means to make better decisions and can be either facilitating or inhibiting, but it also has a value in addition to the information about advantages and disadvantages of the device. It provides an opportunity for learning and skill improvements, and the device becomes an integrated part of the practices of the adopter. Personal experience is therefore more likely to be a facilitating than an inhibiting factor.

The importance of personal experience and experimentation in the adoption process has been emphasized in several fields of innovation research [Arrow & Fisher, 1974; Saha *et al*., 1994; Gelijns *et al*., 2001; Rogers, 2003]. This is also true for hospital adoption of medical devices and a definite decision to adopt or reject a device is seldom made without personal experience by medical professionals.

Personal experience improves skills in using the innovation. This may also come from experience of using similar technologies/practices. It will also increase the familiarity of the innovation, which is a facilitating factor in both diffusion and deployment.

Networks determine the breadth of the knowledge base. Extended and diverse networks provide a broader and more interdisciplinary knowledge base, which increase the probability to find feasible solutions to problems. This is also enhanced by vertical networks in organizations, because communication upwards and downwards in the hierarchy means adding together different kinds of experiences and knowledge. Extended, diverse, and vertical networks facilitate all activities in the invention domain and it is also a facilitator in the diffusion domain.

The **absorption** factor is the capability to link new and old knowledge together [See e.g. Lam, 2005]. A broad and diverse knowledge base is of no value if the different pieces of information cannot be inserted into a structure that gives them meaning. The absorption capability may also be seen as an actor characteristic of the organization as well as of individuals within the organization. Knowledge absorption capability has probably a substantial facilitating impact all over the innovation process.

3. Information flow

The accumulated knowledge may be transferred and disseminated as pieces of information. Information flow is the ease and speed with which such "knowledge packages" travel and spread. It is mainly determined by societal and organizational structures. Inhibitors to effective flow of information may be: *geographical* – separation in space; *cultural* – different frames of reference of the parties involved, for instance professional differences; *procedural* – different ways of defining and conducting operations; and *structural* – determined by internal organizational arrangements or societal structures.

Availability of information: The most important facilitating measure in innovation is to make information available, both at the organizational level and in society as a whole. It has been pointed out that knowledge protection, such as for instance patents, is a driving force in industrial innovation, but this is only as a risk-reducing factor and the advantages of openness and competition are probably greater in an innovation perspective. Thus, the growing commercialization of university-industry relationships is a potential barrier to innovation, as it could slow down the exchange of ideas and information. Concerns over this have been expressed by for instance Finkelstein *et al*. [1995].

This availability of information is not only of importance in the invention domain, it is equally important in the diffusion domain as a means in adoption decision-making. In this, it can act both as a facilitator and as an inhibitor, depending on the nature of the information. However, the lack of data, regarding the safety, cost-effectiveness, and efficacy of new health technologies, has been identified as a significant inhibitor in diffusion of innovations [Greenberg *et al*, 2005].

Networks have been discussed in set 2 (Knowledge accumulation) as a source of knowledge, but networks are also important in the transfer and dissemination of information. Extended, diverse, and vertical networks facilitate the spread of ideas and knowledge in all domains of the innovation process.

When traveling was not so easy and communication channels, such as phone, fax, and Internet e-mail, were not available, **geographical separation** was an inhibitor of significant importance. Geographical separation has become less important for information transfer and its importance will probably continue to decrease in the future. It has however been shown that proximity to information sources has a positive influence on invention and development activities [Mansfield, 1995].

Conceptual separation is an even more influential inhibitor and is a combination of cultural and procedural communication barriers. This may be due to a high degree of specialization and to differences in culture, experience, education, and training. "Words have different meanings in different contexts; what seems normal and logical to one organization in terms of procedures may not seem equally logical to everyone else" [Tornatzky & Fleischer, 1990].

Finkelstein *et al*. [1995] pointed out this as a major inhibitor to successful innovation in medical imaging technology. The conceptual separation inhibits

effective communication between the developing engineers and the clinicians that later will use the devices and interpret the resulting images.

The **change agent** facilitates the flow of information regarding the innovation he promotes. He is thus not acting to improve the overall communication behavior in the healthcare organization, even if that is sometimes a consequence of hospitals' change agent contacts. The change agent works to make the potential adopters' perceptions of the innovation more positive and in this he emphasizes the benefits.

The **gatekeepers** may be positive or negative to diffusion of a certain technology. They identify promising innovations for different applications and are processing information about them. The gatekeeper is usually part of the adopting unit. An effective gatekeeper facilitates the implementation process by moderating the positions taken by change agents versus colleagues within the organization. The gatekeeper also plays an important role in shaping realistic expectations regarding the likely benefits of a new device or procedure.

In decisions on adoption of medical devices the gatekeeper is invaluable, because in his/her absence the vendor might take on this role, which imposes considerable bias to the information underlying the adoption decision. Of course, it may also happen that gatekeepers become overzealous in promoting a technology or misjudge the value of the behavioral change. This can lead to over-adoption and later abandonment of the technology. According to the Danish communication researcher A B Lund, the majority of information concerning new medical technology is censored by influential gatekeepers [Lund, 1990]. He also points out how important this is in healthcare organizations where the patient is not the "chooser" of the technology, which is the standard arrangement in many healthcare systems.

The **linkage** factor is acting against conceptual separation. If there are active links between discoverers, inventors, and developers a common conceptual base is created and the flow of information will be facilitated in the invention domain. Of the same reason, links between producers and users will facilitate diffusion and deployment.

The two factors of separation above may also be called *communication barriers*. Other communication barriers in this model are to be found among the actor and regulatory factors and are dealt with in the facilitator and inhibitor sets 7 and 8.

4. Risk and uncertainty

Risk and uncertainty have an overall negative effect on the willingness to invest time and money to invent, develop, produce, promote, and adopt innovations. The risk of failure and loss of the investment are discouraging all innovative activities. Innovation is a risky enterprise, but – in case a high degree of innovation is the desired outcome – the following measures may be used to make it a little less risky.

High quality information is information that in the best possible way tries to reveal the true advantages and disadvantages of the innovation, and of the production or use of it. In adoption of health technologies, this quality is often measured as the evidence-level of clinical trials and assessments, and the information concerns safety, efficacy, and effectiveness. The consequences of long-term use, however, are not possible to predict, and high quality information can therefore never guarantee total reduction of risk.

The **origin of information** has an effect on the perception of risk. Information that comes from a trusted source (for example an informant with social or network ties to the adopter) is often perceived to better reveal the true potential of the innovation than information from a distant source.

Cost of clinical trial: High cost, large-scale, and time-consuming clinical trials are difficult to perform, which often means insufficient testing and thus low quality information. Finkelstein *et al*. [1995] found, for instance, that an expanding bureaucracy, both in the public sector and within industry, made diffusion of devices more difficult and "threatened to choke the innovation process." The authors did, however, consider it unlikely and not feasible with a return to a less formal clinical testing environment in the litigation environment that has evolved.

By funding of clinical trials and assessments, the uncertainty in adoption decisions could be reduced, but the funding agencies will instead face the uncertainty of not knowing which innovations they should promote.

Observability is the degree to which the benefits of using an innovation are visible to others. If the observability of positive effects could be increased, the perceived risk would be reduced. Observability is a factor partly embedded in the technology, but it is also possible to make the benefits more visible, for instance, by the use of opinion leader adopters.

Compatibility: If the innovation has a high agreement with existing social norms and work procedures it is more likely to be adopted, as the adopter face

a lower risk of being criticized by his peers for the decision. Compatibility is also a factor that is embedded in the technology, but by effective communication between the developer and the potential adopters, much could be achieved to transform the invention into an innovation with high compatibility.

Another aspect of compatibility is that of increased consumer utility as an effect of the larger user population, for example better evidence of the performance, facilitated exchange of staff, and better service networks. See Katz and Shapiro [1985] for a discussion of this.

The **degree of change** that an innovation is representing may be indicated on a scale from incremental to revolutionary. The greater the change, the more risky the innovative activities, as it is more difficult to predict the future effects of unfamiliar technologies. There is also an increased risk of trial failure for very unfamiliar technologies, reducing the incentives to conduct a trial, which implies that information about the innovation will be insufficient. It might thus be better to make incremental inventions, if that is possible, and develop the full potential gradually through several generations of the technology.

Reversibility and **divisibility** are the two components of trialability. This may be defined as the ease with which the innovation can be tried out by a potential adopter, or "The degree to which and the ease with which the status quo ante can be reinstated…" [Zaltman *et al*., 1973].

Both reversibility [Arrow & Fischer, 1974] and divisibility [Marra *et al*, 2003] are important factors influencing the riskiness of adoption. Uncertainty about the net benefits is a powerful inhibitor of adoption, and even more so if the innovation requires a large initial investment (in money or learning) and if these costs are "sunk", i.e. cannot be recovered if the adopter has to abandon the technology. The possibility to try out the innovation on a limited basis is thus of significant importance. A reversible innovation can be abandoned and the previous practice restored without much economic loss, and the reversibility of the innovation is, to a large extent, determined by sunk investments.

A divisible technology can be adopted to varying degrees, for example drug eluting stents for the treatment of coronary artery disease, which are used on a limited number of patients and currently under evaluation for a more extensive use. If the innovation is divisible, the adoption decision concerns whether the new technology should complement the traditional healthcare alternative and, if so, to what extent. The importance of personal experience

and experimentation in this process cannot be over-emphasized. Policies of on-going assessments of new technologies and feedback processes may prevent delays in making use of healthcare innovations and still ensure a reasonably safe care. It has for instance been suggested (and also implemented in some countries) that funding of new health technologies should be on a conditional basis that enables gathering of further information to overcome the main uncertainties [OECD, 2005].

Changing regulatory frames: Inventors, developers, and adopters need a stable regulatory environment, in order to know what the premises are for the innovation. If premises are changing too rapidly, the risk factor will be increased and innovative activities inhibited.

Risk-sharing mechanisms: In decision-making under extreme uncertainty, risk-sharing mechanisms will reduce the consequences of a wrong decision. Adopting units will be much more risk-averse, if the consequences of a wrong decision will fall on only a few individuals. The risks and benefits of an innovation can not be perfectly evenly distributed in an organization, but the more balance there is between risks and benefits among decision-makers, the more likely is the innovation to be adopted [Greenhalgh *et al*., 2004]. Risk-sharing mechanisms can be implemented also among different actors in the process, and for example cost and volume agreements between payers, professional groups, and industry has been suggested [OECD, 2005].

5. Incentives

There are three main incentives that drive innovation processes: *financial profit, utility*, and *social status*. When studying health technology innovations it is often not possible to discern which incentives is the most influential, but a fair guess is that all three are present. Financial profit is probably the most important force in the invention domain. All three incentives are important in the diffusion domain, and utility is more influential in the deployment domain.

