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# LONG TERM FORECAST OF MEDICAL DEVICE MARKETS THROUGH INTEGRATION OF SCENARIO TECHNIQUE AND DELPHI METHOD

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## ABSTRACT

*In this paper it is proposed, that every medical device development project should be preceded by an elaborated project initialization phase and pre-study phase including among others a forecast of market situation for the expected date of market launch. Medical device development projects including target research (development of new technology or adoption of existing technology) can require several years until market launch. The medical device market is one of the most dynamic markets. Due to on-linear changes of demand, disruptive changes through new technologies it is useless to apply linear or other mathematical extrapolation methods for long term forecast. An integrated methodology of Scenario Technique and Delphi Method is developed to fulfill the requirements of intuitive forecast in the project initialization phase of long-run medical device development. It consists of two forecast steps: first, define the epidemiological scenario vision, and second, integrate this forecast of epidemiological factors in the complete market scenario and conduct Delphi survey on the relevant factors.*

## KEYWORDS

Long term market forecast, intuitive forecast methodologies, target research, Scenario Technique, Delphi Method.

## 1 INTRODUCTION

The term Medical Device means any kind of instrument, machine, implant, in vitro reagent or calibrator, software or similar used (alone or in combination) for human beings. The European Union Norms for Medical Device classify all the Medical Devices in three main categories: actives implantable (90/385/EEC), general (93/42/EEC) and In vitro diagnostic (98/79/EC). The Medical Device Market is one of the biggest in the world with the estimated one and a half million different devices on the market and a market size of US\$ 145 billion in 2000. Based on innovation and rapid advancement of technologies, Medical Devices are currently one of the fastest growing industries, and the global market figure for 2006 is expected to exceed US\$ 260 billion (WHO, 2003).

Medical device development including target research (development of new technology or adoption of existing technology) can require several years: a minimum of 6 years to bring in the market the product and minimum 8 years to establish the product in the market. Therefore a market forecast done in the front end of the project is a long term market forecast. Due to the sector characteristics it is inadequate to base long term market forecast on linear or other mathematical projection methodologies. Potential radical or even disruptive changes, like epidemiological scenarios, have to be integrated in the forecast.

Another issue complicates the forecast: The market for many medical devices is really complex, in terms of market players. In the majority of cases the end-user respectively patient is not the customer.

## 2 OBJECTIVES OF THIS PAPER AND RESEARCH METHODOLOGY

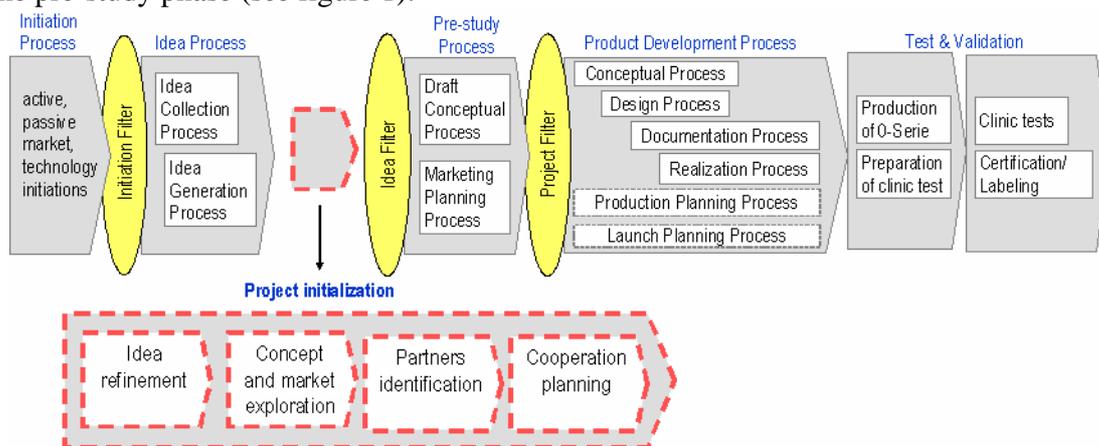
The main objective of this paper is to develop an integrated methodology for long term forecast of medical device markets. By proposing a process model for the front end of medical device development, we give a framework for the methodology to be developed. From this framework the most important requirements for the methodology are deduced. An extensive literature survey on intuitive forecasting methods provides methods component used in the integrative methodology. Additionally input for the development of the Methodology came from observation and analysis of forecast methodologies used by four companies that develop and produce Medical Devices (dental equipment, active implantation, cardiac stents and defibrillators).

