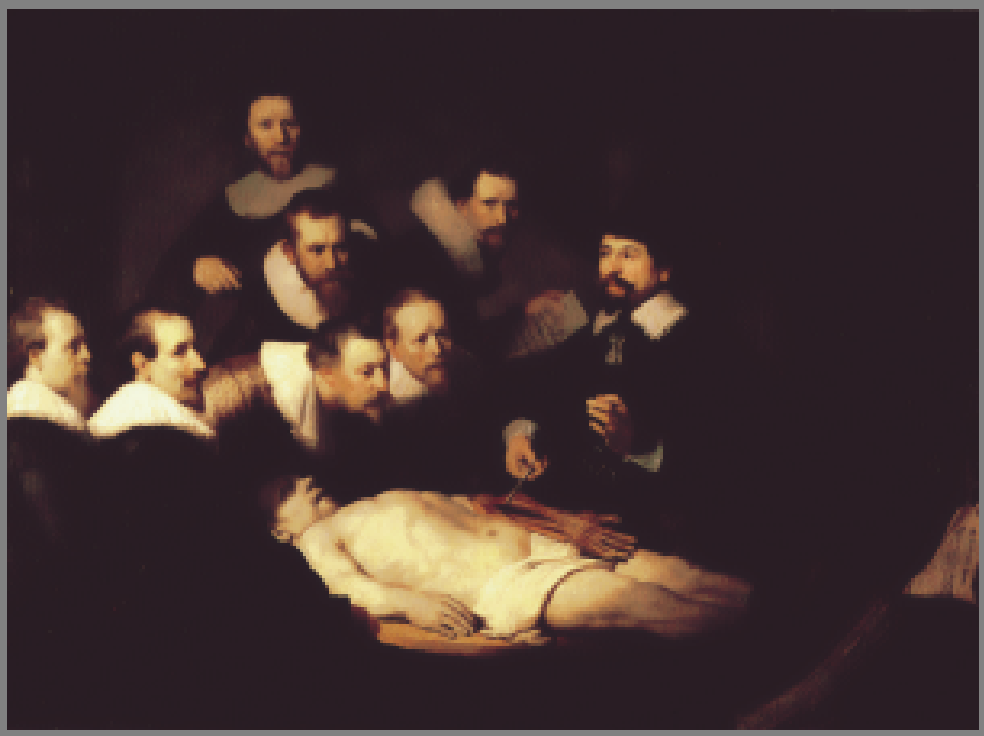
The Argument of Evidence

a Philosophical Investigation of Evidence-based Medicine

M.A. Thesis

Govert Valkenburg



Cover:

'The Anatomy Lesson of Dr. Tulp', Rembrandt van Rijn, 1632
Mauritshuis, The Hague

In Rembrandt's age, man had gained the insight that a study of the human anatomy was the main source of medical knowledge. With EBM we learn, that this study may actually yield incorrect knowledge, and that a statistical analysis of large numbers of cases is needed to confirm it.

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Preface

Einmal ist keinmal, zweimal ist zu oft

When I first encountered this aphorism, only the first half was used. Once is nothing: a single case does not provide us with any knowledge. With the same ease it wouldn't have occurred at all. This is exactly what EBM, the central theme of this thesis, is about: the only way to acquire knowledge, is to observe large numbers of cases.

But then I found out about the second half of the aphorism: twice is too much. One might think that I chose it to express the struggle of graduating twice (in engineering and in philosophy). Although I do not think that twice is too much, I do think it is *enough*. Both times it was an inspiring activity, be it for radically different reasons. In engineering one tries to accomplish a 'thing', whereas in philosophy one doesn't accomplish any-'thing' but descriptions of the accomplishment of things, facts, thoughts, and so on. It was this complementarity, that provided me with inspiration to keep studying for over seven years.

And then the entire aphorism: once is nothing, twice is too much. It is the German equivalent of the Latin *primus error veniam meretur*, which tells us to only punish when one is mistaken for the second time. It expresses a liberty to follow one's own courses, and learn from practice. It is this freedom I experienced when writing this thesis, and I believe it is this freedom that is necessary to achieve thoughts of intellectual value.

Quite a number of people supported me while I was writing this thesis. I am in their debt for an immense gratitude. I wish to thank two persons explicitly. Hans Achterhuis for the many fruitful discussions about my work, and the many hints for improving it. And my father Jan Valkenburg, who acted as a personal 'literature watchdog', by passing many useful articles that he ran into in his medical practice.

Govert Valkenburg
Enschede, November 2002

Chapter 1

Introduction

1.1 Background

A development so new as EBM, deserves attention from the philosophical point of view. I came to it, as usual, with a detour. My first inspiration was a question that had been on my mind for the last few years: how did we ever get so far, that we give medicine its current, nearly infinite, mandate? And how could we ever get this far, that almost measureless demands are put upon medicine? After all, almost any small inconvenience a doctor is consulted for. The government is held responsible for any outbreak of infectious disease (Legionella and Meningococcus are appropriate examples in recent Dutch history). Waiting lists extend to unacceptable lengths, and to my opinion this is not only due to a limited supply, but also to an over-extended demand.

When looking for a subject for a thesis, one comes to several questions. Some of them are moral or ethical by character: Is this the kind of medicine we want? Is it justified, that treatments are applied at sometimes ridiculous expenses? Aren't we, being human, obliged to accept disease to a certain extent? Other questions concern social-philosophical questions: How is medicine embedded in our society? What is the structure of medicine, such that the development can take these great forms? Who is ultimately in charge of medicine? And even some metaphysical questions arise: what is health, and when is it experienced as comfort? What is pain, and is it necessarily unpleasant?

These questions, although very interesting, are very difficult to answer. For an M.A.-thesis, a question should be taken that can be answered within not too large

a research. Then, by chance, I ran into the concept of Evidence-based medicine (EBM). I will discuss thoroughly later, what EBM actually is. Let's assume here, that it is a rationalisation of medicine: only those treatments are to be applied, for which the efficacy has been proven sufficiently. If the concept of EBM really is so simple, it provides us with solutions to numerous problems I mentioned before. It prevents useless treatments, thus limiting the waste of expenses. It would perhaps even reduce waiting lists. It implies which diseases we will have to accept, because evidence for treatments is absent. And so on.

But is EBM so heavenly? We will see that it is not. Its introduction is controversial, and some fundamental problems are inherently connected to it. It is this controversy that I will investigate. Why is EBM not just accepted, or why should we accept it at all? Why doesn't just everybody believe that rational methods yield optimal knowledge? Those are questions I found interesting throughout my studies in Philosophy. And here we find an interface between the medical-philosophical questions I started this section with on one side, and on the other side questions that are well-solvable within the skills of a philosopher of science.

1.2 Evidence-based medicine, an overview

What is EBM? To answer brief: it is a fashion of practicing medicine, with a strong preference for applying methods that have been thoroughly proven effective. I will address it superficially here, and it will be discussed in detail in chapter 2.

Anyone who got into contact with health-care, might have wondered how these doctors know what to do. After all, the human body remains something very complex, and it has a highly 'magical' appearance. But that is not all. Doctors often contradict one another. They follow their own values, and the variety of their opinions may be threatening to the patient. Sometimes what they do seems to be ineffective, speculative, or otherwise completely ridiculous.

It are exactly this multiplicity and speculations that EBM strives against. EBM wants to establish clear methods on how medical knowledge is approved, how it should be applied, and how it should be kept up-to-date. The basic idea of EBM is, that a single case does not provide us with general knowledge. To know something in general, we will have to investigate a large number, say thousand or tenthousand, of cases. By means of statistical methods, knowledge can then be extracted out of such a so-called 'trial'. Clear and distinct rules are established, to warrant reliability of this knowledge. Knowledge that is acquired according to these rules, is called *evidence*.

With every patient, the doctor will have to try to find the best evidence. He

will address recent journals, and databases containing overviews of these trials. The entire medical profession will be set up in such a way, that evidence is easily accessible, and available for most of the problems

The effects of these new ideas are radical. It changes the doctor's daily practice. He will have to organise his time differently. Medical education will also be affected. Students no longer learn standard treatments for certain diseases, but rather how to find current evidence for the problems at hand, and find the best cure for every disease. In sections 2.2 and 2.3 we will go into detail about the consequences and problems EBM invokes.

EBM will be investigated in the picture of regular health-care. As an illustration the discussion concerning population screening for breast cancer, currently going on in the medical world, and in the Netherlands as well, will be analysed.

1.3 Philosophy of science

Throughout the studies of *Philosophy of Science, Technology and Society* (Wijsbegeerte van Wetenschap, Technologie en Samenleving, WWTS) several philosophical movements are discussed. The topics range from Philosophical Anthropology with authors such as Gehlen, Plessner and Heidegger, through Social Philosophy with people like Arendt and Illich, to Philosophy of Technology with people like Latour, Ellul and Ihde. In addition to these topics, also courses on history, ethics, sociology and technology assessment are offered.

From within this broad gamut, I chose two authors to form the basis of my research: Thomas S. Kuhn and Bruno Latour. Kuhn is an American historian, who dedicated himself to the history of science. He is famous for his book *The structure of Scientific Revolutions*, first published in 1962. I will discuss some parts of this book, in which Kuhn gives a bright analysis of changes in science. We will encounter concepts like 'normal science', 'paradigms' and 'paradigm shifts', and these will provide us with the handles to investigate the introduction of EBM.

The second author I will discuss, is Bruno Latour. This French anthropologist studied people acting in science and technology, in the same way a cultural anthropologist would investigate exotic people. I will discuss his books *Science in Action* (1987) and *The Berlin Key* (1993). In *Science in Action* he analyses the way a fact is accomplished. According to Latour, a fact is not something that is hidden in nature, to be uncovered by the objective methods of science. Rather it is a negotiation between different actors in science, who determine in their controversy what facts are accepted and what are not. This is an unpredictable process. We

will see that this idea is very well suited to characterise the discussion around breast cancer, which I will discuss as a part of the controversy around EBM.

In *The Berlin Key* Latour explains how 'things' and people live together. We may be tempted to think, that we control the things accompanying us in daily life. Latour shows the opposite: things are able to control our behaviour as well. Not only are we in charge of how our car drives, the car is in charge of some decisions as well: its built-in speed limiter may prevent us from violating traffic laws. Where the objectives of things and humans collide, a negotiation takes place. The one who finds the most and strongest allies on his side (either human or non-human), wins the negotiation.

We will see, that EBM comprises some of the behaviour Latour ascribes to 'things' and 'facts'. A negotiation is carried out between the several human and non-human stake-holders of EBM. This negotiation is currently going on, and a solution is not yet within the range of vision.

1.4 Medical practice and EBM

Some literature is available on the introduction of EBM in the AMC, an academic hospital in Amsterdam. I will discuss this literature on the basis of the theories by Latour and Kuhn. EBM comprises many of the characteristics Kuhn ascribes to paradigms. It also comprises the characteristics of 'things' as established by Latour.

EBM is introduced successfully in the AMC. Most of the internal protocols and guidelines are established according to the principles of EBM. However, outside the AMC the introduction of EBM has not made such a great progress yet. Scepticism as well as lacking facilities stand in the way of EBM. Why does this difference occur? What is done better in the AMC, such that the introduction of EBM is a success there?

Medicine is a rigid profession by nature: doctors tend to resist change. How does EBM try to break through this rigidity? And will it succeed? Where does the rigidity come from (and why, for example, is medicine more rigid than physics or chemistry)? Apart from rigidity, other problems stand in the way for EBM. What kind of problems are they, and how are they found in medical practice? We will see that, even when a doctor really wants to convert to EBM, he will find difficulties.

1.5 Problem description, methods and thesis outline

The following questions will form the central theme of this thesis:

> *What does the introduction of EBM look like? Are the elements from Kuhn's and Latour's theories well-recognisable?*

To answer these questions, I will keep to the following path. First I will perform a thorough investigation of the literature concerning EBM (chapter 2). Then I will discuss the interesting parts of the technical-philosophical literature (chapter 3). After that, I will start the investigation of literature concerning the practical aspects of EBM. It is a rather one-sided method, to only investigate some published literature about practice. It would be much better, to investigate the introduction of EBM practically. However, within a thesis project, time is limited, and we will have to settle our priorities. Therefore I decided to keep to literature studies (chapter 4). In the end I will put the pieces of the puzzle together in my conclusions (chapter 5).

For words that may lead to confusion, a brief explanation is given in the glossary on page 87.

Chapter 2

EBM: the scientification of medicine

2.1 What is EBM?

Nowadays medicine descends from a long history of gathering empirical and practical knowledge. Only in recent history science and medicine have merged, in this sense that the scientific methods of falsification and verification have become common in medicine. A movement within medicine pursues strengthening this scientific character of medicine, thus not accepting facts that have not been proven with persuading scientific evidence. This scientific approach in medicine is indicated by the name *Evidence-based medicine (EBM)*. David Sackett, one of the founding fathers of EBM, defines thus (Sackett, Rosenberg, Gray, Haynes and Richardson, 1996)[1]:

> *EBM is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.*

The best *evidence* is generally found in recent medical literature. Hence the skill of investigating literature constitutes an important part of EBM. EBM is not 'cook-book medicine', in the sense that for every disease a standard treatment is available. On the contrary, a bottom-up approach starting from the patient's condition is required, in order to find the best-suiting evidence with respect to treatment, prognosis, diagnosis etc. etc.. EBM assumes a continuous renewal in medical literature, and a continuous activity by doctors of updating their knowledge.

[1] verbatim quotations will be printed indented and italic throughout this thesis

As we will see later, it might be comfortable to keep a strict distinction between medicine as a science, and medicine as an applying practice. However, in medicine this distinction is too vague. Take for example the Academic Medical Centre in Amsterdam (a leading hospital with respect to EBM in the Netherlands, which we will encounter often later in this thesis). In this institution both science and medicine are practiced. But that's not all: they are practiced by *the same people*. In the course of this thesis, we will see that science and its application influence each other quite much.

This brief description by Sackett c.s. might suggest that medical intuition is not accepted any longer. On the contrary, this intuition remains an important factor in matching the patient's symptoms to the literature. Just the argument that 'everybody uses this specific treatment in this certain case' is no longer accepted. The practice of EBM actually pursues the optimal collaboration of clinical experience (often resulting in intuition) and scientific knowledge. (Sackett et al., 1996)

The main source of knowledge, according to the EBM approach, is the so-called *randomised clinical trial* (RCT). In these trials large numbers of patients are observed under similar conditions. Whether a treatment deserves the predicate 'effective' or not, is decided by statistical methods. In addition to these trials, *meta-analyses* and *systematic reviews* are propagated in order to secure clarity when investigating literature. These are articles that address a number of randomised clinical trials, thus providing a reliable guide to medical evidence. The Cochrane Society, an international network of over 4000 scientists and clinical epidemiologists, plays a leading role at this issue (Stewart, 1998). When statistically sound evidence is absent, EBM admits less well-built evidence. For example, successful interventions in otherwise fatal conditions are hard, if not impossible, to establish with statistics. In those cases the doctors will content themselves with less strict evidence (Sackett et al., 1996).

For medical research, this has its consequences. Research will have to be performed more thoroughly. Present studies often do still not meet the scientific standards propagated by EBM. But there is one more fundamental consequence for medical research, which we will be confronted with continuously throughout this thesis. It is the fact that EBM implies that chemical-physical knowledge on fundamental principles in the human body (so-called *micro-causalities*) is not only insufficient to constitute medical facts, but that it in fact can yield wrong insights, which is to be determined by investigating large numbers of cases. This insight that micro-causalities are not enough, is a rather large change of the vision in medical research.

With respect to medical practice, EBM should be viewed as a guideline. This guideline consists of five basic steps, which are to be taken by a practitioner, with

every problem he encounters in his practice. These steps are (Sackett and Haynes, 1992):

1. The need for information is transformed into answerable questions.
2. The best evidence answering these questions is pursued.
3. The evidence is judged on its validity and appropriateness.
4. These results are applied in clinical practice.
5. The process is evaluated

These steps are to be taken with each patient, whenever new questions arise. The steps will be discussed in the following paragraphs, following the standard work by Sackett, Richardson, Rosenberg and Haynes (1998)

Formulating answerable questions

During the clinician's daily practice, questions arise all the time. Many of these are initially unanswered. For many clinicians, the effort needed to answer them exceeds the scarcely available reading time. That is, when they lack a well-built method of literature search (Sackett et al., 1998, p. 22 and further). This implies that shortage of time can be overcome by improving the querying methods, but this is of course an illusion. The statement Sackett c.s. make, is that with a sophisticated method, spending a large proportion of his time on queries will provide the doctor with contentment.

A well-formulated question usually contains four elements (Sackett et al., 1998, p. 26 and further): the patient or problem being addressed, the intervention being considered, a comparison intervention, when relevant, and the clinical outcome or outcomes of interest. By 'intervention' we mean for example a cause, a prognostic factor, a treatment etc. etc. Time is scarce, so the doctor must set his priorities, to see which question is most important, which question is most feasible to answer, which question is most interesting, and which question is most likely to be encountered repeatedly.

Pursuit of the best evidence

The doctor then comes to performing literature searches. Nowadays the quality of extraction, synthesis and organisation of evidence improves. Moreover information technologies provide us with good access to information sources (Sackett et al.,

1998, p. 38). Electronic media often outperform paper media, because their access is faster, and their contents are more regularly updated. For many classes of diseases special databases are maintained. Common search engines on the internet often yield poor results, and even the larger medical databases might be difficult to access. Yet this skill can be trained well. An additional advantage of tackling medical questions this way, is the inherent serendipity: the clinician will always encounter information that is not needed right now, but will prove of value later.

Critically appraising the evidence

In judging evidence, two criteria are important. First the doctor has to find out its validity (i.e. its reliability and closeness to the truth), and second he needs to find out whether it is suitable for our problem (Sackett et al., 1998, p. 80). It is often preferred to perform the second check first. This is a valid approach, provided that the validity check is not neglected.

To judge diagnostic methods on validity, the searcher has to check for certain features. E.G. a double blind test, the validity of the population in the test, reference standards being applied independently from test outcomes etc. etc., are known to yield valid results. With respect to prognostic knowledge, the clinician needs to check whether an appropriate population was assembled at an early stage of their disease, whether the follow-up of patients was long enough and complete, whether objective outcome criteria were applied blind. The validity of treatment evidence, comprises similar demands like the diagnostic evidence: the assignment of patients should be randomised blind, all patients who entered the test should be accounted for in the end, and should be analysed in the groups they were assigned to. Similar demands with respect to completeness, objectivity, robustness and credibility are put on meta-analyses and systematic reviews. Sackett et. al. provide us also with methods to judge evidence concerning harm, guidelines and other quality-improving strategies. These qualities by themselves are not of our concern. The point at issue is, that a sound method is available for appraising evidence.

Second the importance of evidence will be questioned. To this end Sackett et al. (1998, p. 128 and further) show some examples of judging the relevance of diagnostic tests, prognostic data, and treatment results. These examples are too specialistic to be addressed here. From the examples I assume that a clinician, conscientiously studying the evidence at hand, will be able to judge the suitability of the evidence when using the guidelines in the book by Sackett c.s.

Application of the evidence

The next step is to integrate the newly gained knowledge with the clinical expertise, and to incorporate it into the care for the patient. The clinician needs to find out, whether a certain test is available and affordable, he needs to establish pretest probabilities (that is, the a-priori probability to find a certain disease in his patient population; his own clinical experience plays an important role at this part!), and he should question whether the post-test probabilities (that is, the probability that the patient has a disease when the diagnostic test tells so) will influence his care and benefit the patient. The difference between the pre-test and post-test probabilities must be large enough, otherwise the test would be useless to carry out.

In case of evidence on prognosis, he should question whether the patients of the study were similar to the patient at hand, and whether the evidence makes a clinically important impact on how to deal with the patient. In case of a treatment, the doctor should question whether the results do really apply to the patient, and how great the benefit will actually be. Finally, a treatment has to comply with the values of the patient, implying that the patient needs a clear assessment of the values offered by the treatment. (Sackett et al., 1998, p. 158 and further)

Evaluation of patient care

The last step is to evaluate the care offered to the patient. Although very useful for clinicians, the evaluation steps formulated by Sackett et al. (1998, p. 207 and further) are quite straightforward and hence too obvious to discuss here. The tenor of this chapter is, that the clinician should wonder whether he consciously used the method described above. That is, whether he postulates his questions the right way, whether his search methods are effective, whether his attitude towards evidence is sufficiently critical, and whether he is applying the evidence successfully in practice. Moreover his skills on each of these topics should be noticeably improving. Although obvious, this evaluation step is perhaps the most important one within the EBM-methodology.

2.2 Consequences of EBM

I already briefly discussed the fact that in medical research the human body can not any longer be seen as a 'sum of micro-causalities'. Yet laboratory research concerning these micro-causalities will remain an important activity. Only it is supported with an extra layer of numerical analysis, to prove the validity of the

insights within the complex system of the human body. This is a rather thorough change in medical thinking, both in science and practice.

Besides in medical research, EBM involves a number of major changes in medical culture as well. It has its consequences for the education of medical doctors, for the relationship between the doctor and his patient, for the doctor's daily schedule, for the way moral decisions are taken, etc. etc.

Working evidence-based will generally increase the effectiveness of taken effort, but the total effort performed will not be smaller. Therefore EBM will generally not be cost-cutting. Besides, using EBM as an argument to cut funds would be a misuse of the philosophy of EBM, according to Sackett et al. (1996)

EBM modifies individual patient care. Therapies and diagnostics are used only if evidence supporting them is available. Physicians become more aware, patients become better educated and a more equitable physician-patient relationship will be established. Furthermore, medical institutions have to improve their facilities for literature searches.

EBM also demands that governmental policy is lined up in an appropriate way. It needs governmental support to establish institutions dedicated to EBM. Especially for institutions dealing with screening and prevention, for distributions of resources within communities, and for the assessment of new health technologies, governmental regulation is needed. Because of their high degree of interwovenness in society, EBM becomes a matter of governmental concern.

The training of medical doctors needs adaptation from knowledge transfer to a problem-based training. Previously medical students were taught 'how' things are, how to tackle clinical problems and how diseases develop. Now they will have to learn 'how to find answers'. It are no longer the facts that are transferred, but the methods. To this end, role models on consultancy problems need to be extended within the curricula of medical education. (Stewart, 1998)

Doctors need about two issues of new evidence for every three patients seen. Most of these needs are never met: a doctor needs to read about 19 articles a day, 365 days a year. Since this is impossible, physicians' knowledge grows out-of-date easily. Continuing Medical Education (Continuing Medical Education) programmes flourish for this reason, but they do not intend to change the clinical behaviour. EBM *does* intend to accomplish this change. When applying the methodology of EBM, that is the methods of seeking and applying evidence as we acquainted in section 2.1, and adopting evidence-based protocols developed by colleagues, doctors are shown to maintain their knowledge as long as fifteen years after graduation. Journals such as *Evidence-based medicine - The Journal* will serve as an important cornerstone in this maintenance, since they provide the clinician with the most

recent developments on methods, resources etc. etc. (Sackett and Haynes, 1992)

The new EBM-methodology puts a much lower value on authority, whereas previously the professor ruled, and what he said was taken for granted. Now assertions are supposed to be underpinned with evidence of a certain quality, regardless whether it is claimed by a professor or a medical student. This does not at all mean that experienced colleagues and teachers of medical practice will not offer useful knowledge, it just means that the practitioner will have to be critical when collecting information and applying their knowledge.

Patient care might become more rationalistic. However, to understand the patient's suffering, and to know how that suffering can be ameliorated by the caring and compassionate physician, remain fundamental requirements for medical practice. This skill can be prevented from going astray by role models and by observing patients carefully. Behavioural science will be involved to find out what really are the needs of the patient, and how physician and patient behaviour affects the care outcome. A method of critical appraisal, similar to the one in EBM, should be applied to these behavioural studies (JAMA, 1992).

2.3 Problems with EBM

A primary condition for successful application of EBM is the presence of sufficient evidence. Unfortunately this assumption is frustrated often: a significant proportion of the medical literature is of poor quality. Even when published in renowned journals such as *The Lancet* or *New England Journal of Medicine*, many of the publications do not meet the EBM-requirements. An additional problem is the so-called *publication bias*: researchers tend to pay more attention to successful projects, than to projects with less desired outcomes. Yet for a practitioner striving for the best objective evidence, both positive and negative results are equally important. And even when the best evidence is found for a problem, the situation at hand might still differ significantly from the situation during the test. Then the opinion of the patient and the clinician's expertise may determine the final decision, thus partially missing the benefits of EBM. (Crul, 2001)

Another interesting problem is addressed by Nederbragt (2000). The situations in which researches are performed, and the situation of clinical practice, comprise highly different structures. This incompatibility may compromise the applicability of scientific outcomes.

Let's first look at the situation in which *medical knowledge* arises. Here medical knowledge is taken to be only those facts we find in journals, textbooks, articles

etc. etc. (The knowledge the individual practitioner gains in his daily practice, is generally indicated as 'clinical experience'.) This medical knowledge results from various activities: epidemiology, diagnostics, pathogenesis, therapy development and clinical trials. Each of these activities focusses on large numbers of cases, thus losing sight on the individual case. These disciplines are heavily dependent on each other, and it is this interdependency that leads to a coherent theoretical system.

Clinical practice, on the other hand, generally concerns only one specific patient, and one specific problem or physical item. Here also numerous topics play a role: (bio)medical knowledge, clinical experience, social relations, economic conditions and ethics. Yet in this case, they do not reinforce each other but a compromise between them is to be reached.

