Theoretical and Empirical Aspects of the Assessment and Practice of Alternative Medicine
The main purpose of this dissertation is to elucidate the problem of assessing and providing alternative medical technologies. The purpose is divisible into three parts: 1. To investigate the bases of assessment for the acceptance of an alternative medical technology; 2. To investigate the professional and ethical problems connected with the practice of alternative medical technologies and find out whether the views of laymen and physicians differ with regard to the provision of treatments which are not in accordance with science and proven experience; 3. To investigate the interest physicians have shown in alternative medicine and the motives for this interest.

These investigations are based partly on a study of the literature on alternative medicine dealing with the effects of the following alternative medical technologies: manipulation therapy, acupuncture, reflexio (zone) therapy, homoeopathy and magnetic therapy, and partly on empirical research into the attitudes expressed by doctors and patients towards non-scientific treatments.

The results of these studies show that the acceptance of empirical data cannot be separated from the scientific paradigm within which the investigation has been planned. The documentation of the effect of alternative medical technologies is often empirically insufficient and based, in many instances, on so-called "personal experience". The interest shown by accredited physicians in alternative medicine is often motivated by the fact that certain complaints brought to them by their patients cannot be rectified by academic medical methods. The study also shows that physicians have professional interests which the patient is not prepared to respect in the same way as the physician is prepared to respect the right of a patient to refuse to undergo life-saving medical treatment.

The main conclusion is that alternative medicine is a heterogeneous field where the interest expressed can be interpreted as a crisis phenomenon and an indication of the need for the assessment of alternative medicine as well as academic medicine. Laymen perceive the ethical and professional problems connected with the practice of alternative medicine relatively differently when compared to physicians. The possibility of scientific co-operation between practitioners of alternative medicine and academic medicine is difficult due to the fact that alternative medicine and academic medicine relate to different scientific paradigms. Clinical co-operation in the case of individual patients, on the other hand, is likely to occur.

Key words: alternative medicine, placebo effect, technology assessment, non-scientific treatment, professional ethics, layman's perspective.
Theoretical and Empirical Aspects of the Assessment and Practice of Alternative Medicine

by

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Umeå 1991
ABSTRACT

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This thesis is based on the following papers, referred to in the text by their Roman numerals:

Paper I.

Paper II.
Lynöe N. The Role of Personal Experience in Scientific and Clinical Practice – With Special Reference to Alternative Medicine. Manuscript.

Paper III.

Paper IV.

Paper V.
Lynöe N. Ethical and Professional Aspects of the Practice of Alternative Medicine. Submitted.

Paper VI.
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**ORIGINAL PAPERS:**

I. Theoretical and Empirical Problems in the Assessment of Alternative Medical Technologies.

II. The Role of Personal Experience in Scientific and Clinical Practice – With Special Reference to Alternative Medicin.

III. Is the Effect of Alternative Medical Treatment Only a Placebo Effect?

IV. Physicians and Alternative Medicine – An Investigation of Attitudes and Practice.

V. Ethical and Professional Aspects of the Practice of Alternative Medicine.

VI. Placebo Treatment – An Investigation of Attitudes and Motives among Patients and Physicians.
The present study takes as its point of departure a problem which was articulated by the Committee on Alternative Medicine in 1986, to wit: Should the Committee initiate research into various alternative medical technologies, or should they instead audit the relevant international literature? The Committee opted for the latter solution, and the Department of Social Medicine at the University of Umeå was given the task of creating a compilation of the most common alternative medical technologies in Sweden.

Eventually, the assignment embraced an assessment of the literature on manipulation treatment (as practiced by chiropractors, osteopaths, etc.), acupuncture (including the traditional Chinese, so-called "cook-book" acupuncture, electro-acupuncture and ear acupuncture), reflexio (zone) therapy, homoeopathy and magnetic therapy. Furthermore, we were charged with analysing the placebo problem in relation to the claim that the effects of alternative medical treatments are merely the result of the placebo effect. The assignment was carried out by the present author, in co-operation with Professor Lars-Olov Bygren, and the results are part of a special report comprising part of the final report of the Committee on Alternative Medicine, prepared during the autumn of 1989 (SOU:1989:63).

Neither Lars-Olov Bygren nor the present author were or are primarily interested in alternative medicine, although both considered it an exciting field for a health care research project. Assessment of the alternative medical literature proved to be a comprehensive task; through information retrieval and via other channels we retrieved and examined upwards of 10,000 abstracts and articles. It soon became clear that assessment entailed meta-theoretical considerations, mainly of a philosophical nature.

The background to the government of Sweden convening the Committee on Alternative Medicine was the apparently paradoxical development in the health care services during the last twenty years. With new legislation regulating the participation of laymen in the health care services (the so-called "Quackery Law" of 1960), the government sought to limit the opportunities for unqualified persons to treat people who are ill. It also sought a reduction in the need for the involvement of laymen, by planning to expand the public health care system (e.g. by increasing the number of physicians in the country). In 1915, there were 1,400 qualified physicians in Sweden, and the number of unqualified persons (mainly homoeopaths) was estimated at 150. By 1951, there were 4,900 physicians and approximately 500 unqualified practitioners, and in 1986, 25,000 physicians and approximately 2,500 practitioners of alternative medicine. Since the most recent legislation on the involvement of laymen in the practice of medicine (passed in 1960), the number of physicians has tripled; one might thus assume that the need for practitioners of alternative medicine would have shrunk in proportion to that trend, which was accompanied by a corresponding expansion in the number of hospitals, health care centres and other health care institutions. However, the proportion of non-qualified practitioners has in fact remained constant, around ten per cent since the turn of the century (1). Interest in alternative medicine and treatments by
laymen had previously been interpreted as a lingering expression of the fact that consumers are unenlightened, perhaps even uneducated. The availability of information throughout the last thirty years cannot be said to have degenerated, and the international literature indicates that those who seek alternative medical treatments nowadays are not unenlightened and anything but uneducated. This trend and these conditions are apparently paradoxical, and indicate the appropriateness of a closer investigation.
1 INTRODUCTION

1.1 General Introduction

The assessment of a medical technology usually comprises an assessment of the efficacy, safety and cost of the technology in question (2). If a medical technology has been developed within the biomedical paradigm, the acceptance of such a technology is seldom controversial, as long as it meets the elementary requirements of efficiency documentation, safety and cost. If it is a case of the assessment of the efficiency of a medical treatment, for example, then documentation in the form of controlled clinical trials is usually required today (3). The safety aspect is directly related to the question of whether or not a technology is risky, and whether the risk can be counterbalanced by therapeutic gains. Since the clinical testing of a new medical technology is usually performed by specialists who will themselves be employing the technology in the future, the matter of who should be allowed to practice the technology in question rarely leads to controversy.

If a medical technology is not developed within the biomedical paradigm, then acceptance does not follow exactly the same route. The demands for efficiency documentation become more pronounced and the question of whether an alternative medical technology can be accepted actualizes instances in the assessment which in normal circumstances are tacit and taken for granted (this is discussed in papers I and II). The question of who shall or ought to be allowed to give or not give an alternative medical treatment also leads to controversies of a scientific, professional and ethical nature, discussed in depth in papers IV and V. Other problems which are theoretically and empirically elucidated in this dissertation concern some of the myths and prejudices which have flourished around alternative medical technologies and their practitioners. The claim that the efficacy of alternative medical technologies is based solely on placebo effects, and that all practitioners of alternative medicine are quacks, is investigated and problematized in papers III and IV. As early as the turn of the century, it was stated that "Placebo giving is quackery" (4); however, even if one can distinguish between quackery and academic medicine on the basis of the biomedical paradigm, the question arises as to how the physician and his patients conduct themselves in practice towards placebo treatment or alternative medical technologies. This is dealt with in papers IV and VI.

1.2 Science and Proven Experience

The rationality ideal of academic medicine is today built up around a concept which is known in Sweden as "science and proven experience" [vetenskap och beprövad erfarenhet]. It is in that concept that research and clinical practice converge, and it is that concept which makes it possible for the physician to draw the demarcation line between academic and alternative medicine. According to the Regulations for Physicians and the Swedish Medical Association's regulations, medical diagnosis and
treatment must be in accordance with "science and proven experience". A similar view of medical knowledge goes back to at least Hippocrates (460–380) and is linked with the development of professional interests (5). The concept of science is relatively new and thus also the concept of science and proven experience (6,7). Although the concept of science and proven experience is most often apprehended as a single term, it is comprised of two distinct concepts: 1) science, and 2) proven experience. One does not say that treatment is in accordance with science or proven experience, even if a medical procedure occasionally is only in accordance with proven experience or at other times is only in accordance with science. There are a number of different interpretations of the concept, and it is almost impossible to define it with the aid of criteria alone. Formally, the term science and proven experience has a legal significance insofar as the Medical Responsibility Board (Swedish acronym: HSAN: Hälso och Sjukvårdens Ansvarsnämnd) is the authoritative body in Sweden which in the final analysis decides whether or not a procedure is in accordance with science and proven experience (8,9). However, it is not the legal definition on which we wish to focus here, but rather the expert judgements which form the basis for HSAN's decisions. These judgements are made and formulated by a competent clinicians who are specialists in the field involving the matter under investigation. The definition of the concept of science and proven experience is thus also based on a consensus which socializing in a common clinical thought and reference framework leads to (10).