The Methodology will be tested and refined by using it in an actual Medical Device research projects the development of a semiautomatic robotics for coronary anastomosis. This paper presents the implementation of the first step of the complete methodology: the forecast of epidemiology factors.

## 3 FRAMEWORK: FRONT END PROCESS FOR MEDICAL DEVICE DEVELOPMENT

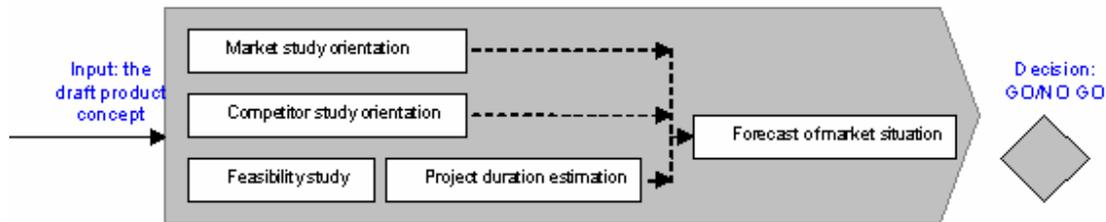
The embryo of a new product is always the product idea. In the Medical Device development after the idea process phase begins a pre-study phase. In many cases the pre-study phase is dedicated to develop a new technology or to adapt an existing technology. These two technologies development activities are focused on research for applied product functionalities. In the context of Medical Device development we will call these activities “target research”. The target research extends significantly the duration of the pre-study phase.

For Medical Device innovation with target research we propose an additional project phase, the “project initialization” phase. This phase should take place between the idea phase and the pre-study phase (see figure 1).



**Figure 1: Adaptation of Reference Product Innovation Process of Centre for Product Design, ETH Zurich, for Medical Device Development and with Project Initialization Phase.**

Two tasks of the sub process “concept and market exploration” of the phase “project initialization” are dedicated to the first market and competitor analysis (fig. 2). These preliminary types of Market and Competitor Analysis have the name “orientation” because the objective of these two tasks is only to analyze the size of the present product market. Later, during the Pre-study phase the potential market share of the product respective the competitor’s products can be deduced. The name of this second und later market analysis is “market analysis quantification”.



**Figure 2: Sub-process Concept and Market exploration of project initialization phase.**

Objective of the task “feasibility study” is to identify of all important product functionalities. Are there technologies or solutions for all functionalities? If not: how big is the development or adoption effort? What are the potential influences on the final product (risk, complexity, difficulty and importance for the product). Portfolios methodology can be used for the evaluation of functionalities as for example Complexity/Difficulty vs. Importance. This classification can help to plan a first and rough technology development or adaptation roadmap and than estimate the duration of the project.

The last task is the “Forecast of market situation” at the end of the project. This is also the objective of the whole sub-process, to explore how the market might look like at the date of market launch.

A methodology used for market forecast in this context has to fulfill following requirements:

- Suitable for long term market forecast (projects may take 6 years and longer). Therefore not only analytic but also intuitive approaches have to be integrated.
- In many cases mainly technical and medical research institutions are involved in the front end of medical device development with target research. Therefore the forecast methodology has to be easy to apply – also without sound business skills.