Medical knowledge and clinical practice thus seem to be incompatible. Let's clarify this with an epidemiological example. As we know, there is a correlation between smoking and the occurrence of lung cancer. This has been proven in numerous trials with sufficiently large populations. But this correlation does not say anything at all about an individual smoker, regarding the question whether he will die from lung cancer or not. Nederbragt (2000, p. 557) gives a similar example for randomised clinical trials. Once that a treatment is developed far enough to be tested on a human population, a sophisticated method is established. A population is carefully chosen. Then tests are performed, and analysed statistically. However, the criteria of inclusion and exclusion of patients influence the validity of the test. The inclusion strategy may for example validate only a limited age interval. The treatment may lose probability to be effective, when applied to patients outside this age interval. Nederbragt states (p. 558) that the outcome of a study is based on deliberate choices:

> *[...] the choice to disconnect a disease from its context, the choice of methods that bring uncertainty under the domain of numerical values. Both in the quantitative and in the qualitative approach of disease, we have to rely on probabilities: those of qualitative extrapolations, and those of quantitative statistics.*

The way a decision is made in clinical practice is entirely different from the way a biomedical fact is sustained. This incompatibility disrupts the applicability of the biomedical knowledge. According to Nederbragt this gap is overlooked by Sackett c.s. Nederbragt proposes two solutions, either of which do not appear useful to me. The first is to accept that this gap will never be filled because of the incompatibility (which is, in my opinion, not a solution) and the second is to deny the gap.

> *Biomedical and clinical knowledge relate to each other like an organ to an organism. The first is an essential part of the second, and the second defines the first. Although they are different, they belong to each other (Nederbragt, 2000, p. 565).*

To me, this doesn't seem to be a solution either.

In the lines above we just considered a decision being made by the practitioner. In reality, most clinical decisions are made in deliberation between the practitioner and the patient. This complicates the process even more. Closely connected to the gap mentioned above is the fact that an individual decision will always remain *individual*. Even if the gap were filled, and the knowledge obtained from a 'general' source perfectly matched the 'individual' needs, then still the decision cannot be disconnected from personal considerations. The perspective in which an individual decision is made (by a doctor together with his patient) is emotionally biased, rather than merely numerically founded. Usually the patient doesn't know how to handle the information used by the practitioner: with respect to physiology, statistics, long-term consequences etc. etc. he is usually a layman (Bonneux and Giard, 2001). This lack of knowledge might give the patient a feeling of misunderstanding: as the expert reasons on basis of numbers and incomprehensible principles, the patient might feel like his emotional needs are ignored. When a suspected tumour is found in a patient, he might not be comforted by the fact that 'in more than 90% of the cases the tumour turns out to be innocent'. (We will get back to this potential decrease of emotional engagement later.) In general we can state, that knowledge will never be conclusive, in this sense that under similar circumstances decisions will not necessarily be the same.

In the article in JAMA (1992) some barriers to introducing EBM into the hospital are mentioned. First, many apprentices (being both graduated practitioners and medical students) start with rudimentary critical appraisal skills, and the topic may be threatening for them. Moreover, people like quick and easy answers. Critical appraisal takes more time and effort than a cookbook approach, which therefore might unjustly pretend to yield more efficient care. Then, the matter of lacking evidence is repeated, which may cause a feeling of futility. Finally, there is some general scepticism about EBM among faculty members, who may not want to change their practice. This stubbornness will remain an important thread running through this thesis. Some more barriers to practicing EBM are mentioned: economic constraints, missing evidence and lack of time can obstruct the practice of EBM.

We already saw that in randomised clinical trials cases are extracted from their context. The conditions of patients participating in the trials are not always equal to the condition of the patient under treatment (Crul, 2001). Apart from that, the broad social context in which medical technologies are applied, is left apart. The qualification of 'good' and 'bad' technologies should be more than only the evaluation of means to an end: it should also be questioned which ends are desired

(Berg and Mol, 2001, pp. 9, 10). Technology and its usage are interwoven. Some ways to apply technology are inscribed in this technology, whereas other ways are excluded. It would be too easy to say, that the majority of medical technologies is inherently good, and if they turn out to be bad, it is the responsibility of the people using them as such. Berg and Mol give the example of the contraceptive pill. In most situations it contributes to female emancipation and autonomy, and to a well-considered family planning. To a certain extent it even contributed to the emancipation of homosexuality, since sexual intercourse with pleasure as its only purpose got rid of its taboo. But in other situations it can be used to force women to limit their number of children, or to force them to have sex against their will. It is then often believed that these functions of the contraceptive pill are not inherently connected to this pill, but that they are the mere consequences of what people *do* with it. Yet this would be too easy. By simply existing, the pill changed the shape of sex, and hence it changed the meaning of forcing women to have sex. We would go too far, when saying that the pill invokes rape, but complete innocence cannot be attributed to it either. Not only the efficacy of a technology should be evaluated (which is usually done in a context-free RCT), but also its applicability, economical availability, its appeal to our sense of responsibility, all kinds of usage that are made possible, the way it may discriminate certain groups etc. etc. This appraisal is not explicitly found in EBM-literature.

A similar problem is found with diagnosis. To judge diagnostic methods, it is not enough just to evaluate whether it provides us with a reliable vision on the 'objective reality' behind the patient's inconvenience. It also affects people and the networks they participate in, their habits and values. For example the availability of a cheap HIV-test might invoke employers and insurers to demand such a test in situations previously retaining from it. But that's not all. The vision on reality these diagnostics provide us is not just transparent. Transparency would mean that a diagnostic method provides us with a complete, untroubled, objective view on the authentic reality. First of all, even if an authentic reality exists, we are not able to know it, since our perception is imperfect and limited. Our world view is coloured by our senses, as well as our personality with its memories, emotions and logical reasoning. But second, even if our perception were not coloured, we still would not be able to see reality in an untroubled manner through diagnostic methods. The methods render the view for certain reasons. To begin with, they are created for a certain purpose, with a certain *selectivity* (i.e. the capability to avoid false-positive outcomes) and a certain *sensitivity* (i.e. the capability to avoid false-negative outcomes). Hence they cast a certain normality or norm onto the patient. And any abnormality is neglected as long as it remains below the threshold defined by the manufacturer. And then, it is up to the practitioner to

decide which method is to be applied and when. He probably reasons on the basis of his intuition, experience, financial aspects, local policy etc. etc. All these factors influence the diagnosis in the end. A diagnostic method with a high sensitivity and a high selectivity, is not enough. It does not warrant either that this abnormality is always found, nor that a treatment is invoked in the right situation.

Due to this non-transparency (or opaqueness) and differences between methods, diagnosis is a unique event every time. Each method attributes its own definition of 'normality' to the human body. The 'truth' or 'reality' on the human body then becomes irrelevant. We should always question what values we find important, before we can know what diagnostic method we should apply. These aspects are neglected in RCT's. An inherent problem occurs to our philosophical mind's eye: if RCT's *did* pay attention to this rendering, it would admit that *all* methods of observation are opaque, including any methodology of EBM and its RCT's. It would undermine itself.

A new problem is discussed by Dickenson (1999). It is questionable whether scientific evidence provides us with enough ethical values: if the objective facts are given the highest priority, they might tend to overrule moral considerations. Medical actions can have a large moral impact, and according to Dickenson it would be a shortcoming if an explicit ethical debate is omitted from the medical practice.

First of all, I do not agree that EBM stands in the way for an ethical debate. Even if evidence leads to a certain treatment, the doctor will not do it if it contradicts his ethics. In several articles on EBM, it is stated that the doctor will not become a 'rationally thinking machine'.

But the second objection is even more interesting. In section 3.5 we will see, that Bruno Latour absolutely disagrees with this objection, for a much more fundamental reason. Latour would say in this case, that some of our moral considerations, such as 'futility', 'usefulness', 'efficacy' etc. etc., are *delegated* to the guidelines of EBM. These morals are then more rigidly executed, than when a human being were in charge of them. Hence, Latour will say, the total amount of morality is *increased* instead of snatched away from. We become more, instead of less moral. I will come back to this when discussing Latour's book *The Berlin Key*.

Upshur (1999) discusses a problem, inherently connected to medicine, and more specifically connected to EBM. He discuses Bayes's theorem on probabilities, with respect to clinical decision making. It would go to far to discuss it here, but the tenor is that probabilities involved in clinical decision making can result from two sources: either it comes from an objective measuring of chances, or it comes from the subjective view of the clinician. The latter corresponds better to the thoughts of Bayes. The probability a clinician attributes to a certain event, is the result of

his clinical experience. It is not a 'willingness to bet', but rather it is a hermeneutic exercise of understanding his practice. Upshur states:

> *In clinical practice, what constitutes evidence is very contextual: to a sensitive and perceptive clinician, affect, tone of voice and a wide assortment of visual and verbal cues are evidence of a patient's emotional state and well being. How reliable one's reasoning is about such processes is revealed in time. One's foreunderstanding expands through contact with the other.*

The merit of Upshur's text is found in the fact that he proposes a linkage between the rationalist character of EBM with the more emotionally biased practice of medicine. At this moment, to me it sounds like a factitious attempt to overcome this gap: it rationalises thoughts that may otherwise be incompatible with rationalism. But nevertheless, it provides us with a useful method to look at intuition when we investigate practice. Will this rationalisation prohibit a collision between intuition and reason? We will see.

We could argue whether the rationalist character of EBM chills the relation between the physician and his patient. In section 2.2 we already addressed the fact that the emotional needs of the patient might be underattended by the rationalist character of EBM, and hence the physician needs active training for his emotional skills. It remains an interesting question whether clinical practice is really 'chilled' by EBM. This might be experienced when the physician appears not to take notion of what the patient wants. In an interview by Henk Maassen (2002), Pim Assendelft proposes to incorporate the patient's needs to judge on what is relevant, and what is not. The situation of the patient may determine the choice for a treatment: the situation can be such that a sub-optimal treatment might be desirable, that would not have been chosen from mere statistical reasons. For example, for certain infections it might (reasoning on reliable evidence) be better to let them develop according to their natural course, instead of treating them with antibiotics. However, if the patient is about to leave for a holiday, it might be better, to cure the infection with antibiotics, though. What we see here, is that the strictness of EBM-prescriptions might overlook the emotional understanding of the patient.

Through the problems previously stipulated, one general problem has not very explicitly come to the light. It is the problem that the benefit of the patient becomes a marginal instead of a central theme, and that therefore the patient loses himself in the large system of medicine. On one hand this is denied explicitly in several sources propagating EBM: EBM is said to attribute a central role to the patient and his problem, applying a bottom-up approach to solve the problem. But on the other hand, some more critical sounds are heard as well. The main argument is exactly this point, that the patient loses sight on the complex information that comes to

him under the label of 'evidence', and hence loses hold of what happens to him at all.

The benefit of the patient being only an indirect aim of the profession, is not new. Ivan Illich (1978) already uttered numerous accusations of *medicalisation*, i.e. the rendering of a non-medical issue by a medical denomination. This term is used for example, with pregnancy: traditionally it was a matter of women among women. The midwife was the expert, and delivery took place at home, with the helping hand of a small number of closely related women. In the twentieth century, pregnancy has become a medical issue, perhaps even a disease. Deliveries at home are becoming peculiarities, the majority of women (not in the Netherlands) give birth under local anesthesia, and gynaecologists are much more involved than before.

Another example of medicalisation is working stress. Originally this was due to a social problem between (e.g.) a manager and his assistant. A solution had to come from a reconsideration of the division of labour. Nowadays often the company doctor is involved in solving the problem. In countries with a habit of prescribing medicines (again not the Netherlands, it is known for its conservatism with prescriptions), he may even prescribe some anti-stress drugs.

To come back to Illich: he discussed not only examples like the two above, but he makes a general accusation to the guild of medicine, of treating only because of the treatment (i.e., for the purpose of making money, and of maintaining the medical class). He then introduces the term *iatrogenesis*, which literally means 'the creation of disease by a doctor'. He subdivides several kinds of iatrogenesis, which I will not discuss here, because it is beyond the scope of this thesis. Illich's conceptions of iatrogenesis range from small infections incurred in the hospital (the most literal and hence common meaning of the word), up to the 'invention' of new diseases, and the creation of social and political structures to force a society, to recognise the disease and pay doctors to treat it. The reason I mention these two concepts, medicalisation and iatrogenesis, is that EBM might provide us with a weapon against them. The patient may be done good, if scientific evidence prevents him from undergoing treatment for diseases that are actually not diseases, or treatment for diseases that don't need treatment, or treatment for diseases that are not really a treatment. But at the same time, EBM may reinforce the authority of the medical profession, complicating its structure, and take away the patient's autonomy. It will then be an interesting question, whether the medical dystopia of iatrogenesis and medicalisation, as sketched by Illich, will be either fortified or attenuated.

Chapter 3

EBM: the genesis

3.1 Case: the breast-cancer controversy

In February 2002 an essay was published by Wim Köhler in *NRC Handelsblad*, concerning the questionability of screening of breast cancer (Köhler, 2002). The tenor is, that the scientific foundation of large-scale screening among women aged between 50 and 75 is questionable.

Years ago it had been proven in seven large trials, that population screening for breast cancer reduces the mortality from breast cancer. These trials were held in several countries. One of them even registered a mortality reduction of 29%. These trials had been integrated in one review by a Swedish team, captained by Laszlo Tabar.

Now two researchers, Ole Olsen and Peter Gøtzsche, connected to the Nordic Cochrane Centre in Denmark, claim that the screening does not reduce the death rate due to breast cancer. The desirability of screening has always been questioned ever since its establishment, but mostly for reasons of expenses and assets, and for socio-psychological reasons: the screening puts a mental burden on the women, even if they turn out to be healthy. It was questioned whether this burden is outweighed by the profits. The current objections are directed more against the methodological hiatuses. Olsen and Gøtzsche state that from the seven trials, three were of poor quality, two were of medium quality, and two were flawed. According to the Danes, the researches altogether do *not* prove a reduction of mortality.

Köhler discusses the argument, that an early treatment of cancer is effective at all. According to several sources it is questionable. Proof seems to be missing,

that tumours treated early are cured better than tumours treated in a later stadium. Moreover, breast cancer is the cause of only a small proportion of the total mortality. It is questionable whether this legitimates such a large-scale and severe project as population screening.

Reactions came to this disruption. Some scientists insisted that the researches, contrarily to what Olsen and Gøtzsche assert, were of good quality. The researches were not believed to be pulled down. They were even underpinned with *expert reviews*: an overview article by some authority, in which he displays his vision, underpinned by various researches. Such a review is written from a highly subjective point of view. The reasons why the expert puts forward certain arguments, are indistinct. A method or criterion is not given, the only thing we can do is to trust the expert in his integrity. This counter-acts the systematic reviews by the Cochrane Society. They are guided by objective protocols, in order to avoid the appearance of partiality. The protocols are established in an international consensus, and open to debate. They are believed to yield the most reliable scientific knowledge. That is, in the eyes of Cochrane members.

The outcome of the research by the Danes is, that the epidemiologists lose the main part of their legitimation with respect to breast cancer screening. Moreover medical biologists do not support the idea that mass screening reduces mortality from breast cancer. We should think of alternatives, and see whether they can replace the screening. Perhaps genetic screening provides us with useful alternatives, as well as self-examination by women. But these are just suggestions, they have not been proven yet in large trials. They show that mass screening is not the only way to deal with breast cancer, even though its rightness has the status of an accomplished fact.

In the example above, we see a couple of scientists trying to fortify medicine's knowledge, by looking for evidence with solid statistical methods. When their outcomes contradict the current manners, they run into the morbidity of medicine, and the stubbornness of those who accomplished the facts. Opposition is found from the side of peer clinicians (both from the side of application, and the side of scientific research), but also from the side of politics, and the public opinion. It will involve a huge effort, to persuade a society with such a radical new opinion.

This is an example of an attempt to replace old, obsolete methods with sound new ones. Apparently the introduction of these new methods, representative for the ideas of EBM, into medicine doesn't go without a blow. That is exactly the core phenomenon this thesis is dedicated to. It would be too easy to assume, that statistics can just take the place of the ultimate authority in medical research. Up to the present, the authority regarding medical knowledge was assigned to the leading

researchers. It would be naive to expect them to get off their throne, and make place for 'statistics'. A controversy has to take place, before statistics will be accepted as the leading source of knowledge.

The purpose of this thesis is to give a philosophical analysis of the introduction of EBM into health care and medical research. Therefore we have to apply ourselves to an overview of relevant philosophical theories, in particular those concerning the development of science. I will first follow an introductory book by G. de Vries, and then discuss T.S. Kuhn and B. Latour, two philosophers of science.

3.2 Development of science

Nowadays the influence of science is inevitably seen throughout our entire life. Gerard de Vries (1995, p. 9) formulates some reasons, why a systematic scrutiny of scientific knowledge, its genesis and character, is desired. They are:

- The prominent presence of science: The effects of science extend through our whole society. It is impossible *not* to be confronted daily with its effects.
- The claim of science, that objective and hence 'true' knowledge is generated: the strive for knowledge is an inherent human property. It has always been accompanied with the quarrel *what* true knowledge is, and how it can be obtained. However, the success of modern science with this claim is unique.
- Its character, believed to provide the Western world with a unique position: Not only in time, but also in space the Western civilisation is unique. It is no longer a local structure, but a global one. It is not kept stable by the politics of a small number of sovereigns, but by a complex (global) network of social and technical relations, in which science plays an omnipresent role.

Philosophers of science dedicate themselves to describing the character of science, to assaying the claims of science, and to providing a vision on science's place in our culture and society. To this end the characterisation of science has to be both historically and empirically adequate, i.e. it should comply with the practice in established fields of science. Moreover it should be philosophically adequate, which means that an epistemological ('knowledge-theoretical') and cultural analysis is needed to judge its claims. This latter topic is narrowly connected to the name of Thomas S. Kuhn, to whom we will dedicate ourselves in section 3.3

Modern science, as comprising most of the characteristics we ascribe to it today, was first found in the seventeenth century, with celebrities such as Galilei, Boyle

and Newton. Science itself was not new: nature, mathematics, technology and philosophy had been studied before as well. Neither were experiments new for that age, nor were systematical observations. Even mathematics had been used in practical applications before. The revolutionary part seems to be the connection of experimental and mathematical methods (Vries, 1995, p. 13). For the first time in history, a more or less standardised method was established for the coupling between mathematics and practical observations.

In the same time new instruments are introduced, such as the telescope, the thermometer and the microscope. Knowledge on mathematics increases exponentially. New ways of reporting scientific knowledge are established, not in the last place stimulated by the art of printing. Results are described more in a quantitative rather than only in a qualitative way. And they find their way through the wold much faster.

Up to the seventeenth century, a strict class division had existed between the theoreticians (university graduates and humanists), and the more practically oriented craftsmen (medical doctors, architects, musical-, nautical- and astronomical instrument makers). This division existed also in terms of a cognitive difference: theoretical skills of these two groups were not compatible. This barrier is broken around 1600, when theoretical and practical skills come together. With this development, science gradually goes beyond 'common sense': even when outcomes are counter-intuitive, they are accepted if they hold from experimental and mathematical results. One example of such a counter-intuitive fact, is Newton's law of inertia. We all intuitively 'know', that to maintain a motion, a force has to be supplied to the moving body: the wind propelling a sailing ship, children kicking a ball, and oxen pulling the plough. Without these causes, the object will sooner or later stop moving. We know now, from Newton and his colleagues, that this vision is incorrect. He stated as his first law (now taught in high-school as the *law of inertia*) that any massive body has the tendency to maintain its movement or stagnation, and to *alter* this movement energy has to be supplied (or taken away). How could Newton come to this, and convince the Western world? Because he calculated on his observations, and found that it is the only consistent way to formalise mechanics. He accepted the methodological thought that observations together with mathematics are more reliable than intuition. Until today, we believe that this mixture of practical and theoretical observations yield the most reliable knowledge. It is this background to which an idea such as EBM, that puts large amounts of systematic observations in a central role, can arise.

3.3 Kuhn: paradigms and revolutions

In the introduction of his book *The Structure of Scientific Revolutions*, Thomas S. Kuhn (1969) proposes to consider science not any longer as 'the constellation of facts, theories, and methods collected in current texts'. This piecemeal accumulation of facts is not apt to explain why sometimes radically new beliefs are accepted, that heavily conflict with current knowledge.

The school-book example of such a new belief is the acceptance of the heliocentric world view by Copernicus and Galilei, colliding with the geocentric world view ruling at the time. Up to then it had been believed that the earth were the centre of the universe, and that the sun, moon, and the stars were revolving around her. Now Copernicus and Galilei proved that the mathematical description of the solar system was far less complicated, when the sun was taken as the centre. This new idea was highly controversial. Even the Vatican mixed into the discussion, condemning anyone who dared to affect the ruling geocentric world view. As we know now, the heliocentric view won. How did people come to accepting such a new view, in spite of the ruling one? How do these radical changes develop? Within this thesis, this will be an interesting question, since some of the changes involved with the introduction of EBM may comprise a similar revolutionary character.

To understand Kuhn's vision on scientific development, we first need to determine a central concept in his work, that is the idea of the *paradigm*. Outside Kuhn's works, this word is generally used for any 'example', or specimen that could serve as a model for an entire class. The 'paradigm of a paradigm' is the sequence 'videbam-videbas-videbat-videbamus-videbatis-videbant' as an example of the conjugation of the imperfect (or 'simple past') of Latin verbs. Kuhn extends this meaning beyond the notion as an 'example'. A paradigm is not just a set of examples and models. With Kuhn, a paradigm is a 'way of life' adhered to by an entire scientific community. It includes examples and models, bus also the publications discussing these examples. Even convictions, symbolic generalisations, metaphysical premisses and values a researcher incorporates are reckoned to it.

A paradigm forms the background against which, or the framework within which, science is practiced. It dictates a normativity on its members with respect to methods, classes of problems that are (or are not) interesting to investigate, the way scientists reason etc. etc. This may feed the impression that a paradigm is an unpleasant constraint, but in fact it is not. Instead, it is the only way science can comprise unity, stability and progress. Without it, science would be a bunch of solitary fanatics, each believing in their own methods and facts etc. etc., and it would therefore actually not be 'science' at all. Paradigms are the 'binding agents' of science.

A second term introduced by Kuhn is *normal science*, which generally indicates the practice in which scientists construct and continue a particular research tradition. There is a high grade of consensus with respect to what problems are worthwhile to investigate, and what standards solutions have to comply with. Normal science exists by the grace of shared paradigms, and is characterised by stability. It is a sign of maturity in the development of a scientific field, when paradigms are acquired, as well as the more esoteric type of research accompanying it. (Vries, 1995, p. 101 and Kuhn, 1969, p. 10 and further)

Yet the existence of various schools is not the triumph of various paradigms, but rather an indication of the lack of consensus characterising normal science (Vries, 1995, p. 124). This is distinctly seen with medicine in the Netherlands: methods were not centralised. There was not one single school, but instead a number of schools existed next to each other. For example, in Amsterdam it was taught to surgeons that during surgery a patient should be situated face-down, whereas in Utrecht it was believed that face-up was the optimal position. This peculiar multiplicity was noticed by the doctors themselves, and a 'consensus committee' was established. Then it was found out that the only way to decide which methods are optimal, was to compare them statistically: an instance of EBM was born spontaneously (Crul, 2001). Taking Kuhn's theories as our point of view, we should see this 'as improving the paradigm', and a 'step in the direction of normal science'. (I am speaking of a practical field of knowledge here, but in the case of EBM, the distinction between practice and science can hardly be made.)

We can now take a brief look at the paradigm that characterises medicine before EBM was heard of. In particular we look at how this paradigm is about to change by the introduction of EBM. An editorial article in the *Journal of the American Medical Association* (JAMA, 1992) gives the following assumptions ruling in the old paradigm:

- *Unsystematic observations from clinical experience are a valid way of building and maintaining one's knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment.*
- *The study and understanding of basic mechanisms of disease and pathophysiologic principles is a sufficient guide for clinical practice.*
- *A combination of thorough traditional medical training and common sense is sufficient to allow one to evaluate new tests and treatment.*
- *Content expertise and clinical experience are a sufficient base from which to generate valid guidelines for clinical practice.*

The same article states for the new paradigm:

- *Clinical experience, and the development of clinical instincts (particularly with respect to diagnosis), are crucial and necessary parts of becoming a competent physician. Many aspects of clinical practice cannot, or will not, ever be adequately tested. Clinical experience, and its lessons, are particularly important in these situations. At the same time, systematic attempts to record observations in a reproducible and unbiased fashion markedly increase the confidence one can have in knowledge about patient prognosis, the value of diagnostic tests, and the efficacy of treatment. In the absence of systematic observation one must be cautious in the interpretation of information derived from clinical experience and intuition, for it may at times be misleading.*
- *The study and understanding of basic mechanisms of disease are necessary but insufficient guides for clinical practice. The rationales for diagnosis and treatment which follow from basis pathophysiologic principles may in fact be incorrect, leading to inaccurate predictions about the performance of diagnostic tests and the efficacy of treatments.*
- *Understanding certain rules of evidence is necessary for correctly interpreting literature on causation, prognosis, diagnostic tests, and treatment strategy.*

This suits the notion of paradigms by Verbrugh (2002, p. 91-95). Previously knowledge was extracted from physical-chemical research (called the 'In Vitro' era by Verbrugh). Now the individual patient grows out of scope, and is replaced by a numerical record. In the article in JAMA it is stated that a statistical analysis is needed additionally this biochemical research. This altogether characterises the 'In Numero' paradigm, as it is named by Verbrugh. It should be mentioned explicitly, that these changes affect both the field of scientific research, and the field of practical application. Thus the paradigm of practice, and the paradigm of science, seem to develop synchronously.

We now want to focus on this paradigm shift. It is obvious that the conversion from the old paradigm to the new one may not go without any trouble. Not only the established ideas have to make place for a new one, but also the specific, professional standards which work has to comply with are pulled down. Kuhn establishes some qualities for these paradigm shifts or revolutions. They are (Kuhn, 1969, p. 6):

- The scientific community is required to reject the current theory in favour of one that is incompatible with it.
- A shift is brought about in the problems available for scientific scrutiny, and the standards by which this scrutiny is performed.