We can clarify the meanings of the concept of science and proven experience by analysing typical cases, by studying borderline phenomena and by contrasting the concept with its antitheses, e.g. quackery, alternative medicine, personal experience, pseudo-science, untested treatment, fraud, cheating, etc. A clarification of what the concept embraces can also be aimed at by investigating just what it is that should be in accordance with science and proven experience. It is, for example, not only a treatment which should be in accordance with science and proven experience; the analysis, the diagnosis of diseases, and the health care should also be conducted in accordance with science and proven experience – this means that clinical thinking should take place within a rather fixed framework. Even if there is a large measure of clinical freedom, there are limits and frameworks which only become clear once they have been traversed. All accredited health care personnel are included in the stipulation that examination, treatment and care must be in accordance with science and proven experience. In what follows below, we shall focus on the significance which the concept of science and proven experience holds for those actions in which physicians are involved.

1.3 Meanings of "Science and Proven Experience"

It is possible to clarify at least two possible meanings of the of concept science and proven experience. A medical technology might be in accordance with science and proven experience with the meaning: "being in accordance with the biomedical
paradigm"; and a technology might also be in accordance with science and proven experience with the meaning: "in accordance with current clinical consensus". The paradigmatic meaning implies among others that "science" is contrasted with technologies and techniques which have been derived from, or can be traced back to, medical science. Here the term "science" has the meaning of "biomedical paradigm" with its theoretical suppositions, group obligations, and methodological preferences (11). According to the Kuhnian paradigm concept, the degree of practical competence possessed by the researchers (and the clinicians) should also be included. This is comprised of personal experience and tacit knowledge developed by the researcher during long-term practice within the field of research in question.

With this meaning of the concept of "science", a reference to the concept of "personal experience" can also indicate such practice as is not actually based on the paradigm, but which despite this is accepted for the moment anyway. Within the limitations of the paradigm there is room for a number of considerations which are not empirically verifiable or which perhaps have the character of tacit knowledge or personal experience. Thus, the concept of personal experience also represents the theoretically non-communicable/verifiable and the difficultly-communicable/verifiable.

The concept of proven experience relates to such practices, techniques and technologies which have been tested empirically under controlled conditions. But the concept might also relate to a technology which is verified over a shorter or longer period. It may relate to technologies or practices which have been employed for a long time, but where practice is based more or less on the personal experience of medical authorities, for instance (12).

The other meaning of the concept of science and proven experience is the pragmatic one. For example, if a treatment is in accordance with science, then this means that the technology has been empirically tested under controlled conditions. In this case the concept of science might be built on a black-box-rationality, which means that the nature of the technology assessed is in principle of no importance (13). According to this way of thinking, the concept of "proven experience" becomes applicable to such technologies and techniques as have not necessarily been tested empirically or under uncontrolled conditions: i.e. the technologies and techniques applied is based on the current clinical consensus. If this meaning of the concept had dominated the biomedical paradigm the problem of assessing alternative medical technologies would have been almost negligible.

According to the paradigmatic interpretation of the concept of science and proven experience it is possible to illustrate why it can be difficult to get a new medical technology accepted, and simultaneously, why it can sometimes be hard to abandon a tried but unspecific treatment. The pragmatic interpretation of the concept of science and proven experience does not make it possible to understand the non-empirical resistance to alternative medical technologies. Thus, this dissertation is based on the paradigmatic interpretation of the concept of science and proven experience.
1.4 Medical Science and the Health Movements

With the introduction of medical education at the universities in the fifteenth century in Europe, we see a delineation between medical "science" and practice, i.e., knowledge and the art of healing, and we observe a shifting of emphasis away from the art of healing towards medical science (14). The relationship and balance between the pairs of concepts – medical science/the art of healing and science and proven experience – can immediately be seen. How far this is indeed the case depends entirely on the significance one assigns to the two pairs of concepts. There has been a tendency to rationalize and to associate the art of healing with the pre-scientific, the speculative or the obsolete view of medical treatment, and to associate medical science historically with the ambition to find natural causes for diseases with the help of empirical investigations (15). The natural-philosophical tradition in medicine goes back to Hippocrates, but even if Hippocrates is still a prominent figure today, as a father of modern medicine, much of his advice and many of his proposals for treatment are controversial in terms of the findings of modern science (7,14); proposals concerning e.g. health care and health information today do not fall as clearly within the domain of medical science. Rather, these areas come under what we would call the traditions of the health movement (16). In the past 150 years, the history of the health movement also seems to have been a history distinct from that of medical science. Even if some of the recommendations for treatment have more or less been incorporated into medical science, the health movement is still seen as more of an alternative medical movement. The reason for this is that, while medical science has become specialized and developed into so many various sub-paradigms, the health movement has retained a general perspective on disease and its causes (7,16). Representatives of the health movement have often been laymen, such as the lawyer Edwin Chadwick in nineteenth-century London (7,14). In Sweden, one of the best-known health prophets, Are Waerland, was not a physician (17). With the growth of modern medicine, physicians who have shown an interest in the health movement's programme have been regarded with scepticism by their colleagues (7,16).

1.5 Professional Interests

The patient-physician relationship evolved away from paternalism towards a relationship which implies an increased respect for the right of the patient to be given adequate information in order to be able to make a decision himself. This development is partly the result of a changed view of the position of the individual in society, a democratization of the patient-physician relationship (18), combined with ethical considerations which have become actualized as research has become a more and more important component of health care.

The Hippocratic codes of professional ethics, which regulate the relationship between colleagues and the physician's relationship with his mentor (and his mentor's children)
and his own students is in some way ill-suited to our era, during which the education of physicians has been a more or less public matter ever since the fifteenth century (14). According to the writings of Hippocrates, not everyone could become a physician or was a suitable candidate for the medical profession. In today's medical education too, there are special criteria for acceptance - which, however, cannot automatically be considered to be suitability criteria. The vow of silence did not only apply to the physician's relationship with his patients, it also applied to people who were not initiated into the medical arts (19). The Graeco-Roman physician, Galen (129-199) was one of the first in the West to write down the accumulated knowledge of the time in a more systematic manner. His influence on medical education was felt for nearly fifteen centuries - not only as regards content, but also as regards language. Thus, the language of medicine became Latin (with Greek loanwords), and in this manner, medical knowledge could be kept secret from the uninitiated throughout the Middle Ages. As far back as the time of Hippocrates, there were medically uneducated individuals who treated the sick, and even then, the medically qualified found it appropriate to distance themselves from so-called "quacks" (21,22).

During certain long periods throughout history, the physician has been an entrepreneur. At such times, there has been a perceptible dilemma between the humanist ambition to help sick and needy fellow human beings, regardless of their ability to pay, and the harsh necessity of making a reasonable living. The physician must somehow be paid for his services, no matter how much of an idealist he is. Thus, in such situations, the physician must sell his services (knowledge and skill) in the marketplace, competing with other physicians. This type of competition among physicians is regulated in different ways, e.g. with regard to the manner in which one may advertise one's services and skills (5,7). With the specialization of medical knowledge (and with it the medical profession), this type of competition has been further regulated in such a manner as to imply that a physician ought not initiate a treatment which lies outside his own area of competence (7,23). In such cases, the physician should refer the patient to a competent colleague who possesses the relevant knowledge. A physician who goes outside his own specialty and area of competence in the treatment of a patient exposes his patient to the risk of harm - that is to say, the development of knowledge and competence within one's specialty, and professional awareness of the limits upon that competence, have ethical implications (24). In a society where the physician is an "entrepreneur", or where health care is a private business, it can be important for the competition among physicians to be regulated. In a society where health care services are largely maintained by society, the need for regulation is less critical. The risk that a physician will "hold on to" a patient unnecessarily is minimal. (On the contrary, there might be a risk that in certain cases, the physician will refer the patient to another specialist unnecessarily or with undue haste). However, something which has always been controversial among physicians is the treatment of sick people by non-physicians, whether or not these are paid to do this.
People without medical education who treat the sick are referred to as "quacks" by physicians and by society as well nowadays, and the types of treatments provided by these individuals are known collectively as "quackery". A quack can be an individual who is self-taught and who does not possess any formal education whatsoever, or an individual with relatively extensive education (25). As far back as the seventeenth century in England, the barber-surgeons and serious apothecaries, groups which we today would call "fringe", attempted to distance themselves from the more "traditional" sorts of quacks (21). Both of these groups are incorporated as important disciplines in today's health care system. Surgeons were accepted on an equal footing with the ordinary medical specialists as early as the 1800s.

