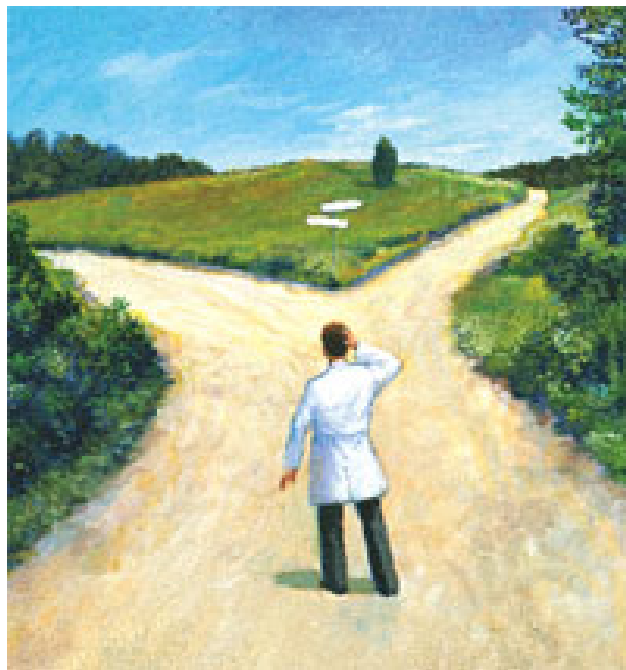


The epistemology of clinical decision-making

*An epistemological analysis of reasoning in clinical
practice, and the role of technological measurements.*



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UNIVERSITY OF TWENTE.

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29-08-2014

Master thesis
Philosophy of Science, Technology and Society

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Acknowledgements

I am thankful to many people for the support, input and feedback that I have received over the past two years that I have been working on this thesis: my teachers, supervisors, co-students and friends in both the Philosophy of Science, Technology and Society and the Technical Medicine program, have helped to shape my ideas about philosophy and medicine.

I am especially grateful to prof. dr. ir. Mieke Boon, who has commenced this exploration of epistemology in medical practice together with me. She has helped me understand what is at stake in clinical reasoning, to frame it in a philosophical discussion and taught me how to do “philosophical research”, through numerous feedback and discussion sessions. I am also grateful to dr. Marianne Boenink for her valuable suggestions and ideas to the draft of this thesis and an earlier version of the second chapter. I am looking forward to proceed our collaboration with both of you in the following years as a PhD student. Furthermore, I am thankful for two anonymous reviewers, who have provided very elaborate and useful feedback on the draft of a journal article that is incorporated in chapter two. My special thanks goes to dr. Pieter Dik, who has shared with me many of his ideas and insights about his work as a doctor. Throughout my clinical internships for Technical Medicine, we had many conversations about specific cases, about clinical reasoning, about medical research and about finding satisfaction in your work. These conversations have been the starting point for this thesis, and will remain a reference for what I think I can say about the clinical practice.

Abstract

The goal of this thesis is to understand clinical decision-making regarding diagnosis and treatment and the role of different types of information, including measurements using technological instruments. From studying the history of medicine I conclude that the development of medical practice is intertwined with the development of science and scientific methods, and with the conceptions of disease and health, societal norms and the organization of care. Therefore, I divide the context in which clinical decision-making takes place, and within which it should be studied, into four dimensions (which are, of course, in reality related and intertwined): the dimension of the patient-physician interaction, the dimension of organization, the material dimension and the intellectual dimension.

Reviewing the current epistemologies of medicine, two opposing views surface: evidence based medicine (EBM) and the “art of medicine”. In my view, both views fail to do justice to the actual work of doctors regarding reasoning about diagnosis and treatment. First, EBM epistemology because of its narrow view on what is scientific and its aim to prescribe clinical reasoning in formal guidelines, thereby promoting rule-based or algorithmic reasoning and confining it mostly to the “organization context”. Second, epistemologies that relate to the “art of medicine” (like those referring to “tacit knowledge”) often fail to provide an account of medical reasoning, making clinical decision-making an implicit and even mysterious process, and confining it mostly to the context of the patient-doctor interaction. Therefore, I reject a strict dichotomy between “objective” and “subjective” and aim to formulate an alternative approach to medical epistemology that overcomes this dichotomy and is able to include all four dimensions of the decision-making context. This alternative should be able to account for specific aspects of clinical reasoning, such as the gathering of relevant information, the integration of different types of relevant knowledge, the use of different types of reasoning styles, and the local and context-specific nature of clinical decision-making, while at the same time securing the desired “scientific” quality.

I argue that the concept “epistemological responsibility” of doctors plays a central role in such an approach. This shifts the focus from the “general” and objectified, represented by guidelines, algorithms and rule-based reasoning, to the specific, the individual doctors and patients. Part of the epistemological responsibility of doctors is then to navigate within, and account for, all four dimensions of the context. To clarify the role and entanglement of the material and intellectual dimensions, I propose a taxonomy of the elements of clinical reasoning, based on Ian Hacking’s taxonomy of the elements that are mutually adjusted in the practice of theory formation in the laboratory sciences. The intellectual work of doctors consist of fitting together and mutually adjusting these elements into a coherent “picture”. This knowledge about the specific patient that is generated by doctors functions as an *epistemic tool* that allows doctors to ask questions and formulate hypotheses about their patients. Therefore, instead of understanding medical epistemology as “objective truth finding”, the knowledge that doctors construct about each individual patient should be considered in relation to the purpose of medicine: to understand and control disease.

Regarding technological measurements, I conclude that quantitative measurements have the reputation of being objective and therefore more reliable than other types of information. However, besides being enabling, they are also limiting. Furthermore, it is often overlooked that data acquisition and processing methods have an impact on the resulting measurement outcome and that the outcome directs diagnosis and treatment decisions. Therefore, I claim that doctors should develop a more epistemologically responsible attitude towards technological measurements, by realizing that they are not as “objective” as they seem but rather provide another perspective on a patient and their disease, among other perspectives. Furthermore, for the development of innovative technologies for clinical practice, a detailed understanding of the role of a specific measurement in clinical decision-making is needed, in order to develop technologies that produce information that is relevant and fitting.

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The Epistemology of Clinical Decision-Making

Introduction

As a student in Technical Medicine I have visited several medical departments in several hospitals over the past years. During these internships I observed specialists at work with their patients. I saw how they collect information about their patients in many different ways, by talking to them, by making images, by measuring things or sending tissue to the lab. Using this information, they formulate a diagnosis and a treatment plan. Sometimes all information points to the same disease. Then, diagnosis is quick and treatment decisions are straightforward. Other cases are more complex and require careful deliberation. These patients keep returning to the hospital, and are repeatedly examined and discussed in multidisciplinary consultations with other professionals of the same or of other specializations. As a student of Philosophy of Science, Technology and Society I became interested in this process. How does a specialist know what he knows? How are all pieces of information integrated into one fitting diagnosis? How are treatment decisions made, who makes them and what is taken into account? In short, I was interested in the epistemology of diagnosis, treatment planning and performance.

Much of the information used in clinical decision-making is obtained using technology. Making medical images using CT's, MRI's or Ultrasound, taking blood samples or listening to lung sounds are familiar aspects of a hospital visit and all require technological measurements. At the same time, doctors also gain information without the use of any instruments, by taking the patient's history, investigating symptoms and how they developed, and by physical examination, observing and feeling for signs related to the patient's complaint. This made me interested in the epistemological status and uses of different types of information for clinical decision-making. How do doctors combine different types of information (qualitative, quantitative, images) from different sources (the patient's story, physical examination, lab results, medical imaging technologies) in order to understand and control the disease?

In order to answer this question, decision-making in clinical practice should first be better understood. Therefore, in Chapter 1 I start with studying the history of medicine, to understand how medicine, as a science and as a practice, developed into what it is today. This analysis shows that developments in medical science and practice are intertwined with developments in science and society. Major developments in medical knowledge are connected to new advances in the scientific method (e.g. the advancement of anatomical knowledge in the 16th and 17th centuries), technological developments (e.g. the microscope) or changes in how society organizes health care of patients (e.g. centralization of care in hospital wards in the 18th century). In the last century, medicine became more "technological" which made it more successful in diagnosing and treating diseases, but also altered the work of doctors, requiring of them to be able to handle instruments, in terms of skills and of the information they bring forth. Furthermore, scientific knowledge about diseases and treatments vastly increased in the second half of the 20th century, leading to the introduction of new methods to find and assess medical information and to apply it to medical practice.

The Epistemology of Clinical Decision-Making

These developments led to the inception of Evidence-Based Medicine (EBM), which I explore in Chapter 2. EBM was introduced as a “new paradigm” for clinical practice in 1992, aiming to bridge the gap between medical science and practice and to make clinical decision-making more systematic and objective. This results in a medical epistemology in which guidelines are drafted based on a hierarchy of evidence and clinical decisions are made by following these guidelines. In short, EBM advertises rule-based reasoning based on objective and quantitative information. Opponents of this view argue that subjective aspects, like a doctor’s experience and their patient’s values should play a more important role in clinical decision-making, regarding medicine as an “art”. The two opposing views of EBM and the art of medicine both highlight important aspects of clinical decision-making, on the one hand the need to work scientifically to warrant a certain quality and on the other hand the individual nature of medicine. To overcome the strict dichotomy between these two views, a new approach for medical epistemology is needed, and I suggest that such an approach should be based on the *epistemological responsibility* of doctors.

In Chapter 3, I explore the aspects of the epistemological responsibility of doctors, which entails making the best possible diagnosis and treatment decisions using good quality information. Focusing on the epistemological responsibility of doctors shifts the emphasis of clinical decision-making from the general to the particular. It highlights that it involves individual doctors fitting together information and measurements using specific instruments within a specific context to create a coherent picture of a particular patient that is consistent with existing general knowledge about anatomy, physiology and pathology and true to the observed phenomena. From this approach, it becomes evident that EBM relies on technological measurement as “objective” and “hard data” without an intricate understanding of the role measurements and instruments. Epistemologically responsible decision-making requires a realistic weighting of all available information, qualitative or quantitative, objective or subjective.

In the last chapter, Chapter 4, I analyze why the role of measurement technologies in clinical decision-making should be studied in more detail and provide an initial exploration of the role of medical imaging technologies. The analysis of the history of medicine and medical epistemology showed that technological measurements are enabling but also directing and limiting, that data acquisition and processing has an impact on the resulting measurement outcome and that the resulting outcome subsequently directs diagnosis and treatment. The analysis of medical imaging technologies shows that a correct appraisal of the epistemic value of clinical information from technological measurements requires a deeper understanding of the relationship between the object under investigation and the resulting outcome.

Based on this analysis, I argue for a more detailed analysis of the epistemological role of measurement instruments in clinical decision-making, in order to improve the quality of diagnosis, of medical education and to improve technological innovations for medical practice by providing better-fitting technologies

1. History of Medicine

Ever since the rise of civilizations, people have been concerned with disease, health and healing. Over two centuries, the way medicine is practiced has co-evolved with the development of science and technology, and over that time, the idea of health and healing has varied. Measurement instruments and practices played a large role in how medicine was performed and how it was regarded. What could be measured and what could be treated was entangled with how a diagnosis was made, defining the medical practice. The available measurement instruments were thereby also dependent on the scientific ideals of that time.

Studying the history of medicine provides insight in the interactions of science, technology, health care performers and the ideas of health, disease and healing. In my analysis of the development of medicine throughout history, several points stand out. First, the joint development of scientific methods and medical science, for example after dissection of the body was allowed in the 15th century, the mechanisms of the body were studied and observed in the same scientific manner as other natural phenomena. Second, the development of technology and instruments independent from medicine (like microscopes) enabled new measurements and diagnosis. But technologies were also developed by physicians when there was a need for a certain measurement, like the stethoscope that enabled listening to the heart and lungs. Third, the ideas about disease, health and healing are intertwined with ideals, theories and values of a society in a certain time. Fourth, the idea and role of theory in medical science changed with the course of history. These four points are all intertwined with the development of medicine and medical sciences, which will be illustrated by the following account of the history of medicine.

In this chapter I will roughly divide the history of medicine into four periods. First, the ancient times, in which large, coherent theories of body, sickness, health and healing were developed. Second, the medieval times, in which first medicine became a matter of spirituality and religion and later the systems from the ancient times revived. Third, the scientific period, in which the new scientific method was also adopted by practitioners of medicine and led to a vast growth of knowledge of the human body and the functioning of several body parts. Last, the technological period, in which the developments of many instruments enabled to obtain more information about the living body and more effective treatments¹.

¹ The majority of this chapter was based on one source: *the Cambridge illustrated history of medicine*, edited by Historian Prof. Roy Porter. In reviews, this book is considered a highly valuable introduction to the history of medicine for students and physicians, giving a thematic overview of topics in the history of medicine. I considered this introductory text sufficiently informative and qualitative as a reference for my purpose, and I have selected relevant chapters to construct an overview of the history of medicine.

1.1. Ancient times

The history of medicine finds its roots in the ancient times. In this period, diseases, including predictions about the development of disease, the onset of death and possible cures have been described. In Babylonia and Egypt, from as early as 1700 B.C. a combination of healing through rituals (driving out demons) and healing by using drugs, potions, bandages, etc. was exercised. Physicians practicing the latter approach employed careful observation, like touching, seeing and smelling patients and a vast range of drugs was known to these physicians.²

In Greece, from about 500 B.C. there was a lively debate about medicine, to which many people participated, including philosophers, obstetricians, priests, exorcists, bonesetters, interested laymen and physicians. Medicine was mainly based on controlling the whole lifestyle to obtain 'balance', but drugs and surgery were also applied.³ Furthermore, medical theory was not restricted to describing the mechanisms of the body or a disease, but also concerned the relationships with other factors, like spirits, lifestyle and religion. Although treatments for some diseases were advanced, knowledge of anatomy and the structure of the human body was limited. Anatomical knowledge started to grow when Aristotle and later physician-scientists started zoological and biological investigation and the dissection of (animal) corpses to obtain knowledge of the internal body.⁴ What was known of the human body was at first based on what could be observed from the outside, by using human senses. This was analogous to the Aristotelian method of science that emerged in that time.

The Hippocratic corpus

The *Hippocratic corpus* (420 – 370 B.C.) is the main text on the subject of medicine from Ancient Greek. It is written by a variety of authors and characterized by close observation of symptoms, and openness to ideas from all sides and a drive to explain the causes of disease. Explanations are formulated in terms of balance (health) and imbalance (disease) of elements, fluids, powers, or of fluxes. A well-known explanation is the balance of fluids. In this theory four fluids: yellow bile (*chole*), black bile (*melanchole*), blood (*haima*) and phlegm (*phlegma*) are in a constant battle and can be influenced externally by diet, activity or vapors. These four humors were correlated to four organs: spleen, gall bladder, liver and lungs, respectively, and to specific diseases. By assigning qualities (hot, dry, wet and cold) to the four fluids, the diseases they cause were characterized. Treatments based on this theory focused on adding or depleting fluids from the patient, like bleeding or giving cups of hot water.⁵

Hence, in ancient medicine, the concept of disease was holistic: it assumed that the fluids need to be balanced, and that this balance affects both the body and the mind. Equilibrium and misbalance were reflected in both the "complexion" or the outward appearance, and the "temperament", the personality type, of a person. In this conception, disease derived from an inner process (in contrast to being caused by an

² V. Nutton (1996) The rise of medicine. In: R. Porter (ed.), Cambridge Illustrated History of Medicine pp. 52-55, Cambridge University Press, Cambridge.

³ Ibid. pp. 55-57

⁴ Ibid.

⁵ Ibid. pp. 58-59

invading pathogen). Furthermore, the concept was “physiological,” disease was the result of a physical process, and not the result of possession by a demon or a godly punishment, and an individual matter. Therefore, healing and health were also a personal concern: a balanced lifestyle and the right frame of mind would promote equilibrium of the fluids and with that health.⁶

The four humor theory reflects other scientific theories in ancient Greece, for example the idea of four elements (fire, earth, air and water, respectively), four seasons (summer, autumn, spring and winter, respectively), age (manhood, old age, childhood and decrepitude, respectively), four planets (Mars, Saturn, Jupiter and Moon, respectively) and four psychological temperaments (ruling, avoiding, socially useful and getting). See figure 1 for an overview of these related theories. The correspondence of these theories illustrates the joint development of scientific theory and medical theory in Ancient Greece, which were formulated as parallel theories with many similar elements.

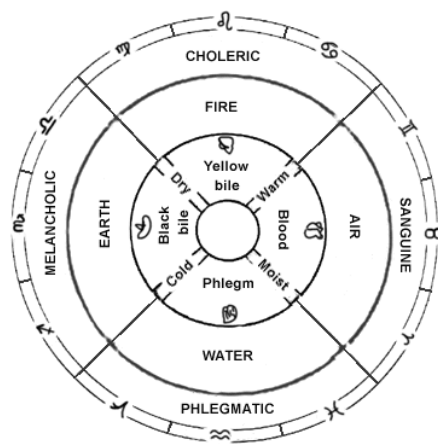


Figure 1: Four humor theories⁷

Galenic medicine

Around 250 the Greek world was overpowered by the Roman Empire. The Romans were the first to build ‘hospitals’, catering domestic slaves and soldiers. A central person in Roman medicine was Galen of Pergamum (ad 129-216) who based his medical theory on the Hippocratic corpus (and the humoral theory), but combined this with Aristotle’s practical investigation and scientific logic. According to him, a good doctor was a philosopher, achieving a unity of reason and experience, analogous to Aristotle’s idea of a “good scientist”. His diagnostic method incorporated observations as palpation, pulse feeling and the inspection of urine, combined with a clear-headed logic. Later, a split between medical theory and practice emerged and Galen’s idea of a philosopher-doctor was taken up to mean that doctors should first study philosophy before turning to the canon of works of Galen and Hippocrates. Thus, “true physicians” became medical theoreticians, their expertise restricted to word and not therapy.⁸ At this time, the idea

⁶ R. Porter (1996) What is disease? In: R. Porter (ed.), Cambridge Illustrated History of Medicine, pp. 92-93, Cambridge University Press, Cambridge

⁷ From: <http://www.phaedrus.dds.nl/app2.htm>

⁸ V. Nutton (1996) The rise of medicine. In: R. Porter (ed.), Cambridge Illustrated History of Medicine pp. 60-64, Cambridge University Press, Cambridge.

of “medical theory” had changed from debatable by many members of society to something restricted to an elite of true physicians.

With the recognition of Christianity from 313 onwards, medicine became an integral part of religious community. As a part of Christian charity, hospitals were built to accommodate those in need (ill or otherwise), providing care (food, warmth and shelter) and sometimes also medical assistance. Around 600, the Roman Empire disintegrated, and the Eastern parts were conquered by the Arabs in the 7th century. The medical texts of Galen (like those of Aristotle) were translated into Arab and taken up, systemized and expanded by Arabian physicians. In the Arab world, the focus of medicine was also on studying texts, downgrading manual skills like surgery. However, large hospitals emerged in every large Muslim city (similar to the Christian hospitals) in which medicine was also taught. Before the decline of the Islamic world in the thirteenth century, the medical system in Cairo and Cordoba had reached a high level of sophistication and effectiveness.⁹

1.2. Medieval times

During the Middle Ages (500-1050) due to a decline in economic prosperity, the circulation and study of (Galenic) medicine diminished. This led to a vast decline of the number of doctors, and the availability of medicine to the public which was replaced by ‘do-it-yourself’ handbooks with a small amount of basic theory and a description of a few diagnoses and treatments. Medicine (both teaching and performance) was taken over by the church. Medical texts were only produced in monasteries and cathedrals and for healing, people reverted to various saints, often specialized in a specific disease or region.¹⁰ This time, the concepts of disease and healing had changed with the emergence of Christianity, analogous to the main worldview. Being sick and getting better were heavily linked to religious life instead of focused on the body and its mechanisms.

From 1050 onwards, medicine rose by a re-introduction of theoretical speculation and the translation of Arab and Greek texts to Latin. The basis of Latin medicine lay in Arab texts, making the medical theories of Galen (based on the humeral theory of Hippocrates) and the natural philosophy theories of Aristotle central to medicine. By 1400, universities were established over Europe and medical teachers joined them. As a consequence, doctors adopted university procedures: lecturing set texts, debating medical question and having a theoretical (Aristotelian) basis.¹¹ Again, medical theory developed together with other sciences, and was performed following the same ‘rules’ which resulted in a split between theoretical and practical medicine. In theoretical medicine, knowledge from texts became more important. A written exam was required to practice medicine and sometimes even replaced practical instruction by apprenticeship.¹²

Contrary to university medicine, practical medicine was performed by many other professions, including surgeons, who were hierarchically below the university doctors.

⁹ Ibid. pp. 65-71

¹⁰ Ibid. pp. 71-73

¹¹ Ibid. pp. 73-75

¹² Ibid.

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Surgeons were sometimes partly trained in universities, but more often in guild-apprenticeships. They had their own books, with descriptions of successful treatments for abdominal injuries, anal fistulae, bladder stones, cataracts and inguinal hernia. Barber-surgeons performed bleeding and attended to cuts, bruises and ulcerations. Other practitioners were apothecaries and spicers, trading and importing drugs and providing medical advice to their clients. Women often worked as midwives and healers of women or children. The multiplicity of people involved in medicine was regulated by institutions, like the church, guilds, medical colleges and town councils and later by Health Boards (developed during the endemic of the Black Death between 1350-1450).¹³ This development illustrates the entanglement of medicine with society: many people were dealing with sickness and health, as patients or as 'healers' of any kind. People lived close together in cities, resulting in epidemics involving large proportions of the population. These kinds of developments ask for an involvement of overarching organizations for management of disease.

Throughout the middle ages, the concept of disease was a merge between the religious (Christian) view and the secular, medical view similar to the Galenic view from the ancient time, both concerned with making body and mind a balanced whole. In principle, the church was concerned with matters of the soul, whereas illness of the body was a matter for physicians. However, the churches also developed healing rituals, and Saints were believed to possess healing powers and disease was also seen as a punishment for sinners, requiring offerings and forgiveness. Furthermore, it was believed that the devil could cause sickness and death, hence when someone fell ill without obvious cause, there seemed to be three possible explanations: disease, fraud or demonic possession. Both doctors and priests were concerned with distinguishing one from another. On the other hand, medicine in the Hippocratic tradition insisted that disease was an aspect of the body.¹⁴

Medicine in the medieval time was, in the Galenic-Arabic tradition, holistic and surrounded with a large, social involvement. Psychological and physical aspects were thought to influence health together, and the humors to influence the psyche in the same way as the body. The mad were often looked after at home and given tasks that would reintegrate them into society. Moreover, health was the responsibility of the whole community, for example birth was a process looked over by a midwife but attended by other women of the village. This made medicine in the middle ages a dynamic organization involving academics, religion, community and guilds, all involved in caring for the sick.¹⁵ Sickness and disease was not a personal event, but affected larger groups, from a whole population in epidemics, to families or communities in childbirth or non-infectious diseases.