#### **4 SURVEY ON INTUITIVE FORECAST METHODOLOGIES IN LITERATURE AND PRACTICE**

Mathematical approaches are not appropriate for long term (more than 8 years) forecast of medical device markets. The survey on forecast methodologies in literature and practices (observation and analysis of forecast methodologies in four medical device companies) was therefore concentrated on intuitive forecast methodologies. In the following the most important findings about Scenario Technique, Delphi Method and Epidemiology Factors are documented.

##### *4.1 SCENARIO TECHNIQUE METHODOLOGY*

Scenario technique has enjoyed a rich history over the past thirty years. The methodology was developed by Herman Kahn in the 1950’s. A very complete history including all

development stages of this methodology can be found in the book of Schwartz “The Art of the Long View” (Schwartz, 1991). A variety of scenario building processes have been developed.

Schwartz identified eight steps to develop scenarios:

- *Step 1, identify focal issue or decision:* Begin with a specific issue or decision to make, and then extend toward the environment.
- *Step 2, key forces in the local environment:* List all key factors influencing the focal issue or decision to make.
- *Step 3, driving forces:* List driving trends in the macro-environment that influence key factors.
- *Step 4, rank by importance and uncertainty:* Rank key factors and driving trends on the basis of two criteria: first, the degree of importance for the success of the focal issue or decision identified in step one; second, the degree of uncertainty of those factors and trends. The point is to identify the two or three factors or trends that are most important and most uncertain. The result is the identification of the axes along which the eventual scenarios will differ.
- *Step 5, selecting scenario logics:* The logic of a given scenario will be characterized by its location in the matrix (spectrum along one axis; matrix with two axes; volume with three axes) of most significant scenario drivers.
- *Step 6, fleshing out the scenarios:* Each key factor and trend (identified in step 2) should be given some attention in each scenario.
- *Step 7, implications:* Once the scenarios have been developed in some detail, then it is time to return to the focal issue or decision identified in step one to rehearse the future. If a decision alternative looks good in only several scenarios, then it qualifies as a high-risk strategy.
- *Step 8, selection of leading indicators and signposts:* The selection of leading indicators and signposts helps to monitor the real evolution of the scenario field.

After Schwartz important methodology innovation came from van der Heijden in his “*Scenarios – The Art of Strategic Conversation*” (van der Heijden, 1996). In this book the fundamental principles of scenario planning are define and explained how this tool can be applied in practice. Interesting are the concept of planning as an institutional learning process (with the “*Institutional Learning Loop*” - van der Heijden’s application of Kolb’s “*Learning Loop*”) and the tools for Generating Strategic Conversation.

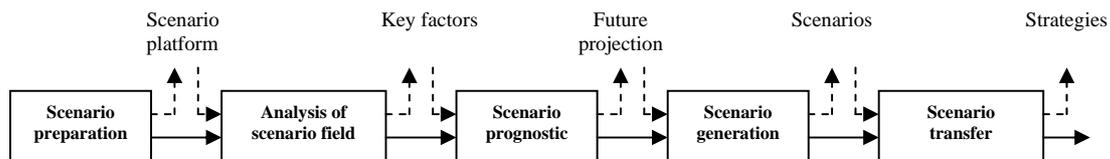
Schwartz and Van der Heijden describe the methodology oriented to strategic issues. A good adaptation of the basis methodology for operative utilization in the product development planning is the book “*Szenario Management: Planen und Führen mit Szenarien*” (Gausemeier, 1996).

Following Gausemeier (1996) there are five phases in the Scenarios Methodology (see figure 3). The scenario preparation, phase 1, includes the system and environment definition (step 2 and 3 of Schwartz). A so-called Influence Matrix is used to analyze the scenario field (phase 2). All the influence factors are pair wise compared regarding question A “how much influences factor x the factor y?” and question B “how much is the factor x influenced by factor y?” The total of influence ratings give active influence score (questions A) and passive influence score (questions B). All the influence factors are introduced in a portfolio with active vs. passive scores. The portfolio is divided in five fields, factors with:

- impulsive proprieties (high active, low passive score - high influence on others),

- dynamic proprieties (high active, high passive score – high influence on and from other factors),
- reactive proprieties (low active, high passive score – highly influenced by other factors),
- puffer proprieties (low active, low passive score – don't influence other factors and aren't influenced from other factor ) and
- neutral proprieties (middle active and middle passive scores).