- The imagination and the world view are transformed rigorously, such that we can legitimately describe it as a change of the world.

Considering what Kuhn said, we concern some features of the development of EBM. First we should question whether the paradigm of EBM is really incompatible with the previous paradigm, which actually embraces the question whether it is a new paradigm at all. With respect to some aspects it is not: before EBM, the source of medical knowledge was already found in scientific research. The main difference is just that statistics were not primarily important. And, both in the old and the new paradigm, the benefit of the patient is the primary aim. The patient already was a 'case' to a certain extent, just a specimen of a large set. EBM may reinforce the vision on the patient's body as an analytic one, that is a view to a number of well- and malfunctioning organs instead of a human being suffering a general distress. Yet this is not new, rather it is a direction to which medicine develops, a direction suited for and supported by EBM. But on some facets there really is some incompatibility.

First we should look at the scientific part. I already mentioned the fact that micro-causalities are no longer a sufficient principle to understand the functioning of the human body. Instead, physiology and anatomy may even yield incorrect knowledge. Therefore a broad numerical analysis is needed, thus entering the 'In Numero'-era. This means that previous knowledge may become invalid, or at least require a renewed investigation.

In the practical field of medicine, we should first think of a radical change of the doctor's way to carry out his tasks. Instead of mainly relying on the knowledge he gained at the University and in his clinical practice, he has to spend the greater part of his time on approving his knowledge by querying scientific evidence. Instead of trusting his knowledge, he now has to question the majority of the relevant facts. The time he needs for reading and surveying, has to be taken away from the time he previously spent with patients, or go at the cost of other tasks. It certainly must come from somewhere.

The second practical shift occurs in the skills the doctor needs. Besides the 'classical' medical skills, such as physiology, anatomy, epidemiology etc. etc., the doctor now needs to be able to judge the validity of evidence, and especially to judge the statistical aspects. What Sackett c.s. call the 'critical appraisal' of literature, is not a skill that is present naturally in medical (or any scientific!) education.

These shifts involve a third one. We should think of the difference in emotional understanding. Scientific outcomes may be contradictory to one's intuition. The patient can 'feel different from what de doctor decides on basis of statistics. If scientific knowledge is then applied too rigidly, the patient may not feel comfortable.

Although the doctor, practicing EBM, might not be less engaged with his patients, the patient can feel this way though. Medical knowledge is organised in a fashion quite unaccessible for the patient, and he may lose hold of it. The patient was probably counting on a doctor explicitly using his 'years of experience' to set the patient to ease, whereas he finds one arguing on unclear data. This emotional distance between the doctor and his patient may have always existed because of the doctor's eight-year education, but the gap might become more explicit when the doctor manifestly uses information that remains incomprehensible to the patient. Although this danger is a bit of a speculation, it *is* recognised in practice, e.g. by Borst-Eilers and van Leeuwen (2002).

Regarding Kuhn's second property of revolutions, that is the change of problems available for scrutiny, an interesting question remains. Kuhn describes mere science, that is the activity of uncovering the secrets of nature, i.c. the human body. There a problem may be a certain corporal phenomenon, that is to be laid bare. According to Kuhn, the solution of such a problem has a shape, that is defined by the ruling paradigm. Superficially one could state, that diseases investigated in EBM are the same as diseases investigated previously. Yet a closer look at these problems does yield a change: previously the micro-causalities formed the objects under investigation, but now also their appearance in a macroscopic view becomes part of the problem. The rise of the discipline of *clinical epidemiology* forms an illustration of this change of problems.

And then there is more. It is clear that within medicine a clear distinction between science and application cannot be made. So, within the field of application we may also find shifts in the problems. This is true: the practitioner's activities are extended with the search for evidence. Whereas previously he was just concerned with the investigation of the patient, he will now spend a significant proportion of his time by performing literature searches. Thus the problems available for the practitioner change as well.

The third characteristic established by Kuhn, concerns the radical change of the imagination. Kuhn addresses an example from astronomy (Kuhn, 1969, p. 115):

> *Looking at the moon, the convert to Copernicanism does not say, "I used to see a planet, but now I see a satellite." That locution would imply a sense in which the Ptolemaic system had once been correct. Instead, a convert to the new astronomy says, "I once took the moon to be (or saw the moon as) a planet, but I was mistaken."*

We may wonder, what the difference is, between a 'new insight' and a 'change of the world view'. After all, what is so radical in 'reinterpreting' the moon as a satellite? First, these changes are irreversible. Once that the new view is accepted,

one cannot return to the old view, even if the new view provides one with new and unexpected difficulties. Second, the new radical insight cannot be seen as a reinforcement of the ruling paradigm, simply because it doesn't fit within it. If it were just a new vision, it should be possible to explain it within the premisses of the ruling paradigm. A new insight can only articulate the paradigm, but it cannot correct it. And third (Kuhn, 1969, p. 121), the data upheld by science are not unequivocal, and even become different. Any data about the moon, acquired when it was a planet, are valid within the presumptions that hold about planets. When it becomes a satellite, these presumptions lose hold, and hence the data become obsolete.

This change of the world view holds for EBM as well: the 'n=1'-trial loses hold, and knowledge is only obtained from large numbers of (hence less tangible) cases. The idea that information is valid, only when tested in large numbers, is quite radical (that is, within medicine). A lot of knowledge, that previously counted for true, becomes obsolete. Clinical experience gets a new meaning: previously it was a very valid foundation for knowledge, whereas within EBM it will only be accepted as an inspiration and starting point for surveying evidence. We could say that generally the imagination becomes much more doubtful and critical. But that's not all. According to Verbrugh (2002), the patient fades out of view, and is replaced by a record of numbers (again the In Numero era).

Let's assume from the preceding paragraphs, that EBM requires a change in medical culture (both the scientific part and the field of application), radical enough to call it a paradigm shift. Kuhn then observes two conditions for new paradigms to be successful (Kuhn, 1969, p.10):

- They are sufficiently unprecedented to attract adherents away from competing paradigms, and
- they are sufficiently open-ended to leave all sorts of problems to resolve for the new adherents.

The first feature, that new paradigms should be sufficiently unprecedented can be interpreted as a 'demand for novelty'. Reconsider the example of the switch to the heliocentric world view. What Galileo did, had never been done before: putting the sun in the centre of the universe. It was this radical change, that dealt with some problems that were not solvable within the ruling paradigm (called *anomalies* by Kuhn). Because it was really new, it succeeded to draw the attention of scientists, and find its way into the scientific community. In general this means, that you don't take the effort of shifting to a new paradigm, if the novelty is insignificant, or if you

don't see an advancement in the solvability of your problems, such that it is worth the effort of shifting.

The second feature, that paradigms should be open-ended enough, can be illustrated by means of the same example. Once that astronomers were convinced that the sun should be taken as the central celestial body, they were free to focus their interests onto numerous new problems. If for example the new paradigm had prohibited to find a sound conception for the course of constellations (which did exist in the former paradigm), and only provided with a conception of the sun and the planets, the astronomers would have been far less interested. You don't turn to a new paradigm, even if you agree that is better in itself, if it prevents you from handling the problems you handled before. The heliocentric world view could only survive, provided that within it all existing problems in astronomy had their new place. (This forms a paradox with the prior statement that in a revolution the shape of problems addressed changes. The problems themselves remain unchanged, only they are looked upon through different eyes, and hence their shape has altered. The problem is what Kuhn calls *incommensurability*, that is: there is no 'objective language' in which the old and new views can be compared. Our vision will always be charged with one of the views.)

Then we come to the delicate question: do these features apply for EBM? At a first glance, the answer will be affirmative.

First consider the extent to which EBM is unprecedented. With respect to its medical aims it is not really new: the human body with its diseases has always been the subject, and curing the diseases has been the target. But attributing a central role to statistics, the RCT and the systematic review, is really new. The individual professor loses the authority he traditionally had, when his findings do not comply with the rules of evidence, no matter with which standards his works *do* comply. Instead, critical appraisal skills become the final authority.

And second, indeed EBM is sufficiently open-ended with respect to its application. A rather large field of problems to be solved remains open when practicing EBM. It is new, and the solution might get more complicated, but in principle there are no (medical) problems that cannot be solved by EBM, that *can* be solved by non-EBM. That is, the is the *pretention* made by EBM, and we will see in chapter 4 that it is not always so easy, to apply EBM to any medical problem.

In the 1969-postscript to *The Structure of Scientific Revolutions* Kuhn determines a new difficulty with paradigms. On one hand, a paradigm is what is shared by the members of a scientific community. On the other hand, a scientific community is defined as 'people who share a paradigm' (Kuhn, 1969, p. 176). Therefore Kuhn assigns primacy to the community, thus redefining the paradigm (or here:

disciplinary matrix) as something constituted by the community. The members of a community usually get their education in the same school or tradition. Thus significant differences can exist between communities. This eventual incompatibility leads to a competition between communities and their paradigms, which is usually ended quickly. That is, for *mature* scientific communities, as discussed by Kuhn. This primacy of the community implies, that if communities are incompatible, their paradigms must be as well. This is certainly seen with EBM: both in the scientific communities, and the populations of practitioners, there is a distinction between the 'pros' and the 'contras'. So even if the changes described before were not that manifest, we should still be able to speak of a paradigm shift, and investigate the problems that usually occur in these shifts.

Kuhn observes, that in some fields of science incompatible communities are much more able to accept one another's existence, without either of them being 'right' or 'wrong'. We saw earlier, that, according to Kuhn, the existence of various schools is a sign of immaturity for science. We saw, with the example of surgery prescriptions in Utrecht and Amsterdam, that this immaturity applied for medicine (not being EBM). Hence the introduction of EBM into medicine may require a circular development: a (mature) scientific background has to exist first, before scientific arguments can solve a controversy. Otherwise the arguments themselves become the object of quarrel, since they will not be admitted by all actors involved. But on the other hand, the controversy needs to be solved before a mature scientific background will be established. We should wonder to what extent current medicine accepts the existence of various schools, and to what extent this sign of immaturity stands in the way for EBM.

One aspect of paradigms framed in Kuhn's postscript deserves special attention for our purposes. It is the aspect of *values* within a paradigm. Individuals may be confronted with the necessity of choosing between two incompatible ways of practicing their discipline. But there is more. Even when values are apparently agreed upon, the application of these values may differ. Kuhn (1969, p. 185) states:

> *Though values are widely shared by scientists and though commitment to them is both deep and constitutive of science, the application of values is sometimes considerably affected by the features of individual personality and biography that differentiate the members of the group.*

Within the EBM context it will be an interesting question, whether individual values keep playing an important role. In any case the strictness of EBM, i.e. the extent to which it allows deviation from its objectives, will be subject to our scrutiny. But in addition to that, we will investigate to what extent personal values of the practitioner influence his choices.

Another aspect is the concept of *intuition*. Intuition can in this context be conceptualised as the framework through which we interpret perceptions of the world around us. Kuhn defines intuition as 'tested and shared possessions of the members of a successful group, and the novice acquires them through training as a part of his preparation for group-membership (Kuhn, 1969, p. 191).' With Kuhn, intuition is not individual at all. In the case of medicine, intuition can be seen as a mixture of associations and presumptions the practitioner has acquired at the University and in his clinical experience. Intuition then *does* have both an individual and a collective part. Whatever conception of intuition we take, it will be very difficult to investigate it. After all, it remains implicit. It would require quite an amount of observation of the clinical practice, before we can say anything reliable about intuition. Therefore we will confine ourselves to what the persons involve tell us about it.

We saw in chapter 2 that intuition is not abandoned by EBM. When a patient comes to his doctor, he will probably have one or more complaints. The doctor somehow has to link these complaints to medical knowledge. The structure of the complaints usually differs much from the structure of the medical knowledge. The latter is more or less uniform, the former is not at all. Consider this example: a young patient comes to his GP, and tells him he is very tired, even after only small activities. This is a very vague observation, not at all fitting the structure of medical knowledge. Then the doctor sees his patient, a young man aged 14 years, with no significant anamnesis. He immediately thinks of Pfeiffer's disease. It is this immediate thought that we should denominate with intuition. It forms the basis for following activities: asking the patient how long his exhaustion has lasted and at what severeness, if he has been ill recently, if personal circumstances have changed (after all, exhaustion can be a psychological problem very well). If the answers match what the doctor knows about Pfeiffer, he decides to take a blood sample, and let the lab screen it for type-M and type-G antibodies etc. etc. We see in this (fictitious) example a very faint observation by the patient ('I'm chronically tired'), in a small number of steps, is linked to a clear question ('Does the blood contain type-M or type-G antibodies?') that fits the structure of medical knowledge. Of course this example is simplified, the point is that these steps of reasoning could not take place without intuition, and hence will be nearly impossible to formalise.

Because of the polymorphism of complaints by patients, the linkage towards medical knowledge will never be uniform. Anything that cannot be formalised, will remain intuitive. In our inquiry, we will focus on the role intuition plays in EBM, and what qualification it is given: something useful we have to maintain, or an inevitable evil?

One more problem is introduced by Kuhn: the solution of controversies cannot be

cast into the shape of a regular mathematical or scientific proof (Kuhn, 1969, p. 199). In a regular proof, premisses are founded at the beginning, and maintained to the end. The solution of a controversy on the other hand, demands a transformation of the premisses. There is no distinction between the 'context of discovery' and the 'context of justification': standards for verification are subject to debate, and result from the new discoveries, rather than judging them (Vries, 1995, p. 103). Realising that these premisses precede any communication, we can assume that communication in a controversy is usually frustrated. Only when members of different 'language communities' recognise each other as such, the step of translation can be taken consciously. With *translation* Kuhn means the measures necessarily taken to perform useful communication between language communities. For example, for an adherent to EBM statistics may constitute a reliable form of induction, whereas for a dissenter it may be a bag of tricks to manipulate numbers. This difference of conceptions stands in the way for a clear discussion. It needs to be overcome: explicit measures need to be taken to understand one another. This translation however, can appear threatening to those who are not willing to change. Translation is foreign to normal science. Furthermore translation alone is not enough to get convinced by unfamiliar world views: one needs to experience the alien world view completely, before one can eventually convert to it (Kuhn, 1969, p. 204). To get back to the example: it is not just the conviction that statistics are a valid method, but also its meaning in the entire system of EBM, and the awareness that statistics overrule what we might learn from anatomy and physiology. The transition is then usually not an individual process, but a process of an entire community instead.

When looking at it retrospectively , the transition to the new world view appears as a piecemeal and sometimes hardly discernible development (Kuhn, 1969, pp. 203, 204). This occurs generally in revolutions: afterwards it looks like the premisses for the new situation have always been there. It closely matches the idea of *inversion* we will discuss later with Latour. It is an interesting paradox: what is viewed today as a huge step we are going to take, will tomorrow look like the one and only possible step we could take, and hence not such a big deal at all. Although beautiful from a philosophical point of view, this point will stand in the way of our empirical surveying of the controversy. We cannot simply walk into a doctor's office, and ask him how he experienced the revolution towards EBM. He just won't know.

Validity of Kuhn's theory

One may have some objections towards the application of Kuhn's theory onto the introduction of EBM. First of all, medicine is not a pure natural science. Actually

it consists of scientific aspects, and aspects dedicated to the application of this science. For an application of Kuhn's theory it may be more comfortable to separate research from medical practice. Yet in reality these two are interwoven quite incomprehensibly. We should be continuously aware of the fact that a change in the paradigm of research has its consequences for medical practice, but that the coincidence of these changes is not the same as saying that the research paradigm and the practical paradigm (which is not an item in Kuhn's theory) coincide. Yet we will see, that quite some of the properties Kuhn ascribes to scientific paradigms, also hold for the practical paradigm.

Secondly, Kuhn's theory implies that the imagination changes rigorously. With respect to this change, one could object that the introduction of EBM with its statistics only offers a solution to the larger part of the induction problem (common to any science), but that the general view to the patient as an analytic chemical-physical system is not changed. Although there is a point in this objection, some counter-arguments exist as well. With Verbrugh (2002) we find a different view on medical paradigms. He states that the first paradigm could be described as 'In Vivo'. That is: any knowledge comes from the living human body. The second paradigm is called 'In Vitro'. In this stage, knowledge is extracted from the chemical and physical experiments in the laboratory. We now enter the most recent paradigm, called 'In Numero', were the patient grows out of view. Instead, the medical view enters a virtual space of numbers. Although Verbrugh does not literally mention EBM, it is clear that this description matches EBM quite neatly. Verbrugh is talking about the patient becoming a numerical record, but this can only be seen to a background were any knowledge is highly quantitative by character. This matches the paradigm shift as described by JAMA (1992), where it is stated that the study of pathophysiological is no longer a sufficient ground for medical action, since at times it may be misleading. A numerical analysis is needed to verify them.

In the 1969-postscript to *The Structure of Scientific Revolutions* Kuhn (1969, p. 174 and further) assigns supremacy to the scientific community, over the paradigm. That is, a paradigm is defined as something shared by a scientific community. It would be wrong to state, that a shared paradigm defines a scientific community. If communities are incompatible, their paradigms must be as well. We will see later, that quite some incompatibilities exist between practitioners of EBM, and those opposing it. Regardless what we say about the change of the imagination, or the validity of Kuhn's theory for medicine (being not a pure or purely natural science), we cannot neglect this gap, and should therefore at least be suspicious for incompatible paradigms.

In the same postscript, Kuhn subdivides the concept of paradigm in *exemplars*, being the examples, models, solved standard problems etc. etc., and a *disciplinary*

matrix being the coherent system of convictions, premisses, commitments, and what Kuhn calls 'symbolic generalisations' (Vries, 1995, p. 102 and Kuhn, 1969, p. 182). With this subdivision he prevents confusion, and in the case of EBM it may also be useful to make this distinction. Convictions on methods for observation are necessarily part of the disciplinary matrix. These convictions are changing with EBM. The exemplars are changing as well, since a problem is solved in a different way (I am still talking here of medicine as a science, although this point holds for medicine as a practice as well). Altogether, speaking of a paradigm shift sounds legitimate.

3.4 Latour: black boxes and controversies

The second philosopher of science we will address is Bruno Latour. In his book *Science in Action* (Latour, 1987), he scrutinised science the way an anthropologist would scrutinise a population on unexplored Pacific islands. He is therefore often referred to as an 'anthropologist of science'. He observes that facts do not result from the truth being discovered. Rather it is a negotiation between fact makers, in which scientific and methodological rules play a role as well as social and political considerations. We will first discuss his theory, and then illustrate it with a short analysis of the ongoing controversy about population screening for breast cancer, which we already met in section 3.1.

According to Latour, a fact is developed following a certain path (Vries, 1995, p. 151 and further). First there is a large amount of texts. They are shaped as schoolbooks, articles, results from experiments etc. etc. These texts form the starting point for a scientist. He uses them, and reorganises them in a new fashion. He may cite them, stimulate their (re)publication, discuss them in seminars etc. etc. The scientist uses the texts to underpin a claim he wants to make. He actually builds a complex network around his claim, in order to provide it with solid ground. In this network, the function of a text may be altered. What for example previously had been presented as a surmise, may now be presented as an undisputed fact. Latour denotes this reordering of texts with *translation* (Vries, 1995, p. 151). (Notice that this conception of 'translation' has nothing to do with the conception by Kuhn!)

Then the claim is published. In renowned journals the researcher accounts for it, referring to the previous texts, his experiment outcomes etc. etc. It then depends upon a number of factors, what happens to the claim. The researcher's colleagues judge it, taking into account what was previously published on the matter, the reputation and competence of the researcher, perhaps even political and social considerations, etc. etc. (Vries, 1995, p. 153). The colleagues will publish their

modalities (qualifications) in new texts. With a *positive* modality, the claim is decoupled from the researcher and the document in which it was published. A positive modality has a stabilising effect, i.e. the claim gets to look more and more like a fact. With a *negative* modality on the other hand, a claim is connected to its genesis, thus corrupting its stability. When the genesis of a fact remains visible, it will not be taken as an accomplished fact (Latour, 1987, p. 21).

In the end the claim is either accepted or it is not. If the claim is not accepted, it will be seen as an *artefact*, a result of a scientific error. It will be forgotten soon. If on the other hand it is accepted, the researcher is credited for it. The claim will then become a *fact*. But moreover, the whole discussion will be forgotten. It will then appear as if the fact has always been there, and that it just needed to be uncovered. This 'forgetting' is called *inversion*, since it now looks like the fact came to the researcher, instead of the researcher working his fingers to the bone to get the fact accepted. We saw a similar phenomenon with Kuhn, where the revolution became invisible in retrospection (page 34).

After stabilisation the fact becomes part of the collection of facts that form central nodes in the network that constitutes 'technoscience'. The controversy preceding this stability becomes invisible: the fact becomes a so-called *black box*. It then looks like the fact (being true) settled the controversy, whereas according to Latour this is only one half of the truth: the controversy needed to be settled, in order to have the fact established (Latour, 1987, p. 258, rules 3 and 4).

To increase the understanding for Latour's vision, we readdress the example of breast cancer screening (Köhler, 2002). I will characterise the controversy 'through Latourian eyes'. Our point of departure is the year 1993. In *The Lancet* a review is published, in which a mortality reduction of 29% is proclaimed among women between 50 and 69 years of age, after participating in mass screening. A number of countries introduced nationwide screening after this publication.

Such a review is an illuminate instance of a reshuffling of texts, and a new network built around the claim that 'population screening reduces mortality due to breast cancer.' The texts enrolled mainly consist of articles, and outcomes of researches previously performed. In particular, a review in 1985 discussing five Swedish RCT's is incorporated. One very important 'text' seems to be the fact that Sweden has been screening women since 1985 (the word 'text' is placed in quotation marks, since it does not concern a single text, but rather an large and indistinct set of texts, that altogether constitute the policy of screening). Although this fact does not comprise any argumentative power, it feeds the notion that screening is useful. Some of these texts clearly confirm the claim, some of them don't or confirm it just very implicitly and marginally, but they all are used to underpin the claim.

What we see here, actually consists of two questions running through each other. First there is the question whether screening for breast cancer reduces mortality from breast cancer. Second, there is the question wether screening should be performed. From the EBM point of view only the first question is relevant, and when it is answered, the answer to the second is obvious. Yet it is typical for Latour's theory that these two interfere. There is no such thing as pure science, that solves scientific problems, and then it is up to society to do something with it. Rather there is a very complex network of scientific and societal actors, that altoghether influence the discourse (on both of these questions!). There is no sharp distinction, and that is what makes the course of the controversy so unpredictible.

The network apparently is strong enough to convince. The acceptation of the claim is the result of a negotiation, both in political and scientific/medical circles. Both scientists and politicians seem to be persuaded, otherwise the screening would never have been introduced. They judged positively on the claim: they have applied a positive modality onto it. What we see here is a (more or less) stable fact: 'screening reduces mortality due to breast cancer by 29%'. It has now become a stable *black box*, not yielding up the secrets of its genesis.

This does not mean that it has always been uncontroversial. Resistance against this practice has always been uttered, but it was mostly from considerations of expenses and assets, and the question whether the mortality reduction should be bought at the cost of the mental stress it invokes, even if women turn out to be healthy. Moreover proof was missing for the assumption that an early-treated carcinoma is cured better. And although mortality caused by breast cancer has been decreasing slightly through recent years, the overall death rate due to cancer in general remains stable. Yet these counter-arguments have remained marginal, and the negative modalities casted by them apparently were not strong enough to thwart the closing of the black box.

But now two Danish epidemiologists, Peter Gøtzsche and Ole Olsen, want to open this black box. They examine the Swedish studies, concluding that their methodologies are inadequate. In some cases the randomisation was poor, some studies were generally poor, and some didn't even meet any standards. In some researches, pathologists determining causes of death, knew about the screening anamnesis of the deceased: 'blindness' was not warranted. Moreover some effects of screening were not taken into account: for example the fact that now cancers were treated, that previously were considered not needing treatment. It is not even clear that the decrease of death from breast cancer is indeed reduced by the screening, rather than other influences such as increased alertness among women, improving of contraceptives or changing habits (with this remark, Köhler refers to the Dutch situation, not to the Danish research). The Danes appeal to the guidelines of the

Cochrane Society. These guidelines are objective, and the resulting meta-analyses pretend to be ultimately reliable.

This is an example of scientists trying to apply a negative modality to a fact. They reconnect the fact to its genesis, thus making it less rigid. They retranslate the original texts for new purposes. Where initially the texts are used to proclaim the effectiveness of screening, they are now used to undermine this effectiveness. The original *inversion* is corrupted: originally, the research was obscured, in order to make the fact appear naturally true, thus invoking the evident research outcome. Now the research is questioned, such that the fact becomes unstable. The black box is opened. Clearly the controversy was not settled because of the fact being true, it was the settlement of the controversy that made us believe the fact to be true. This is exactly what Latour formulated as his first principle (Latour, 1987, p. 13).

Now a renewed controversy breaks out in full violence. One of the Swedish researchers, Laszlo Tabar, fences off the critics. He pronounces confidence in his past research and his near colleagues at that time. To his opinion, the critics do not at all refute the results of millions of life years followed up by his researchers, and dozens of previously published *expert reviews*, showing the effectiveness of mammographic screening. What we see here, is that Tabar refers to texts to which he applies a high degree of positive modality: expert reviews are written, what's in a name, by experts, so why question their credibility? Again a translation is being performed: the conclusions of the expert reviews are now taken as established facts, and used as arguments to underpin claims resulting from Tabar's own researches.

Among Cochrane members, an expert review is like the red cloth in a bull fight: anything will be done to discredit it. After all, it is written from the expert's highly subjective point of view, whereas a Cochrane review is written according to objective guidelines. Hence Gøtzsche replies that these expert reviews are by no means reliable. He sustains his negative modality to the text by Tabar. Gøtzsche proclaims to be open to reflection and discussion of his own investigations. As long as counterproof is lacking, he sticks to his own rightness. He thus expresses confidence in his outcomes, and moreover in the Cochrane guidelines he adheres to. A positive modality is now being applied to these guidelines: practically being the result of negotiations on methodology, they are formulated here as 'facts' on the optimal method.