¹³ Ibid. pp. 76-79

¹⁴ R. Porter (1996) What is disease? In: R. Porter (ed.), Cambridge Illustrated History of Medicine, pp. 86-90, Cambridge University Press, Cambridge

¹⁵ V. Nutton (1996) The rise of medicine. In: R. Porter (ed.), Cambridge Illustrated History of Medicine pp. 80-81, Cambridge University Press, Cambridge.

1.3. Scientific medicine

For almost 2000 years, the main framework to understand and treat disease was the humeral theory, first described in the *Hippocratic corpus*. Ideas about the methods, knowledge and characteristics of a good doctor had been formulated by Galen of Pergamum in Ancient Greece and remained dominant over centuries although the details varied over time. It is notable that, repeatedly, a split between theoretical and practical medicine emerged (in the Roman time, in the Arab world and during the middle ages). Practical medicine was more similar to a craft, learned through apprenticeships in guilds, whereas theoretical medicine was an academic activity. Furthermore, 'care' was separate from healing and provided by the church and other members of the community.

The tradition of Galen was contested by the scientific revolution in the seventeenth century, in which nature was explained as particulate matter uniformly moved by immutable, universal laws. Similarly, the body was studied as a machine. A healthy body was a well-functioning machine whereas disease was seen as mechanical breakdown.¹⁶ Medical science followed the main scientific methods introduced by the scientific revolution, resulting in a new approach to obtaining knowledge: from studying texts to studying the mechanisms of the body.

The custom of dissecting bodies to obtain knowledge of anatomy emerged since the fourteenth century, when the opposition of the church to dissection (as invasion of the sanctity of the body) abolished. By time of the seventeenth century, dissection was the main approach to study the body's anatomy and the function of body parts were described in terms of mechanics (for example by comparing muscles and bones to levers and springs). The knowledge obtained from dissection was collected in very detailed atlases of anatomy. This paved the way for understanding the physiology (functioning) of the body: by the end of the seventeenth century, many physiological theories (for example, about the mechanism of digestion and the working of the female reproductive system) had developed. An important example is William Harvey's theory of the circulation of blood in *De motu cordis* (1628). By careful observation and reasoning from phenomena as the one-way system of valves he concluded that the heart functions as a pump, making blood circulate through the body and (separately) the lungs.¹⁷ This illustrates the role of reasoning from analogy to mechanics like pumps, lever and valves in understanding the "mechanics" of the body, which was also used in other fields of natural science. Furthermore, again it illustrates the entanglement of society and medical science: the common idea of "the body" influenced how bodies can be studied. Only when the idea of the "sanctity of the body" could be given up it was possible to perform autopsies and gain knowledge of functions of several structures.

This entanglement is also exemplified by the influence that the philosopher Rene Descartes (1596 – 1650) had on natural and medical science. He postulated that humans consist of two entities, extension (material) and mind (immaterial). This distinction of

¹⁶ Ibid. p. 93-95

¹⁷ R. Porter (1996) *Medical Science In: R. Porter (ed.), Cambridge Illustrated History of Medicine*, pp. 158-162, Cambridge University Press, Cambridge

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body and mind also demarcated the areas of expertise for medical science (the body) and religion (the mind). Furthermore, it paved the way for reductionism; the idea of “the body” was that of a machine housing the soul and similarly, the body was studied as a complex whole made out of small, simple parts. By 1700, many believed that the body’s structures and functions could be completely understood scientifically, using ideas from mechanics and mathematics. This, in turn, led to great advances in medicine and the development of biomedical science and a scientific approach of medicine. Biomedical science sought an identifiable cause for a disease, like an inflammation, a tumor, an obstruction or a pathogen or parasite. The study of the immaterial soul, or the ‘why’ of life, was deemed irrelevant to medical scientists, who focused on the ‘how’.¹⁸ Hence, disease was now something local that could be identified and pinpointed as the cause for sickness, instead of an aspect of the “whole body” as in the Hippocratic tradition.

Meanwhile, the expansion of hospitals with vast amounts of cases of the same disease (like typhus and tuberculosis) shifted the focus from the individual case to the general, in which the differences between individual patients became of smaller interest than the similarities. The common course of diseases was confirmed by pathological examination of cadavers. In practical medicine, the shift from individual cases to the general aspects of disease was notable as a shift from the focus on relieving a patient’s complaints to attacking the underlying disease. This was marked by the emergence of the physical examination and the use of diagnostic instruments. Before the nineteenth century, the diagnostic process focused on “history taking”, in which a patient was asked to tell about their complaints, when and how they started, characteristics of the pain and symptoms, etc. Physical examination was limited to a visual inspection (skin color and lesions like rashes and inflammations), sometimes expanded with feeling the pulse and listening to coughs.¹⁹

This change toward a more general idea of disease is related to developments in both society and (philosophy of) science. First, the expansion of hospitals, which can be seen as a new attitude toward sickness: sick people were no longer mainly taken care of at home, by members of the community, but concentrated in hospitals and cared for by professionals. This led to a collection of multiple cases of the same diseases, enabling to study the general course of diseases. At the same time, science was getting more concerned with generalizable laws and similarly medical science became more concerned with the general elements of disease (or ‘symptoms’) instead of signs and the histories of individuals. This new approach, named the “medical nosography” (Sanchez-Gonzalez, 1990), was formulated by John Locke and Thomas Sydenham, who claimed that groupings of clinical signs and symptoms should be made by careful observation, without providing an account regarding underlying causes of pathological conditions. This method of classification was analogous to the classification of plants by botanists, and thought to be a-theoretical and inductive.

¹⁸ R. Porter (1996) What is disease? In: R. Porter (ed.), Cambridge Illustrated History of Medicine, pp. 94-95, Cambridge University Press, Cambridge

¹⁹ Ibid. pp. 96-101

Measurement instruments

The invention of several measurement instruments facilitated the collection of more (objective and quantifiable) information about the patient's body by physical examination (for example, sounding chest, taking blood pressure, taking temperature, etc.) The two developments described above (the reductionist view of the body as a collection of simple part and the focus to the general course of disease) resulted in a new view of disease, as an objective, free standing entity that could be studied separately from the body. In the course of the nineteenth and twentieth century, more and more instruments came available to obtain objective information about his entity, "disease".²⁰ The concept of disease was evolving from something that was a misbalance of the whole body and mind, to something that was separate from a person and has an identifiable cause, or from a "physiological" to an "ontological" concept of disease. In the practice, the emphasis changes too, medicine had become less holistic in the sense that only the disease. Before the nineteenth century, a doctor would be mainly concerned with taking a patient's "history", asking the patient about when the complaint had started, how they evolved, the characteristics of the complaint, etc. and some details about the patient's lifestyle. Physical examination was only conducted by the eye, but not by touch. After the turn of the nineteenth century, physicians obtained information by palpation, auscultation, feeling the pulse, taking blood pressure, inspecting the throat, taking the pulse, etc.

In the nineteenth century, medical scientists started to study the living (human or animal) body, interested in the vitality of bodies and the characteristics that distinguish them from machines (like the ability to regenerate or repair themselves.) This was also facilitated by the invention of measurement instruments that could be applied to the living body. New opinions regarding the relations between body, mind and soul emerged: the mechanical conception of the body from the time of Descartes had made way for a dynamic idea of 'vital properties' in the age of enlightenment. In this age, for example, knowledge about respiration (inhalation of oxygen and expiration of carbon dioxide) and the involvement of electricity in muscle movement was produced.²¹

1.4. Technological medicine

In that same era, two important sites emerged and became the central place to study the human body: the hospital and the laboratory. In the hospital new instruments were invented. For example the stethoscope was developed because of the need to listen to heart sound (which was at the time done by applying the ear to the chest) of different kinds of people (men and women, thick or thin). By using the instruments to listen to many different cases of heart and lung sounds, multiple diseases were described in terms of the clinical presentation and the underlying pathology. Clinical science was an observational (rather than experimental) science, concerned with recording and interpreting facts and categorizing signs, symptoms and lesions. Symptoms (information about lesions of organs obtained by examination by the physician) were regarded as

²⁰ Ibid.

²¹ R. Porter (1996) *Medical Science*. In: R. Porter (ed.), *Cambridge Illustrated History of Medicine*, pp. 158-168, Cambridge University Press, Cambridge

more significant than signs (what a patient feels and reports).²² This (observational) approach of clinical science specifically resulted in better knowledge of diagnosis and of the presentation and course of disease but not in new or better treatments.

Furthermore, technology, and specifically measurement equipment, resulted in a new approach to medical science: studying the effects of disease on the living body, finding the general courses and classifying disease.

At the same time, experimental medical sciences emerged, focusing on animal experiments, chemistry, microscopy and physiology, driven by technological advances. Improvements of the microscope enabled the development of histology, linking anatomy to pathology, the development of bacteriology by studying the organisms that cause diseases, and studying the changes in cells caused by diseases (like inflammation or cancer). In the laboratory, medical conditions could be controlled and the pathophysiological course of diseases studied more specifically by eliminating confounding factors. The use of laboratory animals enabled these controlled conditions, and the testing of pharmaceuticals, like vaccines²³. In the 1880's Louis Pasteur developed a method to remove microbes causing tuberculosis and typhoid from milk (and later surgical instruments) by heating to a prescribed temperature: "Pasteurization". This resulted in the "germ theory" disease, the view that diseases are caused by microorganisms like viruses and bacteria. Robert Koch confirmed this theory and developed a number of criteria to prove that a particular bacteria produces a specific condition. This led Koch to discover the bacillae that caused tuberculosis and cholera, and others to identify the causal microbes for many more diseases and to investigate questions of transmission and immunity .²⁴

The development of measurement instruments was important at both sites of medical investigation: in the hospitals measurements were needed to quantify signs and symptoms of living patients. In the lab instruments like microscopes were used to study the underlying processes of diseases, but instruments were also important to measure and control conditions during experiments. The interaction between instruments and medical science resulted in the development of a medical practice in which diagnoses are defined in terms of quantifiable signs and symptoms and the assessment of treatments.

Post-war medicine became successful by the introduction of treatments for a large number of diseases. The leading development was surgery, which had been unsuccessful throughout the previous centuries because of a lack of hygiene and decent anesthesia, which made surgery a very risky and painful affair. With the development of the germ theory, an understanding of the necessary 'antisepsis' rose. In the early decades of the twentieth century, wearing surgical gowns, masks, rubber gloves and sterilization of surgical instruments became standard in the operation room. This enabled experimentation with and development of surgical procedures. During the First World War, the large amount of casualties drove the development of improved wound

²² Ibid. pp. 173-177

²³ Ibid. pp. 177-183

²⁴ Ibid. pp. 184-185

management, repairing of fractures, amputation, reconstructive and plastic surgery and blood transfusion. Applicability of surgery expanded to other cases such as lung and abdominal surgery in the 1950's with the discovery of antibiotics, relieving the risk of infection. As a result, the focus of surgery shifted from removal (of tumors, cysts, infected organs, etc.) to restoration of function, and later to replacement (by prostheses or transplantation).²⁵

For these developments in surgery, many technological innovations have been crucial. The inventions of X-rays and radioactive isotopes were important for diagnosis, by imaging fractures, or measuring the functions of metabolic organs. The heart-lung machine enabled heart surgery by applying artificial circulation and ventilation, bypassing the heart during the operation. Imaging technologies, like ultrasound (1955), computerized tomography (CAT, 1972), magnetic resonance imaging (MRI) and positron emission tomography (PET) made it possible to visualize organs of living people.²⁶ The use of imaging technologies meant a revolution for diagnostics, by being able to visualize the extent and characteristics of a disease inside a living body. Furthermore, it enabled planning for surgeries, by exact localization of lesions. Imaging technologies, as a specific kind of measurement instruments therefore came to play a large role in modern medicine.

For doctors, the rise of available medical technology meant that not only theoretical knowledge of the body and disease needed to be studied, but also the handling of measurement instruments and the interpretation of measurements in relation to other available knowledge. This created a need for suitable education, familiarizing future physicians with basic knowledge as well as the required medical and academic skills. This led to a transformation of medical education, partially driven by the Flexner report.

1.6. Scientific medicine: the role of doctors and education

The report Alexander Flexner wrote in 1910 on medical education in the United States (Flexner, 1910) is said to have transformed medical education and with it the tasks of physicians (Duffy, 2011). Flexner visited all 155 medical schools in the USA and Canada and compared them to his experience with medical schools in Germany. Flexner criticized the quality of many medical schools that were often profit-oriented and lacking adequate facilities. Moreover, he advocated a science-oriented approach, different from the nosographic school. The problems with the nosographic medicine are related to the problems of induction, namely that to induce over diverse phenomena requires a capacity to identify, isolate and group relevant properties and exclude others as noise, which cannot be done in an a-theoretical way (Khushf, 1999). According to Flexner, in "scientific medicine" clinical manifestations of a disease (signs and symptoms) are correlated with a cause that is understood in terms of anatomical structure and physiological processes. This underlying structure or process (which is specified by laboratory science) will provide an explanatory cause that enables one to test a hypothesis derived from clinical manifestations (Flexner, 1910). Therefore,

²⁵ R. Porter (1996) *Hospitals and Surgery*. In: R. Porter (ed.), *Cambridge Illustrated History of Medicine*, pp. 226-241, Cambridge University Press, Cambridge

²⁶ *Ibid.* pp. 242-245

Flexner envisioned that medical students first spent two years studying basic laboratory science before clinical training in the ward of a university hospital (Cooke, 2006).

The educational program proposed by Flexner and widely adopted in the USA and medical schools throughout the world, still sounds familiar to medical students today. By providing a decent medical and scientific background to medical students, as well as hands-on clinical training it has improved medical education and the quality of medical practitioners. According to Flexner, the work of physicians should consist of patient care, education and research in equal measures in which these aspects are equally important and serve each other: research should be informed by questions that were raised from experience with clinical cases and education should be research-oriented, making students familiar with the newest advances in science. However, from the 1960's onward, the pressure on clinicians for productivity has improved, leaving little time for teaching. Furthermore, medical science has become more molecular or technical and has drifted away from the clinic, making it more difficult for physicians to stay up to date about, and to have a role in, scientific studies. Therefore, in modern medicine, the ideal of investigator-teacher-clinician that Flexner envisioned for academic physicians became impossible to be exemplified by one person.

Today, the Flexner report is also criticized for the hyper-rational medicine it endorsed, with little space for the “art of medicine” and a consideration of personal values, doubts and insecurities of patients (Duffy, 2011). In the past decade, a change toward a greater focus on the patient-doctor relationship was set off by paying more attention to professionalism and communication skills throughout the curriculum. However, the Flexner report is still considered relevant, because it advocates the quality of doctors and medical science.

1.7. Conclusion

The description of the history of medicine illustrates how medicine is entangled with several factors, including science, societal norms and values, the development of instruments and education. Norms and values of society are intertwined with medicine and medical science: the concept of “the body”, which is influenced by leading religious and philosophical views, in part determines how the body is studied. Conversely, the concepts of body, disease, health and healing are also influenced by the state of medicine and the instruments that enable measurements of specific characteristics (omitting others). Last, education and the role of doctors are closely associated.

With regard to measurement instruments, the history of medicine reveals the joint development of scientific methods in natural sciences and medical science. The state of natural science drives the medical sciences by adopting scientific approaches and concepts. From the 16th century on, instruments play an increasingly important role in the scientific method, by enabling to observe and quantify phenomena otherwise inaccessible, for example by using a telescope for astronomical observations. Using instruments to do scientific research became an important aspect of medical sciences as well, for example using microscopes to study the morphology of tissues. In the 19th century, specialized hospitals were established to care for large numbers of patients suffering from infectious diseases like typhus or tuberculosis. During that time, it

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became common to use instruments to study shared characteristics of the patient which were associated to the disease. An illustrative example is the stethoscope, developed by a physician to listen to heart sounds, it was used to identify typical lung sounds related to different stages of tuberculosis. The use of these kinds of measurement instruments thus introduced new phenomena (lung sounds) as an aspect of disease (tuberculosis).

The introduction of new phenomena by observation using newly available instruments (developed by doctors or outside of medicine) also led to a different concept of “disease”. Gathering the sick in hospitals resulted in doctors focusing on the general course of a disease in multiple patients, and with that on considering “disease” as an independent entity. Similarly, new instruments had an impact on how disease was conceptualized. For example, the microscope enabled studying tissues at micro level, thus revealing a disease (e.g. an inflammation of that tissue) in a specific way. Combined with the study of microorganisms like bacteria and viruses, this led to the “germ theory” of disease.

In other words, instruments define what we can know about a disease and with that how we understand disease. By their impact on the conception of disease instruments also define what a diagnosis is. Only when a phenomenon that is associated to a disease is observed a diagnosis can be made, and instruments determine for a large part what can be observed and what is associated with disease. In this sense, the use of measurement instruments is enabling, but also directs and limits the diagnostic process. What cannot be observed is overlooked in diagnosis, and doctors will direct their reasoning toward what can be measured.

Certainly, much more can be learned from studying the history of medicine. With this (no doubt incomplete) overview, I want to make plausible that medicine in general and the work of individual doctors is intertwined with developments in science, technology and society. Studying current clinical decision-making, we should be aware of this entanglement. Therefore, I claim that the relevant context in which clinical decisions are made can be mapped out over multiple dimensions: the dimension of the patient-physician interaction, in which the patient and doctor relate in order to improve the health of the patient, the dimension of organization, in which protocols and guidelines prescribe the actions of doctors, the material dimension of the hospital and available equipment, and the intellectual dimension of doctors including textbook knowledge of anatomy, physiology and pathology, and recent scientific advances. I will further explicate these contexts and their impact on clinical decision-making later in this thesis, and show that two of these contexts – the material and the intellectual context - are often overlooked in medical epistemologies. The goal of the following chapters is *to understand the work of doctors in terms of epistemology in diagnosis and treatment, within these dimensions.*

References

Cooke M. Irby D. M. Sullivan W. Ludmerer K.M. (2006) American Medical Education 100 Years after the Flexner Report *The New England Journal of medicine*, 355, pp. 1339-1944

Duffy T.P. (2011) The Flexner Report – 100 Years Later *Yale journal of biology and medicine*. 84, pp. 269 -276

Flexner A., Pritchett H.S. (1910) *Medical education in the United States and Canada*, The Carnegie foundation for the Advancement of Teaching, Bulletin Number Four.

Khushf G. (1999), *The aesthetics of clinical judgment: Exploring the link between diagnostic elegance and effective resource utilization*, *Medicine, Health Care and Philosophy*, Vol. 2, pp. 141-159

Nutton V. (1996) The rise of medicine. In: R. Porter (ed.), *Cambridge Illustrated History of Medicine* pp. 52-95, Cambridge University Press, Cambridge.

Porter R. (1996) Medical Science. In: R. Porter (ed.), *Cambridge Illustrated History of Medicine*, pp. 158-168, Cambridge University Press, Cambridge

Porter R. (1996) What is disease? In: R. Porter (ed.), *Cambridge Illustrated History of Medicine*, pp. 94-95, Cambridge University Press, Cambridge

Porter R. (1996) Hospitals and Surgery. In: R. Porter (ed.), *Cambridge Illustrated History of Medicine*, pp. 226-241, Cambridge University Press, Cambridge

2. From Evidence-Based Medicine to the Epistemological Responsibility of doctors

In current medical practice, as in other fields, the authority of doctors is not unquestioned anymore: physicians cannot simply refer to their experience and authority when they make decisions, but are expected to explicitly justify them. In this chapter, I review the current epistemologies of clinical decision-making. With “epistemology” I mean both an ideology and a methodology of how knowledge can best be justified. In the literature, there seem to be two opposing ideas on medical epistemology in clinical decision making, on the one hand those that defend “objective” or “scientific” rule-based reasoning promoted by evidence-based medicine (EBM), and on the other hand those that defend the “subjective” or “personal”, often expressed as the “art of medicine”. I will shortly review the developments that led to the inception of EBM and some critiques on EBM as an epistemology for clinical-decision making. Then, I will review several alternative epistemologies that refer to “the art of medicine” but propose richer accounts of medical reasoning concerning diagnosis and treatment. Finally, I will present my own analysis and suggest what would characterize a medical epistemology that can overcome the subjective/objective divide.

2.1. Evidence-Based Medicine

EBM as a paradigm for medicine was developed in the 1990’s as a response to the then ubiquitous expert-opinion based medical practice. EBM was formally defined by Sackett (1996) as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (pg. 71). In order to secure objectivity and scientificity of clinical practice, EBM promoted the development of scientific methods for producing clinically applicable and unbiased data, such as clinical epidemiology and randomized controlled trials (RCT’s). Furthermore, EBM promoted the development and use of electronic databases to facilitate the search in the increasing amount of scientific medical literature. Another important element of EBM was the development of a method that guides doctors in assessing scientific literature, by creating a hierarchy of evidence with RCT’s on top and “unsystematic clinical observations” at the bottom (Claridge & Fabian, 2005). Last, for a better application of scientific knowledge to the clinic, EBM guidelines for diagnosis and treatment were developed to prescribe the best actions in fixed situations, based on population science, clinical epidemiology and statistical methods.

History of EBM

EBM finds its roots in the 1970’s with Archie Cochranes work on epidemiology: Cochrane was the first to define RCT’s as a method to assess effectiveness and efficiency of medical treatments (Claridge & Fabian, 2005). The translation of these methods to clinical practice and education started in the early 1990’s with the publication of the *“User’s Guide to the Medical Literature”* (Sur & Dahm, 2011).

Before EBM, clinical decision-making was mainly based on authority, experience and expert opinion and relied heavily on tradition. As a result, biomedical research findings

were not effectively translated to clinical practice. Furthermore, clinical practice involved many uncertainties, posing a need for (mathematical) methods to resolve this uncertainty (Sur & Dahm, 2011). To solve these matters, a new basic science for medicine originated, using statistics (most importantly RCT's): clinical epidemiology. Another important development leading to EBM was a large increase of literature reporting medical research, making a method to effectively and structurally categorize literature necessary. This (together with the emergence of the internet) gave rise to large biomedical databases like MEDLINE. Furthermore, a method for doctors to critically assess the relevant literature before applying it to their patients was needed, resulting in the abovementioned 'hierarchy of evidence' and the formulation of the process of "ask", "acquire", "appraise" and "apply" (Wyer & Silva, 2009, pg. 893). These methods were eventually explicated in the *User's Guide*, with the purpose of providing users with a guide to the content of clinical epidemiology (Wyer & Silva, 2009).

Evidence based in other fields

In "Policy and the Evidence Beast" published by the Dutch Rathenau Institute, the rise of the concept "evidence-based" in other fields than health care, such as in politics, education and justice in The Netherlands is analyzed (Slob & Staman, 2012). In these other fields, there is a growing demand for policy based on scientific evidence, as opposed to policy based on "gut feeling" or expert opinions about how these fields should ideally work. However, the report shows that in these other fields, the possibilities for scientific experimentation similar to RCT's in medicine are limited. As an example the authors explain that experimentation with education is impossible because establishing control groups is considered unethical, especially when research concerns children. Another reason is that the realities of these fields are extremely complex and context-rich. For example, in criminology, what appears to work to decrease vandalism in one community can give very different outcomes in another. Furthermore, basing policy on scientific findings involves translating them to protocols and rigid implementation, leaving little space for professional customization based on an expert's own understanding of the field. Moreover, scientists usually fail to effectively translate their findings into useful tools for policymakers. Instead, science provides many different answers from many different viewpoints from which policymakers have to "choose".