This portfolio helps to identify the key factors for the scenarios development.



**Figure 3: five phases of scenarios management (Gausemeier, 1996)**

In phase 3 scenario prognostic the potential evolutions of every key factor has to be identified: not only probable or more divergent trends, but extreme projections. The factor projections have to be combined to scenarios (phase 4). A consistence matrix (Gausemeier, 1996) can be used to eliminate inconsistent and therefore unlikely scenarios. Additional reduction of number of scenarios is provided by scenario clustering. Scenarios are completed by a textual or even graphical description of all single cluster of scenarios. The last phase (phase 5) is the scenario transfer, where the different scenarios are applied to the start issue (for example planning the future product palette).

A specific scenario methodology for the medical device development sector is not described in literature. The analyzed companies use adapted versions of Scenario Technique.

#### 4.2 DELPHI METHOD

The Delphi Method is another intuitive approach to develop future prognosis or long term forecast. One of the best and generic definitions of Delphi Method came from “The Delphi Method” of Harold Linstone and Murray Turoff (Linstone, 1974): “*Delphi may be characterized as a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem*”. The Delphi method was developed for military use during the “Delphi Project” in the early 1950’s by T.J. Gordon, Olaf Helmer and Dalkey. The objective of this project was to obtain a credible accord/concordance of opinions in a group of expert through a succession of questionnaires during controlled discussion.

The Delphi process exists in two different forms (Linstone, 1974): conventional (Delphi Exercise) und real-time Delphi (Delphi Conference). The difference is that in the real-time Delphi the monitor group, responsible for the design of a questionnaire, summarizes of results, the development of new versions of questionnaire, is replaced by a computer which has been programmed to carry out the compilation of the group results.

In the 1970’s Fowles described the Delphi process with ten phases (Fowels, 1978):

1. Formation of a team to undertake and monitor a Delphi on a given subject.

2. Selection of one or more panels to participate in the exercise. Customarily, the panelists are experts in the area to be investigated.
3. Development of the first round Delphi questionnaire.
4. Testing the questionnaire for proper wording (e.g., ambiguities, vagueness)
5. Transmission of the first questionnaires to the panelists.
6. Analysis of the first round responses.
7. Preparation of the second round questionnaires (and possible testing).
8. Transmission of the second round questionnaires to the panelists.
9. Analysis of the second round responses (Steps 7 to 9 are reiterated as long as desired or necessary to achieve stability in the results).
10. Preparation of a report by the analysis team to present the conclusions of the exercise.

Delbecq (1975) and Martino (1983) declare the importance of the participant selection and their understanding of the aim of the Delphi exercise. The nature of panelists has been controversially discussed. But the most important attribute of panelists is their expertise and knowledge (Rowe, 1999). The number of the panelists is correlated at the complexity of the aim of the Delphi exercise.

Linstone and Turoff (Linstone, 1974) see an important role for Delphi methodology:

- A problem does not permit the application of precise analytical techniques, but can benefit from subjective judgments on a collective basis.
- The relevant specialists are in different fields and occupations and not in direct communication.
- The number of specialists is too large to effectively interact in a face-to-face exchange and too little time is available to organize group meetings.

#### 4.3 EPIDEMIOLOGY SURVEYS

The word “epidemiology” comes from the classic Greek and is the composition of the words “epi” (among, upon), “demos” (people) and “logy” (study). John M. Last in his *A Dictionary of Epidemiology* (Last, 2001) defines Epidemiology as “*the study of the distribution and determinants of health related states and events in populations, and the application of this study to control health problems*”.