Today, quackery is allowed in connection with the treatment of certain types of diseases and age groups, but is illegal in other instances. In seventeenth-century Sweden, an initiative was taken to regulate the activities of quacks (1). Quacks offer their services in the same marketplace as physicians and can be seen as a threat to the livelihood of physicians. Physicians presume that the knowledge they possess guarantees that their patients receive adequate treatment. And that knowledge is based on what we today would call science and proven experience. The educational and scientific ideal of physicians is based on a shared understanding of the concept of science and proven experience, and it is thus the knowledge which is developed around that concept which distinguishes the physician from the quack (23). One way to describe a quack is to say that he is well aware of the fact that the diagnoses he makes are pseudo-diagnoses, and that the treatment he provides is ineffectual. According to this description, the quack is a con-man, and there are many examples of such individuals in the history of medicine (21,22). Another, more positive description of a quack is that he himself believes in his knowledge and in the efficacy of his treatments. This group is usually made up of individuals who have received a shorter or longer education within one or several schools of alternative medicine (25).

1.6 The Authority of the Medical Profession

The trust which society has placed in the medical profession today by giving only physicians who have undergone special academic education the right to treat the sick is based on the traditions of education and knowledge which have developed among physicians over an extensive period of time (23). Physicians have not always enjoyed such elevated status in society. During antiquity, all forms of physical labour were considered unworthy of a free man, and even though the physician was considered necessary, his profession was not regarded as a particularly refined one. In the Roman Empire, many physicians were imported from Greece, and had the same status as slaves (14). It was not until medicine was introduced into the universities that the prestige of the physician increased. Association with the universities meant not only that the reputation of the physician was enhanced; it was also a condition for the development of medicine as a profession. Association with the universities created a more uniform
educational and scientific ideal. Under the supervision of the Church, control over what was taught at the various universities was established, thereby assuring conformity: in other words, primarily the Church-approved galenic theories (14). The galenic teachings were, like the theories of Aristotle, canonized and elevated to the status of Church dogma, and therefore were difficult to challenge. The task of the professors of medicine was to interpret and explain the teachings of Galen, not primarily to seek out new knowledge (14).

On the one hand, the university connection meant that physicians in general enjoyed greater status, but on the other hand it also meant that the distance between theory and practice increased. The academics (ie., physicians with a university education) developed a contemptuous attitude towards practising physicians. Up to the seventeenth century, physicians who studied Galen in the library enjoyed a higher status than those who studied the sick in their sickbeds. The increased dichotomy between theory and practice also contributed to the fact that practitioners (including barbers, apothecaries, "old wives" and others who treated patients) became all the more popular among the lay populace.

Thus the academic ideal can be said to have contributed, on the one hand, to increasing the academic reputation of physicians, and, on the other, to sending patients into the arms of less medically qualified individuals. This situation has recurred at different periods in the history of medicine, and even after people came to terms with Galen's teachings a biomedical research tradition developed. During the development of modern medicine in the nineteenth century, not only were new discoveries made and a new medical paradigm developed; the settling of accounts with the galenic paradigm also meant settling accounts with treatments which can only be considered rational when viewed against the backdrop of the galenic teachings. Apart from galenic pharmacopy, which consisted of over 800 different preparations, blood-letting, cupping, enemas, treatment with purgatives – all methods which were bound to galenic humoural pathology – were also abandoned (26). Even if physicians gained a more correct understanding of the nature and cause of diseases, the trend did not contribute to the simultaneous development of new methods of treatment. On the contrary, during the nineteenth century a so-called "therapeutic vacuum" occurred (7). In other words, physicians could make more adequate diagnoses and even prognoses, but they could rarely prescribe or offer adequate treatment. This contributed to certain forms of alternative medicine winning new adherents among people in general. In the field of academic medicine, it was not until the end of the nineteenth century and the beginning of the twentieth that there were real developments in treatment. It is in particular the development of microbiology and the possibilities thereby engendered for preventing infection through e.g. vaccination which gave the physician something to offer his patients (7).
1.7 Critical Situations

Despite the state of powerlessness physicians found themselves in vis-à-vis treatment during the eighteenth century, it is important to note that it is this period which laid the foundation of modern medicine and the many rational treatments which are available today. It is characteristic of this era that it was pointed out that physicians should not allow themselves to be tempted to provide a treatment which was not in accordance with science and proven experience, merely in order to satisfy a patient's request (4). It is among other things the knowledge of the limitations of their competence and the possibility of curing which distinguishes physicians from the uneducated, the quacks (28). Even if in those cases where he cannot cure a physician should attempt to relieve and give comfort, he may not (even if he is doing so in an attempt to comfort the patient) provide a treatment which is not adequate for the condition to be treated. The physician ought not (not even in order to comfort) lead the patient to believe that there is a treatment which can cure him when in fact such a treatment does not exist. Nevertheless, in situations where the physician finds himself in a position of powerlessness vis-à-vis treatment, it can be tempting for him, in order to do something, to provide treatments which are not in accordance with science and proven experience (paper V).

Another type of perceived powerlessness can arise if the physician with his medical knowledge cannot understand or explain the problems which patients come to him with, or has no treatments to offer them. In such cases there is a discrepancy between medical knowledge and the problems and symptoms of the patients. This type of situation can be described as critical (27,28). In periods when physicians stand powerless in the face of a variety of complaints which cannot be diagnosed, and prognoses cannot be made, the way is paved for an interest in alternative medical treatments and cosmologies. This interest blossoms not only among laymen and patients in search of help – physicians too may turn their interest towards alternative medicine (paper VI). In such critical periods the opportunities are rife for quacks to find a demand for their treatments in the therapeutic marketplace. Furthermore, there is also the risk of the creation of sects and eclecticism among regular physicians. It is against this background that one must see the creation of medical associations and societies, the Royal College of Physicians in London in 1518 (21), and the later establishment of the American Medical Association (AMA) (23), and many other medical associations and societies. Thus, when the AMA was established in 1848, it was not only an attempt to join the fight against quacks, but also an attempt to put an end to increased sectarianism among physicians (23). Even though the AMA is primarily a physicians' union, it is through the AMA that a common educational and scientific ideal is achieved. A prerequisite for being accepted as a member of the AMA, and for remaining one, is that a physician has to have undergone a special education and that in his practice he adheres to the knowledge and ideals with which he was instilled during his education. It is probably no coincidence that it was in the United States at the turn of the century that an educational ideal was developed which became exemplary for the education of physicians in most of the western world.
and which, with certain modifications, still applies today (29–31). In the United States, the concept of medical science quickly acquired a technical and professional significance, while the scientific medical society (The Swedish Society of Medicine) in Sweden long attempted to distance itself from the professional and technical interests represented by the Swedish Medical Association (SMA). When the SMA was established at the beginning of this century, the contents of the members' new journal consisted of reports from provincial physicians on one or another local quack's activities. In Sweden today the difference between the viewpoints expressed by the SMA and the Swedish Society of Medicine has diminished. For example, if one examines the argumentation put forth by both instances in connection with the proposal to accredit chiropractors in Sweden, one finds that the arguments are almost identical, both as regards professional and scientific content (32).

It is of principle importance to differentiate between the medical profession's attitude towards, on the one hand, the creation of sects and the occurrence of eclecticism within its ranks and, on the other hand, its relationship to quacks or other professional groups who wish to secure themselves a place in the health care system. Even though the number of trained and untrained practitioners of alternative medicine is estimated at almost 2,500 in Sweden (1989), this group does not yet comprise any real threat to the professional sovereignty of the medical profession (1). However, the interest in and practice of alternative medicine among accredited physicians can be seen as a threat to the medical profession's long-term interests. According to the sociologist Paul Starr, it is precisely by virtue of the fact that the AMA succeeded in establishing unity with regard to its educational and scientific ideals that the medical profession achieved the cultural authority which has made physicians almost entirely sovereign concerning the matter of who should be allowed to treat people who are ill (23).

1.8 The Alliance Between the Medical Profession and Society

According to Paul Starr, society has delegated responsibility for health care to the medical profession, while, at the same time, physicians have become society's loyal servants. The physician has many different functions – he can determine whether a patient needs to be examined, admitted to hospital, needs treatment, should go on sick leave, receive disability pension, be compensated for e.g. an industrial injury, be exempted from military service; he decides whether a refugee should be granted asylum or be deported, whether an addict should receive compulsory institutional care, whether a person who has committed a crime should be punished or treated, etc. In other words, the physician fulfils many significant functions for society (23).