The difficulties with evidence-based policy in these fields originate from the proposed methodology, which is unfit to generate the knowledge needed to make decisions. It seems like proponents of evidence-based approaches in these fields maintain a very narrow view of what counts as evidence. This narrow view results, first, in focusing on one preferred method, that is similar to RCT's and dismissing other possible ways of generating "scientific" knowledge relevant for these fields. The preferred methodology is not always successful in generating relevant knowledge, because reality is too complex, or because "experimentation" in some practices is unethical or incompatible with responsibilities of policy makers. Furthermore, the narrow view of what is scientific legitimizes capturing the scientific knowledge that is available too rigidly in general protocols and guidelines.

In conclusion, the upcoming term “evidence-based” reveals a demand of objective and scientific knowledge that can inform practical decision-making in medicine and other fields. However, the failure of science to really be helpful in practical decision-making shows that there is a gap between science and practice, which is also an important critique on EBM, expressed by several authors on several levels. In the next paragraphs I will review these critiques in more detail.

Critiques on EBM

From its first inception, EBM has been criticized on several grounds. First, several authors have expressed concerns about the translation of EBM research to the clinic. Tonelli (1998) points out that there is an “intrinsic gap” between the population-based research of EBM and the application to individual patients in the clinic. What applies in general to large groups does not necessarily apply to a specific person. And, although EBM tries to minimize this gap by making differences between individuals explicit, this gap can never be closed completely since not all variations are quantifiable. In the same line, Wyer & Silva (2009) argue that particular aspects of clinical decision-making, like “contextual impediments to implementation and considerations of patient values, patient preferences and experiences of disease” (pg. 894) are poorly defined and integrated in EBM as a model for clinical practice. Therefore, according to Wyer & Silva, the weakness of EBM lies in its’ ambition to dictate clinical reasoning and action. Ashcroft (2004) criticizes the difference in reasoning in medical practice and shows that reasoning based on RCT’s cannot incorporate mechanisms of explanation and causation. In contrast, RCT’s can only “measure” correlation, which gives no insight in processes of (pathophysiological) causation. Knowledge of these processes is, however, needed to make the step from statistical information to the treatment of an individual patient (Ashcroft, 2004).

Other authors, such as Worrall (2002), contest the status of RCT’s as the only methodology to provide scientific evidence. Worrall especially argues that the epistemic power of “randomization” is continuously overestimated. Furthermore, Worrall argues that some treatments cannot be assessed by RCT’s because of moral or practical reasons. Finally he argues that some often-used yet uncontested treatments like penicillin have not been tested on their efficiency by RCT’s, which means that for the clinical practice justification can result from other kinds of evidence than RCT’s only. In other words, Worrall makes plausible that, other types of evidence, like non-randomized studies, should not be so easily dismissed as lower in the hierarchy. Finally, Silva and Wyer identify a shortcoming of EBM on another relevant epistemological level, that of the clinical relationship between doctor and patient. It should be recognized that clinical decisions take place within this interaction, in which a doctor has to be sensitive to a patient’s values, perception and history. Although EBM recognizes the importance of experience for clinical skills, it tends to ignore the role of experience in picking up “unquantifiable” information. Silva and Wyer call this level the “interpretative framework” of clinical action (Silva & Wyer, 2009).

Clinical guidelines

Instead of giving a detailed account of the process of application of the best external evidence into clinical practice, EBM promotes translation of evidence into guidelines for

clinical practice. These guidelines provide an explicit model of medical decision-making based on the best available evidence. Critics describe the use of guidelines as “cookbook” medicine and fear that it does not adequately account for actual clinical decision-making. Sackett (1996) describes this fear as one of the misconceptions of EBM. According to him, guidelines inform but cannot replace clinical expertise: “any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient’s clinical state, predicament, and preferences, and thus whether it should be applied” (pg. 71). “Clinical expertise” was brought up as key element in integrating “clinical state and circumstances”, “patient’s preferences and actions” and “research evidence” by EBM proponents (Haynes, 2002). The guidelines and algorithms that are the product of EBM assume a straightforward process of identifying the relevant facts, finding the best-fitting diagnosis and then choosing the preferred treatment according to the best evidence. Although EBM acknowledges that a doctor’s expertise is important for skills like medical history taking, EBM interprets these skills in terms of the patient-doctor relationship and judging the applicability of RCT’s to a specific situation, instead of assigning an epistemological role of the physician-patient interaction.

A problematic presupposition of EBM guidelines is a negligence of the role of basic knowledge in clinical reasoning. In EBM guidelines, the basic facts of a patient and its symptoms are a given starting point. However, the identification of the relevant facts should be understood as a far more elaborate process. An important condition is basic knowledge which provides a framework that helps doctors understand what they see. Like a forester who knows how to identify trees from its leaves, a doctor knows how to identify basic symptoms from a patient’s story. Furthermore, to obtain all relevant information is more complicated than simply identifying the relevant symptoms. To successfully differentiate between several possible diseases, doctors need to know how a certain symptom is related to a certain disease, and understand the (causal) relationship between facts.

Miriam Solomon (2011) argues in a systematic review of the critiques on EBM that the main problem with EBM as a general philosophy of medicine is the negligence of the role of basic knowledge in clinical practice. According to Solomon, basic science guides medical research by providing hypotheses about disease processes en mechanisms, and medical practice by tailoring the outcome of epidemiological studies to individual patients. Solomon describes EBM as superficial, in the sense that it studies correlations and refrains from formulating models or theories to provide explanations of pathological conditions. Solomon concludes that EBM research even depends on basic scientific knowledge to develop interventions and propose appropriate protocols and the design of randomized controlled trials. Therefore, although physiological reasoning can be fallible, it is not dispensable from medical research and practice. Hence, basic scientific knowledge plays important roles: it enables understanding the relationships between these pieces of information, to decide what other information is needed to make a sound judgment, to understand how symptoms relate to each other, and to understand how treatments cure diseases. Silva & Wyer (2009) make plausible that in EBM epistemology, theoretical representations of disease, like pathology and biochemical processes, are dismissed because they are placed lower in the hierarchy of

evidence. Hence, knowledge from basic sciences, that is indispensable for doctors to collect and interpret information, is not acknowledged by EBM.

In EBM literature, a detailed method to include different components called “decision analysis” (Dowding & Thompson, 2009) is proposed. This method aims to guide in systematically combining the elements required for an evidence-based decision. Decisions are formalized by decision-trees, in which all possible outcomes of different options are identified. To weigh the options, the probabilities of different outcomes are added and patient’s values included by assigning a so-called “utility”, in a scale of 0-1, and combined with probabilities to define the “expected utility”. To identify the best option, the option with the highest expected utility is selected. Besides being laborious, the problem with this method is that it relies heavily on the availability of strong evidence, or, if strong evidence is not available, on “educated guesswork”. Clearly, this method aims to guide the decision-making process by proposing a more refined way of rule-based reasoning that relies on the objectivity of statistical reasoning. However, although this method combines the ideal of scientific objectivity with the need of including particular information about the patient, it does not accommodate the practice of clinical decision-making.

2.2. “Objective science” versus “personal judgment”

Michael Loughlin (2008, 2009) evaluates philosophical claims about reasoning in medical practice and science made by EBM and suggests that the idea of a “hierarchy of evidence” that prefers standardized trials (RCT’s) over professional judgment is an impairment of the professional autonomy of physicians. According to Loughlin, EBM presupposes that objective decisions require impersonal mechanisms in order to rule out unwanted influences by emotions or self-interest. Therefore, in EBM-practice, objective reasoning is achieved by drawing general guidelines, based on scientific research, which however neglect the complexity of medical practice. Loughlin holds that in EBM, the demand for “objective” and “impersonal” decisions, as opposed to “personal” or “subjective”, justifies that professional autonomy is constrained by general guidelines.

According to Loughlin, EBM assumes a “conceptual map” that dichotomizes concepts like “objective” and “rational” versus “subjective” and “personal”. He holds that this dichotomy between objective and subjective is a heritage of the “logical positivist” movement in the first half of the 20th century. Logical positivism defines “objectivity” and “reality” in a very narrow sense: knowledge is grounded in observable facts, and general conclusions can only be made by following strict logical rules. It assumes that the only method to learn something about reality is by repeatable controlled experiments. This expels many other methodologies and forms of knowledge for being “biased”. In this light, the problem with EBM, according to Loughlin, is not its goal of working scientifically, but its claim of a hierarchy of evidence, preferring RCT’s as the ‘gold standard’ and devaluating others.

Accordingly, Loughlin argues that the strict dichotomy between “objectivity” and “rationality” versus “subjectivity” and “personal” is false, because all reasoning involves human subjects, and is situated in local contexts – therefore, all practices that include

rational reasoning is inherently 'subjective'. Loughlin uses the concept of "objectivity" as proposed by the philosopher Thomas Nagel (1986) who has argued that to reason objectively is to realize that one's own perspective is one among many. According to Nagel, these other perspectives are not necessarily less relevant, and as a rational subject, one needs to take responsibility for one's own judgments and decisions, on the one hand taking into account evidence, on the other hand deciding on their validity and drawing one's own conclusion. The philosophical problem that underlies EBM, according to Loughlin, is that the (logical positivist) notion of "science" assumed by EBM omits that the gathering, interpretation and application of evidence requires human subjects making judgments. Instead, what is needed, according to Loughlin, "is a robust defense of sound judgment – not the pretense that knowledge can somehow be untainted by the judgment of human subjects, but a rejection of the simplistic idea that *all* judgments are *necessarily* tainted." (2009, pg. 667). "Sound judgments" take into account several perspectives and weigh several options before coming to one's own conclusion, which makes these judgments "personal" and not "objective" in the sense of EBM – but judgments can still be unbiased in the sense that they are not merely based on self-interest, emotions or opinion.

Loughlin continues his attempt to overcome the objective/subjective dichotomy by proposing an approach to medical epistemology that places personal judgments of professionals at the center. According to Loughlin, this implies that, instead of prescribing standard guidelines for decision-making in diagnosis and treatment as in the epistemology of EBM, medical epistemology should assist practitioners in "developing their own rationally defensible conceptions of good practice and the intellectual basis of their activities". I agree with Loughlin's point that EBM assumes a view of 'scientific' that is too narrow, and with his explanation of how a (strict) dichotomy between subjective and objective leads to a dismissal of other valuable kinds of information. However, the concept "personal judgment" obfuscates the importance of studying relevant epistemological processes in a doctors' clinical reasoning. Calling a judgment "personal" suggests that a physician's own consideration is eventually the primary aspect of a judgment, whereas, what is considered, how this is considered and why a certain judgment is found the most appropriate, is secondary. Conversely, in my view, these latter aspects are primary aspects to the reasoning of a physician, determining the way he or she comes to a judgment.

2.3. Evidence Based-Medicine versus the Art of Medicine

Critiques on EBM epistemology often focus on the inability of EBM guidelines to incorporate individual aspects of clinical reasoning. As an opposing view, authors refer to the "art of medicine" as a process in which doctors make clinical judgment based on experience, intuition, or tacit knowledge. Literature concerning the art of medicine often emphasizes the role of "soft skills", concerning for example communication, the patient – doctor relationship and empathy, and taking into account the patient's values and preferences. In this section, I will not discuss accounts of the art of medicine in much detail, since these accounts often refrain from providing an epistemological account of clinical decision-making. Rather, I will review several theories that can provide an

(starting point of an) alternative epistemology that include ideas related to the “art of medicine”.

Medicine as natural and human science

Hubert Dreyfus (2011) argues that “medicine is unique in being a combination of natural science and human science in which both are essential,” assuming that there is an essential difference between natural and human science. In natural sciences, the studied object is first decontextualized and then objective measurements are performed. Based on these measurements, a theory about invisible objects is formed. In human sciences, this method is also attempted, but, according to Dreyfus, it is impossible to decontextualize humans: for the right interpretation, knowledge and understanding of the context is needed, which makes “objective” measurements impossible. Dreyfus’ analysis of medical practice is valuable because he shows that, to practice medicine, another approach besides the “natural science” is needed. However, in my view, instead of emphasizing the essential difference between natural and human sciences, an epistemology that explains how contextual information and scientific knowledge are integrated will provide a better interpretation of medicine as a practice and as a science. I will aim to grasp this by using the notion “epistemological responsibility,” which describes the specific professional attitude and approach of clinical doctors who, rather than considering themselves followers of EBM rules and guidelines, consider themselves responsible for producing good quality diagnosis and treatment.

Case-based reasoning

Rachel Ankeny (2011) in her analysis of the epistemic role of cases in medicine, shows that EBM is not the only relevant method for gaining and sharing knowledge in medical science. Case reports are descriptions of individuals or small groups, which present us with “surprising” or “problematic” symptoms. Cases do not provide “evidence” in the same manner as RCT’s, but, according to Ankeny, serve as “vehicles” for collecting facts and putting them in contact with each other. By studying series of similar cases, researchers establish the cohesion of facts by prioritizing certain facts and omitting others. This, in the end, leads to the formulation of a working hypothesis, which can be confirmed by more “conventional” research methods. Furthermore, series of cases can provide knowledge of diagnosis, treatment and causations when RCT’s or other conventional scientific methods are not possible for either ethical reasons (e.g. a disease, sign or symptom cannot be induced deliberately for research purposes) or pragmatic reasons (e.g. a low frequency of a certain disease).

Ankeny (2013) argues that, although case-descriptions are based on uncontrolled observations (in contrast to controlled experiments, like RCT’s), causal relationships can be derived from series of cases. In clinical practice, (series of) case-descriptions from medical literature function as sources of evidence to identify causes for the signs and symptoms observed in individual patients. In light of the goal of medicine, the clinical reasoning employed to find these causes is related to the instrumental nature of medicine, rather than aiming at objective truth-finding, clinical reasoning is preferred toward identifying causes that are easy to remove and control in order to cure the patient or prevent disease. Therefore, the key to the determination of causes, according

to Ankeny, is “what can be ‘manipulated,’ not as judged in principle but *in practice*” (pg. 12).

The use of cases in medical practice is an example of complex reasoning towards a specific aim (finding a cause that can be removed to cure disease) using a different source of evidence than that from the RCT’s promoted by EBM. The analysis of Ankeny makes plausible that in clinical practice, doctors use case reports from medical literature to gather (seemingly unrelated) facts, identify possible causes, and consult experience from other practitioners with patients that present similar patterns of symptoms, when diagnostic tools are not readily available. Ankeny illustrates that complex reasoning by means of cases presupposes that facts about individual patients can be projected to other patients, which requires a rational process of systemizing, smoothing out the particulars of the individuals and refining the facts. This specific kind of reasoning is the work of experienced doctors and requires a specific set of skills that relate to the ‘art of medicine’, which goes beyond the objective ruled-based reasoning of EBM epistemology. However, to warrant the quality of case-based reasoning in diagnosis and treatment, doctors carry a responsibility for gathering relevant case reports from medical literature, drawing conclusions and translating the information to the situation of their specific patient. Hence, I argue that the responsible use of case-based reasoning should be considered as part of the epistemological responsibility of doctors, on which I will elaborate more in the next chapter.

Narrative reasoning

In clinical practice, the patient’s story is the starting point for identifying relevant facts of a particular case. Doctors usually ask their patients to describe the developments of signs and symptoms relating to the disease, putting these facts in a structure of time and space. An epistemology that focuses on reasoning based on these kinds of stories in medicine is “narrative medicine.” Miriam Solomon (2008) analyzes Rita Charon’s *Narrative Medicine* (2006). Charon claims that techniques from humanities are required to further develop and apply technical achievements of medicine, and that in this light narrative reasoning “constitutes a logic in its own right”, distinguished from “logicoscientific” reasoning. According to Solomon, Charon’s work convincingly shows that narrative medicine can improve diagnosis and treatment, because it yields more information, captures the uniqueness of a patient’s situation, organizes coherence in (otherwise disconnected facts), and allows for creative thinking and critical reflection of physicians on their own practice. However, Solomon also warns for “narrative fallacy”, besides other things, due to the fact that patients can edit or omit certain aspects of a story in order to maximize coherence of a narrative or the story.

Following up on the work of Charon, Solomon argues that the traditional epistemological dichotomy between medicine as a traditional science, and the ‘art of medicine’ that encompasses the necessary skill of applying general knowledge to individual patients, is “not helpful”. To consider the intellectual skills often associated to ‘the art of medicine’ as ‘nonscientific’ is, according to Solomon, the result of a narrow sense of ‘scientific’ (in Solomon’s words, the “hypothetico-deductive model”.) Solomon argues that narrative reasoning is a way to discover and hypothesize about causal connections, both in medicine and natural science. Making a good narrative is, according

to Solomon “an intellectual achievement that paves the way for more precise causal hypotheses” because “the requirements of narrative coherence and inclusion of all relevant facts put constraints on the stories that are told” (pg. 416). Hence, the use of narrative is another complex reasoning method that enables doctors to gather and fit together relevant information for diagnosis and treatment of a specific patient, very different from rule-based reasoning as it requires specific intellectual skills, and, as Charon suggests, even training in or knowledge of narrative theory from the humanities. The responsible use of narrative reasoning thus entails the epistemological skill to develop a coherent and complete narrative as part of constructing a coherent and consistent story about an individual patient’s illness.

Tacit knowledge

Several authors propose using Michael Polanyi’s (1958, 1966) concept of “tacit knowledge” to understand how doctors pick up and integrate unquantifiable information in reasoning about diagnosis and treatment. Kristi Malterud (2001) criticizes the focus of EBM on quantifiable information. According to her, this rules out other essential elements of clinical decision-making, like interaction, communication, judgment, opinions and experience. Malterud argues that “tacit knowing” of a doctor plays an important role in these elements. To Malterud, tacit knowledge is gained by clinicians through experience, and applied in interactional, interpretive and normative strategies of clinical decision-making. Therefore, she suggests to produce an additional body of medical research using qualitative research methods from social sciences. Stephen Henry (2006, 2010) argues against a “reductionist understanding of medical knowledge”. He points out that people are inherently central to medicine. According to him, clinical decision-making is the work of people interacting with other people and interpreting pieces of information in relation to many other elements like a patients values and fears. Therefore, according to Henry, medical epistemologies like EBM, but also other epistemologies based on basic medical sciences, fail to accurately explain all knowledge processes in medicine because they aim to describe knowledge in general terms, leaving out the personal element. According to Henry “Human’s ability to take the tacit dimension into account fundamentally distinguishes human thinking from the mindless processing of data that machines perform” (2010, pg. 294).

A fruitful interpretation of “tacit knowledge” in clinical reasoning for diagnosis and treatment focuses on what kind of knowledge is used tacitly. Henry explains how, during a physical examination, the attention of a neurologist is focused on observing neurological symptom: “one cannot make sense of a neurological exam without tacit awareness of the patient’s body parts and how they are connected” (2010, 293). This explanation suggests that, although a doctor is at that moment not explicitly aware of the neurological processes, this knowledge is necessary to interpret the outcome and draw conclusions from it.

Henry argues that tacit knowledge cannot be fully captured in formal steps or models, which impedes the integration of a concept of tacit knowledge into an epistemology of medicine. In a reaction to Henry, Michael Loughlin (2010) argues that “features of our knowledge that function tacitly in many contexts can, without contradiction, be made the object of explicit attention in others” (pg. 298). Loughlin argues that it is a mistake to

assume that tacit knowledge is completely “inarticulate” in all situation. As Henry himself wrote about tacit knowledge: “Whether information is tacit or explicit has less to do with its content than it does with how it functions in a particular situation” (2010, pg. 294). In other words, tacit knowledge is not essentially different from explicit knowledge, and therefore, knowledge that functions tacitly in one situation can be reconstructed in another situation to study how it informs clinical decision-making. Hence, an account of tacit knowledge in medical reasoning need not be implicit and mysterious.

Hutchinson and Read (2011) understand the notion of tacit knowledge as “the way in which often-unacknowledged occasion- and context-specific non-generalizable particulars along with background and framing factors play an epistemologically significant role” (pg. 944). They use the metaphor of an “interwoven fabric” of information particular to the situation, in which the data of the specific case is included. This metaphor emphasizes that particular and general knowledge play an important role in clinical decision making, and that the reasoning process concerning diagnosis and treatment is difficult to formalize in guidelines or decision trees. The idea that tacit knowledge is not fundamentally different from other knowledge is crucial because it prevents considering it as something vague or mysterious, but instead as something doctors can assess and control and therefore, something they can be held accountable for.

2.4. Khushf: reflective and determinative Judgments

George Khushf (1999) present a different approach to integrate insights from, on the one side “subjectivity, art, imagination, empathy, ethics and the activity of history taking” and on the opposing side “objectivity, science, logic, rational processes and lab tests that provide ‘hard data’” (pg. 152). According to Khushf, the scientific ideal of modern medicine, such as advocated by Flexner, involves a critique of the mere empiricism that is historically advocated by the nosographic school of Locke and Sydenham (see Chapter 1) and currently by EBM. Instead, the scientific ideal of medicine is according to Khushf closely related to “scientific medicine” as described in Flexner’s report. Khushf describes the following elements of the scientific ideal of medicine: 1) clinical practice follows the same scientific method that is used in scientific research, 2) this scientific method involves the initial development of a hypothesis or theory, which in medicine is formulated for the purpose of understanding and controlling disease, 3) the hypothesis must be subjected to tests²⁷, 4) there are two kinds of data: clinical data, (signs and symptoms) for the initial formulation of hypotheses and data enabling the assessment of hypotheses²⁸, and 5) there are therefore two distinguishable components of clinical practice: an initial phase of discovery and hypothesis formulation, and a second phase of hypothesis assessment and justification.

To link discovery and justification, Khushf introduces a theory of aesthetics which he bases on Kant’s aesthetics that is developed in the context of an analysis of judgment.

²⁷ in Khushf’s account, Flexner identifies three ways of hypothesis testing in clinical practice: laboratory tests, effective management of disease (probabilistic confirmation) or by autopsy

²⁸ Data obtained by the methods described in footnote 1.

Kant distinguishes two kinds of judgment, determinative and reflective judgment. If a universal is already specified, a particular is brought under it by determinative judgment. Reflective judgment is required when a concept (which is not yet determined) is sought out for a particular. In Khushf's words, Kant argues that "a particular manifold can be perceived as purposive with respect to the understanding, which as a faculty seeks to bring that manifold into a conceptual unity [...]. Since the manifold is not yet provided with the needed conceptual unity (the universal is absent), the purposiveness is only *felt*; it is a sense of anticipation that the aim of the understanding will be satisfied. [...] Kant associates this *feeling of accord* between understanding (with its ends) and the particular, non-conceptualized manifold with *aesthetic pleasure*. Aesthetic judgment is made possible by spontaneous activity in which imagination and understanding are brought into harmony" (pg. 148). In this account, reflective judgment involves a preliminary grasp of the universal or whole that integrates diverse parts. In addition, it can also involve preformation of a particular so that it can be regarded as an instance of an as-of-yet unspecified universal (in other words, to make predictions).