Up to this point we can characterise the controversy. The settlement is still out of reach, for as Gøtzsche and Olsen state: it is up to the politics (!) to decide whether screening needs to be continued or not. Here we see again Latour's network theory: it is not nature and its 'truth' that determine which facts are right and which are wrong, but rather it is the network of scientific, social and political actors and

their texts, that will determine the final outcome of the controversy. It is not nature which will tell us whether we should perform screening or not. Rather it is our common decision, that will provide us with a conception of breast cancer and the usefulness of screening. In Latour's theory this is found as third and fourth rules of method (Latour, 1987, pp. 99 and 144 respectively).

The reception of Latour's theories was not without struggle (Vries, 1995, p. 158). The theories imply that for example electrons never existed, until one brilliant physicist conceived of them and found mathematical and experimental proof for their existence (this is an implication noticed by De Vries, not by Latour himself). One could object that this is nonsense, and electrons have existed ever since the beginning of time, only we were as ignorant as not to know them. Their existence was the motive (!) for the pursuit by scientists until they succeeded. But this objection is retrospective! If one accepts a fact as it is, one apparently does either not want to reproduce the process of construction, or not see himself able to do so.

But then, shouldn't 'facts' refer to 'nature'? Aren't they founded on the solid ground of objective observation? According to Latour they are not. They are founded on texts, experimental results, outcomes of instruments etc. etc. According to Latour, 'nature' and 'culture' are the objects to be scrutinised, the *explananda*, and should therefore not be mobilised in the proof, the *explanans* (Vries, 1995, p. 161).

The development of science is more than a collective human effort. It is a network of texts, some of which are generated by humans, others by machines, and whose fate is not just in the hands of the author. This network is not limited to the laboratory or any scientific context. Also the entire social structure is part of it (Vries, 1995, p. 162 and further). The validity of facts beyond the scientific context, demands the social structure to be transformed in favour of it.

Let's clarify this with an example. Imagine an exotic people, believing in traditional magic, and not in modern medical science. They will not agree that Paracetamol relieves pain. Even if they try and swallow, and pain is relieved, they will not believe that it is this small pill that annihilated the pain. For there is no such thing as a small white piece of 'stone' that relieves pain. Pain is only relieved by the witch doctor's rituals. In fact, this is not just their belief, it is their *truth*, their *world*. It demands a conversion to Western enlightened science with its knowledge, prescriptions, norms, values etc. etc., before Paracetamol as a painkiller can capture a place in their world. An observation of the efficacy of Paracetamol is not enough. It will not even be recognised as an observation in our notion of the word. We see here that the fact that 'Paracetamol is a reliable painkiller' is valid in our Western world, but not in the world of a traditional tribe. Validity of facts is not universal,

and hence the facts themselves are not. The same goes with EBM. One of the premisses of EBM is, that statistics yield reliable knowledge. This is contrary to the idea, whichis even present in nowadays intellectual world, that statistics are easy to manipulate, and that not seldom the outcomes are such as the creator wants them to be. It is this idea that needs to be overthrown, before EBM can get foothold.

Another issue in Latour's theory is the accusation of *irrationality*. It is generally made by scientists towards non-scientists. For scientists it is a matter of irrationality when people believe that the sun revolves around the earth, even when the opposite has been proven. Or when people insist that a summer was extraordinarily hot, whereas meteorologists have shown that it was only 0.01 degree above average. Generally, when scientists see themselves confronted with irrational behaviour, they tend to explain it from influences that Latour calls 'outside forces'. We should think of superstition, prejudice, cultural differences, or even just stupidity. This conception is valid only, when one accepts the scientist's position, distinguishing between beliefs and knowledge.

It is not as easy as to say that this accusation is naturally made by people inside a scientific community, towards people outside that community. For honesty demands us to look at it the other way around. When a logic does not match the reason of the scientific community, it does not necessarily mean that there is no reason, or no logic. After all, we see the sun rising, passing the zenith, and setting under the horizon every day! We don't see the earth flying ellipses around the sun! Those 'scientific' proofs are only some conjuring with numbers and graphs, it's not what we see every day! Or about the weather: one could state that one hasn't had so many good cycling days for years, so this summer was hot! The point is, that behind an (apparently) irrational reason, there is always a structure or context in which the reason *is* logical. From within this structure usually the opposite accusation can be made with the same ease: that it is actually science that behaves irrationally.

We now come into a hazardous area. Both for scientific and non-scientific reasonings, sound and clear, it is possible to make them look ridiculous and irrational. And conversely, anything that appears illogical or ridiculous, can be made sound if the appropriate context or internal logic is taken into account (Latour, 1987, p. 191). What are we, scientists, supposed to do now? If any reason can be proven to be logical, then what ground do we have, to rate our knowledge superior to other beliefs?

Is is clear that the accusation of irrationality is a dangerous one, since it can usually be reverted, such that it turns against the accuser. According to Latour, the world is not simply made of rational reasonings that are rarely followed, and irrational ones that are more often followed. Instead, we live in a *logical enough world*. People

don't care about their logics, as long as failing logic doesn't stand in their way. What can we, scientists, tie to our claim in order to make it conquer the opposition? After all, science apparently *does* have a convincing power, and this power should come from somewhere! Meteorologists are believed better than grandma's weather predictions. And we don't trust Tom, Dick and Harry to build a bridge on the Rhine, instead of qualified engineers. What do engineers and meteorologists (whom I will denote with *scientists*) do or have, such that we trust them better? And why are they believed to be more rational than grandma and the do-it-yourselfers (whom I will denote with *believers*, because they adhere to 'belief' rather than 'knowledge' in the scientific sense)? According to Latour the scientists have their networks in which their knowledge is spread. These networks extend through the entire society. By these networks, knowledge is easily accessible for dissenting believers. From the point of view of the scientist, it is surprising that belief holds at all, since knowledge is to be picked up from the floor. That is where the accusation of 'irrationality' pops up. Of course in the case of EBM, 'irrationality' concerns sticking to methods that are proven to be obsolete, void or ineffective, and even the item mentioned before, that statistics are believed to be a bag of tricks that can prove anything you want.

The power of scientific reason comes from the phenomena themselves they describe. Contrarily, the power of an irrational reasoning comes from the person who reasons, and not from the phenomena subject to the reason (Latour, 1997, p. 184). An explanation of a phenomenon by science (i.e. knowledge) can usually not be disproved by belief *within the structure of this belief*, whereas science with its knowledge, as a structure, is able to disprove the belief within the structure of knowledge.

Regarding irrationality, Latour establishes the sixth of his seven *rules of method*, (Latour, 1987, p. 213):

> *When faced with an accusation of irrationality, or simply with beliefs in something, we will never believe that people believe in things or are irrational, we will never look for which rule of logic has been broken, we will simply consider the angle, direction, movement and scale of the observer's displacement.*

Thus, when we see someone accusing someone else of irrationality, we should try to find out what the position of the accuser is, instead of finding out where the accused fails in reasoning.

According to Latour, scientists and engineers form an alliance with the products (i.e. scientific facts, or 'things' in a generalised meaning, anything that is 'made by man') they have shaped. This alliance is rigid, especially if we want to question the validity of the products: at any question we ask, the scientist will tell us *what*

to see. Enter a laboratory in which a pharmacologist is investigating a new cure for anaemia (a deficiency of haemoglobin). The evaluation of his treatment is shaped as some diagnostic kit measuring the amount of haemoglobin and red blood cells in the blood. Now we ask him how he can be so certain that the amount of haemoglobin is increased by his treatment. "Look", he will say, "here you see the proof! These graphs, measuring results, tables etc. etc. show the increase of haemoglobin!" There is no room left, for even thinking of the fact that haemoglobin is not increased, or by other causes than the treatment. Within the laboratory, the scientist's claims are even more powerful than outside the lab. To overrule this powerfulness, we will have to come up with a larger laboratory: to ferret out the claim (and eventually disprove it), we will have to perform more research, in our own laboratory, involving more resources (and black boxes!) than the original scientist did.

Another ally at the side of the scientist we encountered in his lab, is the *instrument*. Latour calls an instrument or 'inscription device' (Latour, 1987, p. 68):

> *any set-up, no matter what its size, nature and cost, that provides us a visual display of any sort in a scientific text*

We find instruments at whatever location we want to open a black box at. When telling us what to see, the scientist engages the instrument on his side. An ignorant person being shown a couple of graphs, would name them 'lines on a sheet of paper', or something. "No" the scientist will object, "those *are* the proportions of haemoglobin! Look, here you see them rising when my medicine is dispensed!" We agree only because he tells us. We would have believed him as well, if he told us it were pathways of his two-year-old kid, taking its first steps. We may want to corroborate his research results externally. This external check will generally be much more complicated than the original research, and will also engage even more black boxes, instruments, and graphs and numbers to underpin our own investigations. The original research will only be corrupted by a research that is underpinned more rigorously.

Latour postulates a number of 'rules of method'. I will not precisely discuss them here, but paraphrase some of them in order to avoid some traps in analysing science. We already encountered some of them in the preceding pages.

It would for example be naive to assume that science, society and technology are separate entities. Rather we find stronger and weaker associations, which constitute the complex structures in which technology is embedded, and which together determine the meaning of a product. Furthermore, in this complex coherence, it is impossible to state that controversies get settled as their consensus approaches facts from nature better, since nature as we know it, is only the result of settling

controversies. The same holds for society: controversies do not settle because of society's stability, but society remains stable because controversies get settled. Latour thus proposes to keep an eye on mutuality: not only look at the effect of products on society, but also mind the effect of society on a product. Not only accept nature as a source of knowledge, but also realise that nature as we know it is constituted by our knowledge.

What happens if science leaves the laboratory? If you launch an idea for a new product (be it a fact or a thing), it is hardly predictable what course the idea will follow. The idea can be developed further to a product by other parties, such that it practically stops being an instance of your ideas. Or the product shaped can be an instance of your ideas, only captured by others, such that your name is no longer attached to it. The quandary exists in the fact that on one hand you need others to have your idea spread out in time and space, but on the other hand you do not know exactly how they will transform your idea. In having your ideas following the desired course, Latour observes two major actions. The first is *to enroll others*, such that they participate in the construction of your product. The second is *to control their behaviour* in order to make their actions predictable. (Latour, 1987, p. 108)

We already briefly encountered Latour's notion of 'translation'. Latour calls *translation* the interpretation given by fact-builders of their interests and those of the people enrolled (Latour, 1987, p. 108). A number of methods is available for performing these translations. It will again be clear that Latour's notion of translation is different from Kuhn's.

The first method is to formulate your goals, such that they join those of the ones you want to enroll. You have to make them believe, that your ideas are a well-suited means to their own goals. In this strategy, you need no other force to transform your claim into a fact: you can 'ride piggy-back', as Latour calls it. For example, as a mechanical engineer you have an idea for a self-inflating backup tire. Normally backup tires are kept inflated, which takes a lot of space in the car's trunk. A self-inflating tire will save space. It will compromise the car's road-holding when used, but it should be able to bring you to the nearest gas-station. But as a solitary engineer, you don't have the resources to accomplish this product. Then what do you do? You visit some car manufacturers. They are always interested in using the space in a car efficiently, and your product can be a means to this end. They can develop your idea, since they have development labs, research divisions etc. etc. The strategy has disadvantages as well. With this method it might not be warranted that your name will be attached to the facts to establish: the tire will rather be named after the car brand, than after you, the engineer who conceived the idea. Moreover, since you are hitch-hiking on others, you may not be able to control

what they will do with your claims. They may end up with an entirely different tire from the one you had in mind (Latour, 1987, p. 109).

This translation actually fits EBM quite neatly. The goals of EBM are not significantly different from those of non-EBM. In both cases the benefit of the patient is the aim. To this end, EBM has an intermediate aspiration, namely to found acting on scientific grounds. The agenda item is then to convince others, that this scientific foundation really leads to the benefit of the patient. One question however is still attached to this translation. I stated that the central aim is the benefit of the patient, both for EBM and non-EBM. Of course, a physician practicing EBM will always endorse this aim. But on the other hand, the value of statistics is highly stressed in EBM-literature. Moreover, it is not obvious that it cannot be reached without EBM, so then why take the effort?

The second translation is to get others interested in your goals (Latour, 1987, p. 111), such that they leave their original goals in favour of yours. You can then guide the new adherent to pursue your aims. Generally the only reason to leave one's goals, is your own courses being frustrated. This does not occur often, according to Latour. I quote here the example Latour gives on page 111:

> *For instance, a rich businessman with an interest in philosophy wishes to establish a Foundation to study the origins of logical abilities in man. His pet project is to have scientists discover the specific neurons for induction and deduction. Talking to scientists he soon realises that they consider his dream as premature, they cannot help him reach his goal yet: but they nevertheless ask him to invest his money - now without a goal - into* their *research. He then opens a private Foundation where people study neurons,children's behaviour, rats in mazes, monkeys in tropical forest and so on... Scientists do what they want with his money, not what he wanted.*

To answer the question whether this translation will be suited for EBM, we have to find examples of practitioners, not practicing EBM, who are frustrated in their courses, such that they start looking for new methods, and run into EBM. It is likely that the founding fathers of EBM started to think about their methodology, when they saw that too often medical aims were not met. In a research by Coumou (2001), we see that a practice specialised in 'second opinion' flourishes, because often patients (not being the doctors!) are not satisfied about their health care. But we also see that the advocates of EBM run into the rigidity of medicine and its habit to treat things the way they have always been treated, just because they have always been treated that way. Thus frustration occurs, but apparently a conversion to EBM stays out.

The third translation is to get others only a little bit distracted from their own courses. The 'detour' they have to take must be well-defined, and appear

to be short (Latour, 1987, p. 111). In this case the original course needs to be frustrated too, only not that rigourously. One has to take care that the detour remains appearing small, since otherwise the illusion of the second strategy might be aroused, and support may be cut off. The acceptable length of the detour is a result of negotiation. Once that the detour has been completed, it will be very hard to decide who is responsible for the move: both the one invoking the detour and the one making the detour can claim credit for the decision.

Again I give an example taken from the design of cars. Electrical cars, to be more specific. With the current state of the art, electrical cars can compete with middle-class regular cars with respect to speed and acceleration. There is only one problem: their range of action is much smaller, since an accumulator can store far less energy, than a gas tank in the same volume and weight. Before these cars can become a serious competition towards cars with combustion engines, a serious improvement has to be achieved of the capacity of accumulators. If you are a chemist with a brilliant idea to improve the accumulator, you will easily find large companies that want to join you (if, of course, you succeed in convincing them of your plans). They have the resources to support your research, both financially and with their own research divisions. In the end, they will have the accumulator they want, you will have implemented your idea, so everybody will be satisfied. The car manufacturer took the small detour of cooperating with you, and you enrolled a powerful companion in your course. This example is fictitious, but I chose it to stay close to the previous example, of the backup tire. Then the difference becomes clearer: a more efficient backup tire is not essential for manufacturing cars, whereas an efficient accumulator in the case of electrical cars is.

Nevertheless this method might be useful for EBM: EBM actually *does* aim for the same as non-EBM does, only with the (pretended) small detour of literature searches. So, small frustrations within medicine should suffice and be used as motivations to convert the doctor to EBM. According to Latour, the adherents of EBM should investigate the practice of doctores who are not (yet) converted to EBM. Then any difficulty, even small ones, in this practice should be used to illustrate the advantages of EBM. Then it should be propagated that the effort to be taken with EBM is only marginally larger than when not practicing EBM. This will be a challenge to EBM, since to most candidate-converts, the detours provided by EBM appear rather large.

The fourth method of translation is to 'reshuffle interests and goals' (Latour, 1987, p. 113). This can be achieved by either changing the goals of the ones you want to enroll, by inventing new goals, inventing new groups to which you can appeal, by shaping the detour such that it becomes invisible, or by having achievements attributed to yourself. As an example, we could think of the introduction of

cell-phones the past five years. The newly invented goal is obvious: being continuously accessible. Apart from very specific groups such as GP's and police agents, nobody felt the necessity of being mobile and accessible at the same time. This need was invoked by network operators and cell-phone manufacturers. With what argument? 'Because everybody should be mobile and accessible!' Teenagers and young professionals, which generally are sensitive to this kind of arguments, where then divided into two groups: the 'haves' and the 'have-nots'. Of course everybody wants to be a member of the former... This way the companies enrolled millions of customers, to create a stable market form their product. And one more: they also shaped the detour invisible, by offering the cell-phones for free with a (not so free) subscription.

In the case of EBM, we should think of the following. Changing the goals of the one we want to enroll comes closely to the second and third translation methods, with all properties discussed there. Inventing new goals is actually what is done by EBM: besides providing the patient with optimal care, the new goal of explicitly underpinning your knowledge with scientific evidence is invented. The old goals (providing with care) are not abandoned. For inventing new groups to which you can appeal, we find a difficulty in our case: EBM needs to be practiced by doctors, and therefore the doctors themselves and the medical students are the only relevant groups. The only new group I can think of, is 'the meticulous doctor', being a subclass of doctors, distinguished from the general class of doctors, which is hereby accused of not being meticulous. We could try to find out whether doctors practicing EBM distinguish themselves explicitly from those who don't. Shaping the detour such that it becomes invisible will be difficult, since the appraisal of statistics is an activity that cannot really be disguised: to me it seems to differ too radically from 'pure' medicine. Having achievements attributed to yourself, finally, is very well suited for EBM: show others that you care for your patients in a better fashion, and use your success to underpin the justness of EBM.

The fifth translation is to formulate your goals in such a way, that others necessarily have to share them. Thus you are becoming 'indispensable' (Latour, 1987, p. 120). Whatever the others want, they necessarily have to pass through your position and support you in your interests. With your position, you acquire some sort of hegemony, a superiority nobody can neglect. According to Latour this strategy is 'common practice, but in order to succeed, other allies have to be brought in, and most of them do not look like men or women (Latour, 1987, p. 121)'.

An example of this fifth strategy is known as the *Gillette-principle*. Gillette, the world's leading manufacturer of wet-shaving products, applies the following commercial strategy. The Gillette-shaver consists of two parts: the holder and the blade. The holders are sold with one or two blades, easily obtainable because of their

low price. Probably Gillette suffers a loss on the sell. Now comes the trick: after a number of times of shaving, the blades become blunt, and need replacement. The blades are sold separately, but for a relatively high price! After some accounting, we could find that in the first occasion we paid actually only for the blades, and not for the holder, but apparently most customers are lousy accountants. They now reckon themselves among Gillette-shavers, and they need Gillette-blades, despite the fact that much cheaper no-brand disposable one-part shavers are available too. By having a holder infiltrated into your bathroom, Gillette became indispensable for its blades.

To apply this fifth strategy to the case of EBM, we could think of proclaiming that traditional medicine is obsolete, and that EBM is the solution. This is actually what is currently done by advocates of EBM. The goal seems to be to practice medicine, and to maintain knowledge by applying statistical skills to large numbers of cases. The latter may not necessarily be shared by doctors not practicing EBM, but if it becomes clear that this yields optimal care, they will have to admit, and convert to EBM. Actually EBM inherently has the pretention of being indispensable.

The question remains why not every doctor nowadays practices EBM: apparently the practitioners of (non-evidence-based) medicine are not ready to accept that it is obsolete, thus not accepting EBM's hegemony. It would be too easy if we attribute this refusal to the 'general rigidity of medicine'. What reasons do we have, to suspect medicine to be more rigid than for example physics, or engineering? We could think of the fact that the construction of medical knowledge has always been less transparent, and more founded on authority than e.g. physics and engineering. Moreover the efficacy of medical treatment is much more fuzzy[1] in evaluation, than the evaluation of new physical theories. This problem has always existed in medicine, but first with EBM it becomes manifest, since now explicit methods on judgement of facts are established.

So far we have seen Latour's visions on how an inventor can engage people into his pathways, such that in some way they contribute to his aims. The next item, is to keep them in line, and to control them such that they will stay an ally, and not drop out untimely. It should be made impossible, or even unthinkable, that the new allies

[1]Here I take the word 'fuzzy' in the same meaning as in 'fuzzy logic'. In traditional logic, an item is either an element of a set, or it is not. In fuzzy logic an item can be 'partly an element of a set, and partly not'. Thus a bottle filled for 54%, can for this 54% be a member of the set 'full bottles', and for the remaining 46% be an element of the complementary set 'empty bottles'. In this light, we should see the difference between the physical claim that 'we finally showed that α-radiation actually consists of He-nuclei traveling at a fraction of the speed of light' and the medical claim that 'we finally showed that over 80% of the cases of lung cancer is the result of smoking'.

will dissent, lose interest or try to open the established black box. The solution Latour proposes (Latour, 1987, p. 122): to keep the allies in line, the fate of the claim should be linked with so many assembled elements that it resists all trials to break it apart. An eye should always be kept on the weakest link in the alliance, and how this link can be fortified. Sometimes new allies are engaged. Then the new alliance will be stronger than the old one.

This inspires an interesting question: once that a physician has made the transition to EBM, how can he be kept to this network? To give a Latourian answer: it should be unthinkable that he will abandon EBM. But how? It should be clear to him, that his new acting is more successful; that results of his partners practicing EBM are more reliable than those of partners not practicing EBM; that abandoning EBM would be a step backward etc. etc. These items sound quite obvious. In fact they are, but they are found in EBM literature mainly. It should be warranted somehow that they become part of the physician's individual daily view, instead of some indistinct statements proclaimed by scientists in a research centre across the ocean.

3.5 Latour: guiding power of technology

The last book I discuss here is *The Berlin Key* by Bruno Latour (1997). The title is derived from a type of locks, found in the suburbs of Berlin. By certain clever tricks, the inventor of the lock forces the user to lock the door, otherwise his key will not be returned. Or, if the local caretaker decides the other way round, the key will only be returned if the door is *not* locked. The tenor of the book is to explain how things can determine our acting more or less rigidly.

In this book Latour emphasises that things and human beings are not separate categories. On the contrary: people shape things, and things shape people. Latour defines technology as 'the whole of relations between people on one hand, and people, things and animals on the other hand' (Latour, 1997, p. 17). The shaping of things and people is a negotiation: each of them has an aim, that interferes with the aims of others. A compromise needs to be reached. Both people and things have to pay their contribution to the compromise. People and things have an equal position in this symbiosis. It is not 'people versus things', but rather 'people and things together'. In this book Latour gives new views on the negotiations we already saw in *Science in Action*. We may assume that things are unstable, but people are even more unstable (Latour, 1997, p. 63)! Latour discusses the evolution of a thing. This can be anything that is shaped by man. In our case we will observe the EBM methodology as such a thing. This might sound far-fetched, since one cannot

buy some EBM in a shop, and put it on one's shelves for decoration. Yet, EBM comprises a lot of the characteristics Latour attributes to things. Both EBM and things are shaped in interactions between people and (other) things. Both EBM and things can take over certain tasks and values that were previously maintained by persons. And both EBM and things mediate our interaction with the world. Things and people are connected by relations, thus forming a network. The evolution of the thing comes together with a number of changes in the network of people and things. Five origins of change are discussed in the following lines.

Latour clarifies his theory with an example taken from *Guust Flater*, a Flemish cartoon hero. I will illustrate it immediately by an experiment of thought, a fictitious discussion between two doctors: one, John Smith, being an adherent to EBM, and the other, Jim Jones, being a stick-in-the-mud with respect to medical practice.

In accordance with Latour, we start from a stable situation, in which there is no such thing as a controversy. But then, new creatures (being either human, animal or abiotic!) are introduced, which then become a participant in the negotiation (Latour, 1997, p. 29). Let us consider the situation we start in. Jones, the stick-in-the-mud, is consulted by a patient suffering from a Mycosis infection. It is very similar to several cases of Mycosis Jones has seen before, yet slightly different. He is thinking of applying standard treatments, but to be on the safe side, he contacts Smith. Smith doesn't have an answer immediately, but, being a friendly colleague, he promises to call back Jones the next day. Smith has access to all EBM resources: *Medline*, the Cochrane Network, and several abstract databases, concerning systematic reviews. For the sake of clearness I will group them under the name Resources. Resources is on the side of Smith. In this initial situation, the set of actors is: Smith, Jones, and Resources. Two more actors are initially present, but they don't mix in the discussion: Mycosis and Patient. Mycosis is not taken serious, because no one of the others is willing to give in to Mycosis' aims (i.e. to bother Patient, use him as a reproduction croft etc. etc.). Patient is taken serious, but his aims are not conflicting with any of the others: Patient just wants to be cured, be it one way or another. So initially he isn't a participant in the discussion. Smith will hand over his research results (from Resources) to Jones, and give Jones the fraternal advise to adapt to EBM.

This is where the new creature, EBM, pops up. Someone that previously accepted the situation, now decides not to support the current compromise, and thus becomes an opponent (or reversely, an opponent becomes an ally). In our small novel, the following happens. Smith, Resources and EBM want to convince Jones that EBM is to be adopted. Latour calls this Smith's *program*. Jones doesn't want to adopt anything, he just wants information on Mycosis. Jones's unwillingness frustrates Smith's program, hence Latour calls it the *antiprogram*. These shifts of

functions are depicted in figure 3.1. Each row corresponds to a stage in the evolution of the discussion. On each row we see all elements that are involved in the discussion. Some of them belong to the program, others belong to the anti-program.

Now Jones has turned from a colleague into an opponent: he does not intend to convert to EBM. This is were Smith introduces a new ally: he advises about the crash course on literature searches, held by the Cochrane Centre in two months. It is a small effort of one afternoon, and the skills to be attained are promising. Let's denote it with Course. Now we have on one side Smith, EBM, Resources and Course trying to convince Jones. The antiprogram is still active: Jones has not converted to EBM yet. But the program involves more: the patient is getting impatient, because of all the fuss about his simple disease.

