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Shaping biomedical technologies — a best practice example?

Accompanying social science research as a tool in technology-shaping and decision-making processes

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Abstract

In a two years lasting program, TU-Vienna research teams on biomedical devices were accompanied by social science research. The project showed that engineers may be fruitfully confronted with social acceptability demands via Health Technology Assessment. The interests of concerned individuals (i.e. patients, doctors, nurses, relatives) were in this project not directly involved in technology-design decisions. Rather the scientists performing the accompanying research served as stakeholders. Nevertheless it turned out that concerned individuals needs and interests could be successfully introduced into the decision making process.

Institutional background of the research program

The overall target of the research program was a socially acceptable and consumer-friendly technical development of Biomedical Devices at the Technical University of Vienna.

Upon the fact that biomedical research is achieving worldwide an ever-increasing rank, Austrian science policy reacted for the first time in 1990 with a commission to the Austrian Society for Biomedical Engineering to initiate a research and technology concept "Biomedical Engineering" (BMWF 1992). In 1994, the Technical University in Vienna acknowledged the increasing importance of biomedical research and development and established the working committee TU-BioMed (TU-BioMed 1994). At the Technical University of Vienna — as most likely on every other Technical University — there are a number of different research programs concerned with biomedical engineering. These programs are dealing with various subjects like laser medicine, pattern recognition and image processing or biomechanics and so on. It has been only in 1994, when a research-cooperation in biomedical research started at the Technical University of Vienna. As many as 24 different groups joined the program. The goals of TU-BioMed are:

- Bringing together groups interested in biomedical engineering.
- Spreading information on related lectures and meetings.

- Presentation of research activities.

The central target was and is the coordination of all biomedical activities at the university. At present 29 research groups participate in TU-BioMed.

The accompanying social science research program

Against this background the concept of a social research accompanying the technical research was developed. In addition to the social acceptability perspective a political steering perspective and a marketability perspective were introduced into the program. The first one is to be seen in the context of the increased need for steering and planning in health policy. The second is due to the specific Austrian situation in the sector of Health Insurances. An additional perspective here was a research need for biomedical technologies and methods with regard to their marketability from a technology and economic viewpoint of placing Austrian niche-products.

The finally chosen design entailed the perspectives

- market research
- social acceptability in technology design
- advisory instrument for technology and research policy
- steering vehicle in health policy

Possible tension areas here are manifold. The cooperation of engineering and social sciences may in principle create tensions and misunderstandings. Furthermore the self-image of accompanying research programs usually is straightforward. It is either a contribution to a socially acceptable and user-friendly technical design (Wild 1990) or to a market research for a product in the stage of development (CCOHTA 1992, DOH 1994, STG 1987). Since the program intended to integrate both positions we were from the beginning very aware of appearing inconsistencies and contradictions.

Making contact with scientists

First of all I want to make some general remarks on the cooperation between social scientists and technicians. We found it in fact very difficult to convince technicians of the usefulness of our studies. As we contacted the study groups via letters and e-Mail, many of them preferred to ignore the offer of an accompanying technology assessment. In the first request only very few institutes replied. These can be divided into two groups. One group seemed to know very well, what could be their benefit. So they sent us very detailed proposals for our accompanying research. As we can expect, these proposals focused very much on market and acceptance research. The other group of scientists that were interested in our proposal were found to be quite unsuspecting but curious without having detailed ideas. This led us to work out detailed proposals for our accompanying studies and re-discuss them with the leaders of the study groups.

Accompanied biomedical research

- Sleeping Apnoea Screening Apparatus
- Liquordiagnosis for M. Alzheimer
- Biosensors
- Hip-implants

The program was carried out by an interdisciplinary team consisting of one social scientist and two technical scientists. It brought results that can absolutely count as a proof for the productive cooperation between technical and social sciences: after a primary phase of formulating information to all TU BioMed cooperation partners, which explained method and function of such a social science accompanying of biomedical research, first cooperations evolved in the field of electrical engineering (Sleeping Apnoea Screening apparatus) and in the field of chemistry (Liquordiagnosis for Morbus Alzheimer). In a second phase two further cooperations evolved in the field of electrical engineering (Biosensors) and mechanical engineering (Hip-implants and Marrow-nails).

Health technology assessment (HTA) as the tool: central elements of the accompanying research:

As known from literature (Banta 1993, Revicki 1993, Shepard 1985) HTA encompasses a wide range of tools. We chose the following ones for our case studies:

- Epidemiology: incidence and prevalence of illness
- Demographic development of population (if of concern)
- Conventional forms of diagnosis practiced in Austria
- Conventional forms of therapies and possible alternatives available
- Costs and insurance coverage
- Financial restrictions
- Health service needs
- International status of knowledge and research "trends"
- Interviews with physicians of the respective specialisation
- Interviews with patients or their stakeholders (e.g. relatives, patients rights organisations)
- Etc.

For further details about the project see (Gebeshuber, Ratzer, Wild 1997a,b,c).