Khushf considers diagnostic practice as an activity that involves both determinative judgment and reflective judgment, in which reflective judgment is propaedeutic. Determinative judgment then proceeds with the (by reflective judgment) "pre-formed manifold which provides an anticipation of the conceptual unity that will be provided by the understanding" (pg. 148). According to Khushf "for the manifold to be purposive with respect to understanding, two aspects of understanding in medical practice must be addressed: 1) the current knowledge base, including medical theory and experience regarding its application; and 2) an awareness of the way determinative judgment proceeds, and the way it is nested within the broader practice of medicine" (pg. 149).

In Khushf's account, "the art of medicine" involves a propaedeutic practice of theory formation which is harmonized in reflective judgment with the demands of understanding, such that it enables the practice of medicine as a science. In reflective judgment, a practice of discovery that is purposive for the understanding is regarded "elegant", hence Khushf refers to the concept "diagnostic elegance" to describe how the convergence of propaedeutic practice and the scientific ideal can direct the initial activity of discovery, and provide norms for that practice. "Art thus constructs medical practice so that it can be a scientific one."

A crucial aspect of the propaedeutic practice is history taking and the physical exam, which is usually the first physician-patient interaction that provides a dynamic, undetermined whole. Khushf describes this practice of reflective judgment as an interplay of "imagination and understanding", in which two wholes are harmonized: the individual whole that constitutes the current individual practice (the physician-patient encounter) and the whole of the physician's medical world (the sum of theory, experience and the scientific ideal of medicine). In this meshing of two worlds, physicians use the full range of medical knowledge, which is why, according to Khushf, guidelines that only articulate a part of the knowledge cannot fully capture all aspects of clinical reasoning.

Khushf's critique on EBM is that it views science as an empirical, deductive enterprise, which excludes the aesthetic, symbolic and imaginative dimensions. In the view of EBM, scientific progress is defined as replacing "subjectivity" with explicit algorithms that can be empirically verified. Accordingly, guidelines, in Khushf's view, only emphasize determinative judgment, leaving out the propaedeutic activity associated with reflective judgment. In contrast, the aesthetic ideal emphasizes the art of history taking in clinical judgment.

In summary, Khushf's theory of the aesthetics of clinical judgment highlights several philosophical aspects of medical reasoning for diagnosis and treatment that is not sufficiently incorporated in EBM epistemology.

- 1) The creative aspect of "theory formation". By analyzing clinical judgment in terms of determinative and reflective judgment, Khushf argues that an important part of clinical reasoning consists of more complex and imaginative processes than formal logic. In my view, this is what other authors have tried to capture by describing the "tacit" aspects of clinical decision-making, which implies a mysterious and implicit process. Khushf makes it more explicit by referring to aesthetics and a "feeling of harmonization" between the particular situation, an anticipation of the subsequent procedure (e.g. treatment options) and more general aspects like basic knowledge and the scientific ideal.
- 2) The process of history taking which takes place in an interaction between the physician, his general knowledge and the specific situation in which an individual patient turns to a doctor with a health problem with the purpose of solving it. Instead of emphasizing the "soft aspects" of this interaction, e.g. the doctor-patient relationship, communication skills and empathy, as often done in the "art of medicine" Khushf makes plausible that this interaction is a crucial aspect of clinical judgment, in which the initial pre-formation of a working hypothesis (or a differential diagnosis) is formed, which is subsequently tested in a more rational process. Khushf also argues that this process cannot be captured in algorithmic guidelines but rather is based on complex reasoning processes and requires a large range of medical knowledge. However, the aesthetic ideal introduces certain criteria by linking the reflective judgment to the scientific ideal.
- 3) Khushf shows that the scientific ideal of modern medicine is rooted in Flexner's ideas about scientific medicine, in which basic science play an important role and therefore not in agreement with the mere empiricism advocated by EBM.
- 4) Finally, Khushf emphasizes that clinical reasoning has a purpose: understanding and controlling the disease of an individual patient. Instead of focusing on generalizable and objective knowledge, Khushf argues that in every single clinical encounter an initial hypothesis is formulated and tested for the specific situation.

2.5. Analysis: a narrow view of science

Apparently, there is a tension between clinical practice and the presuppositions of EBM. Firstly, this tension is the result of a mismatch between *knowledge* provided by EBM methodologies (and formalized in guidelines) and the various kinds of knowledge used in clinical reasoning. Based on my professional experience with how doctors reason in

clinical practices,²⁹ I defend that they integrate many different kinds of information about a patient, such as, clinical observations, clinical measurements expressed in numbers, graphs or images (rather than clear-cut diagnoses), and the individual story of a patient. Also, basic scientific knowledge plays important roles: it enables to understand the relationships between these pieces of information, what other information is needed to make a sound judgment, to understand how symptoms relate to each other, and to understand how treatments cure diseases.

Second, there is a mismatch between the kind of *reasoning* that EBM presupposes and the reasoning used by doctors in clinical practice. The process of coming up with hypotheses is more dynamical and complex than the formal rule-based logic assumed by EBM epistemology and prescribed in clinical guidelines. While considering the available information, options are continually deduced and verified by doctors – this is because they understand, for instance, that one effect can have multiple causes and one cause can have multiple effects. Besides algorithmic, rule-based reasoning, “creative” thinking and nuanced styles of reasoning are an inherent part of good clinical decision-making concerning diagnosis and treatment of a patient, thereby aiming to solve problems and to find compromises rather than “objective truth.” Yet, the epistemology that underlies EBM dismisses these other ways of reasoning as subjective and less reliable. I claim that in the epistemology held by EBM, both the sharp distinction between objective and subjective ways of reasoning, as well as the disapproval of supposedly subjective ways of reasoning, are inappropriate for understanding the epistemology of actual clinical practice.

When considering the mismatch between EBM and clinical practice more closely, two questions arise. First, what is “scientific”? According to Loughlin, the particular idea of science in the medical epistemology underlying EBM entails characteristic concepts of rationality, objectivity as opposites of personal, subjective and contextual. Second, why should medicine work scientifically? Doctors, patients, policy-makers and biomedical scientists regard medicine as a ‘scientific endeavor’, its basic knowledge informed by scientific findings and methods, and its advancement enabled by technological inventions. I assume that the desire of medicine to work “scientifically” derives from the confidence people have in scientific “objectivity” and “rationality”.

When addressing these two questions so as to understand how clinical practices produce good quality diagnosis and treatment, it appears that on a more appropriate account, the epistemology of these practices is interlinked with its ethics. Using the concept “scientific” implies that the quality of knowledge is warranted. However, as Loughlin shows, medical science and practice solely based on the concept of science in the narrow sense will not function satisfactory, since the quality of diagnosis and treatment depend on a broader range of reasoning methods than the rule-based reasoning favored in EBM. Furthermore, the scientific approach preferred by EBM (RCT’s) rarely provide all relevant knowledge that is crucial for good quality diagnosis and treatment. Therefore, “being scientific” in the narrow sense cannot warrant this

²⁹ As a student in Technical Medicine I have worked in clinical practice during my two-year clinical internships at several medical departments.

quality. As a consequence, the ideal of attaining objectivity through rule-based reasoning, as promoted by the epistemology of EBM, cannot be maintained.

Diagnosis and treatment involve gathering all relevant pieces of information, which, in turn, must be fitted together into a coherent 'picture' that best suits the specific situation of a patient. In medical practice, doctors are held accountable both for the information they gather and for how they fit this information together. As has been argued, this involves other ways of reasoning than rule-based reasoning. In other words, rather than being merely guided in their clinical reasoning by medical knowledge provided by RCT's and reasoning strategies provided by EBM guidelines, doctors carry responsibility for how they produce a diagnosis and treatment plan. In order to account for this situation, I claim that a medical epistemology that accounts for how good quality diagnosis and treatment plans are produced involves reference to the *responsibility* of doctors.

2.6. An alternative medical epistemology: epistemological responsibility

Therefore, an alternative medical epistemology is needed that can account for specific aspects of clinical reasoning, such as the gathering of relevant information, the integration of different types of relevant knowledge, the use of different types of reasoning styles, and the local and context-specific nature of clinical decision-making, while at the same time securing the desired 'scientific' quality. Instead of focusing on the "objectivity" of a decision and thereby rejecting all implicit, personal and particular aspects as "subjective" an alternative medical epistemology should overcome this dichotomy. In my view, reasoning that does not explicitly follow algorithms is not simply irrational or unscientific. Loughlin's concept of "personal judgment" and the insight that sound judgment not necessarily follows the logic of EBM allows for recognizing the role of other types of clinical reasoning. I think that a crucial additional aspect of this insight is that it requires doctors to be critically aware of the quality of their reasoning. Therefore, the concept of "personal judgment" should be extended with the concept "epistemological responsibility" of doctors.

According to Khushf, clinical decision-making is a two-step process, analogous to the scientific method: first theory formation (or discovery) followed by a confirmation or rejection of that theory (justification). Khushf convincingly argues that the propaedeutic process of theory formation entails reflective judgment in accord to aesthetic ideals. In his account, this is followed by determinative judgment, which I interpret as entailing a rather straightforward process of performing tests of which the result either agree or disagree with the hypothesis. In contrast, the descriptions of alternative approaches to medical reasoning (medicine as natural and social science, case based reasoning, narrative reasoning and tacit knowledge) make plausible that making justified decisions is more complex and refined than (simple) determinative judgment or the rule-based reasoning that EBM theory suggests. It is a process in which hypotheses are continuously formulated, based on new information and other input, and verified. In relation to this, I claim that doctors have a responsibility in 1) gathering and using *good quality information and knowledge*, 2) valuing types of *reasoning* for specific situations, and 3) making the *intellectual effort* to use these types of knowledge and reasoning so as

to come up with good diagnoses and treatment plans and warrant the quality associated with “scientific”.

I defend that this is a particular professional responsibility of doctors that requires a certain attitude and ability. This responsibility involves epistemic activities generating knowledge about the disease of a particular patient (the diagnosis) and about a treatment that supposedly cures it. The challenge of these epistemic activities is that, in order to generate knowledge about an individual patient, doctors have to gather and integrate different sources of information, such as scientific-medical knowledge on diseases and treatments, diagnostic data of the patient, but also contextual information (e.g., particularities of the patient, availability of specific medical expertise, and (local) constraints of the medical system). In other words, the epistemic challenge of clinical decision-making is gathering and integrating relevant, yet heterogeneous elements so as to construct a coherent picture of the patient’s disease and possible treatment.

These epistemological difficulties of clinical decision-making are insufficiently recognized by EBM’s epistemological ideas on how to meet scientific and professional standards. Firstly, EBM, although recognizing that local information must be integrated when applying clinical guidelines, does not address how this should be done, thereby suggesting that knowledge-formation of individual patients involves a more or less straightforward algorithmic way of reasoning. Khushf makes plausible that the knowledge-formation of individual patients requires of doctors a “creative” method of reflective judgment, and that history taking, situated in the patient-physician interaction is an important aspect of initial theory formation.

Secondly, scientific and objectified approaches such as EBM involve a narrow view of science that may not suit medical practices. This view suggests that the aim of a scientific approach is to find objective “truth” about the patient, and that the method of EBM is the best possible method to get at this truth. However, the epistemological aim of scientific and objective approaches in clinical practice is not firstly to find objective “truth”, but instead, to generate a “picture” of individual patients that enables sound reasoning concerning diagnosis and treatment. Furthermore, this “picture” must be constructed such that it enables further reasoning about the patient’s condition, for instance, in predicting which cure may work, or in explaining why a treatment causes side effects. This is in agreement with Khushf’s point that the *purpose* of clinical reasoning is to understand and control the disease of a patient. Furthermore, the *scientific ideal* of medicine, as Khushf argues is rooted in the understanding of anatomy, physiology and pathology. Initial theory formation for each individual is done in accord to both the purpose of medicine and the scientific ideal for each individual patient.

The epistemological responsibility of doctors

Therefore, I reject that a medical epistemology should exclusively focus on producing rules and algorithms to guide medical decision-making. Instead I propose that to warrant scientific quality, doctors should consider themselves *epistemologically responsible* to produce good quality diagnosis and treatment decisions, instead of deferring their responsibility (and with that accountability) by following the rules laid out by clinical guidelines.

The Epistemology of Clinical Decision-Making

The concept “epistemological responsibility” (ER) finds its roots in the idea that cognitive agents are active in forming their beliefs, and that a knower has an important degree of choice in cognitive processing, for which they can (and should) be held accountable (Code, 1984). Instead of emphasizing what is “known”, this notion focuses on the “knowers”, and their epistemic “location” in a time, place and other epistemological circumstances (Code, 1987). Therefore, the epistemological responsibility of doctors entails that doctors are held responsible for the way in which they generate specific knowledge about every single patient.

Epistemological responsibility can be understood analogous to moral responsibility: in the same way a person can be held accountable for her actions, she is accountable for her beliefs. Code proposes that we structure our epistemological reasoning in analogy with (but not similar to) moral reasoning. For example, in line with consequentialist thinking, the impact that holding a certain belief has on the world has implication for the reasonableness of a belief. Similarly, a “deontological” approach would focus on the intellectual “character” of knowers (Code 1984). By drawing the parallel with moral reasoning, the focus shifts from objective truth finding to justification. Furthermore, Code argues that epistemic responsibility is interwoven with moral responsibility (to the extent that they cannot be separated). For example, to present a drug as safe for the public is a strong knowledge claim, but one with moral implications (Code, 1987, pg.69). This is in line with the work of doctors: in the clinical practice, moral and epistemological responsibilities are strongly intertwined. A doctor’s moral responsibility to help their patients the best way they can, implies an epistemological responsibility to use the best available information.

Therefore, I interpret the epistemological responsibility of doctors as *making the best possible judgment* regarding diagnosis and treatment, using *good quality data*. Hence, doctors have a responsibility to stay up-to-date with scientific developments regarding their field of work, to gather information relevant to the case at hand, and to critically review the quality of that information. Epistemological responsibility also emphasizes that doctors have the responsibility to develop the skills that enables them to do so, and requires a certain attitude to make the epistemological effort, rather than simply following rules. The accounts of other (non-algorithmic) reasoning methods in this chapter - in which narrative reasoning, case-based reasoning and other methods from social sciences are central - show that these methods are better fitting than simple rule-based reasoning.

In this section, I have focused on the epistemological responsibilities of individual doctors, because the goal of this thesis was to understand how doctors gather, interpret and use information to reason about diagnosis and treatment, in order to make justified clinical decisions. This does not mean that I intent to say that doctors carry the sole epistemological responsibility. More accurately, I think that an extensive group of people is (either remotely or closely) involved with clinical decision-making and therefore is epistemological responsible for this process. For example, scientists who perform medical research have the responsibility to make their results available, most preferably in such a way that they are understandable and applicable by doctors.

Technology developers have the responsible to make technology that work consistently and produce reliable data. Instructors and supervisors have the responsibility to teach their trainees the required knowledge, skills and attitude in order to be able to make the epistemological effort. Hospital management has the responsibility to provide the facilities that are required to gather the needed data. Furthermore, clinical decisions (especially concerning complex cases) are usually made in multi-disciplinary consultations, in collaboration with multiple doctors, specialists and care takers, who all bring their own expertise and experience and with that all have their own epistemological responsibilities.

But ultimately, in this diffuse field of epistemological responsibilities (or, more broadly, of different kind of responsibilities carried by different people), doctors are the ones that are continuously making decisions about their patients, from the formulation of a working diagnosis to what tools to use during an operation, and therefore also who carry the main responsibility to make these decisions in an epistemologically sound way. Therefore, in the remainder of this thesis, I refer to the epistemological responsibility of *doctors*, and usually not of others.

2.7. Conclusion

In this chapter, I have argued against EBM, but I have also shown that an emphasis on “the art of medicine” is not a satisfying epistemological approach, because it does not allow for an explicit understanding of clinical decision-making. Rather, in the “art of medicine” as well as in accounts emphasizing “tacit knowledge,” the actual decision-making processes remains implicit and even mysterious. Hence, in line with Loughlin and Solomon, I believe that it is not fruitful to hold on to a strict dichotomy between on the one hand “objective” or “scientific” rule-based reasoning promoted by EBM, and on the other hand the “subjective” or “personal”, often expressed as the “art of medicine”. Therefore, I claim that a new approach to medical epistemology should try to overcome this dichotomy, by emphasizing the inherently personal, individual and contextual nature of medical decision-making, yet warranting the quality associated with objective and scientific. I believe that an epistemology in which the epistemological responsibility of doctors has a central role can overcome this subjective/objective divide and incorporate all aspects of clinical decision-making. In the following chapters, I will first illustrate how epistemologically responsible reasoning differs from EBM with a case study, and then I will explore what aspects are relevant for the epistemological responsibility of doctors.

References

Ankeny, R. A. (2011). Using cases to establish novel diagnoses: Creating generic facts by making particular facts travel together In P. Howlett & M. S. Morgan (Eds.), *How well do facts travel? The dissemination of reliable knowledge* (1st ed. pp. 1–12). New York: Cambridge University Press.

Ankeny RA. (2012) Easy to manipulate? How medical case studies help to reveal causes. Paper presented at the biannual philosophy of science association conference, 17-11-2014, San Diego, California, USA,

Ashcroft, R. E. (2004). Current epistemological problems in evidence based medicine. *Journal of Medical Ethics*, 30(2), 131–135. doi:10.1136/jme.2003.007039

Code L. (1987) *Epistemic responsibility*, Hanover and London: University Press of New England

Code L. (1984) Toward a 'Responsibilist' Epistemology, *Philosophy and Phenomenological Research*, 45 (1), pp. 29-50.

Claridge, J. A., & Fabian, T. C. (2005). History and Development of Evidence-based Medicine. *World Journal of Surgery*, 29(5), 547–553. doi:10.1007/s00268-005-7910-1

Djulgovic, B., Guyatt, G. H., & Ashcroft, R. E. (2009). Epistemologic Inquiries in Evidence-Based Medicine. *Cancer Control*, 16, 1–11.

Dreyfus, H. L. (2011). Medicine as Combining Natural and Human Science. *Journal of Medicine and Philosophy*, 36(4), 335–341. doi:10.1093/jmp/jhr027

Engel, G. L. (1980). The Clinical Application of the Biopsychosocial Model. *Am J Psychiatry*, 13(5), 535–244.

Evidence-Based Working Group (1992). Evidence-Based Medicine. *JAMA, A New Approach to Teaching the Practice of Medicine*, 268(17), 2420–2425.

Haynes, R. B., Deveraux, P. J., & Guyatt, G. H. (2002). Clinical expertise in the era of evidence-based medicine and patient choice. *EBM notebook*, 7, 1–3.

Henry, S. G. (2006). Recognizing Tacit Knowledge in Medical Epistemology. *Theoretical Medicine and Bioethics*, 27(3), 187–213.

Henry, S. G. (2010). Polanyi's tacit knowing and the relevance of epistemology to clinical medicine. *Journal of Evaluation in Clinical Practice*, 16(2), 292–297.

Hutchinson, P., & Read, R. (2011). De-mystifying tacit knowing and clues: a comment on Henry et al *Journal of Evaluation in Clinical Practice*, De-Mystifying tacit knowing, 17(5), 944–947.

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Khushf G. (1999) *The aesthetics of clinical judgment: Exploring the link between diagnostic elegance and effective resource utilization*, *Medicine, Health Care and Philosophy*, 2, pp. 141-159

Loughlin, M. (2008). Reason, reality and objectivity – shared dogmas and distortions in the way both ‘scientific’ and ‘postmodern’ commentators frame the EBM debate. *Journal of Evaluation in Clinical Practice*, 14, 665–671.

Loughlin, M. (2009). The basis of medical knowledge: judgement, objectivity and the history of ideas *Journal of evaluation in clinical practice*. Presented at the Journal of evaluation in clinical practice.

Loughlin, M. (2010). Epistemology, biology and mysticism: comments on “Polanyi's tacit knowledge and the relevance of epistemology to clinical medicine.” *Journal of Evaluation in Clinical Practice*, 16(2), 298–300.

Malterud, K. (2001). The art and science of clinical knowledge: evidence beyond measures and numbers. *The Lancet*, 358(9279), 397–400.

Polanyi, M. (1966), *The Tacit Dimension*, Chicago: The University of Chicago Press

Polanyi, M. (1958), *Personal Knowledge: Towards a Post-Critical Philosophy*, Chicago: University of Chicago Press

Solomon M (2008). Epistemological Reflections on the Art of Medicine and Narrative Medicine. *Perspectives in Biology and Medicine*, 51(3), 406–417.

Sacket, D. L., Rosenberg, W. M. C., Haynes, R. B., & Richardson, S. W. (1996). Evidence Based Medicine: what it is and what it isn't. *BMJ*, It's about integrating individual clinical expertise and the best external evidence, 312, 71–72.

Silva, S. A., & Wyer, P. C. (2009). Where is the wisdom? II “Evidence-based medicine and the epistemological crisis in clinical medicine. Exposition and commentary on Djulbegovic, B., Guyatt, G. H. & Ashcroft, R. E. (2009) *Cancer Control*, 16, 158–168. *Journal of Evaluation in Clinical Practice*, 15(6), 899–906.

Slob, M., & Staman, J. (2012). *Policy and the evidence Beast*. A Dutch Study of the expectations and practices in the area of evidence-based policy (pp. 1–48). The Hague: Rathenau Instituut.

Solomon, M. (2011). Just a paradigm: evidence-based medicine in epistemological context. *European Journal for Philosophy of Science*, 1(3), 451–466.

Sur, R., & Dahm, P. (2011). History of evidence-based medicine. *Indian Journal of Urology*, 27(4), 487.

The Epistemology of Clinical Decision-Making

Tonelli, M. R. (1998). The Philosophical Limits of Evidence-Based Medicine. *Academic Medicine*, 73(12), 1234–1240.

Worrall, J. (2002). What Evidence in Evidence-Based Medicine? *Philosophy of Science*, 69(S3), S316–S330.

Wyer, P. C., & Silva, S. A. (2009). Where is the wisdom? “ A conceptual history of evidence-based medicine. *Journal of Evaluation in Clinical Practice*, 15(6), 891–898.

2b. Case study: urinary incontinence

In the practice of pediatric urology, urinary incontinence is a frequent problem. Urinary incontinence is often accompanied by other symptoms and closely related with other problems like urinary tract infections (UTIs) and obstipation, which make diagnosis and treatment a complicated process. Furthermore, mechanical and behavioral factors are interrelated making intervention at multiple levels necessary. The Dutch guidelines for child incontinence (“Richtlijn Urine incontinentie bij kinderen,” 2010) aim to provide recommendations to deal with these complexities in clinical practice based on the best scientific evidence. The guidelines start with stating the assumption that every user is familiar with basic knowledge of pathologies that lead to incontinence. Therefore, a description of possible measurement outcomes and their meaning is not included in the guidelines.