Milton Terris has summarized the function of epidemiology (Terris, 1992) as:

- Discover the agent, host, and environmental factors that affect health, in order to provide the scientific basis for the prevention of disease and injury and the promotion of health.
- Determine the relative importance of the causes of illness, disability, and death, in order to establish proprieties for research and action.
- Identify those sections of the population which have the greatest risk from specific causes of ill health (and benefit from specific interventions), in order that the indicated action may be directed appropriately.
- Evaluate the effectiveness of preventive and therapeutic health programs and services in improving the health of the population.

Different variants of epidemiology are used: Surveillance, Microbial Epidemiology, Descriptive Epidemiology, “Risk factor” Epidemiology, Clinical Epidemiology, Molecular Epidemiology, Genetic Epidemiology, Entrepreneurial Epidemiology, Testimonial Epidemiology, Social Epidemiology and Global Epidemiology.

#### 4.4 SUMMARY OF SURVEY ON INTUITIVE FORECAST METHODOLOGIES

The Scenario Technique and Delphi Method processes described in literature are oriented to forecasting uses totally different from Medical Device Development like forecast of water or oil resources. Nevertheless adopted versions of Scenario Technique are used in Medical Device developing companies. Due to their excellence in integration of ambiguous trends and radical changes both Scenario Technique and Delphi Method are good bases for the development of a methodology for long term forecast in medical device markets.

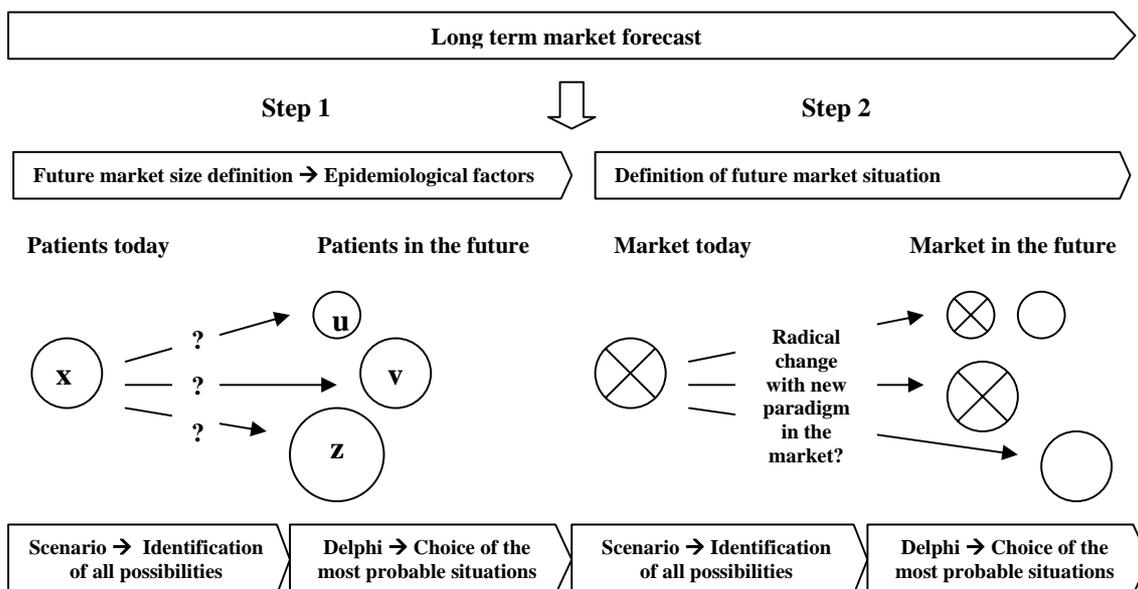
Since Scenario Technique and Delphi Method have complementary performance profiles (the strength of Scenario Technique is the analytical integration of contradictorily trends in a limited number of scenarios, the strength of Delphi Method is to integrated the knowledge and experience of a high number of panelists) it is advantageous to combine both methods. – But there exists nothing or very less (not explicit) in literature about the integration of the scenario into Delphi Methodology.