Incentives may be designed by authorities to facilitate or inhibit innovation processes. Incentives for adoption (the diffusion domain) can be of two kinds: incentives designed to increase the relative advantage and incentives to reduce the risks associated with the adoption [Utterback, 1974]. A similar division of incentives can be made also in the invention domain. Incentives work either to increase advantages or to reduce risks. In the deployment domain, however,

there is less risk involved and incentives are mainly aiming at making it more beneficial to deploy the innovation.

Financial profit is probably the main incentive for the producers' efforts to diffuse their products into healthcare [See e.g. Battista, 1989]. However, financial incentives may be equally important among the adopters. An illustrative example of this is the diffusion of CT scanners in the United States. Physicians and hospitals were paid fees for CT scanning, which exceeded the cost of performing the scans. This provided a strong incentive for increasing the number of scans. When examining the effects of different policies on the use of CT scanning, it was found that only control of the payment level showed an effect and that lower levels of payment was associated with a slower diffusion [Banta, 1990].

A review of studies of financial incentives to implement change in medical practice [Chaix-Couturier *et al*, 2000] shows similarly that physicians' adoption behavior could be influenced by financial incentives. However, the authors conclude that financial incentives alone are not sufficient, and that they ought to be adjusted with other goals such as quality of care, productivity, and satisfaction of patient need (utility factors).

Utility to organization or patients: Utility is also a strong incentive in healthcare innovation. The prospect of increased utility is a facilitating factor in all innovation domains. The utilities can be of several different kinds, of which economic gain is one, but as financial profit already has been dealt with this will not be considered here. Organizational utilities may be a higher productivity, labor-savings, and/or staff satisfaction. Patient utilities are for example a better treatment and increased health, but also a better care process, less discomfort, and increased quality of life.[21]

Status, prestige: Medical device inventions are vital for improving clinical practices. Involvement of clinicians in the development process is equally important, so that the new technologies evolve to useful products that satisfy real healthcare needs. Strong incentives for clinician involvement exist in the form of status and prestige. Professional recognition and scientific publications, following medical device innovation, may lead to an enhanced professional status in a particular medical discipline.

[21] Reflections made in Study IV.

The hospital may also have a strategic orientation as a technological leader, which represents a kind of organizational status. This strategy is a strong facilitator in adoption of medical devices. The pro-innovation position of some hospitals (frequently university hospitals) may be traced to the clinicians' interest in advanced technology, but the reverse mechanism is also true, i.e. the status incentive implies that the technically advanced facilities, provided by technology leaders, also attract highly qualified medical specialists, who like to use new technology.

Funding and reimbursement systems provide tools for both high-incentive and low-incentive regulation of innovation processes. The mechanism is a moderation of the financial incentive.

A reimbursement system where the adopter/decision-maker will have all benefits, while all costs fall on a remote third-party payer, will face over-use of technology. The rapid growth of healthcare expenditures since the 1960s can be partially explained by third-party reimbursement and mechanisms of facilitated diffusion of medical technology. Russell identified this as a major determinant of rising healthcare costs and she also concluded that legislation and regulation aimed to control innovation had, up till then, not had the intended effect [Russell, 1979]. However, during the 1990s this trend was somewhat decreasing, which actually shows that funding principles may have an effect, but perhaps not in the short-term perspective.

A funding system that inhibits adoption of health technologies is the system of fixed budgets, where hospital departments and/or healthcare sectors have their own narrow budgets. This system has become popular in Europe, as a response to rising healthcare cost. It has an inhibiting impact on innovation that adds to the costs of providing healthcare, while it facilitates adoption of laborsaving innovations. This is because costs will fall on the adopter/decision-maker, while utility in the form of increased health and productivity will benefit society at large [OECD, 2005].

Another cost-containment tool is the use of Diagnosis Related Groups (DRGs).[22] In this system funding is provided in relation to the expected cost of treatment of each patient. This will also inhibit adoption, as the use of costly new devices will increase treatment cost per patient. However, while DRGs seem to have had the intended effect in the United States, this tool has been

[22] Diagnosis Related Groups (DRGs) is a patient classification system that group together patients that are similar clinically and in terms of resource use.

less successful in Europe [Kimberly & de Pouvoirville, 1993; and Carrin *et al*., 2003].

Subsidies from vendors: Vendors often try to subsidize the adoption of new technologies by providing free training and other help to potential users or by charging reduced rates for an introductory period. Incentives from vendors may also be in the form of subsidized specialist meetings and provision of free information about the latest research findings within a medical specialty.

6. Competition

Almost all kinds of competition are strong drivers of innovation in all innovation domains. In the diffusion domain, medical device innovations benefit from the competition among hospitals to be a technology leader. Similarly, clinicians are competing for the professional recognition that high-tech innovations bring. Medical device innovations also benefit from change agent activities emanating from the vendor, which is an additional kind of competitive activity.

Walsh-Sukys *et al*. investigated the diffusion of two emerging technologies for treatment of persistent pulmonary hypertension of the newborn (PPHN), one low-tech and one high-tech innovation [Walsh-Sukys *et al*., 1994]. The low-tech innovation could be adopted without additional training or equipment, while the high-tech innovation required large capital investments and extensive training that ought to inhibit diffusion. A survey of implemented practices, however, revealed that the high-tech innovation was more widely diffused. The explanation is that several factors work together and that competition was the more dominant factor in this specific case of innovation. Obtaining the latest technology is a way to attract patients and medical specialists. Hospitals in a highly competitive environment are thus more likely to be early adopters of new technology [Gelijns & Rosenberg, 1994].

There are four different types of competition that facilitates medical device innovation: **competition among hospitals, competition among producers of devices, competition among professionals**, and **competition for higher status**. Hospitals are struggling to be high-performing and the most advanced in a geographical area or within a medical field; producers of devices compete for market shares; clinicians compete for professional recognition and scientific status; and medical professionals and managers are struggling for higher social status within the organization and/or network.

A fifth type of competition is the **conservation of social status and protection of vested interests**. This competitive behavior inhibits diffusion and deployment because people might have financial, political, or social self-interest in the current structure and practices, which they protect. Conservation of the current practices may for instance be of value for a supplier of a competing device or for professionals who want to preserve their social status.

7. Regulatory frames

It is the different actors, who are building the framework of norms, regulations, and laws, within which innovation processes are confined. The regulators are upholding regulatory structures to ensure that innovations fit into the norms of the society, for example effectiveness and safety norms. But organizers, payers, gatekeepers, as well as adopters, non-adopters and rejecters are all important actors in the development and upholding of regulatory frames. If an innovation departs to far from existing norms, it has little chance of surviving cultural and regulatory inhibitors on its way.

The regulators are often legislative bodies, government agencies, or other authorities. But the regulations, imposed by authorities, do often also reflect other less formalized norms, such as moral and equity values and these norms are protected by the whole society and will only slowly be changed.

In the IDD model, the different components of the regulatory framework: social and organizational norms, directives, and laws are seen as different degrees of formalization of the same phenomenon. These thoughts have been inspired by Meyer & Rowan [1977]. The competitive actions of actors, with vested interests in the preservation of current practices, may also be regarded as a part of the regulatory environment, this has, however, been discussed under *Competition* (p. 128).

Basic frames of reference: Technology legislation and regulation may slow down development and adoption of medical devices, but clearly defined laws and regulations are seldom disrupting innovation processes. Social and organizational norms, on the other hand, might stop innovation and are particularly influential in the diffusion domain.

Organizational and management principles are influential in all innovation domains. The organizational culture determines the innovativeness and risk capacity of people working in the organization. A permitting morale and an

identity as an innovator (technology leader) will facilitate innovation. This identity is even more important, as the profit maximizing behavior may be less pronounced in healthcare and is often replaced by decision rules that are applied routinely [Cyert & March, 1963].

Stable laws and regulations are facilitating development, adoption, and use. It is important that the actors know the premises for their activities. But stable frames are not enough; information and interpretations of the laws and regulations must also be highly available and easy to understand.

Complicated laws and regulations will inhibit innovation, as it increases the uncertainty in decisions. It is also likely to lead to a large number of disrupted innovation processes as a result of wrong decisions.

The presence of technological standards is a factor that has a strong stabilizing influence on healthcare innovation. Standards also increase the compatibility of products, which facilitates both development and diffusion. The benefits, in the hospital setting, are primarily a reduction in time and costs spent on education and training, and that it facilitates inter-hospital movement of staff.

8. Actor characteristics

It is not only the characteristics of adopters that influence the spread and use of innovations. The characteristics of other actors such as regulators, organizers, payers, developers, change agents, and gatekeepers may have a substantial impact on the diffusion process, and the risk capacity might be a relevant characteristic in different actor groups, in all innovation domains. However, this set of facilitators and inhibitors is mainly applicable to adopters. The reason is that other characteristics have been studied less and are sparsely described in the literature.

Organizational innovativeness has been regarded as primarily influenced by structural characteristics such as size, age, specialization, centralization, and so on. It is often assumed that they can be treated as variables whose impact can be isolated and independently quantified, but there is probably no "size effect" or "age effect" that can be measured independently and generalized [See e.g. Mohr, 1969; and Kimberly & Evanisko, 1981; Damanpour, 1992 and 1996]. Size and age can, however, sometimes be a proxy for other determinants, such as functional differentiation, slack resources, and risk capacity. A large organization is assumed to have a higher risk capacity, but this effect has been disputed. The small firm may be forced to innovate to

increase its competitiveness and is therefore willing to accept a higher risk, but it has been pointed out that size of the firm seem to have little effect when the firm has grown above a threshold size [Mansfield, 1968].

Damanpour found that size is more positively related to innovation in manufacturing and profit-making organizations than in service and non-profit-making organizations and that the relation between organizational size and innovation is dependent on how size is defined. Damanpour's results also indicate that the initiation of innovation in organizations is independent of size, but larger organizations may be more efficient in implementing innovations [Damanpour, 1992 and 1996].

Many of the structural characteristics are determinants of an overall innovativeness of the organization. Innovativeness is best described as the willingness to innovate and the ability to cope with risk and uncertainty. Innovators are early adopters and adoption early in the process involves more uncertainty than adoption at a later stage when knowledge has accumulated and trial experiences have been communicated among the potential adopters.

Risk capacity: The ability to cope with risk and uncertainty differs between individuals, and a wide range of risk preferences can be found in a population of adopters. The majority seems to be risk averse, but many are risk preferring and quite few are actually risk neutral [Marra *et al*., 2003]. This will of course depend on the nature and size of the investment and the capacity to absorb a wrong decision, i.e. how large the loss will be, relative to the adopter's total resources, if the innovation fails.

Risk preference among individuals in an organization is a strong determinant of its innovativeness. The capacity of an organization to cope with risk and uncertainty is probably to some extent determined by its size and maturity and is not entirely dependent on individual decision-makers risk preferences. Hospital size is generally held to be positively related to adoption. This is probably due to the fact that large hospitals have a "critical mass" of patients which justifies the acquisition of innovations for more specialized care [Kimberly & Evanisko, 1981; Moch & Morse, 1977]. Age and adoption is found to be negatively related, because innovation adoption is more likely in young hospitals that are not yet "established," i.e. the ones that have to compete for survival [Kimberly & Evanisko, 1981]. Another explanation may be that older hospitals have a more trimmed organization with little slack resources to channel into new projects.