To solve a controversy, at least one participant has to change his attitude. In our story, it is most desirably that Jones changes his opinion on EBM. It is not necessarily so, but today we are the novelists. If Jones is convinced by Smith, Resources, EBM, Patient and Course, he will become part of the program (in this sense that he is no longer part of the antiprogram, obstructing the program). Is any antiprogram left now? No, for the time being the controversy is settled. After all, the patient will now soon be helped, thus becoming part of the program too.

This is the fourth stage: participants and their tasks are reshuffled, such that a new compromise emerges. New forms are substituted. The new compromise consists of Smith, Resources, and Course being the explicit allies of EBM, and Jones uttering the intention to at least take a closer look at EBM. Patient is satisfied, thus sustaining the new compromise.

In the last, fifth stage, the new compromise becomes stable, and is put away in a black box. After a while nobody will remember the controversy. Both Smith and Jones will practice EBM, and this harmonious world will look like it has always been there. The guidelines of EBM will be routinised, and every physician will follow his own path. It will look like Patient (in a far past) was treated in the only possible way, and no dispute had been carried on at all.

What we see, is that in the evolution the number of elements increases, until in the end the anti-program becomes void. For the sake of completeness, the program

		AND →
	program →	← antiprogram
1	Resources, Smith, EBM, convince Jones	Jones not convinced
2	Resources, Smith, EBM, Course, convince Jones	Jones not convinced
3	Resources, Smith, EBM, Course, Patient, convince Jones	Jones considers course
4	Resources, Smith, EBM, Course, Patient, Jones convinced	(void)
OR ↓		

Figure 3.1: Schematic representation of Smith's program: 'Convince Jones'

of Jones, to get the information from Smith, is given in figure 3.2. It is left to the reader, to retell the story from Jones's point of view. It shall be clear that in Jones's case, the antiprogram is simply too strong.

Now let's look a bit more to reality. After all, the previous was just an experiment of thought. This morphology casted on a controversy is an abstract level of thought. Its value is should be found in general insight: any controversy found while studying EBM might comprise one or more features described above. Naming the elements clarifies the whole.

The question remains whether the fourth (and hence the fifth) stage will be reached at all in the case of EBM. The character of EBM is such, that it will not accept physicians not adhering to it. The 'program' of convincing opponents will always be triggered. A doctor acting in the spirit of EBM, will always agitate against practitioners not following the EBM guidelines. So as long as not every doctor endorses EBM, there will be a controversy, and the black box will not be closed. But still we may be able to discern the separate elements.

A development as described above, cannot be understood from either only the people (Smith, Jones and Patient), or only the things (Mycosis, Resources, EBM, Course), but can only be understood if the whole of relations is taken into account. An evolution takes place in all actors. That is: the inventors of EBM, their adherents, the opponents, the structure of medicine, and, last but not least, the EBM philosophy itself. According to Latour, these evolutions do not occur parallel, nor in mutual influence. Rather the actors are 'words in a sentence, which are connected to other words. For the things and human beings there is only one syntax, and only one semantics (Latour, 1997, pp. 26-77).' We cannot cancel any word from the sentence. We can replace it, we can group some of them together in routines, but the total number of actors will never be reduced.

This theory provides us with some more concepts to study on the development of EBM: who are the participants, what does the negotiation look like, what is the resulting compromise? What does the final structure, or 'sentence' look like? What stage of the evolution is EBM currently situated in?

		AND →
	program →	← antiprogram
1	Jones, get info	Smith gives info and tries to convince Jones, EBM, Resources
2	Jones, reject EBM	Smith announces Course, EBM, Resources
3	Jones, reject EBM	Smith, Course, EBM, Resources, Patient gets impatient
1	Jones convinced	(void)
OR ↓		

Figure 3.2: Jones's program: 'Get info on Mycosis'

Sometimes, as a result of the controversy being settled, a task or function previously performed by a human actor can now be taken over by a thing. The process where human actors are replaced by non-human actors, is referred to as *delegation*. For example, the closing of a door could be delegated to a door-closer, instead of drawing everyone's attention to close the door. By delegation, the total 'amount of morality' is not affected, simply because it does not depend on who a decision is taken by, what its moral impact will be. By delegating our morals to things, we become even more 'ethical' than we would be without (Latour, 1997, p. 35): once that an ethical position is delegated to a thing, it will generally be carried out more strictly and reliably than when it were performed by a human.

This delegation is seen with EBM as well: by means of the set of steps in chapter 2, the behaviour of doctors is rigidly prescribed. We could therefore state that some classes of medical decisions are delegated to this method, which after all is a *thing*. These decisions certainly have their moral impact, and hence morals are delegated. Whereas Latour would say that this way we have become *more* moral, whereas we saw with Dickenson (1999) on page 17 that according to her opinion we lose morals when strictly applying EBM. I explained there why I did not agree with her (morals are not done away with by EBM, neither in general, nor in the individual situation of a practicing doctor). Here the objection I gave on behalf of Latour's theory becomes clear. The morals that are delegated to the things are not just made up by the creator of the thing. After all, the thing is not created by one man, but in a negotiation between numerous actors. A thing shaped is a compromise, an instance in which most actors will recognise their values. Morals are not done away with nor dictated by others, they are fortified and come from ourselves.

By delegating (moral) decisions to things, we stop being aware of these decisions. This goes together well with the fact that in this new situation the effort needed to warrant the moral correctness is considerably smaller. Decisions made by non-human actors are subject to less doubt, and carried out more straightforward. Human behaviour is in some cases strictly controlled: Latour discusses the example of a car, refusing to ignite its engine, as long as the seat belts are not fastened. This is already far more rigid than the door closer, which can be obstructed by some simple (human!) tricks. Latour denotes this rigid delegation of decisions on behaviour, with the name *prescription*. Accordingly, and in accordance with Madeleine Akrich, the controlled behaviour is called a *script*. With this the object gets moral qualities, and hence *human* qualities. These objects become more human-like or 'anthropomorphic'. It should be investigated in the field of EBM, to what extent EBM acts as a script, to what extent it can be called anthropomorphic and what its moral qualities are.

3.6 Discussion

In this section I will give an overview of what we saw in this chapter. In this way we obtain a set of thoughts that will form the handles of our investigation of EBM in medical practice in the next chapter.

Change in medical science I identified some significant shifts in the science of medicine. Are these shifts recognisable in practice? That is, does medical scientific literature display this shift, or is it just a hypothetical thing?

Application of EBM Sackett c.s. formulated five core steps in EBM: formulating answerable questions, pursuit of matching evidence, critical appraisal of the evidence, application of the evidence, and evaluation. Are these steps recognised in practice? Or are they mere theoretical items, not apt for practical application? Are they supported by the average doctor?

Changes in medicine EBM is said to invoke a shift in medical culture. Are consequences as postulated in section 2.2 found in reality? What changes in efficacy of treatment, politics, education etc. etc. are found? To what extent is the doctor's daily schedule affected?

Problems with EBM Do we find the problems in section 2.3 in practice? Does the rationalist character of EBM stand in the way of emotional engagement between patient and doctor or not? To what extent are the goals of EBM incompatible with those of non-EBM? And are problems such as the publication bias, the unavailability of matching evidence, the problem of losing the context, and the incompatibility between the structure of scientific knowledge, and the structure of clinical experience, recognised in practice?

Kuhn Does the development of EBM follow the pathways described by Kuhn? Are the characteristics he formulated for paradigm shifts recognised in the introduction of EBM? Is his philosophy suited for describing this introduction? We should investigate the unprecedentedness, the shape-shift of problems investigated, the change of the world view etc. etc.

Paradigm shift Assuming that the introduction of EBM *is* a paradigm shift, are both the old and the new paradigm as framed by JAMA recognised in reality? Are

the descriptions sufficient, to analyse the transformation invoked by EBM? And does it thus comprise the characteristics of a *successful* paradigm shift?

Latour Is Latour's vision on the development of science recognisable in the development? Do we find black boxes, machines, modalities, human and non-human actors etc. etc.? Do statistics act like a thing? Is population screening for breast cancer a black box? What kinds of translation do we find? How are adherents to EBM 'kept in line'? Does EBM become a 'thing' with its moral qualities and 'scripts'? Or should we rather prefer Dickenson's vision, that morality is abandoned by EBM?

Medicalisation and iatrogenesis Does EBM provide us with a weapon against medicalisation and iatrogenesis? Does EBM reinforce the power of the medical guild to force the patient to be labeled 'ill', and undergo treatment? And are problems that are not necessarily looked upon through medical eyes, being forcedly drawn into medicine? Or is it rather the other way round?

It is clear that these questions cannot be answered up to the smallest detail. Some of them could serve as themes for entire oeuvres. It is more important to keep them in mind when investigating the practice of EBM. They will inspire us to ask the right questions at the right time, rather than form a rigid set of targets for our inquiry.

Chapter 4

EBM in practice

4.1 Empirical research and methods

In the previous chapter we discussed the genesis of Evidence-based medicine in general, a controversy concerning the screening for breast cancer, and two major theories on the development of science, by Kuhn and Latour. In this chapter we will investigate how these items are visible in the reality of Dutch medicine.

In section 4.2 I will start to further investigate the controversy around breast cancer. This controversy is going on in the world of medicine, and not the least in the Netherlands. I will discuss some articles in leading Dutch journals, and see how the discussion goes astray from rational arguments towards emotionally and politically charged statements.

Then I will give an overview of Evidence-based medicine in practice in section 4.3. The situation in the Netherlands will serve as our specimen. The introduction of EBM will be investigated through various articles. What is seen in practice, will be scrutinised with the theories of chapter 3.

In section 4.4 I will give an overview of this chapter, and briefly revise some of the problems that we saw in this chapter.

A topic such as EBM actually deserves an empirical investigation. Many relevant aspects can only be found on the work floor, that is among doctors, policy makers, managers, scientists etc. etc. Yet the investigation was restricted to literature research. The main consideration regarded time: a handful of interviews would have taken an effort that exceeds the effort of a literature research quite significantly. And second, those who occurred to my mind as interesting persons with respect

to the practical aspects, more or less coincidentally turned out to be the authors of a number of works, discussing the matter of EBM in practice. Hence for a sophisticated design of eventual interviews, the current literature research would have to be performed anyway. Therefore I decided to confine myself to the literature, and leave the interviews as a recommendation for future investigations.

4.2 The breast-cancer controversy

The controversy around mass screening for breast cancer comprises much of the characteristics of a controversy as sketched by Latour (1987) (which should not be confused with the notions of 'controversy' by Kuhn). A claim, 'population screening for breast cancer reduces mortality from breast cancer', is subject to flaming discussions. Modalities are lavishly uttered, black boxes are put upon the stage (and tried to be opened) and an inversion is painfully uncovered.

In section 3.4 we saw how a couple of researchers (Olsen and Gøtzsche, both associated to the Nordic Cochrane Centre in Denmark) casted doubts on the effectiveness of mass screening for breast cancer, thus applying a negative modality to the previously accepted outcomes of trials. When looking at their original report (Olsen and Gøtzsche, 2001), we see a highly self-confident piece of work. Their arguments pretend to be strong. For example, one trial found a reduction of 29% in the mortality due to breast cancer, but according to Olsen and Gøtzsche this reduction was not ascertained to be the result of the breast cancer screening. The methodology of the trial is discredited. Olsen and Gøtzsche find the Cochrane methodology on their side, but as we will see below, not everybody agrees with their specific implementation. Olsen and Gøtzsche proclaim to be impartial: they explicitly deny any conflict of interest, and they both have analysed the trials independently of each other.

As we also saw in section 3.4, not everybody agrees with the critics by Olsen and Gøtzsche. A report of the *Health Council of the Netherlands* (HCN, *Gezondheidsraad*) puts the Danish opinion in perspective (Veen and Knottnerus, 2002, in an issue of the *Nederlands Tijdschrift voor Geneeskunde* that contains a number of articles on the breast-cancer controversy). The Health Council agrees with the standards with which RCT's (randomised clinical trials) should comply, but thinks they are insufficiently explicit to minimise subjectivity in the judgement on the quality of a research. It would be better, to analyse the effect of inclusion of poor-quality researches, rather than excluding them a priori. The HCN agrees that some parts of the researches deserve some criticism, especially the randomisation of some of them. Nevertheless, according to the HCN this is not sufficient to reject them.

Moreover, the Danish researchers are said to have no thorough reasons for rating two of the RCT's much higher than four others. I will not go into detail with respect to the exact argumentation of the HCN. The point to be made is, that the HCN endorses the Cochrane guidelines themselves, only the implementation by Olsen and Gøtzsche is contested. By reinterpreting the outcomes of the same RCT's, the HCN draws the conclusion that the foundation of mass screening is not refuted. The HCN propagates continuing investigation of the causes of the reduction of breast-cancer mortality.

In the same issue of the *Nederlands Tijdschrift voor Geneeskunde*, Bossuyt (2002) gives an overview of the discussion. He smartly touches the sore spot: how are we to determine whether a publication deserves the predicate 'accurate' or not? Olsen and Gøtzsche have their ideas, others have their own too. Bossuyt mentions that the *Cochrane Reviewers Handbook* explicitly states, that a golden standard for evaluating a trial's quality does not exist. Neither is there a standard method to handle differences in quality. Bossuyt states that the Danes do justify their criteria, but they neglect to describe the procedure they followed. He accuses Olsen and Gøtzsche of failing to disprove the appearance of prejudice: they are known to be sceptics about population screenings.

How can this controversy be settled? Performing a new RCT is not an option, just because of the costs and expected time span. It is possible to analyse trends in breast-cancer mortality, and their correlation with participation in screenings. However, even though this may uncover an eventual correlation, it can never prove a causal relation. An RCT (with a control population) is needed for that. To Bossuyt's opinion the effect of mass screening is not brought down, but he admits he doesn't expect too much of it. After all, if the evidence were clear, there wouldn't be such a big quarrel about it. He states that the controversy cannot be solved by science alone, and that to reach stability, a social and political debate will be needed too.

In a recent issue of *Medisch Contact*, the journal of the KNMG (the Royal Dutch Medical Association), the controversy was summarised by Debets (2002). The article is filled with Debets's critical opinion on mass screening, but new arguments are not given. Debets states, to my opinion correctly, that the debate has become emotional instead of argumentative. He summarises the arguments: many women are bothered to only save a handful of lives, the negative effects such as stress are underemphasised, the female body is medicalised, etc. etc. Although Debets questions the foundation for screening, he embraces the advice by the HCN, to stimulate further investigation of the effects of screening. But Debets openly questions whether the costs and mental burdens are worthwhile. This ambivalent attitude is found in all recent articles: the article by Bossuyt ('screening will probably only

yield a marginal profit, yet investigation is necessary'), the article from the HCN ('the past trials deserve some critics, but their outcomes still justify continuing the screening, and continuing research') and now by Debets ('the effect of screening is marginal, screening is not cost-effective, but more research is needed'). It seems that nobody has the courage to make a point, to draw a line. It is apparently not that easy, to say: mass screening is not effective, so let's use the medical resources for a better cause.

Let us now return to Latour's theory from the previous chapter. There I already pointed out some elements such as texts, being either accepted ('stable') or subject to debate ('unstable'), modalities applied to these texts, inversion (although difficult to discern), and black boxes that are opened. We will now go deeper into the application of Latour's theory, and then see what implications this will have.

Let's start with recapitulating what we already saw. We saw the black-boxed fact 'mass screening reduces breast cancer' being opened by Olsen and Gøtzsche, by applying negative modalities to it: its genesis is brought onto stage, and this corrupted the inversion that originally occurred. Tabar, one of the authors of the original research, tries to reinforce his original claim by underpinning it with several arguments, thus applying a positive modality. With the same action he applies a negative modality on the work by Olsen and Gøtzsche

Tabar is not the only one who applies negative modalities to Olsen and Gøtzsche. Bossuyt states that they are known to be sceptics, and that they insufficiently explain their methods. Moreover the HCN questions whether the Cochrane guidelines justify the qualification of some of the researches as poor. With this they indirectly apply a positive modality to Tabar.

One major black box is engaged by Olsen and Gøtzsche, that is the methodology of EBM. They do not explicitly underpin it with arguments, they assume that it is the optimal method. This black box is questioned by several other authors, and hence it is not entirely black (or better: opaque). The unjust assumption that the methodology of EBM is a closed black box, turns out to stand in the way of acceptance of the new claim that screening is ineffective. Instead of discussing the screening, the dispute tends towards the acceptance of the EBM methodology, by means of arguments Olsen and Gøtzsche hadn't counted with.

What translations are found in this procedure? As adherents to EBM, Olsen and Gøtzsche want to enroll others into its reinforcement, and in discrediting the researches. How do they do that? They unjustly assume that everyone wants the same they want (translation 2). They think everyone wants to cut-off the screening after accepting the Cochrane guidelines. But they are mistaken. People seem to have other aims instead. We could think of avoiding disputes for the sake of

peacefulness, or to reassure women, even if its scientific foundation is questionable.

Before people can be kept in line, they have to be enrolled first. So apparently Olsen and Gøtzsche don't have anyone to keep in line. Previously most people followed Tabar, and his claim of the usefulness of screening. What did he do, to keep others in line? Once that governments picked up his statements (actually a matter of 'tying elements together, such that the network resists all trials to break it apart'), he didn't really have to work for it anymore. But when Olsen and Gøtzsche entered the scene, Tabar had to work harder on it. By underpinning his claim with more arguments (i.e. the expert reviews, and the statements that his collaborators are highly reliable etc. etc.), he ties more elements to it. Yet it is questionable whether the claim will be strong enough to withstand the contest, since many of the authors who criticise Olsen and Gøtzsche, also utter their doubts on the claim by Tabar. We see an interesting struggle between several actors, each of them trying to fortify his own claims.

The controversy is not solved yet: the networks are not large and strong enough, and hence the black box cannot be closed yet. The network is so fragile, that any element being attacked will cause the machinery of EBM to falter. How can the controversy ever be closed? First, the network has to be extended further. That is, people like Olsen and Gøtzsche will need to publish more texts to convince others, and to link their targets better to those of the ones they want to enroll. It is not simply a matter of promoting your claims. As long as the opposite sounds are heard, instead of trampled under an offensive of new EBM-sympathetic claims, promoting will be a waste of time.

So far we haven't really come to the application of the theory from Latour's *Berlin Key*. We only briefly ran into the question whether EBM comprises characteristics of a thing. But we should also wonder whether we can cast the controversy around breast cancer into terms of 'programs' and 'antiprograms'. This is certainly possible. Olsen and Gøtzsche pursue the program 'to convince others of the benefits of EBM, and to disqualify Tabar and his researches'. The antiprogram then obviously consists of Tabar c.s. who want to maintain their claims. A scheme is depicted in figure 4.1. Initially we find Olsen and Gøtzsche, trying to refute the screening as an effective measure. They find Tabar as their opponent, who sticks to the effectiveness of screening. Then Olsen and Gøtzsche are approved by Köhler (although, as a journalist, Köhler pretends to describe the controversy objectively, his article is coloured with a sympathy for the Danish point of view), and Tabar gets support from the HCN. We must be aware of the fact, that the HCN is not merely positive about Tabar. Yet their publication results in a diminution of Olsen and Gøtzsche's claims. In the third stage, they get a new support from Debets. But this support

is so parsimonious, that we should rename the program: to *question* instead of to *refute* the effectiveness of screening. The same parsimony is found in Bossuyt's support: although he expresses doubts about the quality of the claims by Olsen and Gøtzsche, he is critical about Tabar too.

We see here, that both the program and the antiprogram extend. A solution is not in sight. The antiprogram is too strong to be refuted, but neither the program nor the anti-program is strong enough to win. The network tied around EBM and the breast cancer controversy grows more complex with every step. It does not only contain scientists, but journalists, societal actors and so on as well. Solving the controversy is not a mere scientific action, and apparently quite some more allies have to be engaged by the program (or the antiprogram).

One of the questions that came up in the previous chapter, was whether EBM and statistics act like things, with their inherent scripts. We see here that this is not the case, at least in this stage of the development. A reshuffling of tasks and interests is not possible yet. As a thing, EBM is not yet stabilised, and it does not behave like a black box. This means that it will not function as a (reliable) element in the network to support or thwart population screening.

Taking one more glance at the struggle, we see an influence in the opposite direction too: not only the struggle around EBM that influences the discussion on breast cancer, but also that the discussion on breast cancer articulates weak points in the EBM methodology. Hence the discussion on breast-cancer screening is an unreliable element in the network supporting EBM too. An eventual stabilisation of the breast-cancer controversy will relax the discussion about EBM, and once that EBM becomes a widely accepted methodology, it will also supply with a well-pondered solution for the quarrel around breast-cancer.

		AND →
	program →	← antiprogram
1	Olsen and Gøtzsche, refute screening	Tabar sticks to screening
2	Olsen and Gøtzsche, Köhler, refute screening	Tabar, HCN
3	Olsen and Gøtzsche, Köhler, Debets, *question* screening	Tabar, HCN, Bossuyt
OR ↓		

Figure 4.1: Program of Olsen and Gøtzsche: 'refute screening'

4.3 The EBM controversy

The funny thing with controversies is that you hardly see them if you don't want to. When for example reading the annual report of the *Dutch Cochrane Centre* (DCC, 2001), one just finds the positive outcomes: a number of successes are enumerated. A number of courses are held, databases are established and maintained, systematic reviews are performed, and practitioners are propagated to make their own reviews. This is an outstanding example of a publication bias (be it in a more generalised sense than before: we used to apply this term to the publications on medical research, whereas here we concern a company report). As the investigators of science, we are interested in negative results as well. These negative results represent the conflicts of the controversy, which arouse the interest of the philosopher of science.

As if it were written for our purposes, an anthology of texts on the practice of EBM is published by Patrick Bossuyt and Johan Kortenray (Bossuyt and Kortenray, 2001). In this booklet five essays on EBM are presented, accompanied by eleven small journalistic articles[1], most of them with a highly anecdotic character. The essays and articles are all connected in some way to the *Academic Medical Centre* (AMC) in Amsterdam, the leading Dutch academic hospital with respect to EBM. In the preface it is stated literally (p. 12):

> *'The introduction of EBM in the AMC can be entitled a success. The institute is drenched with it. Yet as often occurs with appealing ideas and thoughts, the fame of the new approach has outrun the stubborn practice. Not all attempts were successful, and the application of EBM raised new questions.'*

This at least pretends objectivity. Yet most of the articles and essays give a positive impression, and we should remain cautious for a positive bias. The literature simply does not appear impartial.

I will take a closer look, through this anthology, to the introduction of EBM. I will then try to uncover the answers to some questions that came up in chapter 2. For example, is the introduction of EBM really a controversy, or is it just a minor ripple on the otherwise smooth surface of medicine? Is it a paradigm shift at all, and what elements of a paradigm shift are visible? To what extent is EBM supported through the medical profession? Is it easy to apply, and what changes does it involve? In the following subsections these themes are discussed systematically.

Beside the anthology I will discuss parts of other sources, such as Coumou (2001) and Berg and Mol (2001). Altogether these sources form a balanced set of positive and negative sounds on EBM.

In the following paragraphs, I will discuss several topics of the controversy around

[1] the essays are referred to separately, the journalistic articles are not

EBM. First I will discuss some of the successes of EBM, followed by some intrinsic and extrinsic problems. Then I will investigate whether the shifts brought about by EBM are to be called radical, and how the problems investigated and the world view change. Finally I will investigate the two characteristics Kuhn ascribes to successful paradigms: whether they are unprecedented, and whether they are open-ended.

4.3.1 The success-story of EBM

Before we discuss the problems that accompany the introduction of EBM, I will first show some examples of the success of EBM.

Within the AMC the support for EBM is almost complete, to begin with. From several items in the anthology it becomes clear, that most doctors, and even people working in the nursing profession, work in accordance to the EBM guidelines as discussed in chapter 2. The AMC also issues guidelines on specific medical topics, and they are also said to be successful outside the AMC (Bossuyt and Semin-Goossens, 2001, p. 66). Unfortunately a quantitative analysis is omitted, so we should be careful for subjectivity.

Apart from the question whether a doctor tends to adhere to EBM, there is the question whether he has a choice at all. Bossuyt and Offringa (2001, p. 40) state:

> *In 2000 nobody can ignore EBM: books and journals are dedicated to it, and through the whole world courses are held. In 1992 only one article was found in* Medline*, in November 2000 their number exceeds 4597. If EBM had been registered as a trademark at that time, it would have been a blockbuster now.*

In journals such as *Medisch Contact* and *Nederlands Tijdschrift voor Geneeskunde* EBM and related terms often appear. Academic hospitals, preceded by the AMC, seem to turn to EBM. Since this network (in Latour's conception) is growing and extends through the entire Dutch society, it is hard to believe that doctors will be able to keep their back turned on EBM in the longer term. If we follow the enthusiastic sounds from the AMC, we must believe that every doctor at least has heard of EBM.

More concrete examples of the success of EBM are the previously mentioned annual report of the Dutch Cochrane Centre (DCC, 2001), and the successful establishment of a department of *Clinical Epidemiology*. I will discuss the importance of this department later.

In Latour's terms we would say, that apparently quite some allies strive on the side of EBM. The program to convince the medical profession (both scientists and practitioners) of the merits of EBM, is supported by a number of (human and non-human) actors. EBM is not yet ready to become a black box, but it is on its

way. EBM as a method is not yet clear-cut, and hence it is subject to discussion. Therefore its outcomes are still questionable. By improving the method, the network (of doctors, politicians, medical institutions, knowledge-bases) is continuously being fortified. The successes of EBM behave like positive modalities to the ideas of EBM. It is not important whether we see medicine as a practice or a science, since in both fields the successes help rendering EBM as the summit of methodology in medicine.