Against the background of the original purpose of such organizations as the AMA and what has been achieved with it, one can perceive the creation of sects and dissent within the ranks as the greatest threat to the fundamental interests of the medical profession; nonetheless, it is most often the case that the medical profession reacts most strongly when other professional groups come knocking on the door of the health care system.
Some form of professional protectionism seems to exist and not only in the matter of who is to be allowed to provide treatments which have previously been classified as alternative medicine (e.g. manipulation treatment and acupuncture). Professional protectionism has been actualized even in early stages in the history of medicine, e.g. as in the question of barber-surgeons, apothecaries, midwives, nurses, dentists, etc. There have also been controversies this century surrounding the incorporation of psychologists, speech therapists and psychoanalysts into the health care system. The attitude of society towards "old wives" during the middle ages, when these women were burned at the stake as witches, has been interpreted by feminist researchers as the result of an "unholy" alliance between the representatives of the Church and physicians, who felt that their professional interests were being infringed upon. The "old wives" often functioned as local doctors in the rural areas, which suffered from a lack of physicians. These women secured a bad reputation for themselves, not among ordinary folk, but rather with the authorities, especially in their role as midwives, birth-control consultants and abortionists. Control over reproduction has always been a controversial matter for the Church, not only because of the view of the fertilized ovum, the foetus and the status of the child, but also because human control and regulation of reproduction was considered a way of opening the floodgates to dissolution and immorality. When "old wives" acted as abortionists and birth-control consultants, the representatives of the Church were interested in stopping their activities and classifying them as witches. How active a role physicians actually played in this context is, however, still unclear.

The resistance of physicians to uninitiated representatives of alternative medical treatments has often been more vociferous when these representatives were not physicians themselves and represented a radically different world view and epistemology. The founders of both osteopathy and chiropractics were not physicians, and both construed their own particular theories on human physiology and the ultimate causes of disease. It is probably against this background that one should view the powerful reaction to chiropractors which is still to be seen today, even though many chiropractors have abandoned the classical chiropractic teachings. When a treatment is advocated by a non-authorized individual (a quack) who fails to refer to any of the alternative medical technologies (as, for instance, certain "bone setters" in late nineteenth-century England), even a prominent physician can be moved to comment positively on such treatments. Thus, the English surgeon Sir James Paget recommended in 1866 that his colleagues "learn to imitate what is good and avoid what is bad in the practice of the bone setters".

1.9 Homoeopathy

Paracelsus (1494–1541) was the person who was responsible for the break with the galenic theory of disease, which was eventually completed by the end of the nineteenth century. Despite the fact that Galen's teachings were still in currency up until then,
other therapeutic cults sprang up during the intervening period. One of these was homoeopathy, as formulated by the German physician Samuel Hahneman (1755–1843) (42). The difficulties involved in the assessment of alternative medical technologies can be illustrated by means of the homoeopathic treatment principle, which is a typical example of an alternative medical technology which is unacceptable to the practitioners of academic medicine. In order to contrast the difficulties of accepting homoeopathy, the arguments for accepting acupuncture will be presented in the following part (1.11).

The starting point for Hahneman was the feeling that the treatments recommended for patients often led to more harm than good. Treatments such as blood-letting, vomit-inducement and purging were not only unpleasant for the patient; blood-letting in particular often led to death, apparently as an immediate result of the treatment. The methods were drastic and risky and Hahneman found himself undergoing a crisis of conscience when he attempted to reorient himself with the guidance of the Hippocratic principle, which stated that the main responsibility of the physician was not to cause his patients any harm (primum est non nocere) (5,19). What put Hahneman on the right track to what would eventually become his new system was that cinchona bark, which was then a known remedy for malaria, when given to a healthy person in large doses could lead to malaria-like symptoms. Hahneman experimented with this on himself, and then formulated what was to become the leading principle in homoeopathic treatment, "like cures like" (the law of similars). A given medicine is effective against a given symptom if the same medicine can give rise to the same symptom in a healthy individual (42). According to Hahneman the law of similars was a law of nature. With this in mind Hahneman tested a large number of medicaments on himself, his friends and acquaintances. Hahneman initiated the practice of homoeopathy in 1790 and by the turn of the century upwards of 1,500 homoeopathic preparations were already in existence.

Apart from the likeness principle, which gave homoeopathy its name, there was another principle, the dilution principle, or, as homoeopaths themselves prefer to call it, "potentization". If the likeness principle is controversial, then the dilution principle is even more so. The dilution principle also developed a desire to ensure that medical treatment above all else should not harm the patient. Hahneman had observed that a homoeopathic preparation chosen with the likeness principle in mind rarely gave rise to powerful side-effects in the patient. He therefore tried to reduce the dosage by diluting the homoeopathic medicament. Hahneman found to his surprise that homoeopathic medicaments were effective even when diluted in concentrations which, according to prevalent chemical and pharmacological theories, could not possibly have any effect (43,44). Through a special dilution procedure with repeated stirrings after each dilution, Hahneman seemingly found that homoeopathic treatment not only brought about reduced side-effects, but that the procedure also meant that the efficacy of the homoeopathic preparation increased with continued dilution. Dilution was thus considered to cause a potentization of the preparation.
In addition to the likeness principle and the dilution principle, homoeopathy is also based on a principle of monotherapy; i.e., may be given only one treatment at a time – one and only one treatment for each, individual symptom. Should the symptoms change from one day to the next, then the treatment itself must also be changed (42).

According to homoeopaths, diseases of the Galenic sort do not exist. A disease symptom in the galenic meaning, e.g. fever, is actually the symptom of an imbalance among the underlying body fluids. For a homoeopath, only symptoms exist, i.e., such phenomena as can be observed. For a homoeopath, too, theories about underlying disease processes (regardless of whether they are due to an imbalance in the composition of the blood or a pathological process of an anatomical or physiological character), are pure speculation (42). The furthest a homoeopath is willing to go concerning theories of the nature of symptoms is an assumption that a symptom is an expression of a healing reaction. This assumption is based on the idea that the human body, except in the case of the dying (moribund) patient, has a built-in, natural healing capacity. Thus, the aim of homoeopathic treatment is to strengthen the body's natural healing reaction. This is also why homoeopaths feel that a homoeopathic preparation initially strengthens the symptom somewhat. A slight worsening of the symptom as a result of homoeopathic treatment is thus considered to be an indication that the homoeopath has chosen the correct treatment. The homoeopath considers that, through his treatment, he mobilizes and strengthens the body's own healing capacity. Furthermore, the homoeopath considers that that form of curing is the single most radical form of medical treatment, since there is no such thing as a shortcut to health; if one has fallen ill, the only way to become well again is by fighting one's way back along the same route along which one became ill. Thus homoeopaths consider academic medical treatment (so-called "allopathy") to be mere symptom treatment, and in certain cases directly harmful. Modern medical treatment is seen as inhibiting the natural healing process; cf. e.g. treatments with beta-blockers, antibiotics, antihistamines, antidiabetics, etc. Homoeopathic treatment sets out, according to modern interpreters of homoeopathy, to cure the patient in a natural and more radical manner. Academic medical treatment (allopathy) also means that a patient can be treated with several different treatments simultaneously, which is contrary to the homoeopathic principle of monotherapy.

Homoeopathy was relatively popular when it first emerged, both among patients and physicians. Interest in homoeopathic treatment persisted among certain physicians in Sweden right up to the beginning of the 1920s (45). Interest in homoeopathy has always been particularly great among members of the upper classes; there is an interest in homoeopathy in the English royal family, who have a homoeopath among the court physicians (46). The renewed interest in homoeopathy in today's modern society is most likely at least partly due to scepticism concerning the modern project's rationality ideal, and partly to an increased curiosity about so-called "natural solutions" (the Green Wave, New Age, etc.) (47). A significant reason for homoeopathy winning adherents even among prominent physicians during the nineteenth century was not only because
homoeopathy was an attractive form of treatment from the perspective of the patient (few side-effects), but because homoeopathy was and is still based on an almost entirely empirical view of knowledge, a view which corresponded well with the positivist scientific ideal which burgeoned during the nineteenth century in a number of different branches of science (48,49).

The reason that homoeopathy ultimately failed to catch on and emerge victorious from this scientific confrontation is that during the same period, modern medicine was in the process of taking shape. The growth of the French school at the beginning of the nineteenth century, the English (Scottish) school and the contemporary German school meant that Hahneman's new system was never really taken seriously (7). When the microbiological paradigm of Louis Pasteur (1822–1895) and Robert Koch (1843–1910) became established at the end of the nineteenth century, homoeopathy became less and less attractive (7,45).