Personal characteristics include level of formal education, economic status, social status, social mobility, and age. There are also personality variables, for example, communication behavior and personality traits resulting from personal differences and earlier experiences. Such personality variables that might facilitate adoption are definitely the ability to cope with uncertainty, but also as suggested by Rogers [2003] empathy, rationality, and high aspirations.

Attitudes toward change are seemingly related to variables such as education, occupation, age, and sex. The influence of culture, traditions and values are, however, highly influential in the formation of attitudes and the above variables are only proxies for these cultural variables, which are more difficult to measure. The time and social environment in which we live have a substantial impact on our attitudes toward change. The frequency of change is, thus, not only a *result* of such attitudes but also a *cause* [Ogburn, 1922].

Identity as innovator: The innovativeness of hospitals is likewise dependent on the norms and values in the adopter system of hospitals, but it is also formed by management principles and the characteristics of decision-makers and staff. High innovativeness requires a management with good leadership skills, high organizational ability to cope with risk and uncertainty, and the organizational communication behavior.

Communication behavior in organizations that facilitates innovation are e.g. the establishment and use of extended, diverse, and vertical networks; incentives to acquire information; frequent contact between different internal divisions; and slack resources to channel into new projects and information seeking. Barriers to communication between the firm and its environment are limiting the innovativeness of firms [Utterback, 1971] and the support and development of "boundary-spanning" roles (for example assigned gate-keepers) facilitates both awareness and assimilation of innovations [Greenhalgh *et al*., 2004].

Internal organizational structure and management: Functional differentiation (division into subunits) is hypothesized to facilitate adoption of innovations [Kimberly & Evanisko, 1981]. It is also expected that a high degree of specialization should be positively related to adoption, as specialists need specialized methods and instruments. But a higher degree of specialization and differentiation requires high quality management and communication structure (information transfer). Centralization would provide the structure required to facilitate management in differentiated organizations, but is has on the contrary been shown that the degree of centralization is negatively related

to innovation adoption [Grover & Goslar, 1993]. This might be due to inferior routines for making decisions about innovations for use at a sub-unit level. A decentralized decision-making ought, thus, to have a facilitating effect on adoption in differentiated and specialized hospitals.

Adaptation potential of the organization, staff, and workplace: The ability of an organization to adapt to innovation is influenced by the speed at which new skills can be established to match the demands of the new technologies.

Professional knowledge, skills, and attitudes toward change are all important factors that determine the adaptation potential. Reorganizations and changed work routines may be required to make full use of the innovation. This require a certain amount of organizational slack, in time and money, that can be used for reconstructions, education, and training. In a well-trimmed organization, such as for instance an intensive care unit, it might be difficult to find these slack resources.

Slack resources are working hours or financial resources in an organization, which are not committed to an immediate fixed purpose. It does not mean that these resources are in excess, only that they can be used in an optional way. Slack resources have often been associated with low performance and an insufficiently trimmed organization, but organizational slack facilitates innovation and might thus enhance the competitiveness of the organization if the innovation will be profitable. Slack resources help the organization to bear the costs of innovation and to explore new ideas in advance of an actual need.

Slack resources are, thus, expected to facilitate risk taking and innovation. It does not, however, guarantee high performance in the organization. It has instead been shown that high risk taking is related to poor performance [Singh, 1986].

For the innovating hospital, organizational slack means that the hospital can afford to experiment with new products and try new strategies. Excess funding might, however, not have a facilitating effect on adoption behavior, as it makes the competition factor less influential. Innovation is a more attractive option in hard times when the organization has to compete for resources.

Social ties may lead to extended networks, but social ties do also mean confinement to the norms of the social systems in which these ties extend and "position in a network both empowers and constrains opportunities" [Wejnert, 2002]. A strong tie, when considering individuals, is a person with whom you interact on a regular basis, while a weak tie is an acquaintance, or a

friend of a friend. "Weak ties have a longer reach, but a much narrower bandwidth than strong ties" [Powell & Grodal, 2005].

Similar strong or weak ties are also to be found in inter-organizational networks. Granovetter [1973] argues that weak social ties may be as influential as strong ties. Strong ties provide social support and are based on common interests, but the weak ties provide novel information in the form of different practices, ideas, or tastes. Strong ties, on the other hand, may restrict information gathering by reinforcing existing views.

9. Innovation characteristics

Rogers [2003] suggests five characteristics of innovations as main explanatory factors of adoption rate: relative advantage, compatibility, complexity, trialability, and observability. These factors cover many aspects of the value of adoption of a new technology and abandonment of an old practice. I have found *relative advantage* to be the most important factor in medical device innovation, i.e. new devices must be perceived as adding a value to the patient, the ward unit or the hospital [Paper IV]. I prefer, however, to call it *net benefit*, as it is the added value that is important and the benefits must be calculated by subtraction of costs, disadvantages, negative side effects, and the negative effects of abandonment of the current practice.

Net benefits of health technologies are to a high degree determined by the extent to which there exist substitute technologies or other practices for treatment of the actual conditions. Health technologies that treat conditions, for which there are no treatment alternatives, have almost always a net benefit, as "doing something" is perceived as better than doing nothing. But the net benefit is also dependent on whether the health gains are valued higher than the costs of the technology.

A facilitating quality of an innovation is if it produces **returns to the investment**, i.e. economic gain to the adopter. This is perhaps less important for health technologies where health gain may be valued higher (See above). **Safety, usability, complexity, adaptation potential,** and **adaptation need** of the innovation are probably more important factors in healthcare. Medical devices, in particular, have to be safe, easy to use, and easily integrated in the work practices. **Compatibility** with work procedures and other equipment is another quality of great importance, and if the technology is **part of a cluster,** which is already adopted in the hospital, adoption is further facilitated.

Furthermore, deployment of the innovation is facilitated if no **additional education or reorganization** is needed.

Obsolescence: Diffusion could be significantly delayed if the time between different generations of a technology is too short. Concern over early obsolescence, may have the effect that the adopter rejects the current version of the technology and decides to wait for the next generation [Fendrick & Schwarz, 1994].

10. Perception of benefits

Benefits of innovation may arise in all three innovation domains. The benefits are incentives for invention, adoption, and deployment. It is, however, usually not the true values that are considered when planning innovative activities. The perceived values may be lower or higher than what turns out to be true later on. This section will discuss perception of benefits in the adoption decision. Benefits may be *emphasized* in different ways, they may be *easy or hard to detect*, and *benefits or "pseudo-benefits*" may be added.

Prior **personal experience** with similar innovations facilitates adoption because it will increase the familiarity and improve the technical skills of the adopter. This makes it easier for the adopter to detect the benefits of using the new device. (The experience factor is also discussed in set *2. Knowledge accumulation*, p. 118.) **Change agent activity** will likewise make benefits more visible, but a change agent emphasizes only the benefits and plays down the disadvantages.

If an **opinion leader** already has adopted the innovation it will show others in the system that adoption is an accepted and desirable behavior. The potential adopter may strengthen the ties to the opinion leader by following his example as soon as possible. This may be seen as a sort of "pseudo-benefit", as it will be perceived as a possibility to gain in status. Another type of added benefits is generated by the proximity to the inventor or manufacturer of the innovation. The mechanism of this is that if **origin of the innovation** is geographically close or within the same local governmental area (e.g. municipality) as the adopter, the added value of adoption lies in the prospect of a strengthened local economy and higher collective status in the area. For an individual decision-maker in healthcare it may also mean a chance of better support on the products.

The **gatekeeper** is working actively to disseminate selected information and, depending on the position taken by the gatekeeper, this information may emphasize advantages or disadvantages of the innovation. (See set *3. Information flow*, p. 120, for a discussion of the gatekeeper role.)

The mechanisms of low immediacy, high degree of change, and unfamiliarity are that these factors make benefits hard to detect. With the **immediacy** is meant how long it takes between treatment and visible effects for a specific innovation. This may have an inhibiting effect on for instance preventive technologies, for which the observability of treatment impacts is low and it is also difficult to distinguish between effects of the technology and the effects of other factors.

The rate of adoption is likely to be lower for technologies, which are outside the normal range of experience of the adopters. If adoption will result in a high **degree of change**, it also implies that the innovation has a high degree of **unfamiliarity**. Both factors inhibits adoptions, as there are no similar technology that could help to predict the future effects. (The degree of change has also been discussed under *4. Risk and uncertainty*, p. 123.)

11. Promotion of the innovation

Promotion of medical device innovations is primarily a task of the change agents. It may be in the form of advertisements; subsidized meetings; education; trial devices; and personal contacts with potential adopters. But the most important promotion effort is to make the innovation available. High **availability of the innovation** makes adopters interested. A strong facilitating factor is the possibility to experiment with the innovation and evaluate its benefits in the light of one's own experience. **Change agents** primarily promote the adoption of devices, but their efforts are also important in the deployment domain. The adopters may need guidance and technical support, so that the innovation can be fully integrated in the care-giving practices.

Innovation **champions** may also be promotive of health technologies. This have been investigated by Stocking [1985], who concluded that the presence of a local product champion is important in determining whether an innovation will be taken up, but also in maintaining the change. This is, however, not possible without timely **allocation of resources**, i.e. the provision of financial resources (from the payer) and the allocation of resources (the organizer's job) in a way that supports uptake and use of the innovation. The organizer's role

also includes allocation of workforce, so that **involvement** in the innovation activities is obtained at all staff levels.

Health Technology Assessment (HTA) agencies may be seen as a kind of gatekeepers who scan the horizon for useful ideas and transmit valuable information to the healthcare organizations. As such they may promote innovations, which are considered to be beneficial from a healthcare and/or societal perspective.

Measuring diffusion of innovations

There are several different types of measures that can be used to characterize innovation and its different sub-processes (See p. 105). However, in this section I will mainly focus on diffusion measurements. Traditionally, the primary dependent variable of diffusion studies has been adoption rate. Rogers [2003] define this as "the relative speed with which an innovation is adopted by members of a social system." This is, however, a rather impractical definition of a diffusion measure intended for healthcare innovations. There are, in fact, four different measures of diffusion that are relevant for modeling the diffusion of health-related innovations: *extent, quantity*, *speed,* and *probability*.

Probability is an estimation of what might happen in future stages of the innovation process. It is thus also a prediction of the three other measures, extent of spread, quantity of use, and the speed at which things happen. The probability measure is preferred in marketing science and data is often collected from potential adopters via questionnaires. *Extent* is a spatial measure of the spread of the innovation in the adopter system and *quantity* is a utilization measure that tells us how much or how often the innovation is used. *Speed*, finally, may be measured as the time it takes from one point to another in the model, for example from market introduction to a certain spread in an estimated adopter population. The speed measure is the one that corresponds most closely to Rogers' definition, but it may also be estimated in a probability model to predict market acceptance.