Obviously it might be useful to apply Scenario Technique and Delphi Method in Epidemiology surveys – also this hasn't been discussed in literature until now.

### 5 DEVELOPMENT OF METHODOLOGY FOR LONG TERM FORECAST OF MEDICAL DEVICE MARKETS

As stated above a methodology is needed for long term forecast in medical device markets. It seems to be appropriate to use Scenario Technique, Delphi Methodology and Epidemiology Surveys as modules for this new methodology.

It is not appropriate to apply Scenario Technique directly in the forecast of medical device markets because there are too much influence factors with high impact and uncertainty. To apply directly a Delphi methodology will deliver a result complicate to analyze. The background of experts has to be very diverse. It is difficult find experts on all epidemiology factors and the specific application's field at the same time.



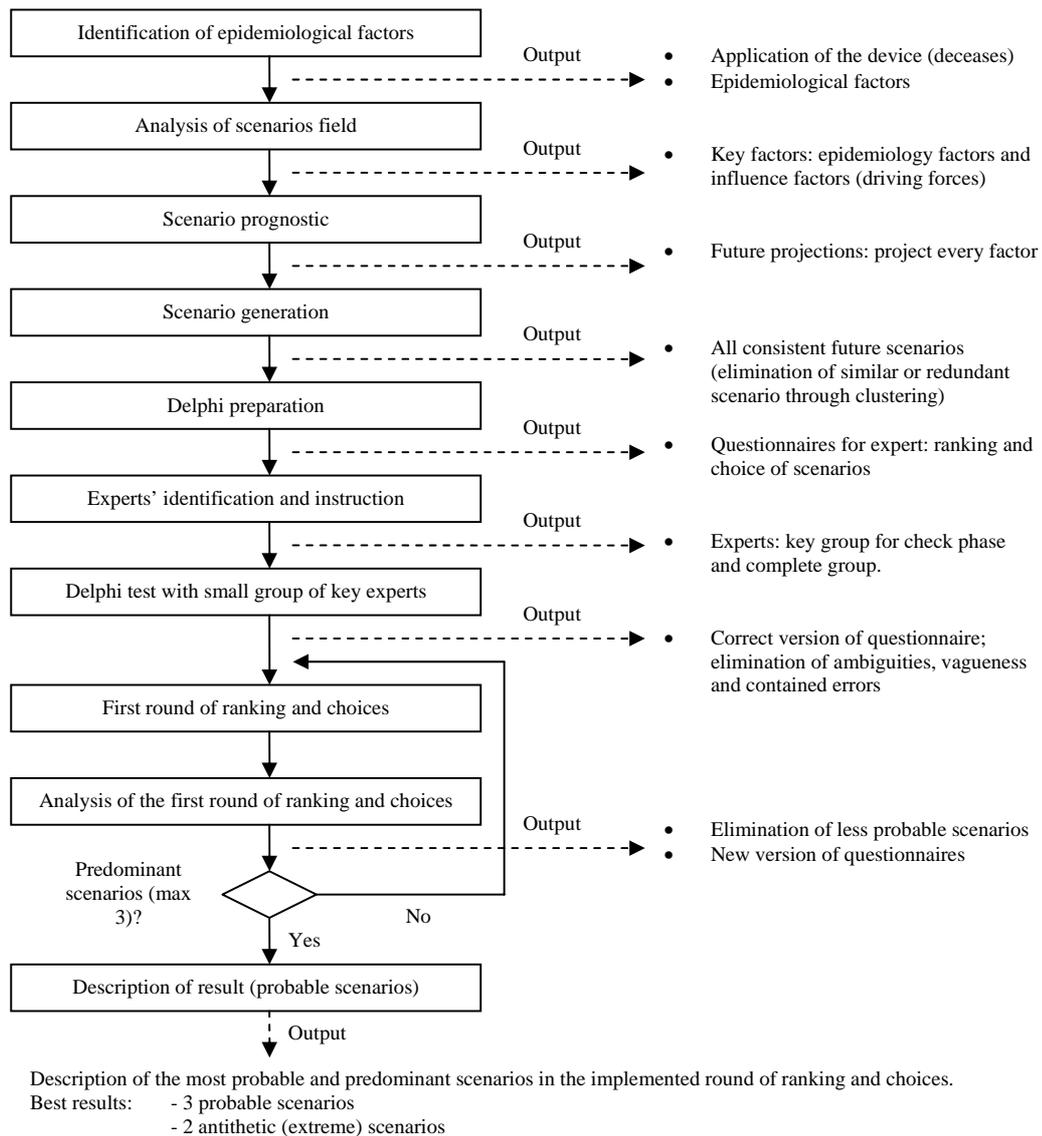
**Figure 4: Integrated forecast methodology.**