1.10 Homoeopathy and the Placebo Effect

The answer to the question of why treatments such as homoeopathy are today classified as alternative forms of medical treatment contributes to our understanding of the significance we give the concept of science and proven experience. With the rationality ideal of modern medicine in mind, we must classify homoeopathy as alternative medicine. Homoeopathy is controversial for a number of reasons, one being that documentation of the efficacy of homoeopathic preparations is mainly built on Hahneman's and other homoeopaths' personal experience. Hahneman is an authority in the eyes of homoeopaths, and up to the middle of this century the personal experience of an authority was considered sufficient reason for accepting a medical technology (paper II). However, personal experience of efficacy can be riddled with mistakes. Personal experience is an important factor in both clinical and scientific contexts when we are concerned with that phase of the scientific process which we refer to as "the context of discovery", i.e., the phase during which we generate ideas and formulate hypotheses. But as an instrument for assessing the efficacy of a medical technology personal experience does not suffice. Personal experience is insufficient because sick individuals do not become healthy solely as a result of a given treatment. When a physician provides a treatment, the patient always has expectations that that treatment will help (or in certain cases, will not help). These expectations of becoming well or worse influence the healing process, in an as-yet unclear manner (paper III). In most cases the patient has positive expectations of being helped, which leads to a positive expectation effect, i.e., the patient becomes well more rapidly than in a situation where the physician either gives the patient no treatment at all, or where the patient has negative expectations (50). The expectation effect plays a role in almost all types of medical treatment and is referred to in its positive form as the "placebo effect". Placebo means "I shall please", and by that it is understood that the physician will please the patient (51). The placebo concept has its meaning clarified in connection with the fact
that controlled clinical trials became increasingly more accepted in the assessment of the
efficacy of medical technology around the middle of this century. Controlled clinical
trials are in many instances aimed at comparing a new medical technology with a
treatment which is biomedically ineffectual (2,3). The theoretically ineffectual
treatment can consist of e.g. a sugar pill (or dummy pill; in German, "Scheinmedikament"), and is referred to as a placebo treatment (paper III). Under as
controlled a form as possible (e.g. where neither the patient nor the physician knows
which treatment is being given), one investigates whether the group of patients who
received the hypothetically active preparation differs in outcome in a statistically
significant manner from the group which received the placebo treatment. In most
controlled clinical trials, it has been shown that those among the group which has
received placebo treatment, a varying number have become well. On average, around
30% of those tested who have received only placebo treatment become well, and the
effect achieved by means of placebo treatment is called the "placebo effect". The
placebo effect can range between 10% and 90% (paper III).

Thus it cannot be entirely ruled out that the self-healing power which homoeopaths
claim to mobilize and strengthen with their treatments is something other than the
placebo effect (52). It is impossible to distinguish a specific biomedical effect from a
placebo effect with the help of the personal experience of medical authorities.
However, it can be done if one uses a controlled clinical trial. In that medical
technologies base their efficacy documentation on the personal experience of
authorities, such documentation can and ought to be challenged, and many physicians
also take it for granted that the effect of an alternative medical technology is simply a
placebo effect.

But despite the fact that the efficacy of homoeopathic preparations in the treatment of
rheumatoid arthritis and hay fever, for example, has been tested in controlled clinical
trials (53,54), the British Medical Association rejected these trials with reference to the
fact that homoeopathy is founded on an incomprehensible dilution theory (45). The
dilution principle conflicts with fundamental presumptions in the natural sciences on the
relationship between dosage and response. The dose–response concept means that the
effect of a medicament increases with increased dosage within certain, well-defined
frameworks. This is a basic pharmaco–dynamic principle, which in turn rests on
theories concerning the chemical and physical nature of various substances (43,44). If
we were to accept homoeopathy, we would be forced to abandon a significant portion
of the fundamental principle upon which the biomedical paradigm is built. It is difficult
to put forward therapeutic hypotheses on the effect of homoeopathic preparations, even
if we attempt to understand such hypotheses as "bold" in the Popperian meaning of the
term. The majority of hypotheses on the possible effects of various medical
technologies are derived from biomedical theories and not from a black box rationality.
The fact that homoeopathy is controversial and is classified as alternative medicine, is
connected with the fact that: 1) the empirical documentation is largely based on
personal, non–controlled experience; 2) the dilution principle conflicts with certain
fundamental assumptions within the biomedical paradigm, which is why it is impossible to interpret empirical data from e.g. controlled clinical trials; and 3), homoeopathy refers to a romantic, obsolete conception of diseases. Homoeopathy is an example of a typical alternative medical technology which cannot be brought into accordance with the medical concept of science. Acupuncture is another type of alternative medical technology which, in contrast to homoeopathy, it has been possible to reinterpret and which has been accepted by academic medicine.

1.11 Acupuncture Assessed as a Medical Technology

Historically, homoeopathy is a relatively new phenomenon, whereas acupuncture is a technology with almost 2,000 years of history behind it (44). The reason that traditional Chinese acupuncture is considered controversial is roughly the same as for homoeopathy (44). Acupuncture is partly based on an understanding of disease and treatment which is completely incomprehensible to western medical thinking. Up to the beginning of the 1980s, empirical documentation of its efficacy was virtually nonexistent, or solely of an anecdotal and personal nature (58). However, in contrast to homoeopathy, it has proved possible to re-interpret some of the central precepts of Chinese acupuncture; at the same time, it has been possible to interpret some of the extant empirical data concerning the pain-relieving effect of acupuncture with the aid of modern pain physiology (paper I). The development of modern pain physiology (ie., the development of theories concerning underlying mechanisms which can explain how manipulation with needles at specific points in the skin can have an effect on the experience of pain (55) has probably had a decisive effect on the scientific status of acupuncture, and in that way, contributed to the fact that in 1982 the Swedish Board of Health and Welfare accepted acupuncture in the treatment of conditions of pain as being in accordance with science and proven experience (56,57). It was accepted at a point in time when empirical knowledge was still insufficient, and acceptance must therefore have been mainly based on theoretical grounds. The importance of the development of theories for the acceptance of acupuncture for states of pain is expressed in the British Medical Association's report on alternative medicine (48). Whilst the report rejects homoeopathy with reference to theoretical obscurities concerning the possibilities for understanding how homoeopathy works, it accepts acupuncture as a treatment for pain by using an argument from pain physiology. Traditional Chinese acupuncture is part of a classical Chinese philosophy, where the treatment of pain comprises but only a limited area of indication. Traditional Chinese acupuncture is one part of an entire cosmology, where the best-known concept pair is yin and yang, which, according to Taoism, can be used to describe both the harmony of the structure of the universe and the harmony within man. When imbalance occurs between the yin and yang within man, he becomes ill. Acupuncture is a technology which can be used to rectify an imbalance, but acupuncture can also be used to prevent diseases (44,46).
In Sweden, acupuncture is accepted only as a treatment for pain, and not for the treatment of diseases. However, modern neurophysiology has evolved rapidly during the last two decades, and today it is possible to explain and understand why acupuncture can have an effect on certain specified diseases. Interest in acupuncture has meant that empirical control has increased, and today, a number of controlled clinical trials have been carried out on the effect of acupuncture on certain diseases, e.g. bronchial asthma (58). One difficulty in the use of acupuncture in the West is that traditional Chinese acupuncture is based on its own disease classification system, which, in certain respects, is difficult, if not impossible, to be made to fit into the international classification of diseases. This can complicate the documentation of an effect and increase the risk of type-2 errors in connection with controlled clinical trials of acupuncture in the treatment of diseases (2,3).

2 GENERAL AIMS OF THE PRESENT STUDIES

- One of the aims of this dissertation is to investigate which criteria and factors are employed and are of significance in the assessment of alternative medical technologies.
- Another aim is to investigate exactly what it is that characterizes alternative medical treatments and, with the starting-point in academic medicine, investigate what it is that makes alternative medicine controversial. Thus, a clarification of what characterizes alternative medicine presupposes contrasting it with academic medicine. Although the direct purpose of this study is not to analyse the rationality ideal of academic medicine, it is impossible not to focus some attention on this subject indirectly.
- A common saying about practitioners of alternative medicine is that they are simply quacks. However, studies in other countries indicate that even physicians are displaying an increased interest in alternative medicine, and in certain instances have begun practising it. One aim of this study is to investigate to what degree accredited physicians in Sweden are showing an interest in and practising alternative medical treatments, and to shed light on the reasons for this.
- Along with the growing interest on the part of patients in alternative medicine, the results of this study actualize another problem: the ethical and professional aspects of practising alternative medicine. Another purpose of this study is thus to investigate these aspects theoretically and empirically.
- It is also said about alternative medicine that its efficacy is solely due to a placebo effect. One aim of this study is to investigate the plausibility of this claim, and to investigate empirically how laymen view placebo treatment (and non-scientific treatment) and compare this with the views held by physicians.
3 SUBJECTS/MATERIAL

The Theoretical Studies (Papers I, II, III, V)

The basis of paper I is an analysis of approximately 10,000 abstracts and articles on the efficiency and safety of alternative medical treatments, including manipulation treatment, acupuncture, reflexio (zone) therapy, homoeopathy and magnetic therapy. The literature was retrieved via MEDLINE, EMBASE and SOCA. Furthermore, we have obtained a large portion of the literature studied from more unofficial channels, including the Ministry of Health and Social Affairs and the Committee on Alternative Medicine.