The aim of this chapter is to illustrate that EBM epistemology, that advocates rule-based reasoning following guidelines based on the best available evidence, does not do justice to actual reasoning in clinical practice. I describe the cases of two young girls, “Anne” and “Betty” that both present with urinary incontinence. The role of this section is therefore, in the first place, *descriptive*: to describe how doctors reason about diagnosis and treatment, especially in complicated cases in which the best diagnosis and treatment options are not evident. To illustrate the contrast between reasoning envisioned by the EBM guidelines and how doctors actually reason in these cases, I compare the reasoning of doctors in these cases to the recommendations about diagnosis of these kind of cases in the EBM guidelines “incontinence in children”, established by the Dutch society of urology, the Dutch society of pediatrics and the Dutch society of incontinence nursing. The recommendations, displayed (in Dutch) in gray boxes in figures 1 to 8, are compared to the conclusions and decisions made in these particular cases by clinicians.

The second role of this section is *normative*. I consider these cases as examples of “good clinical reasoning.” It can be questioned if the results of the decision-making process are satisfactory enough to consider it as such, since both girls are not “cured” by the end of the stories. However, I think that they reflect the course of many cases in (academic) medical institutes. The cases that I have selected illustrate that patients and doctors go through a process to find a solution to their problem, or otherwise find a way to deal with it. Most importantly, they show that multiple elements that are not direct aspects of disease (like behavior, age and irregularities) have an impact on how the disease manifests or can be treated. Therefore, these cases allow me to illustrate how doctors deal with this by including these kind of aspects in their reasoning about diagnosis and treatment, in order to understand what can or cannot be done to help the patient. In my view, this is what makes these cases an example of good clinical reasoning. Therefore I take these cases as starting points to understand the aspects of epistemologically responsible reasoning.

At the end of this chapter you find two diagrams, the first is a flow chart for diagnosis or urinary incontinence provided by the guidelines and second a schematic representation of the processes associated with urinary incontinence as described by pediatric urologists. The numbers between brackets ([...]) in the text below refer to the numbers of the boxes in the schema. The second diagram was composed with the help of Dr. Pieter Dik and Dr. Aart Klijn, pediatric urologists from the Wilhelmina Children's hospital in Utrecht, who were also consulted for the reconstruction of these cases.

2b.1. Guidelines for what decisions?

History taking

Aanbevelingen

De werkgroep is van mening dat een zorgvuldige anamnese onderdeel is van de diagnostiek van incontinentie. Een vragenlijst kan hierbij goed als hulpmiddel dienen. De werkgroep beveelt aan om aandacht te besteden aan obstipatie, hiervoor is de vragenlijst, ontleend aan de Rome III criteria, zeer geschikt (zie aldaar).

Figure 1: history taking

The first case, Anne, is a five year old girl with incontinence [1]. At the age of four she first visits the outpatient clinic of pediatric urology, after multiple UTI's (urinary tract infections, [7]), continuous urge [4] for micturition and uncontrollable loss of urine. At the first consultation, many aspects are investigated to get the full story of the patient and a notion of the severity of the complaints. The volumes and frequency of voiding or wetting and intake of fluid are investigated. Parents fill out questionnaires and the doctor asks about the urinary stream and behavior of the child. The child in this case voids about 10-12 times a day and wears a diaper so volumes are not measurable. The urinary stream is "spraying" and unfocussed. She wets her bed every night and defecates multiple times a day with soft defecation.

This story of Anne conveys many "clues" from which doctors constructs a first hypothesis. The most important clue in Anne's story is the "spraying" voiding stream, which indicates that there is a mechanical obstruction that complicates voiding [5]. This obstruction leads to incomplete voiding which results in residual urine in the bladder [6]. Bacteria and other pathogens in this residual urine can cause UTI's [7]. Furthermore, a mechanical obstruction can result in a thick bladder wall, because the bladder muscle (detrusor) needs more power to squeeze out the urine [3]. The second important clue is about defecation. Defecating multiple times a day and soft defecation can indicate obstipation [8]. The theory is that the rectum is completely filled and only small portions of soft defecation are able to leave. Constipation is related to urinary incontinence because overfilling of the rectum means that the rectum will use up more space in the pelvis [10]. Thus, there is less space for the bladder and more pressure onto the bladder resulting in a disturbance of urge [4]. Also, UTI's are often observed in cases of constipation, for which the pediatric urologists have an unproven theory: fecal bacteria (e. coli) cross the layers between rectum and bladder, causing infections.

For the initial diagnosis, the EBM guidelines (see figure 1) recommend "careful medical history taking" which should include questions about frequency and volume of

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micturition, relation of incontinence to micturition, incontinence during the day and during the night, fecal incontinence, the character of the voiding stream and its direction and UTI's. With that, the EBM guidelines provide a valuable overview of the important aspects of the initial diagnosis of urinary incontinence by giving a list of important questions that can be helpful as a checklist, to ensure a complete overview of the relevant facts. However, the guidelines mainly focus on whether or not history taking should be a part of diagnosis. They acknowledge the amount of information that can be gained by asking the right questions and sum up what kind of information is important to find the cause of incontinence. However, the guidelines do not provide a theory about what answers to expect and how they point to possible conclusions, in the way doctors connect what they observe to what they know by formulating hypotheses and theories. For example, it is advised to pay attention to constipation, without giving an explanation of how it is linked to urinary incontinence.

Based on his basic knowledge of anatomy, pathology and physiology, and his experience with children that have comparable complaints, the doctor recognizes the patterns of processes that are involved. He compares the observations from Anne to his general knowledge of urinary incontinence. For example, the story of a girl with an unusual voiding stream and UTI's is familiar. Based on theories of the relationships between pathology and symptoms, the doctor formulates a hypothesis and makes predictions of what he will find in further examination to confirm or reject it. In this case: following from the obstructed voiding, he predicts that the patient can have a thickened bladder muscle (detrusor hypertrophy [3]), which can be visualized with ultrasound. Furthermore, the voiding pattern will be disturbed, which can be objectified by uroflow measurements. Hence, connections between several diagnostic tools and the story of the patient can be drawn and hypotheses about the disease are tested.

In contrast, the EBM guidelines focus on how to obtain the most objective, quantified and reproducible information. They recommend using questionnaires, pad tests and micturition diaries to obtain standardized information about micturition frequency and volumes, instead of providing a detailed account of history taking. The EBM guidelines refer to evidence that shows the sensitivity and specificity of a diagnostic tool. However, nothing is stated about the sensitivity or specificity to find out *what*. For example, there is no indication of what the outcomes of questionnaires, pad tests and diaries reveal about the gravity of incontinence or other micturition problems. Hence, the interpretation of this standardized information is largely left to clinicians. In other words, the guidelines give recommendations about the quality of a diagnostic test (in terms of sensitivity and specificity) but not about *how to use them*.

Physical examination

Aanbevelingen

De werkgroep beveelt aan bij alle kinderen met incontinentie een lichamelijk onderzoek te doen naar afwijkingen aan de genitalia externa en daarbij ook een neurologisch onderzoek van de lumbosacrale regio te doen.

De werkgroep beveelt aan, tekenen van obstipatie te onderzoeken.

Figure 2: Physical examination

Aanbevelingen

De werkgroep is van mening dat bij alle kinderen met urine incontinentie meer dan 1 uroflowmetrie moet worden verricht met aansluitend echografische residubepaling. (zie echografie abdomen, paragraaf 5.2.1.d).

De ervaring leert dat een eerste flowmeting nogal eens 'mislukt', en fout positief is voor afwijkingen.

Meerdere flowmetingen kunnen door gewenning aan de situatie representatievere resultaten laten zien. Het lijkt zinvol om de ouders te adviseren om voor de flowmetrieen een middag op de polikliniek uit te trekken en het kind veel te laten drinken. De investering in enkele goede flows zou kunnen leiden tot het uitsparen van invasief urodynamisch onderzoek. Daarbij moet echografisch blaasvulling worden beoordeeld voor mictie.

Figure 3: Uroflow

After history taking, the standard work-up of the first visit consists of physical examination, ultrasound and uroflow measurement. Physical examination includes checking for neurological abnormalities and hypermobility and observing the external genitalia for anatomical abnormalities. The EBM guidelines give recommendations about physical examination (figure 2), uroflow measurements (figure 3) and ultrasound (figure 5) as aspects of the initial diagnosis. The recommendations about physical examination describe what factors should be investigated, whereas the recommendations about uroflow describes how to organize the measurement. Again, the main focus of the recommendation is how to obtain the most objective information, without giving recommendations about how to use or interpret the information. The guidelines do not describe any link between the complaints expressed by the patients, the physical examination and the uroflow measurements. In the case of Anne, the description of a “spraying” voiding stream is measured as a “staccato” uroflow graph. This is probably caused by an obstruction, which can either be a meatal stenosis or a functional obstruction caused by pelvic muscle contractions. These muscle contractions can be caused by a malformation of her meatus, causing her to void against her clitoris or because she has learned to do it as a (wrong) way to resist voiding. Differentiation between these two possible causes can be obtained by a cystoscopy, a scopy of the urethra and bladder. These relationships between an observations, measurements, possible diagnoses and differentiation between the possibilities are not described by EBM-guidelines, but play an important role in reasoning to find make decisions about diagnosis and treatment.

In Anne's case, no abnormalities are found. With ultrasonography, doctors can assess the shape and size of the kidneys and bladder and the bladder wall and bladder neck. In this case, the sonogram shows healthy kidneys with no dilation, an unclosed bladder neck, a normal bladder wall, good control over the pelvic muscles and no descending of the bladder neck while coughing. For an uroflow measurement, the patient takes place at a special toilet that measures the flow of the urinary stream. It produces a graph of the flow and measures the maximum flow, flow volume and flow time. Anne's uroflow measurement shows a 'staccato top', which means that voiding is disturbed by pelvic floor contractions during voiding. These test results agreed with the expectation based on the hypothesis formed after the first medical history taking. Hence, the doctor concludes that Anne's incontinence is the result of "disturbed feeling for urge", which is probably caused by an obstruction in the urinary meatus (opening) [5] and the unclosed bladder neck. This means that the girl cannot retain urine properly inside her bladder, and that she has problems

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with voiding completely [6]. Infections are caused by residual urine in the bladder. As treatment, the meatal obstruction will be corrected and the bladder neck will be examined by cystoscopy. Antibiotics are prescribed against UTI's and the feeling of urge is alleviated by medication (oxybutynin, which relaxes the bladder muscle).

After surgery (meatal desobstruction) Anne's incontinence improved, with regular dry days but also an occasional accident. The surgery had helped, but not completely eliminated the incontinence. Although an anatomical obstruction had caused it, surgery alone did not solve the problems. The system has been disrupted and needs to be restored. Many factors can be distinguished in this process. For example, the girl may have adjusted her toilet behavior to the previous problems, or have dealt with her problem by denying it. Therefore, she has "unlearned" how to correctly feel when to void, how to process the sensory information from the pelvis [12]. The physician's action is now limited to giving advice, in this case for the parents to send the girl to the toilet regularly to restrain the urge. Another possibility is to actively train the child how to feel urge, how to void completely and how often it should void. However, four years is too young to be trained effectively. Therefore parents are given advise about how to handle their child and how to help it to stay dry. Sometimes, changing voiding habits results in great improvements and further treatment is no longer needed.

EBM guidelines are based on studies that prove correlations: diagnostic guidelines provide correlations between a certain (test) outcome and the occurrence of a disease. Hence, EBM guidelines are not based on causal relationships or explanations in terms of cause and effect. In contrast, doctors do tend to reason in these kinds of terms. The case of Anne shows that the system of urinary incontinence cannot easily be reduced to simple cause and effect. Knowing what symptoms are caused by what part of the process is a first step in diagnosis. But in many cases, removing the initial cause does not directly solve the problem. First, because the causes and effects are not aligned linearly, in which cause A results in effect B and symptom C. Causes and effects can be better represented circularly, in which symptom C can reinforce cause A and be a cause of itself. But second, because the circle does not always follow the same direction. It is also possible that effect B is caused by symptom C. Moreover, all parts of the so-called "yellow circle" of incontinence can be influenced by multiple factors. This is illustrated by the diagram at the end of this chapter: the relationships between the boxes is not linear and in many cases not unidirectional. Factors affect each other back and forth and are complicated by "extra factors" (in the diagram represented by blue boxes). That these causes and effects are linked to each other in more complex systems makes it difficult to prove relations. When it is not clear what is cause and what is effect, it becomes impossible to formulate general laws or algorithms that apply to every case. A way to deal with this uncertainty is adopted by EBM and these guidelines: by aiming to prove correlation instead of causation. Some of the extra factors can be quantified and correlated to urinary incontinence and these are addressed in the guideline as "secondary diagnoses" or comorbidity, for example constipation and UTI's. Unfortunately, many more factors that are of influence are more difficult to address. Behavioral aspects are very important for incontinence, but are in the EBM guidelines only addressed when it is part of a psychological disorder like ADHD.

Ultrasound & obstipation

Aanbevelingen

Vanwege de relatief grote kans op obstipatie, en de relevantie van obstipatiebehandeling bij urine incontinentie, beveelt de werkgroep aan om bij alle kinderen met urine incontinentie (en / of disfunctionele mictie) het voorkomen van obstipatie te onderzoeken en zo nodig te behandelen. Dit is ook van belang bij kinderen onder behandeling van anticholinergica met obstipatie als mogelijke bijwerking.

Figure 4: Obstipation

Aanbevelingen

De werkgroep is van mening dat de plaats van, en de normaalwaarden voor echografische blaaswanddikte-meting vóór routinematige toepassing nog verder moet worden vastgesteld. De werkgroep is van mening dat echografische meting van rectumdiameter zinvol zou kunnen zijn voor ondersteuning van de diagnose functionele rectale obstipatie. De werkgroep is van mening dat vergelijkend (parallel diagnostisch) en prospectief (voorspellend voor therapie succes) onderzoek naar de waarde van de hiervoor genoemde verrichtingen zinvol is.

Figure 5: Ultrasound

Six months later all improvements have reversed: Anne is now almost continuously wet or dirty. Fecal incontinence has become part of the problem. Oxybutynin helps against the urinary incontinence but aggravates the fecal incontinence. Anne is described as ‘very spirited’ and especially about voiding. She strongly reacts when her parents try to coach her on her voiding pattern, which makes it very hard to help her go to the toilet in time. She is still too young for urotraining, so the only feasible action is to adjust her medication (macrogol for constipation and oxybutynin for urinary incontinence) to make it manageable until she is old enough for training. The parents also take the girl to a psychiatrist to help with behavioral problems.

In the EBM guidelines, the recommendations about ultrasound are two-sided. Although they acknowledge that ultrasound is useful to find a thickened bladder wall and rectal constipation, they also articulate a need for quantification of the outcome measures and the prospective therapy outcome. So, according to the EBM guidelines, to be able to use ultrasound as a standard diagnostic tool, it is necessary to know the quantitative relationship between, for example an increased thickness of the bladder wall and the associated cause of incontinence. In the case of Anne, bladder wall thickness and rectal size are measured using ultrasound, and without any statistical reference considered “large”. It may be doubtful if these kinds of claims can be made when there is no statistical evidence of what enlargement is relevant and what should be treated. However, there is no question that many other, unquantifiable observations can and need to be made with ultrasound. For example, the shape of kidneys or the movement of the bladder during coughing. These observations are linked to the skills of handling an ultrasound probe, and also subject to interpretation. Because these observations are not easily or completely quantifiable, their relation is harder to prove and therefore considered “subjective”.

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A little later, Anne and her parents return to the outpatient clinic because the situation has become unendurable. She is wet multiple times a day, or sometimes even multiple times an hour. Her age and character make treatment by behavioral training very difficult. Oxybutynin does not seem to work properly and it is very hard to find the right doses for macrogol. At this point, re-evaluation is needed to examine further possibilities to improve the situation and bridge the time until it is possible to start urotraining.

A new ultrasound is made. On this ultrasound, the situation has changed as well: a thickened bladder wall and an over-filled rectum are now observed. This means that new symptoms are in play and the attempts to interrupt the circular process have not been successful yet. The overfilled rectum is new proof of constipation [8], which can be either a cause or an effect of fecal incontinence [9]. Like the “yellow circle” of urinary incontinence, a “brown circle” represents fecal incontinence. The yellow and brown circles are connected to each other and affect each other through the disturbance of urge (and possible by causing UTI’s). This is also illustrated in the diagram at the end of this chapter. The recommendations in the guidelines also describe a correlation of incontinence and constipation and recommend to treat constipation (figure 4).

Urodynamic testing

Aanbevelingen

De werkgroep is van mening dat urodynamisch onderzoek bij kinderen met incontinentie moet worden verricht als het eerder verrichte onderzoek niet voldoende informatie heeft opgeleverd om op basis daarvan een niet chirurgische behandeling te starten.

De werkgroep is van mening dat bij kinderen waarbij de incontinentie behandeling niet binnen enkele maanden het verwachte resultaat oplevert een urodynamisch onderzoek verricht moet worden.

De werkgroep is van mening dat voor invasieve/chirurgische behandeling urodynamisch onderzoek moet worden verricht.

Bij een vermoeden op urethrale obstructie kan urodynamisch onderzoek dit bevestigen, kwantificeren, of ontkennen. Doorlichtingsbeelden bij cystografie zijn daarvoor niet sensitief noch specifiek genoeg.

Figure 6: Urodynamic testing

The next steps for Anne will be to try to empty the colon by flushing it with tap water. After that, more information can be gained with urodynamic testing (UDT). UDT is an invasive diagnostic tool that gives information about bladder pressure, pelvic muscle activity, bladder volume and urinary flow. UDT is only performed when it is expected that one of these things is disrupted, and when results from other tests are not sufficient to explain the complaints. This is also recommended in the EBM guidelines (figure 6).

The case of Anne shows that a simple representation of cause and effect is not correct in case of urinary incontinence. In diagnosis, a doctor reasons in terms of cause and effect, but is also aware that causes and effects can be reversed. Therefore, doctors refer to models and theories, that are either based on basic scientific knowledge or on pattern they recognize from their own experience and observations. This helps with understanding how different outcomes of diagnostic tests (measurements, physical exams or patient’s story), are related to possible diseases and possible treatments, thus

in which direction to follow the yellow and brown circles. Hence, instead of focusing on the proven correlation, as in EBM guidelines, doctors deal with uncertainties by using basic knowledge of anatomy, physiology and pathology. For example to explain *why* the occurrence of a staccato uroflow measurement is likely to be caused by an obstruction and *how* this is related to the character of the voiding stream.

Aanbeveling

De werkgroep beveelt aan waar mogelijk het kind met incontinentie in te delen in een van de 'klinische beelden' (hoofddiagnosen): overactieve blaas (OAB); dysfunctional voiding (DV) of hypoactieve blaas (HAB).

Figure 7: primary diagnoses

The complexity of the processes underlying urinary incontinence is acknowledged by the EBM guidelines. The recommendations are therefore constructed as answers to “dilemmas” that clinicians face in practice. The dilemmas mainly consider whether or not to use a certain diagnostic tool and they describe the existing evidence about the sensitivity and specificity of that tool. They guide in choosing the tool or combination of tools that is most specific and sensitive for the disease that is being investigated. However, they do not guide in making decisions based on the outcomes of that tool. At the beginning of the guidelines, it is suggested to focus diagnosis on differentiation between three primary diagnoses: overactive bladder, dysfunctional voiding and hypoactive bladder (figure 7). A short account of the underlying process generating the separate conditions is given. But the sections with recommendations about diagnostic tools do not refer to any of these primary diagnoses or underlying processes. In other words, recommendations do not guide in how to differentiate between the three primary diagnoses or what tool is indicated to prove which diagnosis.

2b.2. Guidelines about what disease(s)?

Hyperlaxity

The second case is about Betty. Betty is now 8 years old and has a long history of incontinence and UTI's. At the age of 3 “dysfunctional voiding” and constipation were diagnosed. However, she was easily potty-trained at this age and constipation was treated with macrogol. A couple of months later she starts to postpone voiding and it is difficult to coach her by sending her to the toilet, which causes urinary incontinence. The urinary stream is directed to the front, and she has recurring UTI's.

As seen in the previous case, the incontinence problems are caused by a disruption of the system by an anatomical obstruction [5], in this case a meatal stenosis (or a stenosis in the urinary opening). First, her meatal stenosis is corrected, making her stream normal. Her parents are advised to send her to the toilet regularly to develop a normal voiding pattern. This seems to solve her incontinence problems for a while. However, after 6 months, she starts wetting her pants again and her character makes it difficult to keep up with the regime of visiting the toilet every two hours. At this point, the pediatric urologist is consulted and observes an overfilled and overstretched rectum and bladder [10]. Hyperlaxity (a condition in which the joints and soft tissues are unusually flexible) was diagnosed and suggests that her complaints are related to it [11]. Generalized hyperlaxity

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is often associated with incontinence problems, as the doctor knows from experience because he has previously observed it in many cases.

Hyperlaxity is not mentioned in the guidelines. Probably, the correlation between hyperlaxity and incontinence has not been investigated yet and therefore remains unproven. However, it is found in many patients visiting the doctor with incontinence problems, and therefore testing for hyperlaxity has become a standard part of diagnosis for him. Hyperlaxity does not cause incontinence, but is a complicating factor that might require a different approach for treatment. As described before, the “yellow” and “brown” circles of fecal and urinary incontinence are influenced by many factors outside of the pelvis, illustrated in the diagram by blue boxes. Hyperlaxity [10] is one of the factors that is found very often, making it a part of a recurring pattern. It is a “confounder”. When it is noted, usually extra advice concerning movement and sports can also be given.

The guidelines for urinary incontinence only give a short account of related diseases and psychological factors. However, factors that are more remotely related to incontinence, like hyperlaxity, are not mentioned. This makes drawing connections between seemingly unrelated complaints very complicated. Moreover, links with other diseases are expressed in terms of correlations (“20-36 % of children with urinary incontinence are also familiar with constipation”) instead of explaining the underlying process. Naturally, knowing that hyperlaxity occurs in a large proportion of the patients with urine incontinence can be helpful in diagnosis, but in thinking about an individual patient, it is more relevant to reason about the effect that it will have on the signs and symptoms. Soft tissues are more loose than usual, making it possible for rectum and bladder to expand and hold more content. This makes it harder to feel when the bladder or rectum is full. When both are filled they exert pressure on each other and one or both will be (partly) emptied involuntary, resulting in incontinence. From understanding this process, a possible treatment comes up: to control her bladder the patient needs to empty her rectum and visit the toilet regularly. Hence, it is not the correlated occurrence between hyperlaxity and incontinence but its explanatory power that makes it a valuable observation in incontinence diagnosis.

Behavior

Aanbeveling

De werkgroep is van mening dat de prevalentie van gedragsproblemen te laag is om bij alle kinderen met urine incontinentie diagnostiek naar gedragsproblematiek te doen. De werkgroep raadt echter aan, vanwege de belangrijke consequenties, om vóór het opstarten van urotherapie rekening te houden met de kans op het bestaan van gedragsproblemen als comorbiditeit.