Looking at the same items, we could state with Kuhn that the paradigm of EBM receives support. When we just look at these successes, we are inspired to say that the paradigm has been introduced successfully. Yet, as we will see in the following paragraphs, a lot of critical sounds are heard as well. We will see then, that the paradigm is not so uncontroversial at all, and that normal science is not reached yet. With 'normal science', of course we can only refer to those parts of medicine that concern scientific research. Nevertheless, similar ideas hold for those parts dedicated to the application of this science.

4.3.2 Intrinsic problems with EBM

An intrinsic problem, is a problem that is part of the object under investigation. Consider a physicist who wants to visualise some sub-microscopic phenomenon, necessary to judge on a candidate new paradigm. He then needs an electron-microscope. If electron-microscopes were non-existent, then this would be an intrinsic problem of the candidate paradigm. After all, it is inherent to the phenomenon, that it cannot be visualised. On the other hand, when electron-microscopes do exist, but only the local faculty lacks resources to buy one, this should be seen as an extrinsic problem. It is not due to the phenomenon itself, that it cannot be visualised, but rather to an external cause. In this paragraph, I will investigate the problems that are connected to EBM, and that cannot be accredited to external causes. Thus: the intrinsic problems.

The first problem we find, is described by Klazinga (2001). The 'evidence' propagated by EBM is said to be incomplete and biased. Partially this is due to the fact that no single method can provide us with 'complete' knowledge. But the effect is fortified by EBM in this sense, that knowledge is 'decontextualised', and hence becomes valid for only a limited class of cases. Trial results, coming from numerous cases, cannot be easily projected onto an individual patient in practice, with a specific problem. We already saw this 'decontextualisation' in section 2.3 with Nederbragt (2000). Klazinga admits this objection, but conversely he states that this can be overcome by paying attention to the explicit coupling and balancing of evidence from literature, and evidence gathered in daily practice. Evidence needs to come from both sides. Therefore evidence from the daily practice should be

registered in an accessible way, and then be linked to evidence from the scientific branch. Coumou (2001, p. 17) confirms this poor quality of the evidence. Different sources of evidence often contradict one another. And the way evidence is presented is not completely consistent, in this sense that it becomes clear immediately what significance should be attributed to it. This problem especially concerns GP's, but it should be seen as a general imperfection of the new (scientific!) paradigm. For the most common complaints, the branch organisation of GP's provides her members with sufficient guidelines. Yet, between 50% and 90% of the actions by GP's are estimated to lack evidence (Bossuyt and Kortenray, 2001, p. 111). A reason for this may be, that the majority of complaints presented to the GP belongs to the class of 'small insignificant diseases', for which evidence is lacking, simply because they are not investigated.

The second problem also comes from Klazinga. EBM only focusses on medical decisions, neglecting the management of *care*. This is refuted by Klazinga, by saying that within EBM there is enough freedom of movement, to pay attention to caring for the patient. And, this care can be developed along EBM methodologies too! According to Klazinga, EBM-guidelines involve medical decisions, whereas local protocols tell how, when and by whom these decisions must be carried out. To my opinion the objection is not completely refuted, since it is not denied that available EBM guidelines generally regard clinical instead of care considerations.

The third problem, also discussed by Klazinga, is that EBM loses sight on the individual patient. It is difficult, if not impossible, to match general data to an individual case with its specific features. Klazinga responds, that one of the arts in EBM, is to match general knowledge with the individual patient in a satisfactory way. The doctor should question whether the values propagated by an EBM guideline, match the values adhered to by the patient. The process of decision will never completely be replaced by a guideline. Coumou (2001, p. 18) confirms this problem of matching. However, she introduces a more practical cause: research populations are generally 'male, under 65, with exclusion of foreigners and multipathology', or in a similar way invalid in application to real-life patients. This requires additional interpretation, which might cause disagreement between different interpreters. This problem is confirmed by Molewijk (2001): the 'average' patient does not exist, whereas the EBM-guidelines apply to such 'average' patients. This touches the problem we saw with Nederbragt (2000) in section 2.3, regarding the incompatibility between several knowledge structures. And then Molewijk adds a more fundamental problem: EBM employs statistics. A statement on a certain probability appears clear, but in fact it doesn't tell anything about the future. Statistics cannot be used as a predictive tool, as long as it remains unclear *why* and *how* causal relations exist, thus Molewijk.

We also find the fourth problem with Molewijk. He states that general evidence-based guidelines standardise the aims of medicine. For example, the maximisation of life expectance may be taken as the central merit, when the patient may be interested in other aims. This mismatch disqualifies the guideline for this specific case. This is a problem that we saw earlier with Dickenson (1999). She stated that EBM lacks ethical qualities, since decisions are left to the guidelines instead of to the doctor with his moral understanding.

Let's now look at the problems described above, by means of the theory by Kuhn. In general we can state, that an intrinsic problem is an indication of imperfection of a new paradigm. This means that even if the new paradigm were accepted completely in its current state, it would not provide a comfortable background to which science (or i.c. medicine) can be practiced. In Kuhn's terms: the new paradigm is not yet able to warrant *normal science*, and hence the practical application of knowledge resulting from this paradigm, will suffer from imperfections to.

The first problem, that evidence is often hard to apply in practice, is an instantiation of Kuhn's statement that one can only convert to a new paradigm, if this conversion is total. If one just views the evidence, it is easy to say that it is incomplete (this is admitted by most EBM-adherents!) and difficult to apply. Only when all accompanying methods are taken into account, the evidence makes sense. But people like Coumou, who tried to convert to the paradigm unprejudicedly, also ran into difficulties. In Kuhn's terms, we could suspect that the translation was performed poorly. That is, doctors did their best to convert to EBM, and tried to adopt all its features. They tried to reformulate their old problems into the EBM-language, and they tried to understand EBM and communicate in its language. But somewhere this translation was frustrated. It is unclear how and where, but it must be somewhere between the AMC (an institute where a mixture of scientific research and practical application within the framework of EBM is carried out successfully), and the GP's practice (a mere application of knowledge, where EBM seems to falter).

Another vision to this problem comes from Latour. He would say that apparently the network tied around EBM is not strong enough, to disguise the defects in it. Even if EBM were a black box in this sense that its genesis had become invisible, it just doesn't work, and it is not accepted. It was closed prematurely. In Latour's theory, it is no problem at all to have practice and science mixing together: both are part of the same complex network in which EBM is developed.

The second problem, that EBM neglects the decisions on care, is a similar accusation of incompleteness towards EBM. In a new paradigm, the problems to be solved will be (slightly or radically) different from the ones solved in the old

paradigm. That is: the new paradigm utters a new *promise* of what it can solve. Then Kuhn (1969, p. 37) states:

> *But the new paradigm can even insulate the community from those socially important problems that are not reducible to the puzzle form, because they cannot be stated in terms of the conceptual and instrumental tools the paradigm supplies.*

EBM is not believed to offer solutions for care problems. That is, one can apply the methodology of EBM on care problems as well, but explicit separate methods are not given. We should question whether the old paradigm of medicine supplied us with explicit methods for care decisions, but apparently EBM draws the attention to this hiatus.

The third problem, that general data are hard to apply on individual cases, seems to be persistent. The solution is often formulated quite trivially: the doctor should use his clinical expertise to couple the general data to the individual patient. Apparently, the ruling presumption is that this coupling *is* possible. This problem cannot be casted in terms of black boxes: it doesn't really seem to be the result of a negotiation or controversy, it is just assumed. There is no solid ground under the presumption that the coupling is possible, and therefore it will not be accepted widely. Then the presumption cannot be used as an element to be tied to the network to reinforce the support for EBM. Thus this problem will remain a serious hiatus in EBM, and it will always remain a displease in the way for a full acceptation. The dilemma is, that to improve the coupling, the authority of statistics should be discredited. But to compromise the authority of statistics, is to compromise EBM as a whole. On the other hand, if statistics are kept on their pedestal, the coupling will remain frustrated.

The fourth problem, that EBM lacks ethical qualities and standardises the aims of medicine, remains interesting. This problem is due to the (sometimes implicit) delegation of morals to the guidelines. We already saw that this was contradictory to Latour's theory. He states that the total amount of morality increases, once that morals have been delegated to non-human elements. The time has come now, to draw a conclusion. It seems very difficult to maintain Latour's point of view. In theory it is a sound idea, but apparently doctors feel their morals ignored, though. In this case we can no longer ignore the sounds from practice, and state that this *is* a serious problem with the new paradigm: it apparently stands in the way of deliberately making decisions on moral topics. We should therefore conclude, that science produces morals that are not apt for practical application.

Concluding we can say the following about these intrinsic problems. They form a serious opposition to the success-story in the preceding paragraph. Regardless

whether we analyse it through Kuhn's eyes or Latour's, it seems that EBM cannot be fully accepted yet. It receives support, but that's not enough. The black box of EBM cannot be closed yet (nor can the smaller ones, supplied in favour of this central one). And the paradigm of EBM is not stable enough to warrant normal science, or 'normal practice', to paraphrase Kuhn's ideas to a more general level.

4.3.3 Extrinsic problems with EBM

An extrinsic problem requires a solution that has nothing or little to do with the object under investigation. In the example from the previous paragraph: when the faculty lacks money to buy an electron-microscope. The introduction of EBM runs into several of these extrinsic problems, which should not be seen as parts of EBM itself. I will discuss them in this paragraph.

The first extrinsic problem is that doctors just don't accept the knowledge provided by EBM, *for unclear reasons*. Of all people David Sackett was heard by one of the AMC-specialists, complaining that his own colleagues wouldn't listen to him (Bossuyt and Kortenray, 2001, p. 100). It is recognised by the AMC staff members, that outside their own hospital the support for EBM is significantly lower. A new guideline on cholecystectomies (removal of the gall bladder) stated that a major part of the treatments could be performed policlinically, instead of by full hospitalisation (Bossuyt and Kortenray, 2001, p. 68). The guideline was provided with good evidence, and published in the *Nederlands Tijdschrift voor Geneeskunde*, in order to reach the whole Dutch medical profession. Whereas in the AMC the guideline led to 90% of the possible policlinical treatments being performed policlinically indeed, outside the AMC only 2% was performed in a policlinic! What we see here, is a fact from scientific origin (we should in this context see the AMC as a scientific institution), that does not find acceptance in the field of application outside this institution.

A number of reasons for this are thought of. First, the circumstances in other hospitals might be insufficient to change the policy. This could regard accommodations, but also the fact that patients may live too far from the hospital, to secure adequate follow up. A second reason is the scepticism that is often experienced towards EBM among non-AMC colleagues. Sometimes they even turn out not to have read the publication at all. Therefore in the establishment of subsequent guideline projects, other institutes will be involved as well in order to increase the credibility of the guidelines. The scepticism is confirmed in the essay by Bossuyt and Offringa (2001, p.45). They state that the majority of doctors confronted with the choice for EBM, senses a sympathy for the romantic ideal of capricious but personal clinical expertise, rather than for the anonymous *critical appraisal skills*. These doctors sus-

pect scientists to pursue the validation of their claims, rather than the truth. Here the aphorism pops up: 'There are lies, perjuries and statistics'. Apparently the sceptics are aware of the fact that anything (or its opposite, whichever you prefer) can be proven by statistics. They don't trust statistics, and refuse to attribute authority to it. Therefore the scientific paradigm lacks support in the field of practice.

The second problem is the general *rigidity* of the medical profession. One beautiful example of rigidity standing in the way for an application of EBM, is also given in Bossuyt and Kortenray (2001). In surgical clinics everybody used to be convinced, that measuring body temperature after surgery was worthwhile. It was believed (the specialist interviewed playfully calls it a 'religion') that information on fever is always clinically relevant. After investigation the opposite turned out: a large proportion of the patients did not have a fever at all, and from patients having fever only a small fraction turned out to have caught an infection. The new guidelines based on thorough investigation ran into the rigidity of the 'belief'. Yet inside the AMC the measurement of body temperature after surgery was abolished. But still the specialist wonders whether this step will be followed by other hospitals. 'Perhaps a lot of colleagues will think we went nuts', thus he comments. This problem is closely connected to the first one, that doctors sometimes just don't take over knowledge provided by EBM. It is a combination of unwillingness and disability to follow EBM that frustrates the courses of EBM.

The third problem, is that EBM is believed to herald the loss of autonomy for the doctor (Klazinga, 2001). It seems to be a standard reaction from doctors to any external attempt to influence their action. A doctor needs a certain freedom to determine his individual action. To a certain extent Klazinga admits this objection, but he objects on the other hand that the autonomy of the professional group of doctors is sustained by EBM and scientific foundation in general. This general legitimation is bought at the expense of individual freedom of action.

A fourth problem, is that EBM runs into the misunderstanding that EBM is equal to the creation and following of guidelines. According to Klazinga this is incorrect. The association probably comes from the fact that making guidelines and EBM seem to go together well. A reason for this compatibility could be that guideline makers were already performing literature searches anyway, and then the conversion to EBM is relatively small. But this inspires a new question: what is wrong with guidelines, after all? Why see this as an objection? Apparently the first objection made pops up again: doctors seem to be afraid of losing autonomy. Even although the objection itself can be disproved, its existence is an indication of unwillingness or disability to accept EBM.

A fifth problem is found in Coumou (2001). She confirms what we find in Bossuyt and Kortenray (2001, p. 113) (she actually refers to this publication), that

the general practitioner lacks time to practice EBM. He may not know what strategy is apt for what problem, and he cannot afford to spend an evening of internet surfing on every problem. The apparent danger of losing himself in literature searches seems threatening.

We now look again to these problems, by means of the theories by Kuhn and Latour. The first problem, that doctors often do not adopt the evidence, is interesting with respect to Kuhn's theory. It was suggested, that some people might want to convert to EBM, but apparently they cannot. Is it up to the AMC, to supply them with facilities such that they will be able to follow EBM? Or should the AMC keep trying to convince them, long enough to make them forget the barriers? Latour would say: the AMC should engage more elements, for example the federal government and its funds, and more and more publications emphasising the successes of EBM, and tie them to EBM, until the network is strong enough to enroll the dissenters. It is clear that up to this moment, the network is not by far strong enough to do so.

The other reason not to accept evidence, was a suspected scepticism. It goes together well with the rigidity discussed in the second problem. Let's first clarify the difference between those two by means of an example. Reconsider the turn from the geocentric to the heliocentric world view, and the Vatican opposing it. *Rigidity* would lead to a consideration by the Vatican such as: 'We should deny the heliocentric world view, since it undermines the Creation in the book of Genesis, and hence it subverts our influence in society.' It is an argumentation against one's own better judgement. *Scepticism* on the other hand, would lead to a consideration such as: 'This man, Galileo or whatever his name, uses tools and methods that have never been used before. How do we know whether they are reliable? Isn't he just an illusionist trying to fool us with a new trick? We better stick to the book of Genesis, that states that the Earth is the centre of the universe. This vision has held for ages, and it will hold for a while more.' This is an argumentation on basis of unbelief, and of just not being convinced by new visions.

The scepticism can easily be viewed to through Kuhn's framework. What we see here is a 'confusion of languages', that demands a translation in Kuhn's sense. There is the community of EBM-adherents, who calls statistics, say, the one and only reliable method to distill knowledge from large numbers of cases, the ultimate methodification of *induction* ($\dot{\epsilon}\pi\alpha\gamma\omega\gamma\acute{\eta}$) already explained by Aristotle. On the other hand, the opponents of EBM may call statistics perhaps a game of manipulating and conjuring with numbers, a big black hat out of which anything can show up. This difference in conception demands explicit measures of translation, and according to Kuhn, these may appear threatening to the opponents of EBM. But translation is the first step to be taken, which alone may not be enough. The

opponents will have to go into the new view entirely, before they can convert to it.

Let's now discuss the difference between rigidity and scepticism in the framework of Latour's theory. Scepticism just requires more effort to convince: engage more texts, black boxes, and other allies, to get your claims accepted. Although the effort may be large, this solution is in fact simple. Rigidity, on the other hand, is not so easy to overcome. It is actually a phenomenon similar to irrationality, as found in Latour's works. When we see someone accusing somebody else of irrationality, we should take Latour's sixth rule of method in mind: we should investigate the position of the accuser, instead of investigating where the accused fails in reasoning. Latour tells us to investigate the 'angle' at which claims and interests collide. In this case it is not a frontal collision: many of the interests are shared, and many of the claims are shared by both the EBM-adherent and the dissenter. Thus it should require only small adjustments of goals and aims, to solve the conflict.

The third problem discussed above, is that EBM is suspected of undermining the autonomy of the doctor. This constitutes a reason why rigidity exists. It actually resembles the example above, that the Vatican is unwilling to accept the heliocentric world view, because of the fear for losing authority. But in this case this fear can be refuted by rational arguments, the most important of which is that the loss of autonomy for the individual doctor yields a reinforced autonomy for the medical profession as a whole. This is a piece of Kuhnian translation: the different notions of 'autonomy' collide, and therefore the new paradigm may appear as a threat, which it is actually not. Once that these notions are clarified, the objection of losing autonomy vanishes like a thief in the darkness. The same goes for the fourth problem, that EBM is believed to consist of nothing but guidelines. A proper translation will disprove this assumption.

The fifth problem I discussed is, that the practice of the GP is not apt to perform EBM. Here both Latour and Kuhn are required. Latour inspires us to say, that more elements should be tied to the network. The first class of elements should be those, that enable the GP to practice EBM. That is, we should supply him with database-access, assistance to divide his time more efficiently, provide him with courses on searching methods etc. etc. The second class of elements should be those, that convince the GP that the difficulties with EBM are worthwhile. We should think of illustrations of successes of EBM, illustrations of the obsoleteness of non-EBM, emphasise the idea that practitioners of EBM form a group to which he should like to belong (actually an instance of Latour's fourth translation).

Kuhn on the other hand, would say that the current practice of a GP cannot be cast in the canonic form of puzzles, that can be solved within the new paradigm (Kuhn, 1969, p. 37). That is, the paradigm of *practice*, which should in this case be seen as a derivative of the paradigm in science. Thus a shift of problems has to

occur in the practical paradigm, before the practice of the GP matches the ideas of EBM. Then the current problems should be reformulated, which is an instance of Kuhn's notion of translation.

Contrary to the intrinsic problems we saw in the previous paragraph, we see that the extrinsic problems in this paragraph can relatively easily be casted in the forms of Latour's and Kuhn's theories, and that in most cases these provide us with a good understanding of the problems. The problems we discussed in this paragraph seem to be common for new developments, regardless whether one sees EBM as a 'new paradigm to be accepted' or as 'a claim that needs to become a black box'. It is a natural thing that translations (both in Kuhn's and Latour's conception) seem to go wrong in these initial phases, that some aversive reactions seem to be 'irrational', that some fear losing authority and autonomy. Even the fact that many GP's see their practice unapt to perform EBM, can be seen as a demand for translation. Once that all this becomes clear, the adherents of EBM can get hold on eventual solutions.

4.3.4 Sweepingness of change

So far we investigated the successes, and intrinsic and extrinsic problems accompanying EBM. As we saw with Kuhn, one of the characteristics of a revolution is, by definition, a radical change. Some of the changes we see in EBM can be labeled radical, whereas some of them only regard small variations. Not every change indicates a paradigm shift, and not every radical change needs to run into resistance, or constitute a problem.

Bossuyt and Semin-Goossens (2001) state that there already was a so-called *consensus model*, adopted from the medical culture in the United States. In this model, guidelines were established and followed, just like with EBM. However, these guidelines were not underpinned with scientific evidence, but based on the authority of committee members. So the structure of EBM with respect to the existence of guidelines is not new, only the legitimation of arguments by means of scientific research with a sophisticated statistical method is new.

But this is not the only radical change. For instance, we already saw that the autonomy of medical practice shifts from the individual practitioner to the collective of the profession (Klazinga, 2001). Whereas before the doctor had his own autonomy, based on his experience and education, now he has to maintain his autonomy continuously, together with his colleagues, in a more or less anonymous way. The general legitimation of the medical profession is (believed to be) fortified at the expense of a bit of individual freedom.

Another radical change is the inherent criticism towards knowledge. Facts will be questioned, and requested to be underpinned with evidence. An impossible situation would arise if every assertion were questioned and investigated, but generally the attitude is critical. Closely connected to this criticism is the entrance of clinical epidemiology as a discipline, which will be discussed in paragraph 4.3.5. This discipline is so new, that we may call it a sweeping change too.

We saw three changes: the methodology for large trials, a shift in the legitimation and autonomy of the medical profession, and a much more critical attitude towards knowledge. These changes strengthen our idea, that EBM is a new paradigm. They help us to understand, why the introduction of EBM doesn't go without struggles and quarrels.

4.3.5 Shift of problems

One of the characteristics of a revolution as described by Kuhn is the change of problems presented to the scientific community. In Kuhn's context, the example that we saw before is illustrative: pre-Newtonian versus Newtonian physics. In pre-Newtonian physics 'movement' was thought of as something requiring a continuous supply of force. An interesting problem would then be, to give a formalisation of the force needed to maintain a certain movement. In Newtonian physics, movement became something that doesn't require a force to be maintained, but that rather needs a force to be *altered*. Then the problem of formalising the force needed to *maintain* a movement fades out of scope, and an interesting question becomes how to formalise the force to *alter* a movement.

However, like I already mentioned before, we find a difficulty in the application of Kuhn's theory to medicine. Kuhn describes mere science, where a 'problem' can be seen as a pursuit of one of natures secrets that needs to be uncovered. On one hand medicine contains research in which 'problems' do match this definition. In the practical part of medicine, on the other hand, the target is mainly the *application* of existing facts instead of the *pursuit* of new facts. Then a 'problem' mostly consists of a disease in a patient, about which knowledge is already available (be it perhaps not in the office of the doctor). These problems do not change with the introduction of EBM. The headaches and sprained ankles seem to be the same for doctors, regardless wether they practice EBM or not.

But with respect to the merely scientific problems, a shift *is* occurring. We already encountered it: it is the rising of the new discipline of clinical epidemiology (Bossuyt and Semin-Goossens, 2001, p. 58). *Epidemiology*, i.e. the branch of medical science that studies the distribution of disease in human populations and

the factors determining this distribution, was not new. It also already incorporated statistics. *Clinical epidemiology* on the other hand is the branch of medicine that concerns the methodology of gathering clinical knowledge in a valid and efficient way, from researches with large populations of patients. This discipline is new (or if it existed before, it was marginal), even this new that the Department of Clinical Epidemiology and Biostatistics, established in the AMC a few years ago, was the first in the Netherlands. An entire new class of problems, that is to investigate phenomena in a large population, and to translate the outcomes to medical knowledge, has come up. Illustrative is a letter in the *Nederlands Tijdschrift voor Geneeskunde* (Heukels, 2002). A doctor publishes his personal findings on breast cancer, which cast a severe doubt on the effectiveness of breast cancer screening. He observes the ten most recent cases of breast cancer in his practice. He is immediately called to order by the editorial reply, which embraces the argument that these small observations are easily biased. Clinical observations may supply us with valuable hypotheses, but they can be misleading as well. The nationwide investigation of the screening, involving tens of thousands of women, disproves Heukels's conjectures. Knowledge from clinical practice is regarded inferior, as is the observation of small numbers of cases. Instead an entire new class of problems is established, which are captured by the name 'clinical epidemiology'.

Now let us discuss changes of problems in the practical sector. One major aspect of EBM previously was not part of his practice: the pursuit and critical appraisal of evidence. Before EBM, the problems he attacked were mere medical ones. A hiatus in his knowledge was solved by research in textbooks and medical journals. But now the doctor has to contemplate whether a source of knowledge (which may be the same textbooks and journals) can withstand the trial of validity. To my opinion this change is radical enough to speak of a 'change of problems'.

Thus we should say, that in medical science the shift of problems is found in the rising of clinical epidemiology, and this is a shift of problems such as Kuhn had in mind. On the other hand, in practice a shift occurs too, but we should be cautious when saying that this is what Kuhn meant (although there certainly is a resemblance).

4.3.6 Change of the world view

Another characteristic of scientific revolutions as described by Kuhn, is the change of the imagination or world view. We saw three differences between a 'new insight' and a 'change of the world view'. First a change of the world view is irreversible, second it cannot be seen as a reinforcement of the ruling paradigm, simply because it doesn't fit, and third, data upheld by science are changed, and may even become

invalid.

The most important change of view is the understanding that knowledge on pathophysiological phenomena is not any longer enough to understand the human body. Even incorrect knowledge may be obtained, if observations are limited to these phenomena. Observation is elevated to a more generalised level: it is not any longer the individual patient that is the object of investigation, but rather a set of invisible patients that are reduced to a record of numbers. We could state that an extra layer of perception is introduced in the medical view. It is what Verbrugh (2002) calls the 'In Numero'-era, to whom I referred already quite some times.

And then, the way a doctor practicing EBM views knowledge is significantly different. Whereas previously scientific claims were mostly judged on basis of the authority of the one who claimed, its recentness, the preferences of the professor who taught the doctor, etc. etc., it is now judged by means of explicit criteria. The local preferences vanish out of view, and they make place for global rules. Regarding the three properties Kuhn establishes, we see that indeed this change of vision is irreversible, it doesn't fit in the old context, and it invalidates certain pieces of knowledge that were valid in the old context. It is not a view which, like in Kuhn's theory, provides scientific action with a framework, but since I already argued that medical science and medical practice cannot be separated distinctly, we should take this change in the imagination into account.

And then there is a second radical change of the imagination. The education of medical students is said to have changed drastically (Bossuyt and Kortenray, 2001, pp. 137-141). It is not any longer 'knowledge-based', but tends to a more 'problem-based' structure. No longer the facts are transferred, but the skills. There is still the relation between the master and the fellow, but the master teaches the fellow how to be critical, instead of what the established facts are. We could imagine that this change of the view is reversible, since in future paradigms the medical profession may return to knowledge-transfer instead of the transfer of skills, but this is very unlikely from within the EBM-paradigm. Moreover it rather undermines than reinforces the ruling paradigm. And it certainly renders many current data obsolete.