Paper II is based on analyses of the research strategies which dominate studies of the efficiency of alternative medical technologies, including case studies, follow-up investigations and the personal experience of researchers of the effects of the technologies. Furthermore, this article is based on literature on the research process and the clinical decision-making process.

Paper III is based on the extant literature on controlled clinical trials and literature on the operative mechanisms of the placebo effect relating to certain alternative medical technologies with similar operating mechanisms.

Paper V is based on literature on the scientific, educational and ethical foundation of alternative medicine, plus a normative analysis of the professional and ethical aspects of two case histories. This study also contains the results of an empirical investigation of four hundred randomly selected physicians from the Board of Health and Welfare's register of accredited physicians. How this data was acquired is presented in detail in paper IV.

The Empirical Studies (Papers IV and VI)

The groups which are studied in paper IV are made up of a random sample of physicians (n=409, response rate 80%), from the Board of Health and Welfare's register of over 25,000 accredited physicians, and the total populations of physicians in two alternative medical physicians' associations. In one of the two alternative medical associations (the Association of Swedish Physicians for Biological Medicine), the number of members was 184 (response rate: 79%), and 98% of the physicians belonging to this group are accredited. In the other alternative medical association (the Physicians' Group for Anthroposophically Oriented Medicine), there are 44 members (response rate: 84%), 95% of whom are accredited physicians. The members of the two groups, as was the case with the randomly selected physicians mentioned above, were found to be evenly distributed geographically throughout Sweden. It has not been possible to undertake a closer analysis of the participants from the alternative medical associations, since we have not had direct access to the membership lists.

The groups investigated in paper VI consisted of fifty physicians randomly selected from a group of 150 specialists at a university and regional hospital, plus a random selection of fifty physicians out of a register of 190 general practitioners from the same
geographical area. The response rate was 94% for both of these groups. The answers provided by these two groups were compared with a consecutive group of patients recruited from a health care centre within the same area. A hundred participants received the questionnaire (response rate 83%).

4 METHODS

The Theoretical Studies (Papers I, II, III, V)

There are numerous different alternative medical treatments which are typical and controversial, each in its own particular way. One ambition of this study has been to isolate and elucidate some general features and characteristics of alternative medical technologies. One way to investigate what it is that characterizes alternative medical treatments and what makes them controversial is to investigate the criteria employed for accepting or rejecting them.

Another way of investigating the characteristics of an alternative medical technology is to contrast it with academic medicine. This makes it possible to identify a number of different implications and aspects of both alternative and academic medicine. Thus, the point of departure for the theoretical investigations has been a systematic description of the research methods used in the studied scientific papers on the effect of alternative medical technologies. Against the background of this process of mapping and systematizing of the alternative medical literature, a historical perspective of the phenomenon has been added.

The ethical problems connected with the practice of alternative medicine or with placebo treatment have been analysed from the perspective of the "actors" (59).

The Empirical Studies (Papers IV and VI)

In the two studies with an empirical investigative design, two populations were compared with one another with the aid of questionnaires. The questionnaire in paper IV is made up of a series of questions concerning age, sex, speciality and circumstances, and space is provided for indicating the alternative medical treatment(s) in which the respondent is interested and which ones are actually used by him. Moreover, there is a series of questions about who ought to be allowed to provide alternative medical treatment; in which situation a physician might consider giving alternative medical treatment or placebo treatment; and several questions concerning reasons for interest. These questions are presented in the form of statements which the respondent can grade on a scale of four options (agree completely, agree for the most part, disagree for the most part, disagree completely). Since not all physicians in the random selection from the Board of Health and Welfare's register could be expected to be interested in alternative medicine, the questions concerning motivating interest were placed on the last page of the questionnaire sent to these physicians.
The questionnaire on the attitudes of patients and physicians to placebo treatment (paper VI) is built around three case histories and arguments/statements concerning these cases (60). There is a distinction between rejecting or complying with a patient's request to receive alternative medical treatment or a treatment comparable to placebo treatment, depending on the patient's age, diagnosis, prognosis with or without treatment and the character of the treatment (cf. paper V). The ethical dilemma is made more explicit if, for example, the prognosis worsens when adequate treatment is not provided. In the three case histories presented here, some of the parameters are varied, so that different ethical problems can be isolated and examined. The relevant principles of moral philosophy studied in this context are the autonomy principle versus the paternalism principle. The investigation starts with the normative ethical arguments adduced in paper V, where it is argued that there is a relevant moral philosophical difference between respecting the wishes of a patient to decline an adequate academic medical treatment and agreeing, at the request of the patient, to provide a treatment which goes against the physician's professional interests.

Each question in the three case histories is presented as an argument/statement which can be commented on according to one of four options. Each argument is ethically motivated and the respondent thus takes a position on concrete acts and their motivations. An analysis of the pattern of responses can in this way also provide an idea of which ethical principle is being prioritized by the patient/physician. After each case history, space is provided for comments and alternative motivations.

Apart from these three cases, which represent concrete standpoints, on the final page of the questionnaire there is a series of general questions.

Through an analysis of the motivations and consistency in the pattern of response, it is possible to group various respondents and relate them to group affiliation and actor perspective. In the present study, the groups of physicians (hospital physicians and general practitioners) have been compared and contrasted with groups of patients.

5 RESULTS AND COMMENTS

Paper I.

The assessment of alternative medical technologies indicates that even in the assessment of medical technologies developed within the framework of academic medicine theoretical considerations play an essential role in the acceptance or rejection of a technology. These theoretical considerations, as well as other phases in assessment, are essential components of the biomedical paradigm. The application of the Kuhnian paradigm concept in the assessment of a medical technology facilitates an understanding of the mechanism of acceptance/rejection. Empirical data and adequate methodological procedures are of significance for both biomedical and clinical research, but theoretical considerations appear to play a greater role in the assessment of medical technologies.
than has previously been stressed in the literature on the methodology of medical research. A scientific paradigm is both rigid and conservative in character, which at the same time is also a precondition in certain phases for science to be able to develop dynamically. An analysis of the case of Semmelweis illustrates this.

In summary, acceptance of an alternative medical technology depends on whether theories of underlying mechanisms already exist or not, and whether the effect of the technology is empirically documented. The relationship between the degree of empirical documentation and the existence of biomedically acceptable theories of underlying mechanisms can be illustrated in the following table:

<table>
<thead>
<tr>
<th>The mechanism is/can be made:</th>
<th>High</th>
<th>Low</th>
</tr>
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<tbody>
<tr>
<td>Comprehensible</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Incomprehensible</td>
<td>3</td>
<td>4</td>
</tr>
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</table>

1. The technology can be made comprehensible and produce a high effect. Thus, the conditions for acceptance are fulfilled.
2. The technology can gain a certain amount of scientific status, but further controlled studies are often required before acceptance.
3. The technology has a low scientific status and is normally rejected with reference to the fact that the empirical data cannot be interpreted.
4. The technology has low scientific status and the effect is also low. The technology is rejected and it is difficult for academic medicine to mobilize a scientific interest in it.

The analysis of the general characteristics of alternative medical technologies shows that there are six common features to be found in the majority of alternative medical technologies/cosmologies:

i) The effect of alternative medical technologies is poorly documented empirically and methodologically;

ii) Alternative medical technologies are often unspecific and therefore difficult to document empirically, e.g. with the aid of controlled clinical trials;

iii) The effects of alternative medical technologies are often impossible to interpret according to accepted academic medical theories;

iv) Alternative medical technologies usually relate to theoretical conditions (alternative medical cosmologies) which conflict with those of academic medicine and current scientific assumptions;

v) Alternative medical technologies often claim to be "universal" and related to an
alternative medical cosmology or theory, i.e., they claim to be generally applicable to all states of diseases, which conflicts with both the scientific and the professional development of academic medicine;
vi) Alternative medical technologies are commonly practised by groups outside the established health care system.

Paper II.

In the relatively large amount of literature on the effects of alternative medical technologies there are only a small number of controlled clinical trials. The literature is dominated by uncontrolled experience in the form of follow-up studies, case histories and papers of a more anecdotal nature.