Figure 8: Behavior

Two years later (Betty is almost 6 years old), her incontinence complaints have improved, and can be completely solved by regular voiding. She still has the tendency to postpone voiding [12], and occasionally she suffers from UTI's. However, she is still too young to be trained. In the meantime, she has visited the hospital frequently for complaints of pain in her legs. These pains seem to be inexplicable and cause sleeplessness, restraining her functioning at school and at home. Doctors consider a neurological disorder causing these

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pains, which can also be related to a disturbed control over the bladder. This is tested with urodynamic testing, which showed no major abnormalities. Hyperlaxity can be a factor in her leg pains as well as her incontinence, but this is not investigated in the search for the cause.

Later, in the outpatient clinic, a full rectum is observed again, and the girl still suffers UTI's. Betty finds it difficult to visit the toilet regularly and in time, but she is now old enough to start urotraining. In the following year she continues to suffer from UTI's. At age 7 she is again operated on to correct her meatus to ease voiding. After recovering from the surgery she is admitted to clinical urotraining (internal, 10 days). However, she is cognitively unable to memorize and apply the theoretical aspects. Also, the pain in her legs keeps her from having a normal upright position on the toilet. So, she stops with clinical training. Her case is discussed during a multidisciplinary consultation. In this consultation the training difficulties are discussed. But more importantly, it is questioned who the primary caregiver is. It is concluded that taking an IQ-test is indicated. Also, her parents should be supported in the upbringing and training of their daughter. The mother also asks for psychological testing.

Like hyperlaxity, behavior is an important external factor in the development and treatment of urinary incontinence. After a time of disturbed urge and voiding, a child needs to be taught how to recognize urge and how to react correctly again. Some children refuse to train because they don't acknowledge that they have a problem with voiding. Other children are cognitively unable to understand training. Often children postpone visits to the toilet because they are so devoted to the task or game they are concerned with at the moment. The guidelines only acknowledge behavioral factors when a correlation in terms of comorbidity is statistically proven, but not with differences in character and cognitive capabilities (figure 8). Behavioral factors are often personal and differ from individual to individual. Therefore, it is hard to impossible to study all kinds of factors and find strong correlations with incontinence. Furthermore, behavior is hardly quantifiable. Insight in how behavioral mechanisms influence the process is, however, crucial. This is illustrated by the cases Anne and Betty. Both girls are not easy to train, but for different reasons. For the first girl, it is a matter of (a spirited) character, whereas the second is cognitively limited. In practice doctors deal with individual differences by understanding the disease processes as being affected by many interrelated factors. When the relations between many causes and effects are understood by a doctor, he uses this knowledge to argue how and why a factor affects the situation. And how this can be controlled. In this way behavioral aspects can also be included in clinical reasoning, whereas EBM guidelines have a difficulty with including these kinds of factors.

A year after the surgery the incontinence and UTI's have stopped for Betty. She still postpones visits to the toilet, but her flow is good and her constipation has stopped. She goes to a special school now. Psychological tests suggest that she is cognitively underdeveloped and that she possibly has an autistic disorder. However, the pain in her legs has not stopped, despite many tests by several disciplines. The question that rises is whether the pain has anything to do with the hyperlaxity found earlier?

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In the last chapter of the EBM guidelines a flow chart for diagnosis is included (see figure 9). This flow chart gives an overview of the steps that need to be taken to obtain the most reliable diagnoses and complete information and the order of these steps. For example, it describes that co-morbidities like obstipation and UTI's need to be examined and treated before a diagnosis can be formulated. But also factors like obstruction or a divergent bladder need to be treated before (uro)therapy can be planned. Thus, surgical or clinical treatment is separated from the treatment that is directly related to incontinence (for example prescription of Oxybutynin or uroflow training). In the previous cases it is shown that these steps are interrelated and cannot be separated from each other as easily as described by this algorithm. Furthermore, in this algorithm only two moments of decision-making are presented: first to decide whether other co-morbidities need to be investigated and second to choose the primary diagnosis. However, this flow chart does not give any clues about what outcomes of measurements point to which diagnosis. It is therefore very difficult to base any clinical decisions on the flow chart as presented in these guidelines.

It is noteworthy that the evidence used in these guidelines is mainly based on “expert consensus” or “un-standardized studies”. Little statistical evidence is presented in the recommendations. This can be one of the reasons that so little recommendations about actual decisions are presented.

2b.3. From evidence-based medicine to the epistemological responsibility of doctors

In the previous chapter I have argued that the intellectual challenge of doctors consists of fitting together and mutually adjusting heterogeneous elements, from personal observations to general scientific theories to data from measurement instruments. The range of elements that has to be included is in practice much broader than EBM guidelines can account for based on a-theoretical correlations. For example, the cases of Anne and Betty show that an important element in urine incontinence is behavior. The behavior of Anne and Betty makes it difficult for both of them to deal with their urinary incontinence. However, the two girls have different problems that are in both cases not recognized by the EBM guidelines, because they are not the result of a disorder, or in any way quantifiable or objectifiable. In contrast, Anne's and Betty's doctors act epistemologically responsible by also addressing the character of the children and how it impacts possible treatment decisions. Another example is hyperlaxity, which is not usually addressed in the diagnosis of urine incontinence, but does provide valuable information for decision-making, because it enables to understand how the bladder and rectum come to be overfilled causing a disturbed feeling of urge and with that incontinence problems.

Comparing the cases of Anne and Betty, it should be noted that the original symptoms that form the starting point of the diagnosis are almost similar: both girls have an obstruction that complicates voiding, suffer from UTI's and obstipation and are initially too young to be trained. However, the outcome of both girls is very different. In the first case, incontinence worsens after surgery and cannot be controlled by medication. In the

second case, incontinence is almost completely resolved but other problems remain. Therefore, these cases show that there is no straightforward line of reasoning that always leads to best results, and that other factors influencing the disease should be taken into account. EBM guidelines seem to advocate an algorithmic or rule-based reasoning, in which the same causes lead to the same effects, and therefore, the same signs and symptoms should have the same cause (the one with the strongest correlation). As the cases of Anne and Betty show, diseases with similar initial symptoms can develop very differently. Doctors make sense of this by more intricate methods of reasoning, as illustrated by the diagram of the yellow and brown circle.

In other words, the doctor in the cases of Anne and Betty shows that rule-following does not result in the best way to handle the problems of the two girls, and that an eye for individual and often unquantifiable information is required in order to find it. He does this by fitting this individual information together with a deeper understanding of the mechanisms of urinary continence, which is summarized in the diagram of yellow and brown circles. This diagram allows reasoning that follows multiple directions and including the impact from multiple external aspects on multiple elements of the process, and can therefore be adjusted to the situation, depending on the individual patient, the available information and suitable treatments. The diagram is based on multiple sources of information, including general knowledge from textbooks and clinical trials, but also from experience and unproven theories (for example the theory of “crossing e. coli bacteria” in case of obstipation, causing UTI’s.) An epistemologically responsible doctor is aware of these different sources of information and their value and is able to use them to make a well-deliberated decision.

EBM guidelines base their recommendations on a-theoretical correlations. Although finding a strong correlation between two factors (like hyperlaxity and urine incontinence) can guide doctors by pointing out which factors are relevant, in order to really include these factors in reasoning concerning diagnosis and treatment, an idea, theory or model of the relationship between a these factors is needed. Doctors usually employ their general knowledge of basic medical sciences like anatomy, pathology and physiology to reason about these kind of relationships and draw conclusion about their observation and possible courses of action. But when this knowledge is not enough, they are guided by their experience or by formulating their own theories about underlying processes (like the theory about crossing bacteria). This description make plausible that professional judgments made by doctors are at the core of clinical decision-making, and that these judgments are informed by many sources of information, that they require different reasoning approaches and several skills like creativity and an eye for detail. In order to account for this type of reasoning, and to guide it to warrant or improve the quality of clinical decision-making, a medical epistemology should be able to incorporate and value different kinds of reasoning and their different roles in this process. This resonates with both Loughlin’s ideas about personal judgment, and Khushf theory of the diagnostic process as a combination of reflective and determinative judgment because it shows that these non-algorithmic methods of reasoning are crucial for clinical decision-making.

Case Study: Urinary Incontinence

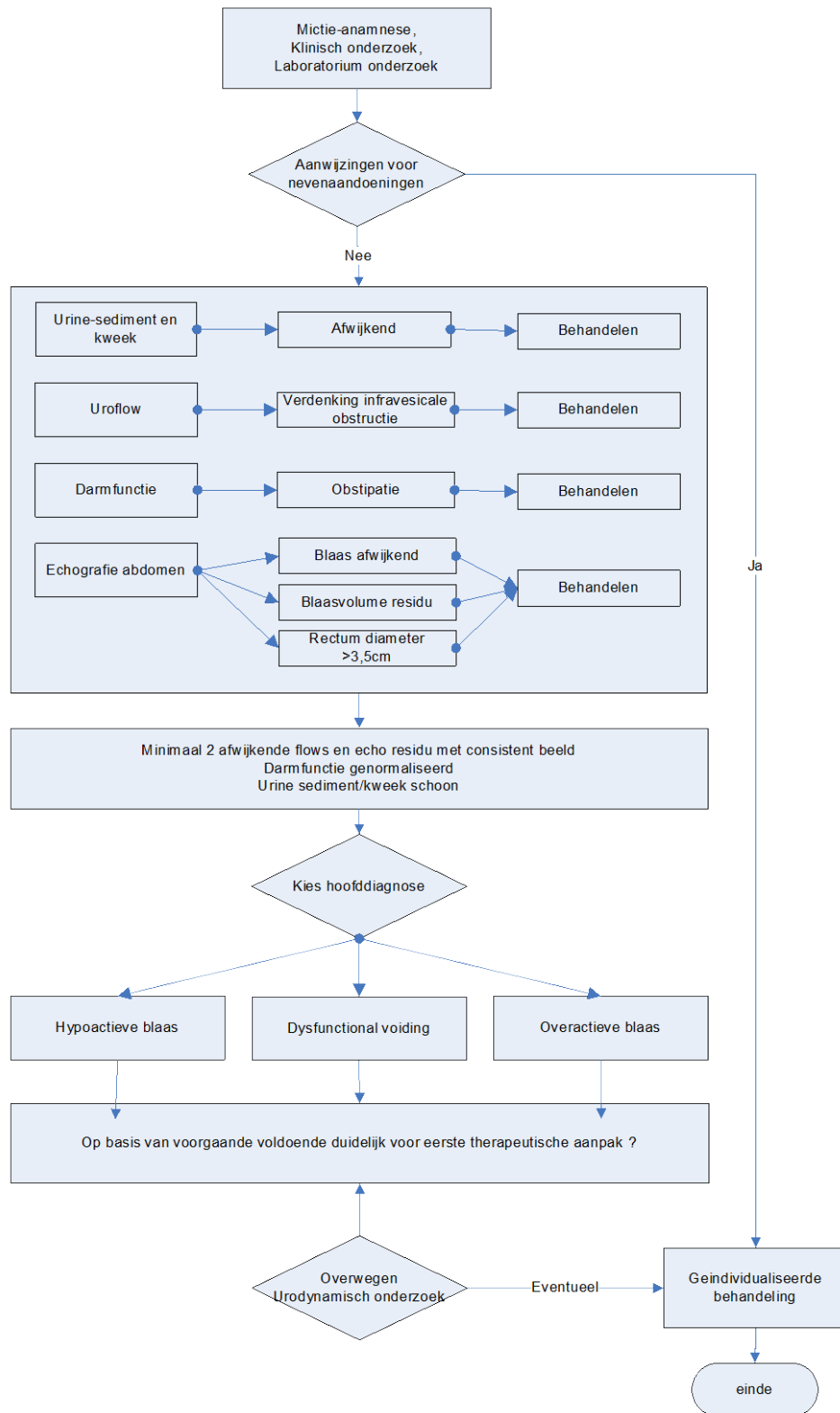
Because of the focus on quantification, the guidelines help choosing the most reliable diagnostic tool for the situation, and provide an indication of when the use of more invasive tools is justified. However, the guidelines do not help interpreting the outcome of diagnostic tools. Therefore, it does not truly guide a doctor in the decision-making process. When the “Yellow” and “Brown” circle are used as a reference, a valuable guide in making diagnostic decisions would be to explain in what cases an bladder wall hypertrophy can be observed (e.g. a meatal stenosis, or a functional urethral obstruction), what the chances are each of these cases occur and what diagnostic tools can be used to differentiate between these cases.

2b.4. Conclusion

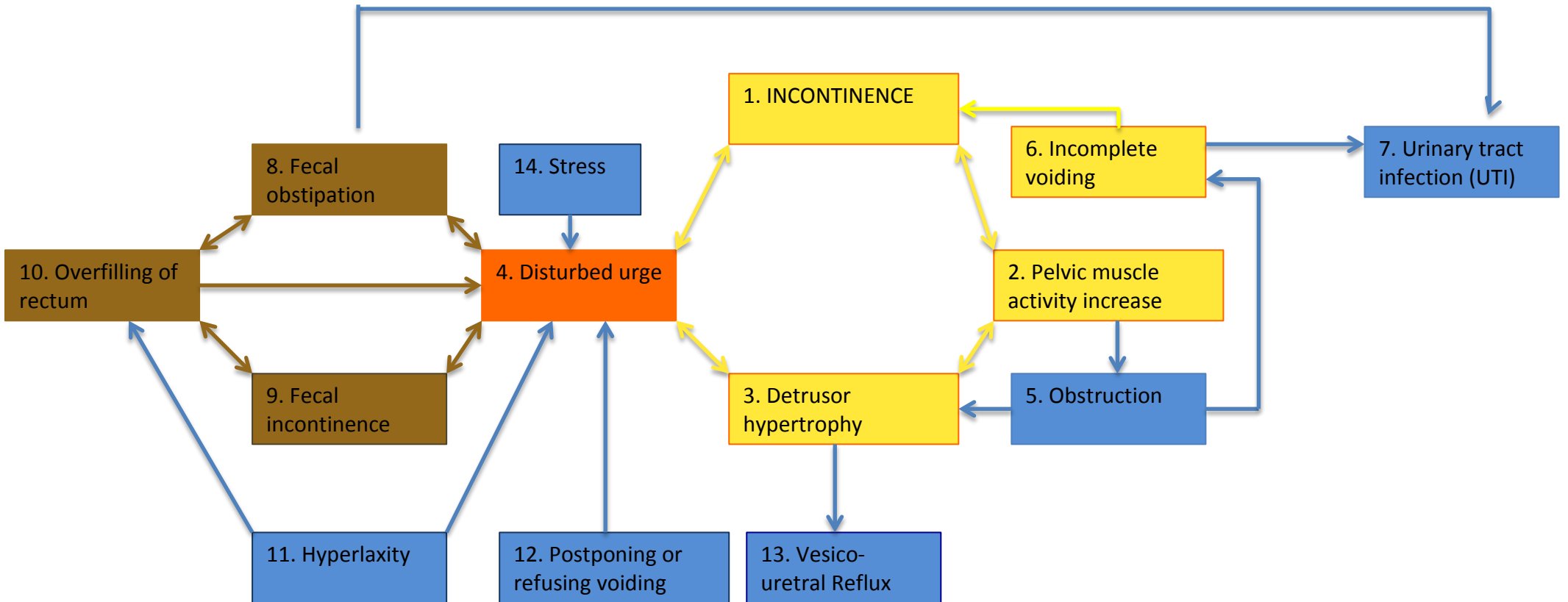
The aim of this case study was, firstly, to illustrate how reasoning in the actual clinical practice differs from the algorithmic reasoning based on guidelines that EBM epistemology envisions. The cases of Anne and Betty show that reasoning for diagnosis and treatment is in an intricate process, in which hypothesis are formulated and verified, based on general knowledge, personal experience, the specificities of the patient (from their stories and measurement outcomes) and patterns and theories that the doctor relates to the case. EBM epistemology fails to account for the whole range of reasoning types and the wide range of types of information that informs the reasoning process.

Secondly, I used these cases in a normative sense: to identify aspects of epistemologically responsible reasoning of doctors. One of the aspects that can be identified based on these case description is combining scientific and general information with personal observations and specificities of the patient, like the character of the patient. These kind of observations are often dismissed as “subjective” because they cannot be formalized as an aspect of the disease in general but yet play a crucial role in making decisions for individual patients. Another aspect is the use of reasoning, that is not algorithmic, but nevertheless systematic and rational. In these cases, doctors are well able to account for the decisions they made and how they came to that decision, by referring to scientific knowledge, to the “yellow and brown” circle, to their own theories and observed patterns and also to RCT’s and guidelines. Hence, the complex reasoning process of doctors that these cases demonstrate, cannot be easily formalized or captured in algorithms, yet in epistemologically responsible decision-making, it does maintain a high standard of rationality.

Diagnostiek en diagnoses



Schematic representation of incontinence (“yellow” and “brown” circles)



The Epistemology of Clinical Decision-Making

1.	Incontinence	The uncontrollable leakage of urine (continuous or intermittent).
2.	Pelvic muscle activity increases	Voiding is controlled by sphincters and other muscles in the pelvis. A typical reaction of children to incontinence is to contract these muscles, resulting in a higher pelvic muscle activity.
3.	Detrusor hypertrophy	The bladder wall muscle is called “detrusor”. When voiding is obstructed or countered by a higher pelvic muscle activity, the detrusor has to work harder for voiding, which will result in an increase of volume (or hypertrophy) of the detrusor.
4.	Disturbed urge	The feeling of urge can be disturbed in many ways, i.e. a continuous pressure on the bladder will result in an impaired ability to feel urge.
5.	Obstruction	And obstruction in the bladder opening, i.e. meatus stenosis (girls) or ureteral valve (boys).
6.	Incomplete voiding	The bladder is not emptied completely. Residue can be observed after voiding.
7.	Urinary tract infection (UTI)	And infection of the bladder or urethra.
8.	Fecal obstipation	The inability to pass stool or gas.
9.	Fecal incontinence	The uncontrollable passage of stool or gas.
10.	Overfilling of rectum	Retention of a large amount of feces in the rectum.
11.	Hyperlaxity	An unusual flexibility of joints, muscles and soft tissue.
12.	Postponing or refusing voiding	Children with incontinence are sometimes known to deal with their problem by postponing voiding.
13.	Vesico-uretral reflux	The reflux of urine toward to the ureters and kidney. Caused by a deficient closing of ureter valve or high bladder pressure.
14.	Stress	

3. Aspects of the Epistemological Responsibility of Doctors

The case study about the urine incontinence of Anne and Betty illustrates that EBM epistemology cannot capture all relevant aspects of clinical reasoning, both concerning the information that is used in clinical decision-making and the intricate methods of reasoning that doctors employ. Therefore, I have suggested that in an alternative medical epistemology the epistemological responsibility of doctors should play a more central role. In the case study I have found some clues to illustrate what I consider epistemologically responsible reasoning, for example specific skills like creativity and an eye for detail. In this chapter I further explore the aspects of epistemological responsibility.

3.1. The four dimensions of the clinical decision-making context

A central role for the epistemic responsibility of doctors shifts the focus from the “general” and objectified, represented by guidelines, algorithms and rule-based reasoning, to the specific, the individual doctors and patient. This shift in emphasis allows considering more closely the specific context in which clinical decisions are made. As I have suggested in the conclusion of the first chapter, I suggest that that context consists of multiple dimensions, that are different in nature but yet all are relevant for clinical decision-making. The first is the *dimension of the patient-doctor interaction*. In this dimension, doctors identify symptoms by “history taking”, in which a patient tells about his complaints. Relevant elements of this context are for example communication skills, giving advice and getting a patient to trust you as a doctor. From the patient’s point of view, it is making clear what your complaints and problems are and getting a treatment that suits your personal values and needs. In Khushf’s theory, the propaedeutic activity of hypothesis formation takes place within the context of the patient-doctor interaction. The epistemologies that refer to the “art of medicine” focus mainly on this dimension of clinical decision-making, and extensively analyze how soft skills, like empathy and communication and “subjective” properties like experience and tacit knowledge play a role in clinical decision-making.

Second, *the dimension of organization*; doctors work in hospitals that standardize actions - from taking blood samples to making a kidney scans - by formulating protocols and guidelines. These are based on EBM research, but also on organizational, economic and political considerations. The epistemological aspects of this context are put forward in the epistemology of EBM, by providing information about the efficacy of treatments and the sensitivity and specificity of diagnostic tools. The epistemology of EBM considers what kind of information guidelines should be based and how these guidelines should be formulated to produce reliable and standardized information about a patient, to warrant an equal quality for each patient. Beside organization by standardization through protocols and guidelines, organization also has to do with other facilitating elements, like the hierarchy of specialists, doctors and trainees, rules and regulations, the use of administration software, the outpatient clinic workflow, and the organization of medical education.

I consider the first two dimensions, of the patient-doctor interaction and of the organization as extensively treated by the two “traditional” but opposing views on medical epistemology (EBM and the art of medicine). Hence, these dimensions are well acknowledged and explored,

and can be well understood through the epistemologies that I have described in chapter 2. However, as I have argued in the previous chapter, although they both identify important and complementary aspects, these two opposing views on medical epistemology do not do justice to actual clinical decision-making, because they seem to overlook the other dimensions of the clinical decision-making context.

These overlooked dimensions are the *material dimension* and the *intellectual dimension*. Diagnosis and treatment always take place at a specific location, like a hospital, a medical department or a treatment room, and with specific equipment. This poses constraints and possibilities on the diagnostic process and the treatment decisions. A hospital can have better facilities or equipment to perform one treatment over another. Simply put, if a hospital does not own a surgery robot, performing robot-assisted surgery is not an option. But the *material dimension* also has a more intricate role in clinical decision-making, through the use of measurement instruments, which I will explicate below. Finally, physicians bring in their own context, their *intellectual dimension*, which consists of knowledge of medical science, their experiences with other patients and ideals about their work (for example Khushf's scientific ideal, but also ideals about what it means to be a good doctor and traditions). In the following, I will more extensively analyze the impact and the content of these last two dimensions.

These four dimensions are intertwined and cannot be separated, but by analyzing them individually the roles of the different dimensions of the clinical decision-making context become clear. In the next paragraph I will further elucidate these aspects of epistemic responsibility, by focusing on the material and intellectual context. First, I will elaborate on the material context by referring to Annemarie Mol's (2002) "praxiography" study of medical practice. Then, I will use the notion of *knowledge as epistemic tools* to better understand how doctors use and generate knowledge of their individual patients to reason about diagnosis and treatment. Last, to understand how heterogeneous types of information are fitted together in order to construct a coherent "picture" that is consistent with general knowledge I will refer to Ian Hacking's (1992) account of laboratory sciences and relate this to the work of doctors in the clinical decision-making.