Two exemplary case studies

Sleeping-Apnoea Screening apparatus

The Sleeping-Apnoea-Screening-Apparatus has been developed at the Institute of Foundations and Theory of Electrotechnics in the Department for Bioelectricity and Magnetism. This study group came up with a very specific proposal for a social science study on their apparatus. The accompanying study was based on these proposals as they were useful within our project.

<u>What is sleeping apnoe?</u>

Sleeping-Apnoea is characterized by multiple interruption of breath (= Apnoea) during sleep. This Apnoeas normally have a duration of some seconds. They also can last up to two minutes and cause a dangerous oxygen-saturation-drop in the blood. As a consequence of a cerebral protection-reflex the patient has microarousals meaning he or she wakes up till several hundred times in one night. This mostly happens unconsciously, the patient cannot remember this the next day. The deep sleep, necessary for our health is not achieved or achieved very rarely. In addition the repeated awakening causes an enormous stress to the whole organism.

<u>What are its consequences?</u>

The consequences are a reduction of life-quality, irritability and sensitivity, depression, drop of intellectual capacity, rise of risk for accidents and incapability to work. Besides, as a consequence of ongoing tiredness of the patients cardio-vascular damages develop that cause stays in hospital, invalidity and premature death.

<u>How many people are affected?</u>

More than 100.000 Austrian suffer from this illness. Other publications are dealing with up to 5% of the whole population, which would be about 400.000 people. Specially affected are overweight men that are over 50 years old. If the Sleeping-Apnoea is not treated the life-expectancy of 50 year old male patients is only 50% of the expectancy of a not affected male.

<u>Sleeping-laboratories-the alternative to screening apparatuses for private use</u>

Sleeping-Apnoea is diagnosed at sleeping laboratories within a polysomnographic investigation or with a sleeping-apnoea-screening-apparatus that the patient can use at home. Currently, this illness it not very well known to doctors and patients. As a consequence there are many incorrect diagnoses. There are 20 Sleeping-laboratories in Austria right now, 13 of them in Vienna. The waiting-list for an investigation is as long as 3 month in advance for the private laboratories and up to 6 month at the public institutes. As well the huge number of not diagnosed patients as the ageing of the whole population within the next years are rising the demand for sleeping laboratories. As a consequence more laboratories must open.

In severe cases the correct therapy is the nCPAP - nasal continuous airway pressure respiration. Air is brought to the throat of the patient with a nose-mask and holds open the respiratory-paths. With this method the symptoms of the illness disappear completely.

The health-insurance is so far paying the nCPAP and the stay in hospital for diagnosis, but they are not paying ambulant investigations with screening-apparatuses. The disadvantage of many sleeping-apnoea-screening-apparatuses today is their unreliability. The electrodes often fall off, patients find themselves unable to deal with the apparatuses. Therefore the doctors often refuse the use of the apparatuses.

<u>Conclusion</u>

The development of reliable, easy useable screening-apparatuses in combination with a deduction of the expenses with the health insurance will surely be a positive contribution for the amelioration of health-care in Austria.

Biosensors for biochemical laboratory diagnosis

Prototypes of Biosensors are developed at the Institute for Microelectronics. These Prototypes had been designed for the measurement of 4 major parameters in blood-diagnosis. They were so far designed as both small portable tools and implants for an in-vivo-monitoring. The questions that the research group had were:

- Is it useful to introduce several additional parameters to be measured — and if yes, which one would that be?
- Is there a need for Implants — if yes, what parameters should they monitor?
- Is there a need for Biosensors in the clinical diagnostics? If yes, how to specify that?

In fact the technology here was just on the way from basic research to applied research and the production of marketable products. This is a perfect moment to introduce accompanying research with regard to the possible impact. The research encompassed the following topics:

Classical biochemical diagnostics

Classical biochemical diagnosis encompasses all tests with samples of blood, urine, saliva, secretion, stool and liquor. Usually they are carried out in hospital- or private laboratories, in rare cases at the doctor's practice. At intensive care units in hospitals and for immediate life-saving measurements at accident places there is a growing demand for portable or bedside tools. There are a small number of common parameters to be measured, such as cholesterol, blood sugar or urea. An average laboratory is yet able to qualify about 400 different parameters.

Biosensors in biochemical diagnostics

There are some advantages that the use of biosensors in biochemical diagnostics could provide. Shorter response times, easier handling of the samples and a better environmental sustainability due to reduction of chemical reagents are the advantages in relation to the now used technologies. Moreover biosensors provide new possibilities for continuous monitoring of crucial parameters.

The role of the health insurance companies

The full costs of biochemical diagnostics in Austria as refunded today by the health insurance companies are about 290.000.000 € a year. The height of a single parameter test varies between approx. 0,7 € to 7 €. (Note that this is very cheap compared to other diagnostic methods like e.g. NMR-spectroscopy that cost about 500 to 720 €). Since the insurance companies are interested in reduction of costs there is an international trend, also visible in Austria at that time, to centralize laboratories. This results in a heightened use of ever larger analysing automates at the growing laboratories. At the same time a need for "bedside-laboratories" i.e. for small tools that provide accurate parameter-measurement in short time grows.