Extent, quantity, and *speed* are the measures preferred in diffusion research. Data are often collected retrospectively from adopters via questionnaires or interviews, and the number of adopters is used as a proxy for diffusion. Diffusion and adoption should be regarded as separate occurrences in

innovation, but diffusion do not occur without adoption, and an estimation of diffusion might thus be obtained by measuring the adoption. In these measurements, however, adoption is often used synonymously with "purchase" and/or "first use" of the innovation, which gives only an indication of the actual change process. Diffusion has several dimensions and it is important to understand that spatial and utilization measures are two totally different measures. Spatial diffusion may have reached a steady state while utilization is still increasing. This has also been discussed by Warner [1974].

Different measures yield different kinds of information and answer different kinds of questions. *Spatial diffusion models* describe the aggregate spread of an innovation among potential adopters. These models have contributed to the understanding of infrastructure and supply aspects in the diffusion process. The measure does only give a hint about the use of an innovation, as spatial diffusion may be high even if the innovation is deployed less than optimal. *Utilization diffusion models* describe to what extent the innovation is used, for instance: how many doses of a drug; how many patients that are treated in a given time period; or how many hours treatment that are given with a new technology. A utilization model can, for example, describe how the proportion of heart disease patients, examined with coronary angiography, has changed over time [Gatsonis *et al*., 1995].

Discussion points in the model

This section addresses selected elements of the IDD model and discusses similarities with other theories. The purpose is partly to illuminate critical events and processes, but also to couple the new ideas to the knowledge base.

Evolutionary technological change

In the course of my work I have adopted the "evolutionary" innovation model from Richard R Nelson and Sidney G Winter [1982], and John Ziman [2000], who are representatives of this theory. The authors maintain that genuine breakthrough innovation does not exist. I will not wholly agree with this, but seemingly revolutionary technologies may look less so, if the development process is broken down into its components. An innovation is often modified

to suit the needs of the adopters, or it is altered to meet new needs that have been discovered as a consequence of using the innovation. It is often not possible to explicitly decide when a modification is just a modification and not a new invention, initiated as a response to a separate needs- or possibility-discovery.

In the case of laparoscopic cholecystectomy (first use 1987) the clinical procedure evolved rapidly and it differed radically from general surgery. The development can, however, be traced back to 1904 and a first attempt to build an optical endoscope [White, 1991]. This predecessor to the laparoscope was a rigid esophagoscope supplied with a distal light filament. The next step in the process was the peritoeoscope, developed in 1937, which during some time was used as a diagnostic tool. With the development of high-resolution laparoscopes and monitor displays the innovation was rapidly adopted as a surgical and gynecological instrument. The first laparoscopic cholecystectomy was performed in 1987. The procedure has four major benefits that facilitate diffusion: fewer complications, less incisional pain, less time spent in hospital and shorter convalescence. This example describes a technological change where several developments eventually lead to a technology with easily observed benefits, which implies a rapid diffusion.

Another "evolutionary" aspect is that innovations seldom can be clearly defined. What is a part of the innovation and what is not? The laparoscopic cholecystectomy, for instance, consists of both a device and a procedure, i.e. the laparoscope and the surgical method. The evolution model, however, also applies to the method part of this innovation. General surgical methods have likewise undergone an evolutionary process and many of the major surgical principles of laparoscopic cholecystectomy today are the same as for open surgery [White, 1991; Gelijns & Rosenberg, 1994].

Supply-driven innovation and the invention of disease

Truly demand-driven innovations are quite rare, but a good example is the permanent arteriovenous shunt, which made hemodialysis possible for chronically ill patients. Alwall, who was a doctor, scientist, and developer of hemodialysis, stated early that treatment for chronically ill patients was his final goal. However, this required long-time access to a blood-vessel and his idea of a permanent shunt could not be realized, as suitable materials were not available. When materials science had caught up, Schribner and Quinton

developed a shunt with teflon cannulas in the early 1960s. After presentation of excellent treatment results at nephrology congresses, hospitals around the world were starting to re-organize their nephrology departments to be able to treat chronically ill patients [Czaczkes & De-Nour, 1978; Klinkman, 1990; Bucht, 1994].

The above example shows that the inventors/developers had an essential role in the diffusion of hemodialysis. This is often the case for health technologies and a useful extension to Rogers' theory, in this context, is thus to include the inventors and developers as main actor groups. This will be further discussed in *Deviations from traditional innovation theory* (p. 144).

Health promotive technologies provide examples of technologies where demand and supply forces may be hard to distinguish. Such technologies can be, for example, drug prevention programs or promotion of physical activity. Health promotion has been strongly advocated in recent years, but there is generally a lack of perceived need among most individuals and this is working against a changed behavior. The topic has been investigated by Guldbrandsson *et al*. [2005]. In a study of health promotive technologies in Swedish municipalities, they found two initiating factors: perceived local needs and provided opportunity. In close examination of these factors, the pull (need) and push (possibility) components may be detected. If the authorities in the municipality perceives ill-health as an increasing social problem, they may start to look for solutions to the problem and perhaps invent local programs (innovations) to meet this need. The push factor can be access to external funding in the form of earmarked money for health promotion. Another push factor is provided by strong commitment of powerful officials, who believe in certain health promotion activities. However, there is often no obvious supply side, but a scenario increasingly common is that commercial organizations market services as health promotion, such as massage, meditation, weight control, and gym and yoga classes. The problem is that opinions differ on what promotes health and what does not, and health promotive technologies are seldom evidence based [See e.g. Guldbrandsson *et al*., 2005].

Medical device advances seem to be possibility-initiated more than needs-initiated. A relationship between supply-side incentives and trends in costly treatments was found in an investigation by the TECH[23] Research Network. It

[23] The Technological Change in Health Care (TECH) Research Network is an international collaboration investigating trends in clinical practice.

was found that different countries had different patterns of diffusion of technologies for heart attack care. The use of costly treatments was more related to incentives and regulatory factors than was low-cost treatments [TECH, 2001].

An extreme of supply-side impact on healthcare is when technological possibilities make us re-define the concept of disease. The possibility to detect and treat physiological variances has in many cases transformed symptom-free people to patients. The possibility to measure cholesterol in the blood and the development of cholesterol-lowering medicine, to mention but one example, has made "high cholesterol" a treatable condition. A high cholesterol level is not a disease in itself, but it is often regarded as one in the medical literature and by people diagnosed with high cholesterol levels. This indicates treatment of people who perhaps would not have experienced any symptoms during their lifetime. This example shows, that the subjective experience of individuals has become a subordinate determinant of disease. High cholesterol is only one example in a very large class of treated asymptomatic diseases. The problem of these "pseudo diseases" has been addressed by e.g. Fisher and Welch [1999].

Another class of possibility-initiated "disease" is the treatment of normal variances in the human appearance. Advances in plastic surgery has made it possible to restore functions and looks after injuries, but it has also enabled us to change quite normal features. Today, having a big nose or small breasts are considered abnormal variances that ought to be treated, which is gradually changing our perception of normality. If you never see a woman with small breasts, you certainly believe that it must be some rare disease. "Innovations transform the perceptual experiences ... of those who use them" [Reiser, 1978:228].

The technological possibility to treat a disease may thus alter the conception of disease. Expressed in another way, one may say that treatability constitutes disease [See e.g. Wolf & Berle, 1981]. Hofmann [2001] has called this "the technological invention of disease." In a discussion paper, he claims that medical technology has become the measure of what is to be treated, and hence, what is a disease and what is not.

Promotion of change

Changes in healthcare practices may be promoted by hospital management, healthcare administrators, governmental agencies, and producers of medical devices or pharmaceuticals. The role of the change agent is to influence adoption in a direction perceived desirable by a change agency. Change agents in hospitals, promoting medical device innovations, are often sales representatives from the device industry. Another scenario is when a gatekeeper, working for an organization under the Ministry of Health, promotes adoption of a new technology.

The most powerful actor in the hospital setting is, however, the change agent. He/she may work in several ways, but the communication between the change agent and the adopting unit is of vital importance in accomplishing behavioral change. The first step is to establish an information-exchange relationship. After building a favorable relation the change agent can start to pinpoint a specific problem which can be solved by the promoted change and thus develop a need for innovation. When a need is established within the adopting unit, the role of the change agent is to facilitate adoption and implementation of the innovation. However, in the actual adoption decision, involvement of the change agent can be perceived as an obtrusive behavior, which might damage the relationship with the adopter.[24]

Rogers [2003] pointed out that the change agent is responsible for seven tasks in the process of introducing an innovation into a client system. These are: (1) to develop a need for change; (2) to establish an information-exchange relationship; (3) to diagnose problems; (4) to create an intent in the client to change; (5) to translate an intent to action; (6) to stabilize adoption and prevent discontinuance; and (7) to achieve a terminal relationship.

In the IDD model the role of the change agent could be summarized in three "to do" points:

- Establish a favorable "change climate" through an information-exchange relationship with the adopting unit.
- Pinpoint a specific problem which can be solved by the promoted behavioral change and thus induce a need for innovation.

[24] Reflexions made in Study IV.

- Facilitate adoption and implementation of the innovation by provision of training and support, and to sustain continued use of the innovation.

Promotion of change may also be achieved by different actor incentives or by the promotion of learning and knowledge accumulation. As stated earlier, newness seems to have a value in itself (p. 118) and thus new technologies have a slight advantage over equally beneficial older technologies. That is why information about new technologies more often facilitates innovation than inhibits it. Resistance to change is most often an expression of uncertainty and lack of information. Incentives to acquire information are thus strongly facilitating as long as the information is positive and of good quality. Negative information, on the other hand, may not be an equally strong inhibitor.

The value of knowledge accumulation, trialing and learning lies in the reduction of uncertainty. There is, however, always a risk involved in innovation. If there are risks and costs, which probably will decrease in the foreseeable future, there might be an option value of delaying adoption. Promotion of change may thus also be achieved by a reduction of risk and uncertainty or by risk sharing mechanisms. I have identified the following values of information, trialing, and learning that should be thought of as elements in the adoption of medical devices:

- Reduced uncertainty in the perceptions about the relative advantages of the new versus the old technology, including the cost of abandonment of knowledge.
- Improved insight in the probable future consequences of the new technology, including both private and public consequences.
- Improved ability to implement the new technology, shorter implementation phase, and better exploitation of the technology.
- A general skill improvement, which enables the adopting unit to make better adoption decisions for future innovations.

Warner [1974] concluded that the value of learning-by-doing lies both in the reduction of uncertainty and in the improved efficiency which accompany learning. This has high relevance for diffusion of innovations in hospitals. The individual department's experience with an innovation, on a small-scale experimental basis or during the implementation phase, will supply the information and knowledge needed for optimal exploitation of the innovation. Thus, the early adopter's learning has spin-offs for other adopters, who will learn from the first adopter's experience. The uncertainty about the consequences of adoption will diminish, the implementation phase will be shorter and the innovation's full potential can be utilized. History shows that

some of the most innovative hospitals will adopt innovations despite a high level of uncertainty. This might bring unanticipated costs to the adopter, but is beneficial to the whole society of potential adopters. The reason is that it will reduce the general level of uncertainty, which in turn will lead to better adoption or rejection decisions.