Before controlled clinical trials won acceptance during the 1950s, empirical documentation of the effect of a treatment was based on the personal experience of medical authorities. Personal experience in the documentation of a treatment effect is based on the clinical significance which an uncontrolled comparison between e.g. a new treatment and an established treatment gives rise to. It can also be a question of a comparison between a new treatment and no treatment of one or several patients. This sort of scientific documentation is controversial not only from an empirical standpoint; even if one applies theories of underlying mechanisms, a certain form of empirical investigation is usually necessary, and in such instances controlled clinical trials are generally preeminent instruments for assessing the effect of a medical technology. With the help of controlled clinical trials it is possible to focus attention on otherwise uncontrollable variables. With the aid of randomization, blinding of both researcher and patients to avoid selection bias and special observation procedures, a researcher has the opportunity to determine whether the effect of a new technology differs from the placebo effect or not.

Thus the controlled clinical trial is not only a step forward, providing increased validity in the assessment of empirical (clinical) data, it also represents a democratisation of the decision-making process in the instance of choosing treatment. It is difficult to challenge a medical authority's personal experience, but it is at least possible in theory if one has access to data from a controlled clinical trial. When it comes to the assessment of the effect of a medical technology, personal experience is thus not only an unreliable source of knowledge, it may in such a context be directly misleading and result in society investing money in a treatment which may merely be based on a positive expectation effect.

Through previously having been used as an instrument for assessing medical technologies, personal experience has acquired a tarnished reputation, which very probably is largely responsible for the fact that the significance of personal experience has been toned down, even in contexts where it has indeed played a role. Personal experience continues to play a role in both scientific and clinical contexts. In scientific contexts, personal experience helps to generate ideas and hypotheses. Personal experience can also play a role in the carrying out of medical experiments. The
significance of personal experience is most apparent in clinical contexts, in diagnosing and in e.g. surgical treatment. There are several formal aspects in the diagnostic process where probabilistic reasoning plays an integral part. However, even if it is possible to employ computers, for example in diagnostic contexts, the use of a computer presupposes personal experience on the part of the one using the computer.

Thus, personal experience plays a role; however, at the same time, it is important to designate an area of application and a limited area of validity in order that personal experience should not be used in contexts where it is not applicable and where it would be discredited.

Paper III.

A common assertion about alternative medical technologies is that any effects are due to the placebo effect. Under closer inspection, this statement proves not to apply to all alternative medical technologies, and the placebo phenomenon as such is problematic, not just in relation to the assessment of alternative medical technologies, but rather it also illustrates problems which can occur when the clinical researcher is also a clinical practitioner. The placebo effect is the effect which occurs in connection with medical treatment and which is based on the patient's expectation of becoming well. The placebo effect varies according to a number of different factors, but in the majority of treatment situations it comprises a relatively essential part of the effect. The placebo effect has been elucidated in connection with the increased use of controlled clinical trials, where the control patients often receive so-called "placebo treatment", i.e., a treatment lacking any known intrinsic medical effect, e.g. sugar pills. By compiling and analysing a large number of controlled clinical trials with a placebo-controlled design, it has been shown that the placebo effect is on average 30%, and varies between 10% and 90%. The extent of the placebo effect varies according to: 1) the character of the patient, 2) the qualities of the physician, 3) the interaction between 1 and 2, 4) the nature of the technology; 5) the nature of the diseases; and 6) the situation. It has been shown that the placebo effect varies very little (55% +/- 1) in the case of pain treatment, and even then regardless of whether it is a question of strong, moderately strong or weak analgesics. In this context, the placebo effect has the character of a natural constant. With the development of modern pain physiology, it has been possible to explain and understand certain of the operative mechanisms of the placebo effect in terms of neuropeptide stimulation induced by conditioned reflexes.

With the controlled clinical trial in mind, it is not possible to apprehend the placebo effect as anything more than a disruptive factor which must be brought under control. An aspect of the rationality of the controlled clinical trial can be summarized as \( R=T-P \) (real biomedical effect equals total effect minus placebo effect). The total effect is the accumulated average effect which occurs in the group which has been given e.g. the hypothetically active new pharmaceutical, and the placebo effect is the average effect which occurs in the group which has received placebo treatment. If the total effect
differs significantly from the placebo effect, the difference is referred to as a real biomedical effect.

The claim that the effect of alternative medical technologies is merely a placebo effect is correct insofar as the placebo effect has been shown to be high in the case of several of the alternative medical technologies tested in controlled clinical trials. This in turn has made documentation of a clinical effect more difficult. This risk of committing type-2 errors can be compensated for by recruiting a large number of participants. However, economic and practical problems limit the number of test subjects who can actually take part in a clinical experiment. When assessing certain alternative medical technologies, where the underlying mechanism is apprehended to be based on modern pain physiology, there is the further question of an interaction problem. If the interaction is positive (synergistic), documentation of an effect is easier. However, if the interaction is negative (antagonistic), the documentation of a real biomedical effect is more difficult. If the placebo effect in connection with controlled clinical trials is something which one wishes to gain control over and minimize, it is also something one wishes to maximize in the clinical context. This often places the clinician who also conducts research in a difficult situation, since there is a risk that he will transfer his research perspective over into the clinical situation.

It is concluded that a broadening of the rationality concept of academic medicine is necessary if one is more actively to make use of the placebo effect in the clinical situation.

Paper IV

Among physicians a common idea about those who practice alternative medical treatments is that they are all quacks. However, interest in forms of alternative medical treatment is not only increasing among patients; accredited physicians have also shown an interest in alternative medicine, and some have indeed begun providing alternative medical treatment. The purpose of this investigation was to determine the degree of physician interest and the number of physicians who actually practise alternative medical treatments. Since it is paradoxical, from an academic viewpoint, that after extensive medical education and clinical training physicians should begin to show an interest in treatments which are not in accordance with science and proven experience, we have also found it worthwhile to attempt to determine the reasons for this interest.

This investigation was carried out as a mail-questionnaire study, and included all the members of two alternative medical associations (n=228, response rate 80%), and a random selection (n=409, response rate 81%) from the Board of Health and Welfare's register of accredited physicians.

The results indicate that a relatively large group of the regular physicians maintain a positive attitude to certain alternative medical treatments. Thus one third of the regular physicians proved to be favourably disposed to manipulation treatment, acupuncture in the treatment of diseases, and dietary treatment of certain diseases, ie., forms of
treatment which are more or less on the threshold of being accepted and incorporated into academic medicine.

Members of the alternative medical societies were generally more favourably inclined to alternative medical treatments and more inclined to forms of treatment considered far from acceptable by regular physicians (e.g. homoeopathic treatments). More physicians in such organisations employed alternative medical treatments in practice as compared with the comparison group, where interest was of a more theoretical nature.

Table I. Percentage of physicians who treated or prescribed alternative medical treatment.

<table>
<thead>
<tr>
<th>Interest groups</th>
<th>Comparison group</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=182</td>
<td>n=330</td>
</tr>
<tr>
<td>Traditional Chinese acupuncture</td>
<td>48</td>
</tr>
<tr>
<td>Auricular acupuncture</td>
<td>12</td>
</tr>
<tr>
<td>Homoeopathy</td>
<td>25</td>
</tr>
<tr>
<td>Manual therapy</td>
<td>46</td>
</tr>
<tr>
<td>Injection with anthroposophical remedies (e.g. Iscador)</td>
<td>33</td>
</tr>
<tr>
<td>Reflexio therapy</td>
<td>8</td>
</tr>
<tr>
<td>Natural remedies</td>
<td>50</td>
</tr>
<tr>
<td>Injection with THX</td>
<td>14</td>
</tr>
<tr>
<td>Fasting</td>
<td>44</td>
</tr>
<tr>
<td>Vegetarian diet</td>
<td>66</td>
</tr>
</tbody>
</table>

The dominant reason given for showing an interest in alternative medicine was that the problems expressed by patients could often not be adequately treated with academic medical methods. Members of the alternative medical groups also explained their interest in terms of direct dissatisfaction with academic medicine. Among them there were also some who, even before beginning their medical studies, had developed an interest in alternative medicine.

Compared with a similar study carried out approximately ten years earlier (61), the present study showed that the number of physicians interested in and favourably disposed to alternative medicine has generally increased both in total and expressed as a percentage.

Paper V.