Market perspectives for biosensors

Biosensors may compete with traditional technologies if they are cheaper in acquirement and at work OR if a higher accuracy of measurement is achieved OR if they provide organizational advantages. Their quick response time is an advantage when fast diagnosis for fast introduction of therapy is necessary. Measurement of additional parameters that are not available today might also be a perspective.

The above mentioned aspects are to be regarded against an organisational background. The precise requirements for a use in central laboratories are other than those at the doctor's practice or at intensive care units. All of the mentioned uses are possible, yet again economy plays a crucial role. Only when cost reduction for the insurance companies is obtained, they are willing to include new devices into their refund-catalogues. (Notice that in Austria there is no "health market" as in e.g. USA.) The system of obligatory insurance leads to a situation where not single doctors or administrations of hospitals are to be convinced but the solely insurances.)

Different actor's interests

Four groups of interest were identified in this case:

- public authorities incl. health insurances
- existing laboratories
- physicians
- patients

In specifying and contrasting them with each other interesting constellations of disagreement arose. While the first two groups show very similar interests the physician's and patient's interests differed considerably from theirs.

In the doctors practices physicians are interested in an intensified contact to their patients (i.e. to conduct blood testing etc. in their practices and not to outsource this task to central laboratories as it happens now), in quick response times and of course in a creation of economical value for themselves. The patients interest here is higher comfort and a saving of time as well as a reduction of pain due to minimal invasive technologies. In spite that the insurance companies estimate a rise of costs when relocating such diagnosis from laboratories into the doctors practices. Their assumption was that doctors tend to indiscriminately use such diagnoses when they are refunded by the insurances.

In the hospitals a use of biosensors was more likely, since as well advantages for patients (quicker response times, minimal invasive methods -> minor loss of blood) as for physicians (quicker response time, bed-side analyses, quicker interpretation of results, etc.) did not collide with the insurances interests. In case of critically ill patients the time-argument serves as cost-argument as well. This means that the quicker a (appropriate) therapy is started the lower are the expected costs for curing the patient.

Conclusion

The development of biosensors for intensive care units can be seen as a valuable contribution to Austrian health care. In case of the decentralist use of biosensors there is a need for information as well at the insurances side as on the physicians side.

Central Conclusion for the project:

The result can be assessed as satisfactory. Accompanying research to screening apparatuses led to a EU research proposal and additionally has made a definite contribution to further product design and development, while in the area of Biosensors the working group based the decission for the further research direction on our report (and a bit later additionally on the suggestions of two financiers that could afford the international patent-fees.). In the case of the Hip-implants no impact of our research could be seen while in the area of liquor-diagnosis the research must be considered as an argumentation help, which points out the importance of diagnosis techniques for Morbus Alzheimer.

All cases of accompanying research show, despite the success anticipated by technology research, the problems of social scientists not to be "swallowed up" by the project as being pure market research, but to keep a distant view, that of the consumer or the society.

Difficulties and Questions

Being an equal partner

While the accompanying research was performed under the aegis of the TU-Institute for "Technology & Society" and was understood as a service of an equal partner for other TU-Institutes, a further focal point emerged increasingly: in the course of investigating the state of the (international) research and the market and consumer needs, it turned out that not all research-programs met international standards. One research group worked on extending their expertise without taking a change of direction into consideration, although external factors, such as pressure towards higher efficiency in the health services or aspects of increasing the quality of patients´ lives through less invasive interventions called for it. In this specific case the use of artificial (exchangeable) implants that were internationally more and more replaced by biocompatible implants was kept. Here the possible task of accompanying research to serve as a future-oriented advisory and corrective service to technology and research policy became quite clear. But here we felt also the tension of being an equal partner who claims to know better than the experts what was the state-of-the-art in the respective area.

The stakeholders position

While the questions the research groups formulated themselves concentrated on marketing issues we saw our task in introducing additional perspectives. Especially social acceptability perspectives and an account of the interests of involved actor-groups were further aims. In two of the four cases the introduction of interests of patients, physicians and/or health care staff was possible while in one case this matter of concern failed. The fourth case (Liquour-Diagnosis) did not involve such demands.

We saw our position as mediators of the interests of various groups as absoultely necessary. It had already been difficult to develop dialogue forms between the different scientific cultures. Additional communication requirements would most probably not have been accepted. So we might see this as a successful strategy to introduce various social interests into this process.

Still the question arises what different kinds of results were to expect in case of direct involvement of concerned individuals. Besides possible impacts on the shaping of technologies there is to expect a sensibilisation process for the concerned individuals. Health and maintenance of health depend as well on the mental state of patients as on the doctor's stillness. A strengthening of patients’ consciousness to more self-determination must especially in Austria be regarded as a valuable contribution to public health care.

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