Adaptation, development, and the technology life-cycle

A period of adaptation and development often occur in the deployment domain and may continue even after establishment of the innovation in regular use. The time perspective of this adaptation period might be very long. The infant incubator is an example of a medical device, which has been used during a long time but still undergo developments. The in-bed weighing scales and the humidity control are two recent incubator developments.

It is often not possible to decide if a development is an adaptation or a new invention with an innovation process of its own. For example seat belts in cars were once considered a new innovative product, but are now an integrated detail of the car. It may be seen both as an adaptation of the car and as a path-dependent invention as a response to the need for higher safety.

After several developments the technology take on its final form. Eventually it will be replaced by technology, which is perceived as more advantageous, and it will fall out of use. In the incubator example this will not happen in the foreseeable future, and this is the usual pattern of proven beneficial medical device innovations – they are adapted, but not easily replaced. Individual items of a technology, on the other hand, may have extremely short life-cycles. For instance, the intravenous syringe, which now a days is disposable, has a "technology life-cycle" that extends over 150 years [Coleman, 1974; Hamilton & Baskett, 2000].

Deviations from traditional innovation theory

The most important deviation from traditional theories in the IDD-model of innovation is the integration of the invention and deployment processes. Modeling of the innovation process has mostly focused on the diffusion of innovations and ignored the actors, factors, and consequences present in other

areas. The invention domain – including activities such as initiation, invention, and development – has been seen as a process separated from diffusion and use. Few authors have addressed both invention and diffusion, and if so, the two are most often dealt with separately [See e.g. Edquist, 1977; and Bonair, 1990]. However, activities in all areas, or sub-processes of innovation, influence the speed and extent of technological change, and early events in the process may influence how later events evolve. Many students of organizational innovation have recognized the importance of some initiating force, but are presuming that an innovation has been developed without involvement of the organization [See e.g. Pierce & Delbecq, 1977], and thus overlook organizational interactions with the inventor and developer.

Furthermore, a fundamental component of an innovation model is the set of factors determining how the different processes evolve. In the IDD model they are called *facilitators* and *inhibitors*. Facilitators are the promotive factors, which will make diffusion possible or speed up the process. Inhibitors are the restrictive factors, the barriers to diffusion, which will impede initiation of a diffusion process, or otherwise slow down or stop the process. If we go back to Rogers' five perceived attributes of innovations [Rogers, 2003], one can easily sort them into either of these categories and into the sets of factors proposed in the IDD model (See Table 2, p. 83). *Perceived relative advantage, compatibility, trialability,* and *observability* are facilitators, while *complexity* is an inhibitor. However, I have chosen to depart from the original theory and to categorize these factors differently. Only *compatibility* and *complexity* has been kept as innovation characteristics and the wide concept of *perceived relative advantage* has been moved to the closely corresponding set of factors that I have named *perception of benefits*. One reason for this is that the five attributes are not mutually exclusive. Compatibility and complexity may, for instance, be seen as independent factors determining the relative advantage. I have also chosen to characterize compatibility, trialability, and observability as risk reducing factors. The reason for this deviation from Rogers' theory is that I wish to emphasize the risk component, which is a very central aspect of innovation. Furthermore, trialability has been separated into its two distinctly different parts: divisibility and reversibility [Zaltman *et al*., 1973].

The actors are also fundamental in innovation models. Traditional theories have mostly focused on the adopters. Rogers [2003] suggests a categorization of the adopters from early to laggards, and that the degree of innovativeness is determined by social and psychological factors. It is true that potential adopters are more or less receptive to change, but other factors are probably

more influential. The potential adopter is not a passive entity in the innovation diffusion system, who once aware of the innovation is late or early to adopt. In moving from a state of awareness to actual adoption, the influence of other actors, contextual factors, and information accumulation are important ingredients, but these are difficult to estimate in a model. Regarding age and innovativeness, for example, it is not always the case that younger hospital staff has a more positive attitude to change. The adoption study (Paper IV) indicates that the age of medical professionals, involved in adoption, is not a significant factor. More important factors seem to be the ability to cope with risk and uncertainty, self-confidence, social status, and professional ambition [See also e.g. Haider & Kreps, 2004; Wejnert, 2002]. Our study shows that readiness for a decision depends on the amount of time that can be allocated to information seeking and processing of information. When the "information and learning process" has reached a certain stage of maturity, the adopting unit is prepared to make a decision, which may be adoption or rejection. Hospital innovativeness seems to be determined, to a high degree, by the flow and uptake of information and this is in turn determined by the following factors: the amount of time and resources that can be spent on information seeking and network contact, by individual staff members; the availability of communication channels; and the amount of external information exchange in the sub-units of the hospital.

It is, however, not only the characteristics of innovations and adopters that influence the spread and use of innovations. All actors contribute to the course of events and the regulatory environment is determined by activities in all the involved actor groups. According to Rogers [2003], the main actors in the diffusion process are the *adopters*, the *change agents*, the *champions*, the *gatekeepers* and the *opinion leaders*. However, it has been shown that health technologies, and in particular medical devices, are constantly subjected to "incremental" or "marginal" innovations during the diffusion and implementation phases. This occurs not only in industrial R&D laboratories, but in the context of clinical practice as well [Finkelstein *et al*., 1995; Hailey & Harstall, 2001]. This implies that the *inventors* and *developers* have important roles in the diffusion of health technologies. A useful extension to Rogers' theory, in the healthcare context, is thus to include these as main actor groups.

In a social system there is often also a group of individuals or units who cannot be included among the potential adopters. The innovation may not improve their particular practices or it does not match their needs. A totally deaf person, for instance, does not benefit from an improved hearing aid. The

estimation of the potential adopter population is, however, often over-optimistic, taking it for granted that everybody eventually will realize the benefits of the innovation. In fact, not all individuals or units will benefit from the innovation, or they might never believe they will benefit, because of erroneous or insufficient information.

In the IDD model of innovation, the adoption process is divided in three different stages: (1) awareness, (2) attitude formation, and (3) decision. Rogers' model suggests five stages in the diffusion process: knowledge (awareness of an innovation), persuasion (attitude formation), decision (to adopt or reject), implementation (putting the new idea into use), and confirmation (reinforcement of the decision) [Rogers, 2003:169]. Both these sequences describe supply-driven adoption of innovations. The potential adopter becomes aware of the innovation and realizes that it might be useful. In the case of demand-driven diffusion, the process also comprises definition of a problem, a stage where some kind of performance gap is identified. This is followed by a search for possible solutions, or invention of a technology aimed at solving the problem. In traditional diffusion theory this has been treated rather summary. In the IDD model the "performance gap" and "problem definition" are treated in the invention domain as a needs-discovery, as is also the following search for solutions and the matching of a solution to the problem.

An additional difference between traditional innovation theory and the IDD model is the graphical presentation of the process. I have deliberately played down the importance of the diffusion function (the logistic equation) and the S-shaped curve, as it gives rather scanty information about what is going on. The diffusion curve is the graph describing a general course of successful innovation diffusion. It is often representing the accumulated number of adopters plotted over time. The first time it was used to describe innovative behavior was in a work by Gabriel de Tarde, "The Laws of Imitation" [1890, English translation 1903]. Warner [1974] concluded, in accordance with de Tarde's theories, that learning and imitation are central ingredients in the adoption process. He interpreted the logistic function as the potential adopters initially having a cautious attitude toward adoption. They seek information on the benefits and costs of the innovation, they perhaps experiment with it on a trial basis, and they learn from other adopters. As the decision-makers are able to increase their knowledge about the innovation and the best use of it, the uncertainty will be reduced, which will lead to an increased pace of adoption. Warner also argued for the learning-by-doing hypothesis, i.e. that efficiency in

the use of an innovation increases with experience, which implies that more adopters will benefit from the innovation. For more examples of innovation research applications of the logistic curve see e.g. Griliches [1957], Mahajan & Peterson [1978], and Mahajan [1986].

There are two leading theories trying to explain why the diffusion curve normally has this S-shape: the *consumer heterogeneity* and the *consumer learning* model [Hall, 2005]. The heterogeneity model assumes that the degree of benefit of the innovation in the adopter population is approximately normal distributed, and that the cost of the new product is constant or declines gradually over time. Adoption will occur when the benefit for a particular adopter is greater than the cost. The learning (or epidemic) model, assumes that benefits can be evenly distributed among the adopters and the cost of the new technology can be constant over time, but not all adopters learn about the innovation at the same time. Adopters hear about the innovation from other adopters. Over time, as the number of adopters increase, the encounters with the innovation will become more frequent, leading to an increased rate of adoption. At the same time, the population of potential adopters becomes smaller, and eventually the adoption rate decreases again. Both these models yield the familiar S-shaped diffusion curve, but so does a function of reported cases of a contagious disease. The mechanisms of diffusion are, however, far more complicated than the conception that potential adopters are more or less receptive to innovation. An obvious disadvantage of the logistic equation is that it does not give any hints about innovation developments, and the technology at the end of the curve may be substantially different from the first version in the first part of the curve.

There are in fact a number of assumptions that have to be made when applying the logistic equation to diffusion of innovations [See e.g. Mahajan & Peterson, 1985; Mahajan 1986; and Knudson, 1991]: (1) The potential adopter adopts or does not adopt. No reversed decisions occur. (2) Each adopting unit does only purchase one item of the innovation. (3) The social system of adopters and potential adopters is constant over the diffusion process. (4) There is a constant "coefficient of diffusion" that indicates how fast and to what degree adoption occurs. (5) The innovation is not modified during the diffusion. (6) The diffusion is independent from the diffusion of other innovations.

These conditions are not likely to be fulfilled in medical device innovation and e.g. Fineberg [1985] has recognized that it is difficult to accurately estimate the adopter population and that adjustments have to be made over time. The

possibility of incorporating dynamic factors in diffusion models has also been explored by Knudson [1991].

Furthermore, for an on-going process, it might be difficult to estimate the current position on the final curve. What looks like a complete S-shape may in fact be only a fraction of the first part of the curve. The time span of different innovation life-cycles vary from less than a year to fifty years or more. And finally, the processes do seldom produce perfectly smooth curves and it is easy to wrongly interpret a temporary decline as the end of the technology life-cycle.

The role of HTA

Not all innovations are good. It is important that current practices are not knocked out by inferior innovations. Questioning and assessment of health technologies have to be performed all through the technology life-cycle, and the new technologies have to be compared to old ones, so that the uncertainty about benefits may be reduced and resources can be allocated efficiently.