There are numerous professional and ethical problems associated with the practice of alternative medical treatment. These problems can be clarified if one applies an actor’s perspective and isolates the various interests at play. In this way, it becomes clear that there are ethical dilemmas among the different actors, e.g. between the physician and the patient. Both have a common interest in seeing to it that in the best circumstances
the patient becomes well or at least receives qualified help. However, whereas the physician has certain professional interests associated with his concept of science (science and proven experience), no such interests are held by the patient; nor does the patient share the physician's belief that scientifically based knowledge leads to optimal treatment. Sometimes, an alternative medical treatment can be perceived as optimal for the patient, when in the opinion of the physician it is sub-optimal or just dangerous. Due to the fact that the majority of unauthorized practitioners (so-called quacks, naturopaths or practitioners of alternative medicine) have no or limited diagnostic competence, there is an indirect risk that the patient will be improperly treated or end up receiving more adequate medical treatment at too late a stage. Thus, it may be in the interests of the patient for the physician to provide or prescribe alternative medical treatment. However, this is not in the best interests of the physician (or the medical profession), insofar as his cultural authority and therapeutic sovereignty are based on a scientific and educational ideal which is completely at odds with alternative medicine. From the analysis of this actor's perspective, it becomes apparent that the extent of the ethical dilemma varies depending on the actual conditions in which the patient finds himself. The patient's age, diagnosis (malignant or benign), prognosis with or without being treated, the nature of that treatment (mild or strong side-effects), are of significance for the gradation of the ethical dilemma. According to the Swedish Health Act, the physician has a responsibility to respect a competent patient's desire to refuse medical treatment, even in cases where such treatment would be life-saving.

By extension, the question arises as to whether the physician has a professional responsibility to comply with the wishes of a patient who wants to receive treatment which is not in accordance with science and proven experience (this can include both alternative medical treatments and treatment where the effect does not differ from the placebo effect). The problem can also be formulated as follows: Does a patient have an obligation to respect the physician's unwillingness to provide e.g. alternative medical treatments in the same way that the physician has a responsibility to respect a patient's desire to refuse academic medical treatment? Seen from the perspective of the physician's professional interests, it can be generally argued that such is indeed the case. At the same time, however, situations can arise (e.g. with someone who is hopelessly ill), where the physician must be allowed to improvise, and waive his professional autonomy out of sheer human compassion.

Paper VI

The normative ethical analysis (in Paper V) indicates opportunities for the physician to improvise and evaluate the ethical dilemma in order to provide alternative medical treatment depending on certain factors. Therefore, it is also appropriate to investigate empirically how physicians judge concrete cases where there are built-in ethical and professional dilemmas. The three case histories exemplify both professional dilemmas in relation to the physician's participation in cases where patients wish to receive placebo treatment (active placebo treatment) in connection with an non-threatening
diseases and alternative medical treatment in a life-threatening but treatable case of cancer. The final case concerns a physician who, in order to reduce side-effects (not harm), chooses to give a hopelessly ill patient a placebo.

The results indicate that patients are more willing than physicians to accept placebo treatment, especially in connection with the treatment of terminally ill patients. Even if some patients believed that the physician ought to comply with the wishes of the patients, the majority of patients felt that the physician should not give in to the demands of the patient in instances where it is not medically justified. The patients who have answered these questions have generally had great or very great faith in the health care system and in physicians in general.

Physicians are prepared to go as far as it takes in their deception, as long as it does not endanger the doctor-patient relationship. Even if respect for the patient's right to self-determination dominates the answers from the physicians, the harm principle is not emphasized. The Hippocratic ideal — "to do good, but above all, not to do harm" — combined with a certain medical paternalism, is usually anticipated as the ethical grounds for the values of the physicians, but in this study patients tend to be more paternalistic than the physicians. Comparatively, physicians more often feel that the patient has a responsibility to respect a physician's desire not to provide a treatment which is tantamount to placebo treatment.

6 SOURCES OF ERRORS

In Paper IV, certain limitations exist concerning the non-response analysis, since we had only indirect access to certain portions of the material and subsequently the non-response rate. In the random selection of accredited physicians (409) from the register of the Board of Health and Welfare, only 111 of the 330 who returned the questionnaire answered the questions on the last page (dealing with the reasons for interest in alternative medicine). By not answering the questions on the last page of the questionnaire and through the pattern of their answers in general, the 219 accredited physicians underscored the fact that they were not favourably disposed to alternative medicine. The internal non-response rate was otherwise negligibile. The 79 accredited physicians (out of a total of 409) who, despite two reminders, chose not to respond, account for the actual non-response rate in this group. However, otherwise, this group proved not to distinguish itself as regards sex and speciality.

In the instance of the two alternative medical groups (the interest groups), the internal drop-out rate in answering the questionnaire was also negligibile. The response rates in the two groups were 79 and 84 per cent. Since we distributed the questionnaires via the secretaries of the respective organizations, we have not been able to perform a non-response analysis. We learned, however, through the secretaries that the geographical and sex distribution appeared to be the same among non-respondents as among those who answered the questionnaire.
Our ambition from the beginning was to follow up the charting of the accredited physicians' interest in alternative medicine with selected interviews of a small number of typical respondents. We were especially interested in investigating more closely the reasons for abandoning academic medicine and completely converting to an alternative medical cosmology. Unfortunately, this was not possible, out of respect for promised anonymity, which had been a precondition for our being allowed access to the membership register; furthermore, it might also have been a reason why we enjoyed such a relatively high response rate.

In paper VI the non-response rate among the physicians was low (response rate: 94%), and there was no tendency to geographical concentration or any other concentration based on sex or speciality. Randomization led to a satisfactory distribution among specialists at the regional hospital, and geographically among the district medical officers. The questionnaire was three pages in length and it seemed interesting enough for the physicians to take the time to fill in. The internal non-response was limited.

The non-response rate among the consecutively selected patients at a primarily health care centre in Umeå was more evident. A total of 100 questionnaires were distributed; 80 were returned answered. Since the questionnaires were sent in anonymously, it was not possible to send reminder notices to those who received a questionnaire during their visit to the health centre, but who failed to return it. Certain assumptions can be made about the respondents concerning cultural competence and educational background. The breakdown in the group of patients also indicates that those who answered were younger than the age groups who otherwise characterise the typical clientele of a primary health care centre. However, the selection of patients can still be considered representative of a patient perspective, and this is also expressed in the various answering patterns, which differ significantly from the physicians' perspective. The chosen approach can, of course, be challenged, and yet justified since the patient group does not comprise a control group comparable to those used for clinical testing. Rather, the patient group is to be seen as a comparison or contrast group.

7 GENERAL CONCLUSIONS

- The condition for the acceptance and incorporation into academic medicine of an alternative medical technology is that controlled clinical data should be made available which, against the background of the biomedical paradigm, are interpretable or can be made interpretable. Theories concerning underlying mechanisms also play an essential role in the acceptance of clinical data developed within the academic medical paradigm, but in such instances theories are usually implicit or anticipated.

- Personal experience plays a large role in both clinical and scientific contexts in diagnosis and in the context of discovery. However, personal experience cannot be
used as scientific documentation of the effect of a treatment. The theoretical and empirical assessment of alternative medical technologies ought to be performed on the same grounds as the assessment of academic medical technologies.

- Certain alternative medical technologies engender a high placebo effect, which makes the documentation of a real biomedical effect more difficult. The grounds for being able to assess an effect of an alternative medical technology are that a precise area of indication for the technology exists. The risk of rejecting an alternative medical technology because it is not possible to distinguish between the total effect and the placebo effect increases the broader the area of indication is.

- Interest in alternative medicine has increased among accredited physicians, which seems paradoxical against the background of the educational and scientific ideals of physicians. Among certain groups of physicians interested in alternative medicine, this is not merely an academic interest. The reasons given for this interest indicate that there is a discrepancy between the problems brought by the patients to the physicians and the knowledge at the disposal of the physicians received through their educational training. Thus the interest shown in alternative medicine by physicians can be interpreted both as a sign of crisis in academic medicine and as a sign that certain alternative medical technologies ought to be assessed with regularity vis-à-vis their efficacy and safety.

- Due to their diagnostic competence, it is in the best interests of a patient that a physician should be the one who provides or prescribes (including referring to) treatments which are not in accordance with science and proven experience. This procedure conflicts with the professional interests of the physician; there are however cases where the physician may have a difficult time refusing a patient's request for e.g. alternative medical treatment, thereby directly or indirectly harming the patient. A patient seems to have an obligation to respect a physician's professional autonomy, in the same manner as the latter must respect a patient's desire to forgo treatment.

- Because of the different perspectives and interests of the physicians and the patients they should also make different ethical assessments. However, in this study we found that there was no unambiguous agreement between the group-specific interests. Against all expectations, patients tend to be significantly more paternalistic than physicians. The study indicates the need for empirical test of the theoretical and normative ethical analyses. Studies of this nature should, however, be followed up by interviewing typical respondents in order to provide a better foundation for the analysis of contradictions and seemingly inconsistent answers. The study also indicates the need for more information about how laymen and physicians understand the ethical values of health care.
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REFERENCES