3.2. The material dimension

One way in which the material dimension is epistemological responsibility of doctors, is pointed out by Annemarie Mol. In *the body multiple*, Mol performs an ethnographic study of the practices in which a specific disease, atherosclerosis, is "done". Mol calls this approach to study medical practice a "praxiography" and argues that in studying medical practice, it is not sufficient to focus on a disease as a pre-existing object at which you can look from different viewpoints, but that the different practices in which a disease is situated should be central. With her ethnographic approach Mol shows that the atherosclerosis experienced by a patient as pain in the leg brought on by walking is something different from the atherosclerosis that is visible under the microscope at the pathology department. In Mol's view, in different situations or practices, the disease multiplies. With this notion of multiplicity, Mol draws attention to the socio-material context and shows that this context determines for a large part how doctors (and other health care professionals) interpret (or in Mol's word "enact") a disease in a specific situation.

Mol studies clinical practice with a goal different from mine, namely to understand what disease *is*, instead of understanding clinical decision-making, or what can be known about a disease. Therefore, Mol comes to a conclusion that, in my opinion, does not offer much clarification when studying clinical decision-making, namely “that ontology is not given in the order of things, but that, instead, *ontologies* are brought into being, sustained or allowed to wither away in common, day-to-day, sociomaterial practices” (pg. 6). However, this conclusion does offer a crucial insight for clinical decision-making: Mol makes plausible that diseases cannot be considered separately from the instruments, settings and people that are used to investigate them. A disease is not something that can be known without “the techniques that make things visible, audible, tangible, knowable” (pg. 33) and these techniques direct how a disease is “enacted.” For example, measuring the decrease of blood flow around an atherosclerotic plaque by Doppler ultrasound directs toward a treatment that increases this flow (e.g. angioplasty) whereas from seeing the narrowing of a blood vessel visible on an X-ray a doctor may sooner opt for surgical treatment. Yet other ways to quantify atherosclerosis, like the distance somebody can walk without pain, may lead to less invasive treatments, like exercise.

In summary, the material context steers the clinical decision-making in complex and hidden ways. It is probably too much to ask of physicians to consider the possible steering mechanism for each diagnosis or treatment decision. However, doctors should be aware that for each case there might be several solutions and that in choosing between them they do good to not only be led by measurement data from instruments, but to choose the solution that best fits the needs of the patient.

3.3. The intellectual dimension

Mol’s theory makes plausible that in clinical decision-making diagnosis and treatment are intertwined with the material dimension of the context, including technology, instruments, measurements, people and places. In her approach - studying clinical practice by studying the specific practices, in terms of objects, people, and interactions - Mol intentionally leaves out epistemology since, according to her, “Epistemology is concerned with reference: it asks whether representations of reality are accurate” (pg. vii). I agree with Mol that the idea of epistemology as “objective truth finding” obscures thinking about the role of knowledge in medical practice. However, for a complete understanding of the clinical decision-making context, knowledge practices should be an aspect of the “praxiography” that Mol envisions. The “knowledge context”, or the intellectual dimension of the decision-making context shapes the process of reasoning about diagnosis and treatment in the same way as the material and social context. Therefore, an alternative approach to knowledge in medical practice is needed to understand the intellectual dimension of the decision-making context. Instead of a view that focuses on how doctors ideally find *objective truth* about their patients, a view of how knowledge serves the purpose and the scientific ideal of medicine is better suitable to understand the intellectual dimension.

As I have previously argued (following Khushf), a crucial aspect of reasoning in clinical practice is that it has a specific purpose, that of understanding and controlling the disease of an individual patient. For this purpose, doctors have to construct a coherent “picture” of their individual patient, which is *consistent* with the available information, for example basic knowledge of anatomy, pathology and physiology, state-of-the-art scientific discoveries,

specificities of the patient (like age, gender, etc.), the outcome of observations, physical examination by the doctor, the outcome of technological measurements and the doctors' personal experience. I consider this "picture" that is constructed by fitting together heterogeneous elements the *knowledge* that a doctor generates about that patient. The knowledge about a specific patient is thus produced for a specific epistemic purpose: in order to reasoning about diagnosis and treatment. Hence, instead of considering the knowledge that doctors generate of patient as a true representation of that patient, this knowledge should be considered as that which enables doctors to think about the diseases of their patients and to make clinical decisions.

An account that explains how knowledge is constructed for a specific purpose is considering the knowledge that doctors generate of their patients as an *epistemic tool*, rather than a representation that is true in relation to reality. Boon and Knuuttila (2008) describe how *models* function as epistemic tools for engineering sciences as "things that are used by scientists to do some work, in other words, to fulfil some purposes" (pg. 689). In their account, Boon and Knuuttila consider models to be "used in various ways, for example, for the purposes of scientific reasoning, theory construction and design of other artifacts and instruments" (pg. 689). They make plausible that, through models, scientists can gain knowledge about a hypothetical device, by predicting observable and measurable parameters, hence connecting the model to the real world. Furthermore, it enables further reasoning about the system by introducing imaginary phenomena. In a more recent article, Mieke Boon (2012) argues that in the engineering sciences, *concepts* of phenomena can also function as "epistemic tools for creating and intervening with phenomena that are of technological relevance" (pg. 219). In her analysis Boon emphasizes the intertwinedness of theory formation and technological measurement: "concept formation goes hand in hand with the construction of a theory of the domain of the phenomenon [...] but also with producing an experimental set-up for investigating it" (pg. 223). In the construction of concepts for epistemic uses, heterogeneous content (both conceptual and empirical) is put together. This heterogeneous content enables epistemic uses, for example conceptual content guides the questions that can be investigated. Boon argues that "concepts can function as epistemic tools because of this heterogeneous conceptual and epistemic content, which must be fitted together, thereby drawing coherent, consistent and relevant relationships by means of which the concept is developed to a whole" (pg. 234).

I propose that the knowledge that doctors construct of their patients functions as an epistemic tool in clinical practice, similar to the way models and concepts function as epistemic tools in engineering sciences. By fitting together heterogeneous elements (conceptual and empirical), doctors construct a coherent picture of an individual patient in order to generate an epistemic tool that enables them to reason about their patients in the best possible way. The objectivity and scientific quality of this epistemic tool does not firstly consist in its *truth*, but rather in meeting other relevant epistemic criteria, such as its *logical consistence* and *coherency* with other relevant knowledge, like basic or state-of-the-art scientific knowledge. In other words, the epistemological tool has to be consistent with the intellectual dimension of the clinical context. Another important epistemic criterion is its *utility* for this specific situation thus for the individual patient. Therefore, the empirical content (the content that is obtained by observations and measurements) of the knowledge that doctors generate of their patients consists of data specific for the *individual* patients. This

data is either collected in the patient-physician interaction, for example signs and symptoms identified by history taking and physical exam, and by measurements using instruments. This requires fitting together a broad range of heterogeneous elements, by a process of mutually adjustment in order for them to form a coherent whole.

The case of Anne and Betty, shows that diagnosis is a process, in which new information continuously becomes available, requiring adjustment of the constructed knowledge of that particular patient to the situation, which generates a new epistemic tool that enables to ask new questions and follow new lines of investigation. In other words, with the concept of “epistemic tool” the intellectual work of doctors can be understood as consisting of gathering information about a patient and fitting this together with other elements to construct knowledge of a patient. This knowledge functions as an epistemic tool and is “flexible”, allowing adjustment when newly available information is fitted in as new empirical content of the epistemic tool, which enables to think differently about the patient.

3.4. Fitting together in medical practice

The epistemological responsibility of doctors involves generating knowledge about their patients that enables them to ask questions, set up lines of investigations and make decisions. Instead of true representations, I consider this knowledge an epistemic tool, constructed for a specific purpose. Doctors are held responsible to generate this specific knowledge for every single situation. I believe that the epistemological difficulties of this task – i.e., of constructing a coherent ‘picture’ from heterogeneous bits of information - are insufficiently recognized in other medical epistemologies. To understand the process of fitting together to generate an epistemic tool, I compare medical practice to the practice of laboratory science, as analyzed by Ian Hacking.

The process of theory-formation in the laboratory sciences has several similarities with the process of the generation of knowledge about patient. First and foremost is the use of instruments to obtain data in both practices. As argued in chapter 1, a characteristic of modern medicine is the use of instruments to obtain information about a patient. Already in the initial encounter with a patient, doctors use multiple instruments like stethoscopes, blood pressure meters and thermometers to observe phenomena of a patient that are otherwise not observable, similar to instrument that are used in laboratory sciences. Secondly, in both the laboratory sciences and medical practice combine a large intellectual aspect (interpretation, reasoning, theory formation, etc.) with a large practical aspect. Practical skills and knowledge are required in order to handle instruments and obtain data, and are equally important as intellectual skills. Of course, there are also major differences between laboratory science and medical practice, most importantly the role of the patient in the decision-making process, but in my view, Hacking’s analysis is fruitful to understand the intellectual dimension of the decision-making context, and how this dimension is closely intertwined with the material dimension.

In *The self-vindication of laboratory sciences* (1992), Ian Hacking analyzes how laboratory scientists are continually fitting together heterogeneous kinds of elements to produce “a coherent theory of thought, action, materials and marks” instead of a “coherent theory of the truth” (pg. 58). Hacking argues that in laboratory sciences, types of theory, types of apparatus and types of analysis co-evolve and are mutually adjusted to each other, resulting in a closed-

system. Theories produced by these sciences are not directly compared to the “real world”, but are “true to” phenomena produced by laboratory instruments. Theory production relies on theories about the phenomenon, but also theories about how instruments work and how to analyze data. Hacking describes a meshing of “a network of theories, models, approximations, together with understandings of the workings of our instruments and apparatus” (pg. 30). Thus, according to Hacking, science is not about finding true theories of how the world works, but about fitting together many elements, including theories about the phenomenon, about how instruments work, the instrumentation itself and the data they produce.

On a common view, approaches to medical epistemology that represent a narrow view of science (like EBM, see chapter 2) aim at a “true description” of patients, whereas I proposed that knowledge generated by doctors (and used as epistemological tools) must be considered as “true to” phenomena, like the patient’s story, medical theories and measurements from diagnostic tools. Therefore, I claim that the process of fitting together and mutually adjustment of a range of elements in laboratory science is similar to the process of knowledge generation in clinical practice. In his paper, Hacking presents a taxonomic scheme of the elements of laboratory science, divided into three groups: “ideas”, the intellectual component of an experiment, “things”, the material substance that we investigate or with which we investigate and “marks”, the outcomes of an experiment and the subsequent manipulation of marks to produce more marks. I will use Hacking’s scheme to analyze what elements are fitted together to form the epistemological tools of clinical decision-making. By translating Hacking taxonomy into one that applies to medical practice, it becomes evident that the intellectual and material dimensions are strongly intertwined: both the material dimension (in the form of “things”) and the intellectual dimension (“ideas”) are prominently present in Hacking’s taxonomy. The other dimensions are also reflected in the elements of the taxonomy, but to a lesser extent.

3.5. A taxonomy of the elements of clinical reasoning

First, in Hacking’s account “ideas” involve questions, theories and modeling of how the apparatus works. In clinical practice, the question that directs the investigation is introduced by the patient, who enters the clinic with a certain complaint, usually resulting in a question like “what disease causes this complaint and how can it be treated?” Then, Hacking divides “theory” into three distinct kinds of knowledge. First background knowledge, which is unstructured and often remains implicit or is taken for granted. I think that the background knowledge can be interpreted as the aesthetic ideals that Khushf identifies: the purpose of medicine and it’s the scientific ideal. The second kind is the systematic theory, that I interpret as basic scientific knowledge of anatomy, physiology and pathology, but can also refer to outcomes from clinical trials and other general medical knowledge. The third kind of theory Hacking calls the “topical hypothesis”, that what connects systematic theory to phenomena. In the cases of Anne and Betty we saw that doctors often make predictions about what they will find in a diagnostic test, or how diagnosis or treatment decisions are affected by a certain outcome. Thus, topical hypothesis are often used in clinical reasoning. The last aspect of “ideas” is the modeling of an apparatus. Doctors often have a (undetailed) notion of how an apparatus works, for example how sound waves produce an image in ultrasound, but this notion plays only a small role in clinical decision-making. Rather, doctors learn how to connect the outcome of a measurement to a clinically relevant theory, like a diagnosis, a

prognosis, or possible treatments. This often results in a “naïve conception” of how measurement instruments work and their role in clinical decision-making. Later I will elaborate on this naïve conception in more detail.

Second, Hacking describes the category of “things”, entailing the following elements: the target of the experiment, the source of modification, detectors, tools and data generators. Hacking describes that the target of investigation is prepared to enable experimentation using a specific apparatus. In clinical practice, the target is the patient, who also needs to be prepared or adapted to make a measurement. For example, patients have to lie still in a certain position in order to make a MRI-scan, and an ultrasound requires applying a gel to conduct sound waves. Often, only a piece of a patient is investigated, like a blood, urine or tissue sample. For the laboratory sciences, Hacking then describes a source of modification, an apparatus that alters or interferes with the target. Here, the clinical practice deviates from the laboratory science practice. In clinical diagnosis, an apparatus that modifies the target (patient) has a different role. Although they are not often used during clinical decision-making (some diagnostic devices require an alteration to enhance a specific property, for example in contrast enhanced MRI), treatment decisions are intertwined with treatment options, which is dependent on available treatment devices and medication. In other words, the availability of modification devices has an impact on what should be measured to inform diagnosis that allows treatment. The detectors in the clinical setting are the physical set-ups of devices, for example the MRI-scanner, or the ultrasound probe. The data generator is related to this set-up, but entails digitalization and connection to a computer (as in many imaging devices), in order to produce graphs, images or numbers. In some cases, this data generation is not yet automated, for example in histological pathology the pathologist examines the prepared tissue samples. With tools, Hacking mean “ any off-the-shelf device, especially one developed in a discipline unrelated to the immediate experimenter”.

Last, Hacking identifies a third category, which he calls “marks and the manipulation of marks” and includes data, data processing and interpretation of data. *Data processing* consists of three types, of which the first is *data assessment*, for example statistical methods to assess the probable error or other types to estimate the systematic error. According to Hacking, this requires “explicit knowledge of the theory of the apparatus”. The second type of data processing is *data reduction*, which transforms vast amounts of data to something that researchers (or doctors) can work with, for example, a graph, a number or an image, by supposedly theory-neutral methods. The third, *data analysis*, is not theory-neutral, rather, the best approach to data analysis is chosen in light of the experimental question, the topical hypotheses or the modeling of the apparatus. Finally, the *interpretation of data*, according to Hacking, “demands theory at least at the level of background knowledge, and often at every other level.” Data in clinical practice are processed (assessed, reduced and analyzed) in an extensive system of technicians, radiographers and computer programs before appearing at the physician’s desk. These processing steps are standardized for each hospital, by choosing a certain analysis program developed by medical technology companies or academic engineers, and producing protocols that describes which steps should be taken by whom to go from the (raw) data to images or graphs. Thus, an individual physician does not deal with data processing. For particular types of measurement, the interpretation is left to specialists, for example radiologists who interpret MRI’s, CT’s and X-rays, nuclear physicians who interpret nuclear medicine images like PET-scans and pathologists who analyze histological samples.

Together with the images, physicians receive a report of the specialists' finding. In summary, in terms of marks and measurements, the work of doctors is mainly concerned with the interpretation of measurements, to answer the clinical question initiated by the patient. The standardizing and "outsourcing" of data processing results, again, in a naïve conception of the role of measurement instruments in clinical reasoning.

In his theory of "self-vindication", Hacking argues that in laboratory sciences ideas, apparatus and observations are mutually adjusted to construct a "coherent theory of thought, action, materials and marks" (pg. 58). It is due to this mutual adjustment that sciences produce theories that are "true to" phenomena, measured by the corresponding apparatus. This process of mutually adjustment entails tinkering with apparatus, dismissing data, selecting data analysis methods, changing topical hypotheses or adjusting the question. In clinical decision making, physicians have to go through a similar process for each individual patient. The question initiated by the patient's complaint, gets adjusted to match topical hypotheses that fit together with systematic and background theory, and the data acquired from measurements.

What is notable in Hacking's theory is his emphasis on the role of what he calls "materiel": "the apparatus, the instruments, the substances or objects investigated" (pg. 32). It is by adjusting the interpretation of measurements, adapting a processing procedure, tinkering with instruments and the mutual adjustment of those aspects to the "ideas" that scientific theories true to phenomena are constructed. Therefore, comparing the elements of medical decision-making to Hacking's elements of laboratory experiments also underlines the role of instruments, data and data processing in diagnosis and treatment decisions. By translating Hacking's taxonomy into one that applies to medical practice, it becomes evident that the intellectual and material dimensions are strongly intertwined: both the material dimension (in the form of "things") and the intellectual dimension ("ideas") are prominently present in Hacking's taxonomy. The other dimensions are also reflected in the elements of the taxonomy, but to a lesser extent. In the following chapter, I will apply Hacking's taxonomy to the cases of Anne and Betty, to further investigate how the material and intellectual dimensions are combined in the process of theory-formation (or the generation of knowledge of individual patients), and how this relates to the other two dimensions.

3.6. Conclusion

At the beginning of this chapter I have divided the clinical decision-making context into four dimensions: the dimension of the patient-doctor interactions, the organizational dimension, the material dimension and the intellectual dimension. In this view, the epistemological responsibility entails navigating within this context and accounting for all four dimensions. The intellectual work of doctors is to gather and fit together heterogeneous elements to construct a coherent picture of a patient that is consistent with general knowledge.

Referring to Hacking and Mol, I have argued that measurements and data play a crucial role in the construction of theory, and that the material context structures how clinical decisions are made. The notion that the generated knowledge of a patient functions as an epistemic tool clarifies that the fitting together of these elements is performed with a specific purpose: understanding and controlling disease, to make the best possible diagnosis and treatment decisions. With this taxonomy, based on the taxonomy of the elements of laboratory science

Aspects of the Epistemological Responsibility of Doctors

by Hacking, the material and intellectual dimensions are bridged by emphasizing the entanglement of knowledge, theories, measurements, instruments and data.

The relevance of this entanglement for the epistemological responsibility of doctors is that by emphasizing the importance of the material and intellectual dimensions and their entanglement, it is also emphasized that the specificities of a case are important. An epistemologically responsible doctor is aware that specific instruments are used to generate specific information for a specific patient which is included to construct an epistemic tool for a specific purpose. Within these specific context, the role of an individual physician is to make good quality decisions for their patients, while taking into account aspects of all four dimensions of the context. By shifting the focus from “objective truth” to “epistemic use”, thus introducing alternative scientific criteria for guiding and assessing clinical reasoning, I believe that the strict dichotomy between subjective and objective resulting from the narrow view of science can be overcome. Ideas about the quality of clinical reasoning is covered by the notion of the “epistemological responsibility” of doctors. Therefore, this notion does better justice to the work of doctors, which is both epistemologically challenging and inherently bound to a specific situation.

In summary, the epistemological responsibility of doctors consists of navigating between four dimensions of the context, each with their own specificities. The intellectual challenge is to fit together heterogeneous elements, from scientific theories to measurement instruments, by mutual adjustment. In this process of fitting together, doctors construct a coherent “picture” of a patient that is consistent with existing general knowledge, and true to phenomena. This picture allows them to reason (e.g. asking questions, forming hypothesis and making plans) for a specific purpose - to make the best possible diagnosis and treatment decisions.

References

Boon M. (2012) Scientific concepts in the engineering sciences: epistemic tools for creating and intervening with phenomena, In: Feest U, Steinle F, editors. *Scientific concepts and investigative practice*. Berlin studies in knowledge research, p. 219–243, Berlin: Walter de Gruyter;

Hacking I. (1992) The self-vindication of the laboratory sciences, In: Pickering A. (ed.) *Science as practice and culture*, p. 29-64, Chicago: University of Chicago press

Knuuttila T. and Boon M. (2011) *How do models give us knowledge? The case of Carnot's ideal heat engine*, *European journal for philosophy of science*, 1 (3). pp. 309-334.

Mol A (2002) *The body Multiple. Ontology in Medical Practice*, Durham and London: Duke University Press

3b. Case study: The taxonomy of clinical decision-making

In the chapter 2b, I have introduced the cases of Anne and Betty, who both had urine incontinence, to demonstrate how clinical reasoning in these cases was different from the rule-based reasoning put forward by EBM epistemology and illustrate some aspects of epistemologically responsible decision-making. I have argued that the range of elements that should be included in clinical decision-making is much broader than EBM epistemology accounts for. Elements that EBM epistemology leaves out are for example unquantifiable and “subjective” elements, like behavior. Another undervalued element is knowledge of instruments that produce data. In the previous chapter I presented a taxonomy of the elements of clinical reasoning, based on Ian Hacking’s taxonomy of laboratory sciences. This taxonomy provides a detailed description of the elements of the knowledge of instruments and their role in theory formation. To clarify the role of the different elements in practice, below, I will apply the taxonomy to the case studies of Anne and Betty.

3b.1. Ideas

1. question(s), initiated by patient

The initial complaint of the two girls, Anne and Betty, is similar: urine incontinence. This initial question is explored by doctors by starting the conversation with an open question (e.g. “how can I help you?”). After formulating this first (broad) question based on the reason for the patient to visit the doctor, the question is adjusted to one that is workable for physicians. For example, in Betty’s story, the initial question, posed by Betty’s parents, “what is wrong with my daughter?” changes into “what caused the urine incontinence?” When new information comes available, the question is adjusted again. When the meatal obstruction that was the initial cause of Betty’s voiding problems was obviated, the incontinence problems returned and hyperlaxity was diagnosed, changing the question to “what is the impact of hyperlaxity on urine incontinence, and how to deal with this?” Finally, when the girl starts suffering pains in her leg the question (for the urologists) changes into “how is this related to the urological disorders and the hyperlaxity that was found?”

In other words, the questions for investigation, although initiated by the patient, are continuously altered and adjusted to newly available information and experiences. This is the process in which knowledge about the patient functions as an epistemic tool: adjusting the “picture” a doctor has constructed of the patient by newly available information, allows adjusting the question to the new situation. This, in turn, results in a new direction for the diagnostic process, introducing new diagnostic instruments and hypotheses.

2. background knowledge, scientific ideal & purpose of medicine

Doctors operate against a background of knowledge and presuppositions. These are so “basic” that they are “forgotten” or taken for granted in the day-to-day practice. Earlier, I interpreted the background knowledge as the scientific ideal and purpose of medicine, which is to understand and control diseases (as expressed by Khushf). Another aspect of “background knowledge” are presuppositions and traditions: for example, one of the presuppositions of medicine is that there is an identifiable cause for a complaint, and an

important medical tradition is that young doctors learn by apprenticeship in a strongly hierarchical system.

In the cases of Anne and Betty, background knowledge is not easy to identify because of its implicit character. For example, the idea the notion of causes and effect: although the causal reasoning of doctors is much more complex than the simple “if A, then B” found EBM guidelines, doctors are continuously looking for a cause of disease as a starting point to cure the disease. Therefore, in both cases, the meatal obstruction that causes a disturbed voiding pattern is the first thing that is addressed. Furthermore, there is a preference for certain types of causes, for example, “physical causes” or more specific “mechanical” or “local causes” (like a meatal obstruction) over “behavioral”, or “systemic”.