The diffusion of medical device innovations is the result of lots of adoption decisions by individuals and collectives within the adopting units. A decision may result in the acquisition or rejection of the device in question, and the decision-making is a process of information and learning. Organizational adoption involves individuals as well as administrative constellations, advisory boards, and committees. It can be conceptualized as a multi-stage decision process. These stages are defined differently by authors with different perspectives [See e.g. Abadi Ghadim *et al*., 1999; Wolfe *et al*.; 1990, Rogers, 2003], but a relevant division in healthcare is the following:

1. *Awareness:* The first knowledge about the innovation and its possible benefits. This information is often rather biased and fragmentary, but may trigger an interest to know more. At this stage, learning almost exclusively occurs at the individual level.

2. *Attitude formation:* This involves estimation of need, benefits, and costs. Learning occurs both individually and collectively, however, always in communication with others. Perceived benefits may be improvements of treatment or care process, but also individual benefits such as higher status or reinforcement of social ties. Learning at this point is influenced most by informants with a trusting relation to the potential adopter. HTA can be a

valuable tool at this stage, but attitude formation frequently occurs with a minimum of information available and it is always the potential adopters' own subjective processing of the information that is the basis for the resulting attitude toward the innovation.

3. *Decision:* At this stage the processing continues and the available information and knowledge is applied to the actual practice, for which the innovation is intended, including the regulatory environment of the practice. This process has three outcomes: *adoption, rejection*, or *postponement*. The adoption of medical device innovations are usually collective decisions, even though influential individuals may strongly impact the outcome.

The adopting units may vary in their risk preferences and their perceptions of an innovation's riskiness and advantages. It has been pointed out earlier that medical devices sometimes are adopted into healthcare use without convincing evidence of clinical effectiveness and cost-effectiveness. There are, however, also cases where risk factors dominate the decision and a device is denied market access despite promising scientific evidence. Depending on the uncertainty in the adoption decision, rapid diffusion or controlled diffusion may be the optimal strategy to obtain a purposeful use of devices. The concept of *optimal diffusion* may be defined as: (1) a quick adoption and integration of proven beneficial and cost-effective devices; (2) slow or step-wise diffusion of devices with weak evidence of benefits; and (3) withdrawal of ineffective or harmful devices. This implies careful planning of assessment and reassessments of each device or procedure. Several authors have addressed the need for assessments after adoption and during the implementation phase. In a handbook for clinical engineers it is expressed like this:

> "Even if a particular technology does perform well when guided by its innovator or medical champion, it may still prove insufficiently robust to produce substantial benefit when used routinely in a less controlled environment" [Bronzino, 1992].

The role of HTA involves, somewhat simplified, the valuation of consequences of technological change and the making of policy instruments. HTA is thus closely connected to innovation at all stages, but has in particular been associated with diffusion of innovations. Funding bodies and ethics committees must be kept up-to-date with scientific evidence and it is important to show that it is highly probable that the changed practice will be better than the practice it is intended to replace. Evaluation measures must also be able to track progress over time. Emerging medical technologies are often described as moving targets and evaluation criteria must evolve to focus

on the key changes. HTA should be an aid in innovation decision-making. It should act to speed up the decision-making process, however, not make the decisions. HTA agencies may act as a kind of gatekeepers who process useful information and transmit valuable information to the healthcare organizations.

However, there seems to exist a communication barrier between HTA agencies and healthcare. It is a recurrent problem that assessment reports do not reach the intended target group. Furthermore, it is difficult to predict which future adoption decisions will need aid from HTA. The consequence of this is that, when healthcare decision-makers are asking for advice, there might be little evidence available, and important adoption decisions are made with a minimum of information. Even life sustaining technologies may be adopted without evidence from e.g. randomized trials. This was the case for treatment of persistent pulmonary hypertension of the newborn. Hyperventilation was used as the standard therapy for this condition during two decades until more evidence-based strategies evolved and were diffused [See e.g. Walsh-Sukys *et al*., 1994; and Gross, 2000].

Unquestionable evidence of health benefits are, however, not always sufficient for funding of a new technology. We must also ask if it is beneficial enough, i.e. prioritize in the allocation of resources. We must compare "apples and pears" to be able to invest in innovations that give the most "health utility" for money.

Usefulness of innovation models

Prediction of the ultimate acceptance of an innovation is of interest not only to producers of innovative products but also to authorities who want to promote or restrict change. It has been experienced, however, that the prediction power of most models is low. This fact does not implicate that modeling of adoption and diffusion is of no value. On the contrary, these attempts of predicting the future have contributed a great deal to the increased understanding of the innovation process.

Many studies have been conducted in the fields of sociology, economics, marketing, politics, and technology forecasting. Diffusion models are a common means of forecasting. These models are most often built on historical innovation examples. The most aspiring studies are not only noting the speed and variation of diffusion, but in their attempts to explain the speed of

diffusion and the acceptance of innovations, they also try to correlate the rates of adoption to characteristics of the technologies, their potential adopters and the environment. Characteristics of innovations and adopters as well as communication and environmental factors are identified as the most powerful explanatory variables [Rogers, 2003]. Innovations, adopters and context are categorized in the studies and future innovation processes are supposed to follow the historical examples. A problem is the large number of factors and the complex interaction patterns between factors. Researchers have to circumvent this difficulty by gross simplifications, which often mean an arbitrary choice of variables to include in the model.

The validity of the model is also dependent on whether the decision is made collectively, by individuals, or by a central organizational authority, the latter, which is often the case in medical device innovation. Furthermore, the flow of information about new products is an important factor, both interpersonal information exchange and the flow of information from outside the organization.

A common approach in predicting innovative behavior is mathematical models based on adoption probability [Mansfield, 1961; Fourt & Woodlock, 1960; Bass, 1969; Wilton & Pessemier, 1981; Smith & Swinyard, 1999; Norton & Bass, 1987; Abadi Ghadim *et al*., 1999; and Sillup, 1992]. The Bass model [Bass, 1969] of adoption of consumer durables is probably most useful to forecast diffusion of medical equipment, while the diffusion of disposable medical devices is better described by the Fourt and Woodlock model [Fourt & Woodlock, 1960]. The Bass model gives information about the timing of initial purchase of new products. The model was constructed as a market prediction for consumer durables. It is built on the assumption that potential adopters can be divided into two main groups, innovators and imitators; and it yields an S-shaped cumulative adoption curve that has a high proven empirical fit with adoption data for a wide range of products. The Fourt and Woodlock model is an earlier work [1960], a market penetration model that also includes repeat purchases.

Wilton and Pessemier [1981] described an attempt to predict an innovation's acceptance before market introduction. The first step in the prediction was measuring the state of knowledge (awareness) about the innovation in a systematically selected sample of potential adopters. The next step was to artificially advance the knowledge to the state normally encountered prior to an adoption decision. Then the probability of adoption was measured within this group whose knowledge is equivalent to what it would be at the time of

making an adoption decision. The investigated innovation, in their study from 1981, was an electric vehicle for private urban transportation. The authors made an attempt to predict the probability that a particular object would be the individual's first choice (or most preferred object) in a set of similar objects. The test subjects were provided with different amounts of information about the vehicles to test the information load factor as an explanatory variable. Further, two different risk conditions and two different cost conditions were tested. In predicting the ultimate acceptance of the electric vehicle, the model showed, however, no substantial improvements over naive chance. But the study indicated that the amount of information influences the aggregate perceptual structures, and that the choice (adoption decision) may depend on how information is communicated to the potential adopters. The authors also found that the most important distinguishing features of the potential adopters in this context were their financial resources, their transportation needs, and their inventory of knowledge about the characteristics of electric vehicles, which are factors that can be easily transferred to the hospital setting and adoption of medical devices.

In order to promote or restrict innovation it is necessary to decide whether the process will be too slow or too fast, which can be anything but easy. It is also necessary to include other factors than those apparently involved in the adoption decision. The IDD model is the first step toward a model that can be used for estimation of all parts of the innovation process. It might be an estimation that invention activities are insufficient in an area of a discovered need, which indicates that the promotive measure should be incentives to inventors. Or it might be an estimation that the deployment of an innovation will be a slow process, which implies that information and learning must be prioritized. Regarding medical devices, however, the most common measure is to try to influence the adoption decision. If convincing evidence is available about the benefits of a specific health technology, this might be a reasonable thing to do. For example, when the probability of adoption of a new promising device is low in a specific ward unit, and this seems to be caused by high uncertainty, the hospital may increase change agent contact, facilitate inter-hospital information exchange, or use other information promotive measures. It might also be that the evidence level for a device is low and adoption probability high, than the potential adopters most likely have been misinformed, perhaps by a hard-working vendor. To counteract this, the hospital has to harness a well-informed gatekeeper to stabilize the situation.

For the purpose of controlling technological change in healthcare, it is essential to keep track of the *facilitators* and *inhibitors*, and sort out which ones will be most influential in the actual process. In an increasingly cost-conscious environment efforts to control change have become more common and, for example, Fineberg pointed out, as early as 1985, that regulatory agencies and medical care insurers may exercise direct and indirect control over the diffusion of medical practices. It has also been pointed out that managed care in the United States, the so called health maintenance organizations (HMOs), seem to have had a cost-reducing effect by means of diffusion disincentives [Baker & Wheeler, 1998; Baker & Phibbs, 2002]. Some important facilitators and inhibitors have been discussed above (p. 117), but as opinions differ among experts, about their relative importance, I will not intend to suggest an absolute ranking within this list. It is also the fact that the most influential factors in one particular innovation process, regarding one particular device, may be less influential regarding another device.

A great difficulty in modeling innovation is to select the dominant factors for each innovation category. Innovation is a complicated process, but it is still necessary to have a low number of variables to explain it. The model has to be manageable and it must be possible to collect and process input data without consuming too much time and resources. Empirical tests of the model may lead to a reduction of variables, but for some innovation categories it might be possible to exclude or merge together variables merely by logic thinking. For instance, both trialability and observability are characteristics that can be recognized as learning or uncertainty factors, as they both reduce the level of uncertainty faced by a potential adopter. Furthermore, geographical variables, such as ecological conditions, are just cases of compatibility [Wejnert, 2002]. One such example is the adoption of a profitable modern coarse cereal[25] cultivation method. The innovation was, however, not appreciated in a society of Indian peasants. The reason for this was that the cereals were not compatible with (had low resistance to) the frequently occurring floods [Jansen *et al*., 1990]. This obviously caused the estimated value of the innovation to drop below zero.

The complexity variable is another example of how factors in a model can be organized in different ways. Complexity may as well be included in an overall advantage factor, the *perceived relative advantage* [Cf. Rogers, 2003]. High

[25] The major coarse cereal crops are maize, durra, and millets.

complexity reduces the relative advantage of an innovation, as the need for investment in education and learning increases.

A useful model may be very simplified in some respects, while complicated in others. The model has to make clear the essential features of the phenomenon it is intended to explain. It is however crucial that collection of input data can be easily performed. The predictive power does not always increase with the number of variables. It might be better to intervene as little as possible in the process. Furthermore, a model can be useful even if the predictive power is not perfect in every application.