A third change is discussed by Molewijk (2001): the pretention of EBM to support clinical decisions.

> *The word* support *of decisions turns out not to represent the concept. It suggests that the existing decision practice is maintained, and that it is just supported with additional information on certain points. [It has] become clear that the decisive information does not only support the process of decision making, but it also transforms the definition of the clinical problem, and the roles played by the surgeon and the patient in the process of decision, and*

hence their interaction.

The transformation Molewijk discusses, certainly cannot be seen as a reinforcement of the old paradigm, it certainly is irreversible, and it renders old patterns obsolete.

In this paragraph we saw some senses in which the world view has changed by the introduction of EBM. Some of them are again beautiful examples of what Kuhn taught us about the development of science. And moreover, we see that changes in science do imply similar changes in the application of that science.

4.3.7 Absence of precedence

We also saw with Kuhn in section 3.3, that successful new paradigms are sufficiently unprecedented. With 'unprecedented' we mean, that in the past there haven't been any movements similar to the new paradigm. Both successful and unsuccessful precedences are negative: if they were successful, the newness of the new paradigm is undermined, and it will fail to arouse interest. And if they were unsuccessful, the negative outcomes may keep potential adherents from converting to it anyway.

We will search in the context of EBM, for items that seem unprecedented. The most important unprecedented item immediately draws our attention: the entrance of a new discipline, namely the discipline of *clinical epidemiology*. That is the discipline that concerns the methodology of performing and appraising trials in large populations. This methodology is not entirely new, but it always played a sidelong role. An example of this sidelong role is given by Bossuyt and Offringa (2001, p. 30). Already in the 19th century the French doctors Jules Gavarret and Pierre Louis performed a statistical research on the effectiveness of blood-letting as a cure for pneumonia. They concluded that the treatment was useless, but their conclusion was rejected by their contemporaries: a numerical method was thought not to be able to tell anything about medicine. In this case, it seems to be that either the scientific culture was not ready to accept numerical knowledge, or the numerical method was not strong enough to convince.

As a similar example of precedence for clinical epidemiology, Oudshoorn (2001) discusses a short history of the male and female contraceptives. She mentions population research for contraceptive medicines among women. These researches were carried out long before EBM was heard of, yet they comprise some features of the modern trials. However, it did not follow a rigid EBM-like methodology. We should conclude that it is not the (clinical) population trial itself that is new, but rather its rigid methodology of randomisation, and the status attributed to statistics.

We see the same issue in the controversy around breast cancer. When Olsen and Gøtzsche (2001) discuss the trials that had previously served as a legitimation

for screening, it becomes clear that trials are not new at all. The references go back as early as 1966, when an evaluation was published on periodic breast-cancer screening with mammography. But it also becomes clear, that trials in the past were not so well-organised at all. The methodology was questionable (that is, from the Cochrane point of view). When performed, each trial had its internal consistency (at least, we should expect that in scientific enterprises in Europe and the United States), but it turns out to be nearly impossible to compare them one to another. The methods are not consistent in an 'inter-trial' manner, but only in an 'intra-trial' manner. When we were discussing the breast-cancer controversy, we also saw that most authors confirm the questionability of the trial methods, only they heavily disagree about the consequences.

What seems rather unprecedented too, is the new character of the relationship between the master and the fellow. It is not very common for any science, but certainly not for medicine: the *method* taught, of gathering knowledge, is more important than the *facts*. Take for example a professor in chemistry. Let's say he teaches his students about the properties of some new synthetical substance. He may be aware of the fact that his knowledge is valid for today, but might expire tomorrow. A good professor will share this awareness with his students. But he is very unlikely to say: "Go to the library, check what I just said by searching for the latest evidence. Do so with every substance I discuss in this course, and get used to it, for it is the most important skill you will acquire in this institution." Rather he will present it as the status quo, and suggest that if the fact becomes corrupted, the students will run into it by themselves. For medical education in the culture of EBM the former expression will be likely, whereas in the 'old' medicine the latter is more common.

4.3.8 Open-endedness

Beside the absence of precedence, Kuhn also states that successful paradigms are sufficiently open-ended. With this, Kuhn refers to the problems investigated in science: within the new paradigm scientists should be able to resolve the same problems they were interested in before. We saw this in section 3.3 too, with the example of the heliocentric world view. Just like a scientist refuses to change over to a paradigm in which for example the prediction of (lunar) eclipses is not a problem under investigation, a medical scientist will never change over to a new paradigm that prohibits him to investigate the (medical) problems that arouse his interest. Before a scientist converts to EBM, he will first make sure that he will still be able to investigate those diseases, treatments, etc. etc. he was interested in before.

Although these problems change shape, as we saw in the previous paragraph, the new problems should be interesting to the same scientists.

A similar principle holds in the practical application of EBM. Before a doctor converts to EBM, he will first make sure that he will be able to serve the benefit of his patients, and that the clinical questions that were answered in the past, will also be answered in the future.

This open-endedness seems to be warranted, after reading the articles in Bossuyt and Kortenray (2001). Any medical problem that could be handled before, can be handled in an evidence-based way as well (although a reformulation of the problem might be needed). One might think that the absence of evidence for a certain clinical question will prevent the doctor from performing any intervention. But it isn't that way: any problem for which sufficient evidence is lacking, can still be handled. The methodology urges to apply the *current best* evidence. It allows less reliable evidence, if better evidence is missing.

Connected to this is the possibility to ignore evidence, as long as there is a good foundation for it. The same neurologist we encountered before in the anthology (Bossuyt and Kortenray, 2001, p. 51) asserts not to feel any barrier to overrule the EBM guidelines, as long as he has a thoroughly pondered reason for it. He tells that in this case intuition plays the same important role it played before: the personal considerations of the specialist are given room, but they should be followed critically. EBM would stand in its own way, if it prevented the doctor from following his own paths.

What we see here, is that the new paradigm does allow new members to handle the things they used to handle before, be it perhaps in an altered appearance. To use Kuhn's (1969, p. 10) own words:

> *It was sufficiently open-ended to leave all sorts of problems for the redefined group of practitioners to resolve.*

4.4 Discussion

In this chapter we analysed two controversies. The first was the controversy around population screening for breast cancer, and the second was the general controversy around the introduction of EBM. The breast-cancer controversy should be seen as a controversy on a lower level than the EBM-controversy: the screening only concerns a couple of facts, whereas the introduction EBM influences the whole structure of medical practice. Although both Kuhn and Latour have their merits for either type of controversy, it is clear that Latour fits the smaller controversies better, and the

larger controversies are better analysed with Kuhn.

The breast-cancer discussion was relatively easy to cast in the shape of a Latourian controversy. To fit the EBM controversy in Kuhn's terms, was a bit more of an effort. The most important problem was that it is questionable to what extent Kuhn's theory is apt for non-scientific developments. Some parts of medicine must certainly be denoted as non-scientific. First of all, it has been noticed often that Kuhn uses his concept of the paradigm quite flexibly. Therefore it sounds legitimate to apply it to medicine, even when it is not purely scientific. But moreover, if we apply Kuhn's theory only to its scientific parts, we found enough indications for a paradigm shift.

On page 34 I gave some arguments, why the changes in medicine should be seen as a paradigm shift. These arguments are again found in this chapter. The most important argument I repeat here: Kuhn assigns supremacy to the scientific community over the paradigm, so if communities are incompatible, we should identify incompatible paradigms as well. Assuming this incompatibility, most of the problems found with the introduction of EBM can be seen as instantiations of Kuhn's theory.

But some of the problems could not be fit into Kuhn's theory. I therefore decided to call them *intrinsic* problems, which form a serious threat to the success of EBM. The first was that EBM standardises morals. It may therefore withhold both practitioners and scientists from conversion. The second problem was that EBM standardises the patient, which yields a general difficulty in applying the knowledge in practice.

The extrinsic problems on the other hand fit better into the structure of Kuhn's theory, and hence their existence shouldn't bother us much. The successes of EBM strengthen the idea, that the extrinsic problems can be overcome. This idea is also supported by the fact that EBM seems to be unprecedented and open-ended, two characteristics Kuhn presumes for new paradigms. And the adherents to EBM will need these positive sounds, given the shift of problems, change of world view, and in general the radicalism of some changes accompanying the introduction of EBM. As far as I can see now, the only thing the adherents to EBM should really worry about, are the intrinsic problems.

Chapter 5

Conclusions

5.1 Chapter outline

In this chapter I will give a general overview of what I discussed in this thesis. In section 5.2 I will revise EBM and its consequences and problems. In section 5.3 I will take a last glance at the items of Philosophy of Science, and especially to the problems we encountered while applying it. In section 5.4 I will try to look in the future, although predicting the future obviously remains precarious. In section 5.5 I will make some recommendations, to overcome the problems I see in EBM. And finally, in section 5.6, I will clarify my personal opinion on the topics discussed in this thesis.

5.2 Evidence-based medicine

In chapter 2 I described the characteristics of EBM, and the problems and implications that its introduction invokes. By means of the theories by Kuhn and Latour, some of these problems could be identified as 'common for the introduction of new developments'. Other problems, however, should be seen as serious threats to the successful introduction of EBM.

The most important are those problems, that I previously indicated as intrinsic. Two of them remain intact: the problem that general data seem hard to apply in specific cases, and the problem that morals, values and norms are standardised.

The first problem, that is the hiatus between general knowledge and individual application, can only be solved by undermining the core ideas of EBM. EBM denies

the value of single observations. But to apply (whatever) knowledge to a single case, observations on this case will have to be taken into account. This is a fundamental conflict. Several sounds have been heard, to overcome this gap (Nederbragt, 2000). Yet most of these sounds are half-hearted. They admit that the individual observation *is* valuable, but refuse to take this individual observation as a source of general knowledge.

The second problem is the standardisation of morals, values and norms. To establish knowledge, EBM preforms trials. These trials are designed by scientists, and when designing they apply certain ideas on values and morals. For example, they could take the maximisation of life expectance as the central merit, or the minimisation of treatment duration. Knowledge resulting from the trial will then be charged with these values and norms. This problem can (theoretically) be overcome by performing several trials with various ideas and values, such that for any thinkable normative situation a treatment will be available, supplied with 'best evidence'. This would heavily trouble the clarity that is heralded by EBM, and undermine its ambition to distill the optimal treatments from the variety of more and less doubtful treatments.

These two problems raise questions on what role should be attributed to the practitioner, according to EBM. As I already mentioned in the beginning of this thesis, EBM may feed the impression that the doctor becomes a rationally thinking machine, which could be replaced by a computer as well. I also mentioned that this impression is denied by EBM. We saw that the linking of general medical knowledge to the individual patient will always contain intuitive factors, and hence it cannot be formalised. Therefore the doctor will always remain the most important factor in decision making. With the same reasoning, we can see that tasks such as the consolation of patients, setting them to ease, explain medical knowledge in a manner a layman can comprehend, etc. etc. will always remain human, and cannot be delegated to a methodology, or 'logical machine' such as a computer.

Most other problems such as the rigidity of doctors, the problem that evidence is of insufficient quality, the problem that doctors not practicing EBM are hard to influence with evidence, the problem that EBM is misunderstood to be equal to the making and following of guidelines etc. etc., are easily casted into the theories by Kuhn and Latour. This doesn't mean that they will be solved automatically or easily, but it does mean that they are common for such a development. Similar problems have been solved with other movements in the past, and hence we may expect that a solution will be possible in this case, too.

I tend to say, that the intrinsic problems from paragraph 4.3.2 have to be solved before the extrinsic problems from paragraph 4.3.3 can be dealt with. Regardless whether one follows Kuhn or Latour, any problem from within the new paradigm

(or black box, or claim) will prevent others from accepting it. E.g. as a practitioner, you can acquire the methods of EBM, in the assumption that in the near future the amount of evidence will be sufficient to cover the problems in your practice. But you will hesitate to convert to EBM, if you know for sure that until the end of ages, you will only be able to maximise life expectance of your patients (and not pursue any other value).

We could wonder what role the AMC should play, and what role they can play to propagate EBM. According to Latour we could say, that it doesn't matter exactly *what* they do, but rather *how much* they do. It is more important to provide us with an overload of courses, seminars, articles, flyers, suggestions for (governmental) policies, examples of the successes of EBM etc. etc. By such an offensive, he opposition to EBM should be rendered invisible. These vehicles are at the disposal of the opposition as well, and it is up to the AMC to outperform them. Of course the AMC is only one of the many actors in the game, but with these vehicles any other actor can be enrolled, and be put on stage as an ally.

According to Kuhn, the process will be a bit more complicated, and less arbitrary. The new paradigm will have to be 'perfectionalised', that is the disadvantages that we saw must be overcome. The most important are the intrinsic problems mentioned above. The AMC could for example use their international status, to get these problems more centrally on the agenda. They will not be able to solve it all alone, they will need others to strive together with them. And to enroll those others, we are back with Latour.

In the end of chapter 3 I stated some thoughts on EBM and its introduction. I will briefly discuss some of them now. The change in medical science is found: explicit demands on the methods of research are formulated and pursued. The changes in practice and education are found as well, as we saw in the anthology on EBM in the AMC. Whether EBM will offer a solution to iatrogenesis (in Illich's wide conception) and medicalisation, remains a matter of speculation. When looking at some anecdotes about the AMC, we should say that useless treatments are really banished. But on the other hand, I once heard a doctor telling, that he could not withstand the impression that with the secularisation people tend to visit their GP more and more, for problems that have nothing or little to do with real medicine, problems they previously consulted the vicar for. Perhaps we should expect too much of EBM, confronted with this (sort of) hypochondria.

5.3 Philosophy of science

In chapter 3 I discussed the works by Thomas S. Kuhn, and Bruno Latour. Both of them have proven to be highly relevant for investigating science. Yet both of them have their problems when applied to medicine, which I would like to discuss here.

Let's start with Kuhn. I already stipulated the problems in paragraph 4.3.5 and on page 34: one may raise objections to the application of Kuhn's theory to this specific case in medicine. Yet in the course of this thesis, I gave arguments why to my opinion there is a paradigm shift, and why I think that Kuhn's theory can be applied onto medicine, even while it is not merely scientific. With respect to the paradigm shift, I repeat shortly here: Kuhn assigns supremacy to the community over the paradigm, hence incompatible communities must have incompatible paradigms. As we see a distinction between the pros and the contras of EBM, there must be a difference in their paradigm. And with respect to the application of Kuhn's theory to a practical business such as medicine, I would say: since I argued that in the scientific part of medicine a paradigm shift is noticed, and the distinction between pros and contras is not only found in science but also in the field of practice, we should also accept the statement that in practice a paradigm shift is going on. Even though this conception of a paradigm is not found with Kuhn, we should still notice that many of the developments in this field closely resemble the developments that were described by Kuhn with respect to science.

And then Latour's theory. We saw that it could be applied quite straightforwardly on the case of population screening for breast cancer. But a rather fundamental objection grew in its application to EBM as a general idea. We saw with *The Berlin Key* (Latour, 1997), that according to Latour the total amount of morality increases when tasks and interests are reshuffled. This sounds like a desired outcome: we all strive to be moral persons, and we should be content if the amount of morality in our neighbourhood increases. But when morals are delegated to non-human beings, they are carried out much more strictly. In cases of speed limiters in cars, or door closers preventing for heat loss, this might be desirable. But in the case of medicine it yields a feeling of restraint in moral freedom. Most medical actions have moral implications, and both the doctor and the patient will feel oppressed if their decisions are fully determined by EBM. In geriatrics for example, it may not be useful to take 'maximisation of life expectance' as the ultimate goal. But this generally *is* the value that trial outcomes are charged with.

Of course we ran into some more difficulties when applying the theories by Kuhn and Latour, but to my opinion these were just matters of casuistry. They do not disprove the theories, nor do they discredit their application to practice.

5.4 The future

If one thing remains impossible, it is predicting the future. In section 5.2 I already pointed out some problems, which I expect to stand in the way for EBM. I think the two problems I addressed above will remain intact, but other problems (also some that have been called intrinsic) will be solved in the course of time. For example, the objection that the available evidence is insufficient and biased, will be solved in time. After all, evidence is growing every day, methods are improving etc. etc., so one day the amount of useful evidence will be enough, not to stand in the way for practicing EBM. And for example, the rigidity of doctors and their fear of losing autonomy, will be overcome once that the merits of EBM are propagated well. That is: *if* the controversy turns out to develop in this direction.

For if one thing is made clear by Latour, it is that it is impossible to predict a development from its own qualities. It is well-thinkable that from the side of politics measures are taken that obstruct the courses of EBM. Or the economy may falter, which causes a decrease of funding for EBM-oriented research, such that other movements get the upper hand. To get more insight, a thorough empirical research would be needed, to investigate the networks that EBM is involved in. This would take years, and even then predicting the outcome of the controversy remains impossible.

5.5 Recommendations

The adherents to EBM will have to strive actively to overcome the problems sketched throughout this thesis. The two problems in section 5.2 will form the most difficult obstructions, and they actually cannot be solved without changing the core of EBM.

These two problems are actually similar by nature. Both the moral charge and the generality of knowledge, can be seen as a matter of failing *deduction*: to see a single case as a specimen of a generic concept. This should be ascribed to an imperfection of the generic concept: apparently the general knowledge is inaccurate for application, and the inscribed morals are inapt.

So far these problems were provided with a trivial and *ad hoc* solution. Most solutions heard of so far can be paraphrased as: 'To warrant sufficient moral freedom, the doctor should take explicit measures to warrant his moral freedom'. And: 'To overcome the gap between general knowledge and its individual application, the doctor should use his years of clinical experience.' These are not real solutions, since they do not tackle the problem at its roots, but rather at its effects.

To overcome the undesired charge of trials with moral considerations, trials

should be set up in a value-free fashion. When designing a trial, the researcher has to be aware of the (many) different moral points of view. He should design the trial such that the majority of these points of view is respected. If it is possible at all, this will demand a huge effort, and it will radically increase costs. But it is necessary, before the accusation of being morally charged will be diminished.

The hiatus between general knowledge and its individual application can be overcome in the same way. The designer of a trial should be aware of the fact that the patient on whom knowledge will be applied, is not always 'male, Caucasian, aged between 25 and 40'. Then knowledge gained in trials will find a much larger field of application validity. Again this will be at the expense of radically increasing efforts and costs.

The fundamental phenomenon that a trial is usually charged (be it either with morals, or an idea of a standardised patient), will never be averted. Therefore, this charge should be employed for a better cause, and be used to implement moral freedom and broad validity. I am aware of the fact that these solutions may be beyond reach. And that is not only for financial reasons: it also demands a thorough revision of the concept of EBM. Yet if solutions like this one are not considered, and trivial ones are preferred, I think EBM will remain an immature paradigm. Hence it will keep running into the resistance that is common for immature paradigms.

5.6 Critical position

The most intricate part of performing a research, is to choose ones own position. Yet it may be the most interesting part as well.

Those who know me in my personal life, will probably describe me as a fervent advocate of rational thinking. I am indeed, and therefore I prefer a medicine-by-the-ratio above a medicine-by-the-feeling. If doctors are offered the opportunity to found their action with objective facts, I think they are obliged to do so. To my opinion any fundamental refusal is unacceptable.

Yet I see a lot of difficulties in the direct application of EBM as it is now. Most of them can be overcome, although the two I reemphasised in section 5.2 will demand a huge effort. It is understandable if nowadays' doctors hesitate to convert to EBM. EBM currently appears immature, and then one can legitimately wonder if the patient's well-being is served with it.

To make these two items consonant, I hereby express the hope, that EBM will grow mature, such that it can enroll most of the doctors. It will take an effort compared to which this thesis will seem a bagatelle, to formulate how this maturation can take place. A first onset however was given in section 5.5.

Glossary

Antiprogram Term used by Latour, used to indicate all those elements, that support the opposition, when pursuing a certain target.

Artefact This word is generally known with three meanings that have little to do with each other. Yet all of them would fit in a medical-philosophical context. They are:

1. A mutilation that is inflicted on a human body, i.e. one is not born with it. A leg amputation is an artefact, but a tattoo could be considered an artefact too.
2. An inaccurate observation, that is due to inaccurate methods. A few years ago the French authorities proclaimed that over 80% of the drugs smuggled into their country was of Dutch origin. The truth was that they only searched Dutch vehicles.
3. Anything that is 'man-made'. A brick, being manufactured in an oven, is an artefact, whereas a pebble found in a river is not, since it is shaped by nature.

In this thesis the word is only used in the second sense, as being complementary to the word 'fact', which indicates a piece of knowledge that is *accepted* as a result of correct observation (be it scientific or not).

Black box Term introduced by Latour, nominating a fact, machine or theory, of which the genesis has become invisible. It looks like it has always been there, thus hiding the controversy that preceded its establishment.

Clinical epidemiology The branch of medicine that concerns the methodology of investigating the effectiveness of treatments, diagnostic methods and prognostic properties in large populations. Clinical epidemiology maintains the *randomised clinical trial* as its central object. (Bossuyt and Semin-Goossens, 2001, p. 58) It should not be confused with *epidemiology*.

Delegation Latour uses this term when behaviour or values are maintained by things rather than human beings. The value that a door should remain closed as much as possible can easily be delegated to a mechanical door-closer.

Epidemiology The discipline within medicine, that concerns the distribution of disease in a population. It uses statistics, and pursues to uncover the causes that influence this distribution. See also *clinical epidemiology*.

Iatrogenesis Term closely connected to the works of Illich. Originally this means 'any disease caused by medicine itself'. Illich extends this meaning to any form of man causing disease, which can be by means of social and political structures as well.

Instrument Term used by Latour: 'any set-up, no matter what its size, nature and cost, that provides us a visual display of any sort in a scientific text'. (Latour, 1987, p. 68)

Inversion Term introduced by Latour, indicating that once that a controversy is solved, it will look like the outcome was the only possible one, that had always been pursued. Controversies are not visible in retrospection. When they are going on, it is clear that their outcomes are not so obvious at all.

Medicalisation Term used for any problem that is not (or not merely) a medical problem, but is treated purely medically, though. Pregnancy used to be a matter of women among women, but nowadays it is *medicalised*, since most births take place in the hospital under supervision of a gynaecologist.

Modality Term used to label an expression, that (eventually implicitly) expresses a judgement of value about a statement or action. Thus it can fortify or undermine the statement or action.

Normal Science Term introduced by Kuhn, to indicate 'science at rest', i.e. science that is not currently in a revolution or paradigm-shift. During periods of normal science, the ruling paradigm guides scientific behaviour. The paradigm is not explicitly present then.

Paradigm Term used by Kuhn, meaning the framework in which science is practiced. It contains values, habits, methods, and presumptions that guide scientific research.

Program Term used by Latour, used to indicate all those elements, that form an ally in pursuing a certain target.

Randomised clinical trial Research involving large numbers of cases, with a strict methodology of randomisation and control-groups. It is believed to yield the most reliable medical knowledge.

Script Term established by Madeleine Akrich. It defines the human behaviour that is invoked by things. I happen to have a smoke detector, whose cover can only be closed if a battery is placed in it. It thus invokes the behaviour of placing a battery.

Transparency Used in two ways. They are:

1. Contrary to 'black', in case of a black box: anything that is not accepted yet, not established, and still subject to controversy.
2. To indicate that a diagnostic method (or generalised: any method of measurement or observation) provides us with a fully objective and unbiased vision on nature, or generally: on 'the truth'. A transparent method is a fictitious ideal. A practical method is always charged with the considerations of the one who invented the method.

Summary

In this thesis, the introduction of *Evidence-based medicine* (EBM) is investigated. EBM embraces the pursuit, to found medical acting in a more scientific way. The introduction of EBM is investigated by means of the theories by Thomas S. Kuhn and Bruno Latour. The central question in this thesis is:

> *What does the introduction of EBM look like? Are the elements from Kuhn's and Latour's theories well-recognisable?*

(Chapter 1)

EBM is a relatively new movement within the medical practice and research. The tradition of medicine comprises a highly guild-like character, where people with a certain authority (professors, experienced clinicians etc. etc.) determine what treatment is applied in a certain case and how. Pupils are educated to qualified doctors, by teaching them these facts. EBM intends to replace this guild structure by a more rational one. Not the professor tells what is right, but a rigid methodology is used to gain knowledge. A central role is attributed to the *randomised clinical trial*. In such a trial a large number of cases is investigated, with strict methods of randomisation and blinding. The results of these trials are made available to doctors in *systematic reviews*, *Cochrane reviews* and *meta-analyses*. This type of knowledge is called *evidence*. According to the EBM-guidelines, a doctor should try to find and apply the best available evidence for every patient.

The introduction of EBM demands a number of changes in the culture of medicine. Authority is drawn away from individuals and attributed to a methodology. Medical education has to convert to the training of searching for evidence, rather than merely handing over facts. The daily practice of a doctor changes, since he now has to spend time pursuing evidence. Governmental policy on medicine may have to change. And last, but not least, medical research will be set-up in a much more strict methodology.

Beside the changes, there are some problems. Evidence may not be available for a large proportion of the medical problems. Knowledge gained from large trials may still be difficult to implement on an individual patient. Applying evidence may contradict our intuitive moral considerations. (Chapter 2)

According to Thomas S. Kuhn, *normal science* is characterised by a stable *paradigm*. A paradigm is a set of examples, models, theories, methods, problems to be solved, habits and so on, that guide the practice of science. It is the paradigm that enables scientists to work together, and share their findings. In normal science, the paradigm is hardly visible. Sometimes the paradigm does not suffice any longer. Then a *controversy* arises, mostly resulting in a *paradigm shift*. Such a paradigm shift is characterised by an incompatibility between the old and the new paradigm, a change in the problems to be investigated by science, and a change in the world view. Successful (new) paradigms are generally unprecedented and open-ended. A conversion to a new paradigm can only take place entirely, and not partially. In retrospection, a paradigm shift fades out, and will become only a minor ripple in the past.