The complexity of the forecast can be reduced by splitting it into two steps (figure 4):

- First step: forecast the epidemiology situation in chosen time horizon
- Second step: define the future market situation for a specific medical device application within fixed epidemiology situation.

We propose to use for both steps a combination of Scenario Technique and Delphi Method:

- Scenario Technique to identify all potential situations (step 1: epidemiological situation, step 2: market situation),
- Delphi Method to choose the most probable situations (step 1: epidemiological situation, step 2: market situation).



**Figure 5: Integrated methodology of Scenario and Delphi methodologies. Adaptation of Gausemeier's Model (Gausemeier, 1996) and Delphi process of Fowels (Fowels, 1978).**

Figure 5 shows the whole process of Scenario building and selection by Delphi exercise for step 1 (forecast of epidemiological situation). It is an Adaptation of Gausemeier's Scenario process (Gausemeier, 1996) and Delphi process of Fowels (Fowels, 1978). The main and central "Scenario Design" with the three process phases "analysis of scenarios field", "scenarios prognostic", "scenarios generation" stay. The first process phase "scenario preparation" will be replaced with the phase "identification of epidemiological factors" where the project team has to identify which kind of diseases need the utilization of the device, and which kind of epidemiological factors determinate the disease (figure 5). The analysis of scenarios field contain the analysis of every single epidemiological factors and identify their eventually influence factors on the politic, society, demographic, social and in some cases atmospherically trends. The number of scenarios will be limited by:

- the choice of most important epidemiological factors using Gausemeier's (1996) "Influence-Matrix",
- elimination of inconsistent scenarios using Gausemeier's (1996) "Consistence Matrix",
- Delphi exercises to rank resulting scenarios regarding probability.

The Delphi questionnaire contains 3 exercises:

1. Choose the two most probable and the two less probable scenarios (from the list of resulted scenarios; max. 15 scenarios).
2. Rank the scenarios; from the most probable to the less probable.
3. Choose from a selection of scenarios the most probable (repeated for ca. 30 different couples of scenarios).

The Delphi exercise is repeated three or even more times. The questionnaire is updated every time (above all elimination of scenarios) but the structure stays the same. The answers of the expert panel help the project team to identify 2-3 predominant scenarios. Additional two divergent scenarios complete the picture. They have to be used to test the robustness of the product concept and market forecast.

## **6 USE CASE: CORONARY HEART DISEASES (CHD)**

The methodology was tested and refined by using it in a Medical Device research projects of Swiss National Science Found, The National Centre of Competence in Research (NCCR) Co-Me: the development of a semiautomatic robotics for coronary anastomosis. Three different technical universities institutes, a surgery research institute and two enterprises (component suppliers) collaborate in these two projects. Actually a market forecast has to be done to explore if in 6-7 years (anticipated date of market launch) there will be a sufficient market for bypass devices. The system is for this use case extremely complex:

- Two principal concepts are competing on the market: cardiology with the PTCA Technology and heart surgery (including the device to be developed).
- A patient suffering from heart problem is normally checked up cardiologist. He decides whether he has to undergo a heart surgery or a cardiologic no invasive and ambulatory operation (e.g. PTCA) is sufficient.
- The pharmaceutical industry invest massive on the development of medicament to eliminate or to reduce the coronary diseases (or on single epidemiological factors as high blood pressure, overweight, cholesterol, ...).