Involuntary use of innovations

It is not always possible to control diffusion of innovations or their assimilation into the society. Several examples of "involuntary use" of innovations exist, on which authorities have not been able to exert their influence. Among these is for example non-medical use of drugs (drug abuse), which is an established practice in most countries. The adoption of this practice might be voluntary by some in the total population, but its consequences spill over to the whole society. Another example is the use of the Internet. Organizations may have mandated use of the Internet, such as e-mail systems. And even if Internet use in organizations, in most cases, is voluntary [Prescott & Van Slyke, 1997], for an average citizen of the Western World, it appears that Internet use is not entirely voluntary. For example, as a cause of path-dependency and momentum in the development of Internet-based services, many face-to-face services are disappearing, such as bank services. I do not intend to classify this as a good or bad long-term consequence, but the example shows that a lot of people today are forced to use innovations they have never asked for.

8. CONCLUSIONS

The most salient conclusions of my work are: (1) Diffusion of medical devices can not be studied as a process isolated from initiation, invention, and development, i.e. the invention domain; and (2) it is not meaningful to study diffusion but not the actual integration and use of devices, i.e. the deployment domain. These two conclusions are embedded in the title of the book and in the suggested innovation model (Chapter 6) and it is not necessary to develop this further. In the following I will give examples of what my work revealed besides these conclusions. I will also suggest improvements of the model and of the methodology used in innovation studies. Finally, I will list a number of actions to consider in the management of medical device innovation, from the hospital perspective as well as from the device company perspective.

What the work revealed

This section presents a selection of findings that have added to my understanding of the innovation process and that I specifically would like to emphasize.

When studying the path of a medical device innovation, from idea to regular use, it is important to be aware of the complexity of the different change processes involved. It is actually not one but three innovation processes going on, intertwined in close relation. First, the process of transforming an idea to a useful medical device and integration of it in routine health care. Second, the process of integrating a new article into the product range of a manufacturing firm. And third, the process of developing a technically feasible and profitable production process to manufacture the new product.

The inventor and the innovating firm. When picturing innovation in this way, it is easy to understand why the innovating firm is to be considered a necessary and influential actor in all medical device innovation. A committed inventor within the firm is a highly facilitating factor in the stages before diffusion, but it has also been shown that university inventions require continuous involvement of the inventor to be successfully commercialized

[Goldfarb *et al*., 2001]. Consequently, the inventor and the innovating firm are essential actors in medical device innovation.

Evolutionary change. Medical device innovation is an evolutionary process rather than a quick change from one technology to the other. This has been recognized in other areas by for instance Utterback, who wrote: "Many innovations of great commercial significance are of the relatively low-cost, incremental type, the result largely of continuous development efforts" [Utterback, 1974:621]. This is, in large, an appropriate description of the evolvement of many health technologies and technological change in hospitals. Even though there may exist a readiness for change [Lehman *et al*., 2002] and a wish for continuous improvements of treatments and work procedures, too radical changes have little chance of success. Inertia and wish for change are opposing forces. These forces are, however, equally valuable, as the wish for change otherwise might cause untimely disuse of technologies.

Attitudes toward change. The opposing forces of resistance and wish for change are also reflected in the innovativeness of organizations. Management principles are major determinants in medical device innovation in hospitals. However, for specific devices, individuals not directly involved in the adoption decision are forming favorable or unfavorable attitudes toward the innovation, which may affect the later integration and utilization of the device. This happens already when the new device is introduced, but even more during the education and training period.

Increased communication. The existence of broad and viable communication networks has been recognized formerly as a facilitating factor in diffusion [See e.g. Rogers, 2003]. This is, however, equally important in the early stages of innovation. An increased communication between inventor, manufacturer, and end-users is of value, not only for the development of useful devices, but also for the evaluation of early innovation projects.

Information and trialing. Gathering of information and encounters with the innovation are crucial elements of the adoption decision process. In cases where treatments are converted from traditional care to the use of new (and improved) medical devices, the value of information and trialing lies in reduced uncertainty, an improved care processes, health benefits, and/or cost savings. Trialing for skill development always leads to an improved care process, while trialing for reduced uncertainty may lead to a lower estimate of the benefits of the device. This does not imply, however, that the information

has a negative value, since a potential rejection or reduction in use might be a better decision in the specific case.

Trends in utilization. Devices might have somewhat overlapping functions, which leaves some freedom of choice within the treatments. This enables development of trends in favor of one or the other device. Proven beneficial technologies might, therefore, be used inadequately or less than optimal. The motivation to use a device comes from knowing that it will benefit the patient, but also from the usability of the device and from trends within the profession.

Evidence-based adoption and disuse of technologies. Both the literature and the empirical studies, presented in this thesis, are indicating that the use of scientific evidence is dependent on the size of the investment. Low-cost devices seem to be adopted in a more preference based manner, even though the added costs of long-time use might account for considerable amounts of expenditure. Furthermore, adoption often implies disuse of some older technology. In the case of substituting technologies, the benefits and costs of the new device is preferably assessed against the currently used technology. This old technology might be a device, but it is frequently not. This was the case when manual counting of the pulse was substituted with the pulseoximeter. Manual counting of the pulse has still its applications and will probably not be totally abandoned. However, in many cases of innovation it is difficult to distinguish in advance which technologies are going to be abandoned, and this is complicated further by the fact that technologies are seldom perfectly substituting for each other, but to a high degree overlapping in function.

Suggestions for model and methodology improvements

The IDD model of innovation presented above (Chapter 6) is in the form of a "handbook" in medical device innovation, and it is intended to be used for estimations of innovation processes all the way along the chain of events leading to technological change. The model presents a large number of factors that influence these events. Unfortunately, the complicated nature of innovation processes has created a set of factors, most of which poses considerable measurement problems. The best use of the IDD model is therefore to initially determine which factors are present and then to use quite

wide estimations of the magnitude of these factors. I do not recommend trying to characterize all influences in numbers. The model will thus give a picture of the actual situation, a picture colored by the investigator to some extent, but nevertheless more complete and more integrated than the picture that a few selected numbers would yield. Adopting the IDD model does not, however, in any way, require the abandonment of quantitative research methods. In cases where quantitative values can be obtained, these are easily integrated in the model. Furthermore, quantitative methodologies, such as mathematical programming offer superior possibilities for simulation of innovation processes over time.

The practical use of the IDD model could be improved in several respects:

First, selection of factors needed for specific purposes could reduce the model complexity. The investigator might for instance be interested only in the transformation of ideas into innovations, i.e. invention and development; and another investigator may be interested only in a certain product category, which innovation process may be covered by a sub-set of factors.

Second, identification and involvement of relevant informants can save a lot of work. If the factors in the model have to be ascribed a value, this could be done on a level that is more or less detailed. One example is the degree of *relative advantage* (from Rogers's model, 2005). This factor contains several sub-factors, such as cost, treatment outcome, social prestige, work convenience, and patient satisfaction. To take each factor down to this sub-factor level would be extremely time consuming and yield an unmanageable model. A shortcut might be to find a suitable mix of informants and instead ask them about their perceptions of the possible advantage of the innovation relative current practices.

Third, data in innovation studies has traditionally been collected via questionnaires or structured interviews. These methods are appropriate for collection of large amounts of data. I would, however, like to see more of semi-structured, in-dept interviews and observation studies, as this might lead to the discovery of important explanatory factors that have not yet been considered.

Fourth, the impact of marketing strategies employed to innovate and to diffuse innovations are not yet thoroughly investigated. Are the innovating firms actively considering how the innovations can be perceived as more advantageous in healthcare organizations? Are they conscious of prevailing norms and values within these organizations? Are they trying to increase the

trialability of the innovations and to build in options for local adaptations? Further insights into the medical device industry and the development work would probably add valuable knowledge to the model.

Future work

Technology clusters and disease specific case studies. Using traditional innovation and adoption theories to study medical device innovations, may be insufficient in order to capture aspects of interdependency between different technologies and between technologies and organizational structures. Studying innovation without considering the context of related technologies is likely to result in an inferior understanding of the process. An attempt to manage this is to turn to theories of technology cluster innovation [Silverman & Bailey, 1961; Prescott & Van Slyke, 1997] (See also p. 100). Another way of studying the interrelation between innovations in a technology cluster is to apply a "disease state management approach." This has been described as the study of "…technologies related to the medical care of a specific disease during an extensive period of time" [Sennfält, 2005; see also Carlsson, 1987]. An understanding of such sets of technologies as clusters may be required to appreciate the advantages and dis-advantages of each technology, as perceived by their adopters. Research on such interrelations is scarce and I strongly believe that this could be developed further.

Investigation of policies aimed at controlling technology diffusion. There are obviously several options for influencing innovation. Many authors summarize their conclusions in policy implications for regulation and control of technology diffusion. It is unclear to what extent these implications have been adopted by authorities and if they have had an impact in actual cases of diffusion of innovations.

A common problem with many of the suggested policies is the pro innovation bias, which often is embedded in the implications. It has, for instance, been suggested that negative consequences of an innovation should be de-emphasized to enhance the acceptance of innovations. "Diffusing an innovation in a way that emphasizes its benefits and downplays the negative consequences can considerably enhance the social acceptance and ultimate efficacy of a public health campaign" [Haider & Kreps, 2004]. I consider this a depreciation of potential adopters' ability to value objective information and to make their own adoption decisions.

It has been shown that it is possible to impact adoption of medical devices by market regulations. For example, the certificate-of-need (CON) regulations enacted during the mid-1980s, in the United States, retarded the adoption rate of magnetic resonance imaging (MRI), as compared to the CT scanner that was spread a decade earlier [Steinberg *et al*., 1985]. Market regulations of different kinds have been implemented in many countries, and research has been conducted on specific local regulations, but there is a need for an overview of this field and the possible impacts and consequences in healthcare.

Societal consequences and global diffusion of innovations. Another area for future research is societal consequences of healthcare innovation. Studies are needed on the net consequences of specific health technology innovations. Will the innovation widen or narrow socioeconomic gaps? How are the socioeconomic benefits of the innovation distributed within a social system or among different systems or countries? Global adoption of technological innovations is facilitated by the growth of multinational corporations, world connectedness via modern communication systems, media effects, and by a generally low threshold of diffusion of technological innovations [Wejnert, 2002]. To this must be added the increasing mass of world culture, for instance sports, motion pictures, and music industry, which promotes the spread of similar norms, practices and societal structures. The relationship between the spread of world culture and medical practices provides an interesting research option for people investigating global diffusion of innovations.

Policy implications for management of technological change

Technological change in hospitals is influenced by several different actors. None of them alone has the capacity to force innovation in a desired direction. A management of technological change, that will benefit the society, requires cooperation among different actor groups and a will to strive for the common good. However, different actors have different incentives and there is often a lack of agreement on what will give the most benefit.