These features can be seen in the introduction of EBM too. The most important change, is the view to the patient. Previously knowledge on pathophysiological principles was believed to be enough to understand the human body. Now these principles remain important, but they are known to yield incorrect knowledge sometimes, and this has to be investigated by a broad numerical analysis. This is sometimes referred to as the 'In Numero' era: the individual patient fades out of view, and is replaced by a set of numerical data.

Hence we are inspired to see EBM as a new paradigm. The old and new ways of constituting knowledge are incompatible. A doctor (or scientist) can only convert to EBM if he makes the *entire* change. The world view changes in this sense that knowledge is viewed much more critically, and by means of a numerical analysis. A new class of problems arises, implemented as the new discipline of *clinical epidemiology*. Moreover, in general the introduction of EBM runs into rigidity, which is an indication of the radicalism of change.

According to Bruno Latour, scientific facts are not just the result of a small piece of nature being uncovered. It starts as a *claim*, stated by a scientist. He tries anything to fortify it: underpin it with texts, supply it with graphs and tables, appeal to established authorities etc. etc. After a while of *controversy*, the claim is either disproved (i.e. its opposition was too strong), or sustained. When it is sustained, the dispute becomes invisible, and the claim becomes a *fact* or *black box*. The way the black box was established, becomes invisible. Latour calls this *inversion*, since it now seems that the fact was already there, only it had to be uncovered. If on the

other hand, the claim is disproved, it becomes an *artefact*.

In the discussion around *breast cancer* the elements of Latour's theories are well-visible. Through the years it has become an established fact, that mass screening for breast cancer reduces mortality from breast cancer. This fact is accepted, and comprises the character of a black box. But recently, two Danish researchers tried to open this black box: they have several reasons to question the effectiveness of screening. The controversy that arises now, contains a lot of *modalities*, i.e. a qualification that is applied to a claim. We see that it is not just nature that determines whether a claim is correct, but that a large discussion, involving more than only medical actors, is carried on about it.

Additionally, Latour constitutes a framework to analyse controversies on an individual level. Actions are then fit in terms of *programs* and *antiprograms*. We can then see how tasks are being delegated to non-human actors. This is important when we want to judge the moral qualities of EBM. (Chapter 3)

Two items are investigated in practice. First the ongoing controversy around breast cancer is investigated. And second, the introduction of EBM in the Netherlands is investigated.

The controversy around breast cancer follows the pathways as described by Latour. The fact that population screening for breast cancer is widely accepted, seems to lose hold. The effect screening for breast cancer has always been questioned. Yet there is a difference: previously the discussion was directed towards the indirect consequences, such as the mental burden that is put on women, and matters of expenses and benefits. Now the effect itself is questioned. It used to look like a black box (i.e. a fact, of which the genesis has disappeared from the view), but this is corrupted by Olsen and Gøtzsche. They show that the closing of this black box has been premature. Then a game of applying modalities, both to the claims by Olsen and Gøtzsche and to the claims by adherents to the screening, erupts. We see that the discussion goes astray from rational reasoning, towards politically and and personally coloured considerations. The discussion is diverging to a broad scala of disagreements, rather than converging to a consensus. The controversy can only be solved by a huge trial, which is not one of the serious options: it will take too much time, and too much resources.

Olsen and Gøtzsche use one large black box: they assume that everybody agrees, that the methodology of EBM and the Cochrane Society are optimal. They are mistaken, given the many questioning reactions. A lot of counter-arguments are given, up to the *argumentum ad hominem* that they are known to be sceptical about breast-cancer screening. A complex quarrel between people involved is the result.

According to Latour these quarrels can be casted in the shape of 'programs' and 'antiprograms'. The program is anything that is adduced to support a certain pursuit. The antiprogram is anything that obstructs this pursuit. A controversy can only be solved if one of these two gets the upper hand. Casting the breast-cancer controversy in such a shape, clarifies that currently both the program and the anti-program are to weak to win. Therefore the controversy cannot be solved yet. (Section 4.2)

Then the controversy around the introduction of EBM was investigated. The majority of the literature tends to express a positive view on the introduction of EBM. Yet some negative sounds can be heard as well. Positive sounds are, that in the AMC the introduction of EBM seems to be complete. The term EBM is often found in leading Dutch medical journals, and the Dutch Cochrane Centre is flourishing.

A number of problems that come to the light with the introduction of EBM, are labeled 'intrinsic'. The first is that 'evidence' seems to be incomplete and biased. Knowledge is 'decontextualised', since the 'general case' never occurs in practice. EBM is said to neglect decisions on care. Moreover, it loses sight on the individual patient, and aims and morals are standardised. The problem that evidence is incomplete and biased, can be seen as a result of 'not entirely undergoing the new paradigm' (referring to Kuhn): once that a doctor fully converts to EBM, this problem will disappear from the stage. Or with Latour: the network tied around EBM is not strong enough yet to convince. The same goes for the problem that EBM neglects questions concerning care. The problems that the individual patient is lost out of sight, and that morals are standardised, seem persistent.

Some other problems are labeled 'extrinsic'. One problem is that doctors often refuse to accept new knowledge, even if it is well-founded. This is caused by cynicism and rigidity. Another problem, is the misunderstanding that EBM heralds the loss of autonomy for the doctor. Moreover, EBM is believed to be equal to the making and following of guidelines. A final problem is, that general practitioners (and other specialists as well), may see their practice unapt to perform EBM. The first problem, of rigidity and cynicism, is not easy to fit into Kuhn's theory. He does not really tell us what to do, when people do want to convert to EBM, but actually they cannot. Latour would tell us, to engage more elements such that the network becomes more convincing. Rigidity touches Latour's sense of 'irrationality', and he then advises us not to make an accusation, but to investigate why frameworks of thought collide. The two misunderstandings, that EBM implies the loss of autonomy for the doctor, and that EBM equals the making and following of guidelines, can be solved by what Kuhn calls 'translation', that is to take explicit measures to overcome a 'confusion of languages' between adherents and opponents to the new paradigm. The final

problem, that EBM is difficult to practice for many (willing) doctors, demands a transformation of the practice of those doctors.

Kuhn states that a paradigm shift is characterised by a radical change. The introduction of EBM comprises some radical changes. Guidelines are not new, but the sophisticated way in which they are founded is rather new. The shift from individual autonomy of the doctor, towards a profession-wide autonomy based on well-pondered methods is a radical change too. The inherent sceptic attitude towards knowledge is quite new as well, as is the insight that pathophysiological principles may yield incorrect knowledge.

Kuhn also states that by the introduction of a paradigm the problems investigated by science change. In the scientific part of medicine, this shift is found in the rising of *clinical epidemiology* as a new discipline. In the practical application of medicine, the change of problems is found in the fact that the doctor now has to pursue evidence, and perform the critical appraisal.

Another characteristic by Kuhn was the change of the world view. This change is found in the fact that knowledge is viewed much more critically, and in the insight that pathophysiological principles may yield incorrect knowledge.

The second change is found in the fact that medical education not any longer takes the transfer of *knowledge* as its central aim, but rather the transfer of *skills*. The third change is that the clinical problem changes shape, by the new process of decision making.

Kuhn also states that new paradigms are usually unprecedented. What seems to be unprecedented, is the fact that previously large trials were not accompanied by a sophisticated statistical method.

The final characteristic by Kuhn, is that a new paradigm should be *open-ended* enough, such that all kinds of problems can be resolved within it. This seems to be warranted, since any classical medical problem can be dealt with in an evidence based way as well. Moreover, if a doctor has a good reason for it, it is legitimate to ignore certain evidence. (Section 4.3)

In the end the following conclusions are drawn. The extrinsic problems and most of the intrinsic problems, can be cast in the framework of Kuhn's and Latour's theories. Two problems remain barriers to the introduction of EBM. Those are: the fact that general data are hard to apply on specific cases, and the problem that morals and values are standardised.

The theories by Kuhn and Latour have proven to be highly relevant, when analysing a development in science. With Kuhn we saw a difficulty, that it is not so easy to cast a practical field into his theory (which was necessary, since medicine has ha large practical component).

With Latour we saw the problem that the delegation of morals results in a more strict application of these morals (something that is appreciated positively by Latour), but that this more strict application is not appreciated by all doctors involved.

It is recommended to investigate how trials can be set up in a more 'value-free' fashion. Moreover, it should be investigated how trials can be set up, such that their outcomes can be applied to a wider range of patients, instead of just being valid for a fictitious generalised patient. Yet this fundamental phenomenon that a trial is charged with the considerations of its creators, will always be there. (Chapter 5)

Samenvatting

In deze scriptie staat de introductie van *Evidence-based medicine* (EBM) centraal. EBM behelst het streven, om geneeskundig handelen beter op wetenschappelijke basis te funderen. De introductie van EBM wordt onderzocht aan de hand van de theorieën van Thomas S. Kuhn en Bruno Latour. De centrale vraag van deze scriptie luidt:

> *Hoe ziet de introductie van EBM eruit? Zijn hierin de elementen van de theorieën van Kuhn en Latour te herkennen?*

(Hoofdstuk 1)

EBM is een relatief nieuwe beweging in de geneeskunde en geneeskundig onderzoek. De geneeskunde wortelt in een traditie die sterk doet denken aan een gilde-structuur. Sommige mensen (bijvoorbeeld hoogleraren, of zeer ervaren artsen) hebben daarin een autoriteit, en bepalen welke behandeling in welk geval moet worden toegepast, en hoe. Studenten worden opgeleid tot artsen, door ze deze feiten en handelswijzen te onderwijzen. EBM stelt zich ten doel om deze gilde-structuur te vervangen door een meer rationele. Kennis komt niet meer bij de hoogleraar met zijn ervaring vandaan, maar uit een vastomlijnde methodologie. Daarbij speelt de *randomised clinical trial* (RCT, gerandomiseerde klinische test) een centrale rol. In zo'n trial wordt een groot aantal gevallen onderzocht onder strikte voorwaarden van randomiseren, en het garanderen van blindheid. De resultaten van deze tests worden aan artsen ter beschikking gesteld via *systematic reviews* (systematische overzichten), *Cochrane reviews* en *meta-analyses*. Deze vorm van kennis wordt *evidence* genoemd. (Hiervoor is geen goede Nederlandse benaming beschikbaar. Evidence is sterker dan een 'aanwijzing', maar zwakker dan een 'bewijs'.) Volgens de richtlijnen van EBM, moet een arts in elk voorkomend geval de beste evidence opzoeken en die toepassen.

De introductie van EBM vereist een aantal veranderingen in de cultuur van de geneeskunde. Autoriteit wordt ontnomen aan individuen, en toegekend aan een methodologie. Geneeskundig onderwijs moet meer gericht worden op de vaardigheid

evidence te vergaren, dan op het overdragen van feitenkennis. De dagelijkse praktijk van een arts verandert, omdat hij zich nu ook met het zoeken van deze evidence bezig moet houden. Ook kan een verandering van het overheidsbeleid met betrekking tot de gezondheidszorg vereist zijn. Bovendien wordt geneeskundig onderzoek onderworpen aan een veel strengere methodologie.

Afgezien van deze veranderingen, treden er enkele problemen op. Zo is evidence vaak in onvoldoende mate aanwezig. Kennis die wordt opgedaan in trials is niet altijd makkelijk toe te passen in de praktijk, waar het individuele patiënten betreft. En het toepassen van evidence kan in tegenspraak zijn, met onze intuïtieve morele overwegingen. (Hoofdstuk 2)

Volgens Thomas S. Kuhn wordt *normale wetenschap* (normal science) gekenmerkt door een stabiel *paradigma*. Een paradigma is een verzameling voorbeelden, modellen, theorieën, methoden, problemen die een oplossing behoeven, gewoontes enzovoort, die tezamen de praktijk van de wetenschap aansturen. Zo'n paradigma maakt het voor wetenschappers mogelijk om samen te werken, en hun bevindingen te delen. In normale wetenschap is het paradigma nauwelijks zichtbaar. Soms voldoet het paradigma echter niet meer. Dan komt een *controverse* op gang, die in het algemeen resulteert in een *paradigmaverschuiving* (paradigm shift). Zo'n paradigmaverschuiving wordt gekenmerkt door een onverenigbaarheid van het oude met het nieuwe paradigma, een verschuiving in de problemen die een oplossing behoeven, en een verandering van het wereldbeeld. Succesvolle (nieuwe) paradigmata zijn in het algemeen origineel (*unprecedented*), en zij laten nieuwe doelen voldoende open (*open ended*). Een bekering tot een nieuw paradigma is alleen mogelijk als zij volledig plaatsvindt. Een gedeeltelijke bekering is niet mogelijk. Wanneer achteraf wordt teruggekeken op de paradigmaverschuiving, valt zij nauwelijks meer op. Het is slechts een kleine rimpeling in het verleden.

Deze eigenschappen zien we ook bij EBM. De belangrijkste verandering is de visie op de patiënt. In het verleden werd kennis van pathofysiologische principes voldoende geacht. Op die manier kon het menselijk lichaam voldoende begrepen worden. Deze principes zijn nog steeds belangrijk, maar de overtuiging is opgedaan, dat deze principes ons soms foutieve inzichten verschaffen. Daarover kan slechts in uitgebreide tests uitsluitsel worden gegeven, waar een numerieke analyse de doorslag geeft. Dit wordt ook wel het 'In Numero'-tijdperk genoemd: de individuele patiënt raakt buiten beeld, en wordt vervangen voor een verzameling getallen.

Op die manier zijn we geneigd EBM een nieuw paradigma te noemen. De oude en de nieuwe manier van kennis vergaren (individuele autoriteit versus een gemeenschappelijke methodologie) zijn niet verenigbaar. Een arts (of wetenschapper) kan zich alleen wenden tot EBM als hij dat *volledig* doet. Het wereldbeeld verandert in

die zin, dat kennis veel kritischer wordt beoordeeld, en wel in een numerieke context. Een nieuwe klasse problemen doet zich voor. Deze problemen zijn ondergebracht in de nieuwe discipline *klinische epidemiologie*. Bovendien heeft de introductie van EBM in het algemeen last van de *rigiditeit* (onwil tot verandering) van artsen, hetgeen een aanduiding is voor de radicaliteit van de verandering.

Volgens Bruno Latour zijn wetenschappelijke feiten niet het resultaat van het stukje bij beetje blootleggen van de natuur. Een feit begint als een *bewering* (claim) door een wetenschapper. Die doet alles om de bewering aannemelijk te maken: onderbouwen met teksten, grafieken en tabellen toevoegen, appelleren aan gevestigde autoriteiten enzovoort. Na een periode van *controverse* wordt de bewering ofwel verworpen (de tegenstand was kennelijk te sterk), ofwel geaccepteerd. Als zij geaccepteerd wordt, wordt de hele discussie onzichtbaar, en wordt de bewering een *feit* (fact) of *zwarte doos* (black box). Latour noemt dit *inversie*, omdat het er nu op lijkt dat het feit eigenlijk altijd al waar was, en dat het slechts hoefde te worden ontdekt. Als de bewering wordt verworpen, dan wordt het een *artefact*.

In de discussie rond borstkanker zijn de elementen van Latour's theorie goed zichtbaar. Door de jaren heen is het feit geaccepteerd geraakt, dat grootschalige screening de sterfte ten gevolge van borstkanker verlaagt. Dit feit gedraagt zich als een zwarte doos. Echter, recentelijk hebben twee Deense onderzoekers gepoogd deze zwarte doos te openen. Ze hebben diverse redenen om te twijfelen aan de effectiviteit van de screening. De controverse die nu optreedt, bevat een groot aantal *modaliteiten*, dat zijn kwalificaties die aan een bewering worden gekoppeld. We zien dat het niet de natuur is die bepaalt of een bewering juist is of niet, maar dat hieraan een grote discussie ten grondslag ligt, waarin meer dan alleen artsen betrokken zijn.

Bovendien geeft Latour ons een methode om controverses op een individueel niveau te analyseren. Acties worden dan besproken in termen van *programma's* en *anti-programma's*. Op die manier wordt duidelijk hoe taken kunnen worden gedelegeerd aan niet-menselijke aktoren. Dit is van groot belang als wij de morele kwaliteiten van EBM willen beoordelen. (Hoofdstuk 3)

Twee onderwerpen zijn in de praktijk onderzocht. Ten eerste is gekeken naar de discussie rond de screening naar borstkanker, die op dit moment gaande is. Ten tweede is de introductie van EBM in Nederland onder de loep genomen.

De discussie rond borstkanker ontwikkelt zich zoals Latour dat heeft beschreven. Het feit dat bevolkingsonderzoek naar borstkanker breed geaccepteerd is, brokkelt af. De effectiviteit van screening heeft altijd ter discussie discussie gestaan, maar toch is er een verschil. Voorheen ging het om indirecte consequenties, zoals de mentale belasting die de vrouwen wordt aangedaan, en overwegingen van kosten en

baten. Nu staat de effectiviteit zelf ter discussie. Deze effectiviteit zag er eerst uit als een zwarte doos (dat wil zeggen, het was een feit waarvan de constructie onzichtbaar was geworden), maar deze zwarte doos wordt opengebroken door Olsen en Gøtzsche. Zij laten zien dat het sluiten van de zwarte doos voorbarig is geweest. Daardoor komt het (zwartepieten)spel op gang, waarin modaliteiten worden geuit, over zowel beweringen van Olsen en Gøtzsche als over beweringen van aanhangers van het bevolkingsonderzoek. We zien dat de discussie verzandt in politieke en persoonlijke overwegingen. De discussie escaleert tot een breed scala van onenigheden, in plaats van uit te monden in een overeenstemming. De controverse kan alleen worden gestabiliseerd door een mega-trial. Dat is echter geen reële mogelijkheid: ze kost te veel geld, en te veel tijd.

Olsen en Gøtzsche passen een grote zwarte doos toe: ze nemen aan dat iedereen het ermee eens is, dat de methodologie van de Cochrane Society de optimale is. Ze hebben het echter mis, gezien de vele vragen die rijzen. Er worden veel tegenargumenten gegeven, tot aan het *argumentum ad hominem* dat zij bekend zouden staan als sceptici van het bevolkingsonderzoek. Een complexe discussie is het resultaat.

Volgens Latour kunnen deze discussies worden gegoten in de vorm van 'programma's' en 'antiprogramma's'. Het programma bestaat uit alles, wat ter ondersteuning van een bewering wordt aangevoerd. Het antiprogramma bestaat uit alles wat daarbij in de weg staat. Een controverse kan alleen tot rust komen, als een van deze twee de overhand krijgt. Als we de discussie rond borstkanker in deze vorm gieten, dan moeten we constateren dat kennelijk zowel het programma als het anti-programma te zwak zijn om te winnen. Daarom kan de controverse (nog) niet tot rust komen. (Paragraaf 4.3)

Vervolgens is de introductie van EBM in Nederland nader bekeken. Het grootste deel van de literatuur laat een positief geluid horen. Enkele negatieve punten zijn echter ook te horen. Successen vinden we in het feit dat in het AMC praktisch alles in overeenstemming met de EBM-ideeën gebeurt. De term EBM komt veelvuldig in vakliteratuur voor, en het Dutch Cochrane Centre leidt een bloeiend bestaan.

Enkele problemen rond de introductie komen aan het licht. Sommige daarvan worden beschouwd als 'intrinsiek', dat wil zeggen 'onlosmakelijk met EBM verbonden'. De eerste daarvan is, dat evidence vaak incompleet en gekleurd is. Kennis wordt bovendien 'gedecontextualiseerd', want het 'algemene geval' vindt in de praktijk nooit plaats. Verder wordt EBM verweten, dat het zorgvragen verwaarloost. De individuele belangen van de patiënt kunnen over het hoofd gezien worden, en normen en waarden worden door EBM gestandaardiseerd. Het probleem dat evidence incompleet en gekleurd is, kan worden geweten aan het 'niet volledig ondergaan van het nieuwe paradigma' (Kuhn's theorie): als een arts zich volledig op EBM toelegt,

zal dit probleem verdwijnen. Of om met Latour te spreken: kennelijk is het netwerk dat EBM moet ondersteunen nog niet sterk genoeg om te overtuigen. Hetzelfde geldt voor het probleem dat EBM zorgvragen zou verwaarlozen. De problemen dat de individuele patient uit het oog verloren wordt, en dat normen en waarden worden gestandaardiseerd, lijken echter fundamenteel van aard te zijn.

Enkele andere problemen worden beschouwd als 'extrinsiek'. Een probleem is dat artsen nogal eens weigeren evidence aan te nemen, zelfs als die helder onderbouwd is. Dit is een symptoom van scepsis, en rigiditeit. Een ander probleem, is het misverstand dat EBM het einde zou betekenen van de autonomie van de arts. Bovendien wordt verondersteld dat EBM hetzelfde is als het maken en opvolgen van richtlijnen. Een laatste probleem is, dat huisartsen (en andere specialisten), hun praktijk ongeschikt achten voor de uitvoering van EBM. Het eerste probleem, van rigiditeit en scepsis, past niet makkelijk in de theorie van Kuhn. Hij geeft ook niet echt een oplossing voor het probleem dat mensen zich wel *willen* bekeren tot het nieuwe paradigma, maar het niet *kunnen*. Latour zou zeggen, dat we meer elementen aan het netwerk moeten hangen, zodat het netwerk overtuigender wordt. Rigiditeit raakt Latour's begrip van *irrationaliteit*. Hij adviseert ons in dat geval, om geen beschuldiging te uiten, maar om te onderzoeken waarom overtuigingen botsen. De twee misverstanden, dat EBM het verlies van autonomie behelst, en dat het gelijk is aan het maken en volgen van richtlijnen, kan worden opgelost met wat Kuhn *translation* (vertaling of verplaatsing) noemt, dat wil zeggen: expliciet maatregelen nemen om een 'spraakverwarring' te voorkomen tussen de aanhangers en tegenstanders van EBM. Het laatste probleem, dat EBM moeilijk uitvoerbaar is voor veel (bereidwillige) artsen, vereist een verandering van de praktijk van deze artsen.

Kuhn stelt dat een paradigmaverschuiving een radicale verandering inhoudt. De introductie van EBM houdt ook enkel radicale veranderingen in. Richtlijnen als zodanig zijn niet nieuw, maar de doordachte manier waarop ze worden opgesteld is wel degelijk nieuw. De verschuiving van individuele autonomie, naar een autonomie voor de beroepsgroep in zijn geheel, gebaseerd op degelijke methoden, is ook een grote verandering. Tenslotte is de kenmerkende kritische houding jegens kennis nieuw, alsmede het besef dat het begrijpen van pathofysiologische principes soms foutieve medische kennis oplevert.

Verder stelt Kuhn, dat bij de invoering van een nieuw paradigma de problemen veranderen, die door de wetenschap worden onderzocht. In het wetenschappelijke deel van de geneeskunde, bestaat die verandering met name in de opkomst van de *klinische epidemiologie* als nieuwe discipline. In de praktische tak van de geneeskunde, bestaat de verandering met name in het feit dat de arts zich nu ook moet bezighouden met het zoeken naar evidence, en deze kritisch moet beoordelen

(*critical appraisal*).

Een ander karakteristiek punt is de verandering van het wereldbeeld. Deze verandering ligt met name in de veel kritischere kijk op kennis, en het reeds genoemde punt dat pathofysiologische principes niet voldoende zijn om het menselijk lichaam te begrijpen.

Een tweede verandering ligt in het feit dat geneeskundig onderwijs zich niet langer (primair) bezighoudt met kennisoverdracht, maar met de overdracht van vaardigheden. Ten derde veranderen de klinische problemen van aard, door de totaal nieuwe manier waarop beslissingen worden genomen.

Kuhn stelt ook, dat succesvolle nieuwe paradigmata in het algemeen origineel zijn. Een origineel punt van EBM is het feit dat voorheen grote trials niet werden voorzien van een doordachte en gestandaardiseerde methode.

Het laatste kenmerk dat Kuhn opmerkt, is het verschijnsel dat een nieuw paradigma open moet zijn, zodanig dat alle denkbare problemen er een plaats in krijgen. Dit lijkt gegarandeerd, omdat elk medisch probleem net zo goed als voorheen binnen EBM onderzocht kan worden. Bovendien is het, als de arts er een goede reden heeft, toegestaan om evidence naast zich neer te leggen. (Paragraaf 4.3)

In het laatste hoofdstuk worden de volgende conclusies getrokken. De extrinsieke problemen, en de meeste van de intrinsieke problemen, kunnen gevat worden in de theorieën van Kuhn en Latour. Twee problemen blijven echter een barrière vormen. Het betreft het punt dat algemene kennis moeilijk toe te passen is in specifieke gevallen, en het feit dat normen en waarden worden gestandaardiseerd.

De theorieën van Kuhn en Latour hebben hun waarde bewezen, bij het onderzoeken van een ontwikkeling in de wetenschap. Bij Kuhn merkten we dat het niet heel eenvoudig is om zijn theorie op een praktische activiteit toe te pasesn. Dit was echter wel nodig, omdat in de geneeskunde theorie en praktijk niet los van elkaar gezien kunnen worden.

Bij Latour zagen we dat het delegeren van morele waarden aan dingen leidt tot een striktere toepassing van die moraal (hetgeen door Latour als positief wordt gezien), maar dat juist deze strikte toepassing van de moraal artsen tegen de borst kan stuiten.

Het is aan te bevelen om te onderzoeken, hoe trials kunnen worden opgezet op een 'waardevrije' manier. Bovendien moet worden onderzocht, hoe trials kunnen worden opgezet, zodanig dat hun uitkomsten zijn toe te passen op een breder scala van patiënten. Nu zijn ze feitelijk slechts geldig voor een fictieve gegeneraliseerde patiënt. Toch zal dit fundamentele verschijnsel, dat een trial geladen is met de overwegingen van degene die haar opzet, altijd blijven bestaan. (Hoofdstuk 5)

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