Therefore the split up in two steps (step 1: epidemiological situation, step 2: market situation) as proposed above is absolutely necessary to handle complexity also in this case.

The epidemiological factors of CHD are for example: smoke, high blood pressure, high cholesterol rate, diabetic, movement inactivity, overweight, stress, ages. Other driving forces that can extremely change the epidemiological situation in the future are factors as politic (smoke prohibition, actions of sensitization, school action for kids and teens, ...) and pharmaceutical new products (medicaments against the high blood pressure, ...).

Helpful for the team, with 3 surgeons, was the "influence matrix" to identify the passive and active influence between factors as for example is the high active influence of movement inactivity with the overweight.

Before the start of Delphi rounds with all experts, the team needs 4 workshops, every between 2 and 6 hours. We suggest that all four workshops are supported by a moderator and a support person for the "homework". In the first workshop the key factors are identified (epidemiological factors and driving forces, and compilation of the influence matrix) and forecasts of key factors are explained and completed as homework. In the second workshop the factor forecasts are combined to scenarios using the consistence matrix. The consistence matrix and all the designed scenarios should be checked in plenum during the second workshop. For this complex workshop we suggest a maximal duration of 4 hours, because motivation and attention with all the portfolio, matrix and scenarios decrease. Results of this second workshop are the definitive and corrected scenarios. The moderator prepares the questionnaires (with the 3 exercises proposed above). The team checks the 3 exercises for the test with key experts and makes the go decision for the test round with the key experts in the 3<sup>rd</sup> workshop. The 3<sup>rd</sup> workshop has a duration of less than 2 hours. The last workshop is for eventually correction or adaptation after the answer of questionnaire on behalf of key experts group.

Actually we have ended the correction phase with key experts (2 cardiologists and 2 surgeons, a diabetic doctor and a dietetic doctor). The experts group for the Delphi's rounds is 80% completed and includes: 2 professors of cardiology, 2 professors of heart surgery, 1 professor of diabetic science, 2 experts of dietetic, 1 government expert of smoking statistic, 2 experts of pharmaceutical sectors and blood-pressure/cholesterol medicaments.

Two test and refine the methodology a second Delphi exercise with experts from 5 companies of the cardio sector is conducted. Especially incongruence between result from industries and academic experts will be analyzed. Additionally two of these industry partners use and thereby test the complete methodology in two operative projects.

## **7 CONCLUSION**

In this paper an integrated methodology for the long term forecast of medical device markets is developed. It is proposed to apply it during the project initialization phase of medical device development including target research.

By the use of this methodology a project team can not only get insights on potential future situation of the respective medical device market, but it also is training to all project team members on future oriented thinking. The team builds a shared vision of what can influence the market success of the device to be developed – and uses these insights in the development process.

A clear vision of the future market is absolutely necessary to acquire funding and helps to identify supplementary project partners. Financial project evaluation and go-or-no-go-decisions have to be based on insights about future market situation. Indicators, derived from identified divergent scenarios, help to monitor the actual evolution of the market. This

helps to conduct necessary project plan adoptions or project-termination-decisions as soon as possible.

At end of July 2006 the validation of the methodology in the use case CHD market will be completed and the operative results of this use case can be published in August 2006. The methodology is one central element in the guideline for the project initialization phase of medical device innovation with target research. Our ambitious research objective is to create a complete and in-depth guideline to simplify the transfer and sharing of research results between universities (research and teaching) and industries through cooperation in innovation projects.

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