From the hospital perspective there are still actions that can be taken in order to mitigate the effects of unfavorable forces in the innovation process, and the producers of medical devices may also influence the process in a direction of sustained use of beneficial products.

There are also opportunities for improvements in the regulatory environment. Successful innovation involves fruitful research and entrepreneurial activities, which may create a win-win solution for economic growth and health care development. Many governments could facilitate innovation by reforming their public innovation systems. The regulatory environment must support research and development within public-private partnerships, where health care, industry and academia are working close together. Such partnerships would facilitate transfer of new ideas to inventors, and to entrepreneurs who can transform ideas to beneficial products. A partnership of this kind would also decrease the risk of wasteful investments in unfruitful projects.

Regulations must, however, also leave room for local needs and adaptations. The steering of technological change is a balancing act, where restrictions and freedom of choice exist in harmony. It must be "… balanced enough to provide local agents with sufficient flexibility to implement changes in a manner that is consistent with the unique needs and interests of various settings" [Ginsburg & Tregunno, 2005].

Management practices and work organization in hospitals

Networks and partnerships A hospital's potential for innovation is a function of its internal and external regulatory environment, the state of technological development, and the flow of information. The external environment includes industrial and healthcare market as well as social and political factors that may facilitate or inhibit innovation. The impact of technological renewal is primarily an advanced state of development that is associated with high status of the hospital, and this status is sustained by innovation. The most influential factor in this is probably the flow of information. This factor includes both information from external sources and the flow of information within the hospital. The information flow is dependent on characteristics of the organization, including its patterns of communication and decision-making, allocation of resources, functional differentiation, and individual characteristics of the staff. Barriers to the information flow between the hospital and the environment will limit its knowledge of social and market needs, new and existing technology, government programs and regulations, and the state of development and work practices of other hospitals.

If increased innovation is a desired state, hospitals have to invest in people and knowledge. At the center of successful innovation are often enthusiastic

individuals with clear visions of what they are trying to accomplish, i.e. the actors that are called innovation champions. These innovators do often not innovate to obtain money, status or positions, even though such informal and formal mechanisms have a facilitating effect, but visions take time and the champion may need freedom and space to achieve the innovation. This will mean freedom from some day-to-day duties, and implies that there are slack resources available in the organization (See p. 133). These slack resources might be used for sustaining and extending communication networks and to seek and process information, or else to ensure that there are sufficient resources to drive a creative process, whenever such a process is initiated.

An important network tie is that to industry. A product idea has greater chance of survival if an industry partner is involved at an early stage. The industry partner has the necessary knowledge for evaluation of manufacturing possibility, profitability, and field support capacity. This will lead the development onto the right track earlier in the process. However, many ideas and wishes are simply not practically possible to realize, and early termination of such projects will prevent waste of resources.

Another network and information seeking activity is the monitoring of current research and innovation worldwide. This is not primarily within the range of commitments of the hospital or other healthcare organizations, but is preferably left to a Health Technology Assessment (HTA) agency. However, as there is a need for reinforcement of the communication between HTA and healthcare, it might be useful to have specially assigned gatekeepers, who maintain contact with HTA organizations and transfer information to the medical profession.

Adoption of devices The following questions cover the most essential topics to consider before adoption of medical device innovations:

1. What effect will the new technology have on treatment, care process, economy, demand, and physician interest?

2. Which of the currently used technologies might be abandoned or used less? What are the value of the potentially lost knowledge and skills?

The effect on treatment has probably been evaluated in clinical trials, before the device is considered for adoption into the hospital, but experiences from other hospitals, which have used the same technology on a similar patient population, are invaluable in reviewing treatment effects. This will also reveal information about the effects on care process, such as how the new technology

will affect staff education and training, responsibilities, and product supplies and support. The hospital staff's own experiences from trialing are preferably also integrated with experiences from other users, and adoption decisions ought to be group judgments with consensus among the experienced staff.

Economic impact and demand for the new technology are often evaluated in an economics department, but may also be left to an outside service such as an HTA organization. The demand for the new technology is, however, always difficult to evaluate, and the decision-makers frequently have to base their decision partly on subjective opinions. The same is true for the evaluation of physician interest, although this is often a heavy argument in adoption. The opportunity for physicians to perform forefront research and to further their professional development will attract people and activities that strengthen the hospital's image as a technically advanced organization.

When evaluating the innovation, if it is a diagnostic technology, the treatment effect has two dimensions to be considered: the diagnostic impact and the therapeutic impact. An additional diagnostic technology might perhaps not lead to a more accurate diagnosis or to detection of more cases; and if so, it might not influence the selection or delivery of therapy and thus not improve the treatment.

Adoption of new technologies for treatment of diseases implies that other technologies will be used less. Technologies are seldom perfectly substituting for each other and the old technology is therefore often kept and used in parallel with the new one. However, having numerous alternatives within a treatment pose a risk of confusion and is an inhibitor to successful integration of new technologies (See *New technology load* p. 78). It is, therefore, of value to consider which of the currently used technologies that might be abandoned or used less, and what consequences this will have for work practices and for the staff. Substantial knowledge and skills might be embedded in the older technologies and it is important to ensure that this can be restored in case an adoption decision turns out to be unfavorable.

The use of scientific evidence Adoption of medical devices is not always based on sound scientific evidence. Decision-makers sometimes have to trust their own perceptions and recommendations from early adopters in their adoption decisions. A well-trimmed work organization does often not leave room for time-consuming inquiries and reading of comprehensive reports. But the problem is probably also caused by communication barriers. Adopters of healthcare technologies might be better in asking for specific assessments,

which they need, and they could be more specific as to the preferred form of the requested information. Assessment agencies, on the other hand, might be better in providing the right kind of information. It is important to be aware that assessment reports, in their current form, constitute only one element of the decision framework, and other information might be perceived as equally important.

There are three major driving forces for innovation in hospitals: resource utilization, patient need, and competition. *Resource utilization* is a question of labor savings and cost-effectiveness of the technologies; the force of *patient need* is grounded in the wish to improve health for many and for those with the most severe conditions; and *competition* comes out of the hospital's wish to be high-performing, to have clinical excellence, and to be the most technically advanced. Traditional assessments of medical devices do not take all these aspects into account. The evidence provided by assessment agencies is therefore only a part of the total decision framework.

Leadership skills and integration of medical devices The innovativeness of the adopting unit and the integration of innovations is very much dependent on leadership skills and management principles. The quality of management may be the difference between an innovation that fails and an innovation that improves the performance of the adopting hospital.

Examples of essential leadership skills are:

Responsiveness to change. Not necessary having a pro-innovation standpoint, but being aware of both problems and benefits accompanying technological change. Problems, such as excessive technology load, may severely inhibit integration of innovations.

Responsiveness to innovative ideas. Encourage staff members to develop innovative ideas through information seeking and network contact. Create possibilities for re-prioritization of resources to enable specific innovative activities.

Creative problem solving. Integration most often requires adaptation of the innovation, of other medical equipment and/or of work routines. Creative problem solving must therefore be encouraged, even though creative ideas frequently turn out to be difficult to realize.

Ability to motivate others. Proper motivation can give the organization an identity of innovativeness. Motivation includes encouraging creative ideas among the staff and to create a positive change climate.

Faith and trust. Creation of a working climate of faith and trust allows innovators to achieve results, even though the decisions and actions sometimes involve a high degree of riskiness. Risk-sharing mechanisms and autonomy are vital ingredients in this. Staff members who experience high levels of autonomy seem to be more involved in decision-making. This will probably also go together with an identity of innovativeness, seeing new technology testing as a potential for improved care.[26]

Better integration of devices could also be achieved if the routines for introduction were complemented with a more systematic follow-up of how adopted devices are assimilated in the care process [Paper IV]. This should be made in conjunction with device manufacturers in order to ensure feedback for improvement of the adopted devices. There seems to be an unmet need for assessments during the integration phase of the innovation process. A smoother integration of innovations could be obtained by continuous monitoring of factors to be corrected in the future and by scheduled reassessment points.

Advice to the producers of medical devices

The strategies employed in medical device companies to innovate and to market new products may be highly influential in the diffusion and deployment of products. It is important to increase the trialability of the products and to develop built-in options for local adaptations by the end-users. Knowledge about the prevailing norms and work practices in healthcare organizations might also benefit the device company, and this ought to be an integral part of the education of sales representatives working as "change agents" within hospitals.

The change agent has three major tasks: (1) Establish a favorable "change climate" through an information-exchange relationship with the adopting unit. (2) Pinpoint a specific problem which can be solved by the promoted behavioral change (the new device) and thus induce a need for innovation. (3) Facilitate adoption and implementation of the innovation by training and support, which also will stabilize continued use of the innovation. A wise change agent stands back during the actual adoption decision, and works only

[26] Reflection made in study IV.

as an external information source, available on demand. The change agent might not have all the facts about the work organization of the adopting unit and a pushy involvement in the decision process may be perceived as an obtrusive behavior [Paper IV]. This might damage the relationship with the adopter and later, in the implementation phase, complicate the change agent's work to stabilize use of the new device.

Adoption of new medical devices represents a certain degree of change in work practices in the hospital, which may be indicated on a scale from incremental to revolutionary. The greater the change the more risky is the adoption, as it is more difficult to predict the future effects of unfamiliar technologies. It is also more difficult to conduct a trial if the innovation goes beyond the familiar range of technologies, which implies a lower than normal evidence level of the information obtained from the trial. It might thus be better to make incremental inventions, if that is possible, and develop the full potential gradually through several generations of the technology.

Some closing thoughts

One of the conclusions in this thesis is that highly divergent innovations may have little chance of immediate assimilation. Revolutionary changes are rare. They occur over long periods of time and only if the innovation is divisible and can be accepted in small portions, one at a time, like when boys started growing longer and longer hair in the 1960s, so that the new fashion of long-haired boys was almost completely accepted a decade later.

Different innovation and diffusion models have been suggested by numerous different authors since de Tarde first investigated the subject. Each of these models is in itself an innovation, and if innovation theory is applied to this, one will have to consider the following aspects on diffusion probability: Does the model diverge too much from earlier theories? Is it compatible with existing norms in the innovation research system of adopters? Is adoption of it perceived to have a positive net value? However, all the inventors, developers, and adopters of these models have contributed to a deeper understanding of the processes involved and have given us a tool for future investigations in the field of innovation.

Finally, however, when looking back to where it all started – de Tarde's *innovators and imitators* (1890) and Ogburn's model of social change: *invention,*

accumulation, diffusion, and adjustment (1922) – it is not obvious that the more than 100 years of innovation research has brought us so much further, considering the fundamental theories of technological change. These two theories have caught the essence of diffusion and innovation. Different times have had their own words to describe, in large the same thoughts, but with somewhat different foci – and perhaps that is what innovation is all about – to deploy the thoughts of others in a little different way, just like each new generation of young people discovers *language* and invent a new jargon, so that it will suit their needs and provide a valuable tool in their everyday lifes.

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