3. systematic theory, basic scientific knowledge of anatomy, physiology & pathology

This knowledge consists of both general textbook knowledge, obtained by education, and recent scientific insights, obtained by visits to conferences, exchanges with colleagues and reading scientific journals. The basic knowledge of urine incontinence, relevant for the cases of Anne and Betty are (partly) summarized in the diagrams of the “brown and yellow circles” at the end of chapter 2. As said before, this diagram can be applied in a flexibly way, by reversing cause and effect and accounting for the impact of external factor in multiple possible ways. It is therefore possible to adjust systematic theory to the current case.

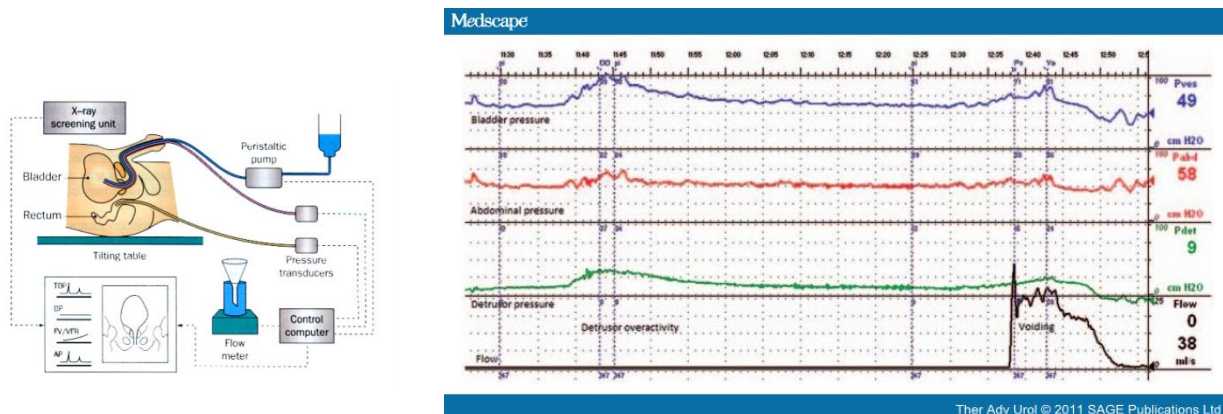
4. topical hypothesis, what connects systematic theory to observations

Based on their experience, doctors learn to recognize patterns and relations and use these to make predictions about what they will observe or find in diagnostic tests. For example, in the case of Anne, the story of a girl with recurrent UTI's and obstructed voiding is familiar, and can also be related to an overactive pelvic floor or hyperlaxity. Observations that play a role in this story are a thickened bladder wall – which can be detected with ultrasonography – obstructed voiding pattern – which is detected using uroflow measurements – and overactivity of the pelvic muscle – which can be detected using urodynamic examination. Furthermore, observations that do not require measurement devices also play a role in these cases. For example, the hyperlaxity of Betty is observed by the physician by testing the flexibility of the wrist and ankles, and included in the diagnostic story by a theory about the relation between general hyperlaxity and urine incontinence and fecal obstipation.

5. modeling of the apparatus, the theory of how an instrument works

In the previous chapter, I have argued that doctors usually have a limited, undetailed notion of how an instrument works, which results in a naïve conception of how these instruments generate information: as a device that passively registers facts about patients. An example is ultrasonography with which the kidneys and bladder can be visualized in real-time, based on the reflection (or “echo”) of sound waves by these organs. The probe both emits ultrasound waves and detects the reflected ultrasound waves that are translated into black and white images. Because ultrasonography is quick, safe and painless, it can be used in the outpatient clinic during regular consultations. Doctors learn how to interpret the images they see on the screen and how to relate these to the complaints of their patients. For example, both Anne and Betty receive an ultrasonography, to check for a thickened bladder wall and a large rectum diameter. Doctors know how these look on an ultrasonography image, for example an overfilled rectum appears as a light spot behind the bladder. By their

training, doctors can immediately recognize a kidney by their shape and size, and therefore, for them, looking at an ultrasonography image is like looking at a picture.



A.

B.

Figure 1: Urodynamic examination. A: set-up of an urodynamic examination (including X-ray to visualize bladder filling and reflux), B: pressure and flow graphs resulting from an urodynamic examination

3b.2. Things

6. target, patient, or sample of patient (blood, urine, biopsy)

In these cases, Anne and Betty are the target of investigation. To undergo measurements, they have to be prepared. For example, to make an ultrasonography image, they have to lie down on the examination table so that the probe can be placed at the right location and transducer gel has to be applied to conduct sound waves. For uroflow measurements, children have to take place at a special toilet. In order to be able to void, children have to drink a big glass of water or lemonade when they arrive in the hospital, so that their bladder is full by the time of examination. The pediatric urologist first makes an ultrasonography of the full bladder, then the child is taken to the uroflow-toilet by the doctor's assistant and afterwards another ultrasound is made to see if the bladder is completely emptied.

Ultimately, when no solution can be found for Anne and Betty, they are also uroodynamically examined. This requires a lot of (uncomfortable) preparation: two catheters are inserted in the bladder, and one in the rectum, and sticker electrodes are placed around the rectal sphincter. The catheters inside the bladder and rectum measure pressure, whereas the sticker electrodes measure muscle activity (electromyography, EMG). During the examination, the bladder is filled with sterile water. The patient is asked to indicate when she feels urge, but to hold it until the examiner allows voiding. Furthermore, patients are asked to cough or squeeze during the examination, to simulate situations that cause high pressure in the bladder or stomach.

In short, the target of investigation has to be adjusted to the apparatus, enabling measurements. When the target is the patient, the amount of adjustment is limited. Often only a sample is examined, in that case the preparation can be more extensive, for example the fixing, cutting, selecting and coloring of a biopsy tissue sample for microscopic study.

The Epistemology of Clinical Decision-Making

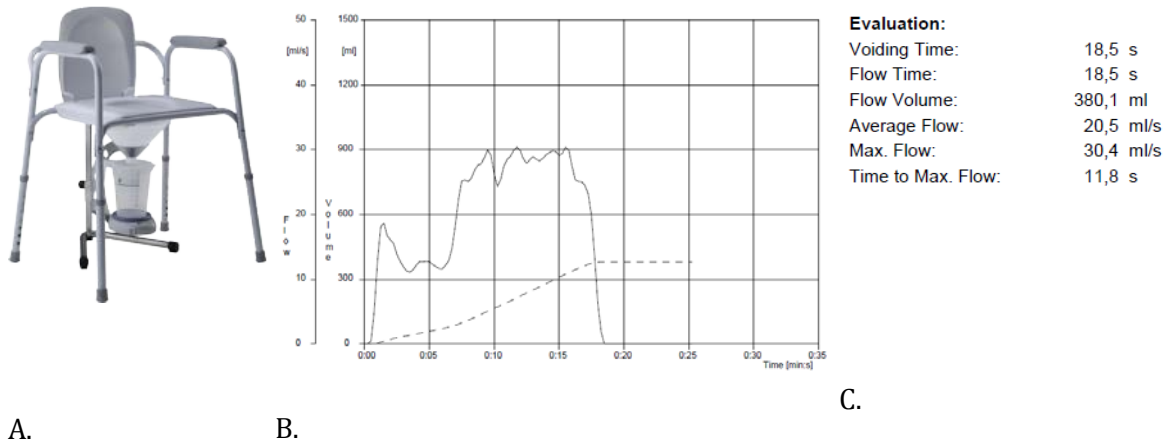


Figure 2: Uroflow measurement. A: Uroflow toilet, B: flow and volume graph, C: flow values

7. source of modification, treatment options

As mentioned in the previous chapter, the source of modification has a different role in the clinic than in the laboratory sciences. It does not play a role in measurements that should provide information for diagnosis and treatment decision. Nevertheless, modification of the target (patient) is one of the core businesses of medicine, if treatment is seen as a source of modification. Therefore, I interpret this element as “possible sources of modification,” or in other words, the treatment options. This is indeed an important aspect in clinical reasoning: the available treatments direct how a disease is diagnosed.

For urine incontinence possible treatments are urotraining, medication and surgery. The two girls both receive all three treatments, both starting with meatal desobstruction thus relieving the mechanical obstruction that made voiding complicated in the first place. But for Anne and Betty, this was not enough, since for both girls the signaling pathways that are responsible for the feeling of urge had been disturbed. This can be improved in two ways: by urotraining, which is either an intensive, 10 day in-house training program focused on how the bladder works, how to feel when you have to pee, voiding regularly, etc. or intensive counseling for training at home. For this treatment, children need to be old, compliant and motivated enough to understand the goals, theory and feedback of the training. Furthermore, the “mechanics” need to be in order, meaning that obstructions are removed prior to training, but also that doctors have to be sure that there is no neurological disorder or problems with the pelvic floor. If there are reasons to suspect that there are problems, it will be assessed by urodynamic examination. Medication (oxybutynin, which relaxes the bladder muscle and macrogol, a laxative) are used as support for other treatments, and can help by fighting of the first big difficulties (like diminishing incontinence from several times a day to several times a week in the case of Anne) but usually do not solve all problems. Furthermore, medication often require a lot of adjustments to find the right dosage and intake scheme, making it somewhat of a trial-and-error process.

A last treatment option is “advice”. When removing the mechanical obstruction that had caused her problems did not completely cure the incontinence, Anne was still too young to be trained. Beside adjusting the medication, doctors give advice on how to deal with the problems, not solving them but making them manageable.

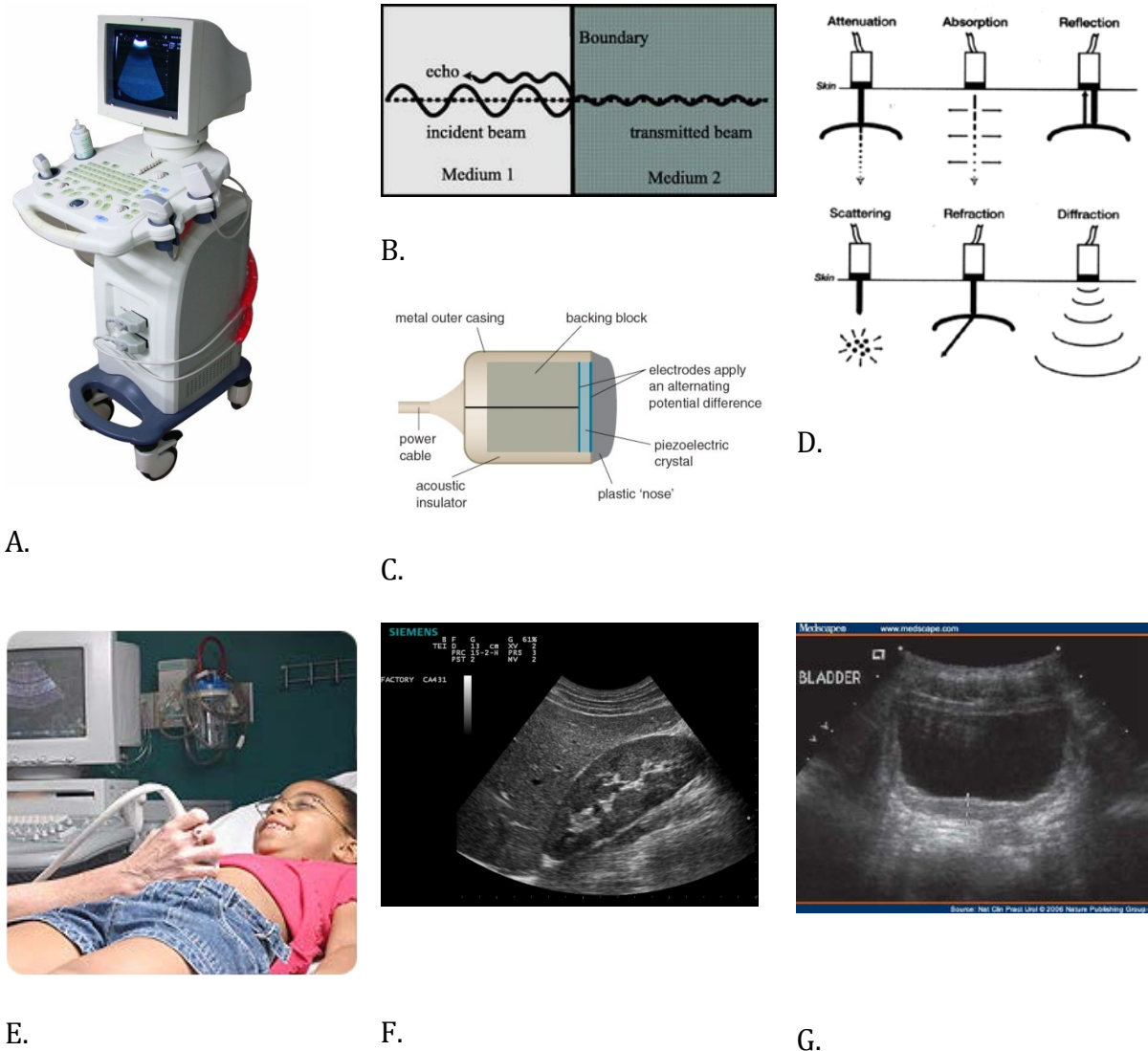


Figure 3: Ultrasonography. A: Sonography equipment, B: Ultrasound echo, C: transducer, D: ultrasound tissue interactions, E: making an ultrasonography, F: kidney ultrasound image, G: bladder ultrasound image

8,9,10, material set-up, Detectors, tools and data generators

For the clinical practice, the following three aspects can be taken together as one element of the taxonomy. Although it is good to realize that the material set-up exists of several elements with a different process, the instruments that are used in clinical practice are in such a stage of development that the elements are integrated and a strict distinction between them is not relevant anymore. The relevant understanding is that the material set-up of an instrument, consisting of detectors, tools and data generators, shapes the resulting measurement.

8. detectors, determine or measure the result of interference or modification of the target

Detector are, for example, the ultrasound probe detecting reflected sound waves, the pressure meters in the catheters, the electrode stickers measuring electrical activity, and the flow meter measuring the voided volume per second.

9. tools, things we rely on for measurements, off-the-shelf devices

These include, for example, the sound wave conducting gel for ultrasonography and the catheters for urodynamic examinations.

10. data generators, for example scanners (no sharp distinction with (9))

In ultrasonography, the received sound waves are turned into electrical pulses by the transducer. In the urodynamic measurements, the amplitude, peak time and number of phases in the EMG are registered and in uroflow measurement, the change of measured volume is expressed in numbers before sending the information to the computer for data processing.

3b.3. Marks and manipulation of marks

11. data, 'raw data', what a data generator produces

In the clinical practice, physicians do not get to see the raw data of a measurement, but the end product of data processing (12, 13 and 14): sonography images, the pressure and EMG graphs from the urodynamic examinations and the uroflow graph.

12. data assessment, theory-neutral

Data assessment plays only a small role in clinical decision-making, but doctors are often aware of differences in quality of measurements and follow criteria to ensure this quality. For example, in ultrasonography, the whole kidney should be visualized, and in uroflow the voided volume should be sufficient. If the quality of a measurement is not sufficient, the measurement is repeated if possible. Otherwise, doctor are careful to draw conclusions based on these measurements.

13. data reduction, transformation of vast numbers of data into manageable quantities

For example, in uroflow measurements, the volume change per second is visualized in a graph, and the peak flow, flow time and voided volume are calculated. The sonography measurement are translated into images (this process overlaps with (14), since reconstruction of an image requires models and presuppositions about the behavior of sound waves in tissues, which is built into the image reconstruction algorithms.) The urodynamic scans are also visualized in a row of synchronized graphs.

14. data analysis, analysis with theory-laden techniques

Sonograms are analyzed by physicians by performing length-measurement: the length of the kidney, the bladder diameter, the thickness of the bladder wall, etc. In urodynamic examinations several events are marked in the pressure and EMG curves, for example the first feeling of urge, the moment of voiding, etc. In other types of measurements, like X-rays, MRI scans or histology, another specialist provides analysis of the data. For example, in a biopsy, pathologists describe the morphology of the cells and the presence of inflammation, and associate these with disease processes. In those cases, data analysis has overlap with interpretation of data.

15. interpretation of data, demands theories at several levels

After measurement, doctors receive the results of the measurements in the form of numbers, graphs and images. They assign meaning to these measurements by relating them to the relevant systematic theories and the topical hypotheses. For example the shape of the

uroflow graph in the case of Anne is “staccato”. This is an observation that is in line with the prediction made based on the available information, knowledge, patterns and relationships. UTI’s and voiding problems are the result of an obstruction, which will be manifested in the uroflow graph with a “staccato” pattern.

3b.4. The taxonomy of clinical decision-making within four dimensions

In the previous chapter I have argued that clinical decision-making takes place within a context that consists of four dimensions. Furthermore, I claimed that the intellectual and the material dimensions are entanglement in the process of generating knowledge about individual patients, as the empirical and conceptual input of the epistemological tool. The taxonomy of the elements of clinical reasoning illustrates this entanglement. But by applying this taxonomy to the cases of Anne and Betty, it also becomes clear that the other dimensions play role in the process of generating knowledge about a specific patient. As a consequence, all four dimensions should be considered as a source of input for this process. The kind of input the dimensions yield and its role in the knowledge construction process can be analyzed in relation to the taxonomy. To summarize and illustrate the relationship, I present a matrix (figure 4) to equate the four contexts to the elements of the taxonomy. Because of their similarities, I took the three different types of data processing together in this matrix.

	I Patient-doctor interaction	II Organization	III Material	IV Intellectual
1. Ideas				
a. Questions	[I-1a]			[IV-1a]
b. Background knowledge				[IV-1b]
c. Systematic theory				[IV-1c]
d. Topical hypothesis	[I-1d]			[IV-1d]
e. Modeling of the apparatus			[III-1e]	[IV-1e]
2. Things				
a. Target	[I-2a]		[III-2a]	
b. Source of modification	[I-2b]	[II-2b]	[III-2b]	[IV-2b]
c. Material set-up			[III-2c]	
3. Marks				
a. Data	[XX]		[III-3a]	[XX]
b. Data processing		[II-3b]	[III-3b]	[XX]
c. Interpretation of data	[I-3c]	[II-3c]	[III-3c]	[IV-3c]

Figure 4: four contexts vs. taxonomy matrix. In the matrix, context/element combination are marked with a code combining the context number (I-IV) and the number of the element (1a-3c).

This matrix illustrates several points: first, that many elements relate to more than one context, which illustrates that for many aspects of clinical decision-making, multiple dimensions are relevant and intertwined. For example, by formulation of the question and hypotheses (1a and 1d), dimensions I and IV are intertwined. The material and intellectual dimensions overlap and are intertwined for many elements; the element of modeling of the apparatus (1e), the source of modification (2b) and the interpretation of data (3b). Furthermore, the dimension of organization is relevant for the elements source of modification (2b, for example RCT's about the efficiency of treatment), data processing (3b, e.g. protocols on how to use data processing programs), and the interpretation of data (3c, e.g. are images interpreted by radiologists, in multidisciplinary meeting or by the doctors themselves).

Secondly, in the group “marks” there are several dimensions that I would claim are relevant for some elements, but that are in my opinion not sufficiently recognized in the taxonomy I have presented so far, based on the theory of Hacking and the comparison to the cases of Anne and Betty. I have marked those with [XX]. First, the dimension of the patient in the category data (3a). In the taxonomy, the only source of data is from measurement instruments, omitting the patient-doctor interaction as a possible source of data. Although in this taxonomy the relevance of the patient-doctor interaction is recognized for the formulation of questions and hypothesis and even for the selection of possible treatment methods it is not seen as data that should be processed and interpreted. In my view, for the epistemological responsibility of doctors, this type of information should be assessed, processed and interpreted similar to information from measurements. Second, the intellectual dimension should be more pronouncedly included in the elements “data” and “data processing”. Doctors are often not aware of the raw data and the data processing underlying the resulting measurements (numbers, graphs, images) that are presented to them for interpretation. In my opinion, these three “missing links” should be included in clinical decision-making more pronouncedly as an aspect of the epistemological responsibility of doctors.

3b.5. Conclusion

In the self-vindication of laboratory science, Hacking argues that the elements of the taxonomy above are mutually adjusted to construct a coherent and consistent theory. In my theory of clinical reasoning, doctors have to construct a new coherent and consistent theory or knowledge for each individual patient, by fitting together and mutually adjusting heterogeneous elements. This knowledge is used as an epistemic tool, that enables doctors to ask questions, form hypotheses and to define new directions for investigation. Applying Hacking's taxonomy to clinical decision-making and subsequently to the cases of Anne and Betty reveals that this process of mutual adjustment entails several types of theories, topical hypotheses, questions, instruments and data. This makes clear that in the decision-making process there is continuous adjustment of systematic theory, questions, topical hypothesis, the target and the possible manipulations of the target. By comparing the elements of the taxonomy to the four dimensions of the clinical decision-making context, it becomes clear that these dimensions are all relevant and intertwined aspects of the epistemological responsibility of doctors.

Measurements in Clinical Decision-Making

Doctors have the responsibility to be prudent and informed about all dimensions. This implies for example to practice their communication skills to be successfully informed about the patient's story, and keeping up-to-date with the protocols and guidelines regarding their field of expertise and hospital. But also to be aware of the role of the material dimensions, how instruments are entangled with what we (can) know and how we make decisions.

4. Measurements in clinical decision-making

In the first two chapters, I have studied the historical development of clinical medicine and the current epistemologies concerning clinical decision-making, to better understand the work of doctors. In the third chapter I have touched upon an alternative epistemology by providing an outline for a framework in which the epistemological responsibility of doctors has a central role, enabling to focus on particulars instead of the general, in order to overcome the objective- subjective dichotomy and account for influences from multiple contexts. In relation to the alternative approach, I have introduced the idea that technological measurements are more complex and play a more sophisticated role in clinical decision-making than usually assumed. In this chapter, I will argue that a better understanding of the role of measurements in clinical decision-making is required, and provide an initial exploration of the role of medical imaging technologies as an example.

4.1 A naïve conception of measurement instruments

In chapter 3, I argue that the traditional medical epistemologies, like EBM and “the art of medicine”, pay no explicit attention to the role that measurement instruments play. Yet, in EBM, there is an increasing preference of measurements like lab data and images in reasoning about diagnosis and treatment, because it is considered as “hard data” that is more objective and therefore more reliable than “soft data” acquired by history taking and the physical exam. This undue reliance on measurement is the result of a naïve conception of how measurement technologies are used in medical practice: as a device that passively registers facts about patients.

For example, in this naïve conception making a medical image is understood as taking a “photograph” of a person’s inside in which a doctor can directly see what is wrong (see figure 1). However, as also highlighted by the taxonomy of Hacking, the data recorded by most imaging devices (like CT and MRI) require multiple processing steps before presentation as an image. These processing steps are performed by analysis programs and technicians following standardized protocols, without doctors being involved in this process.

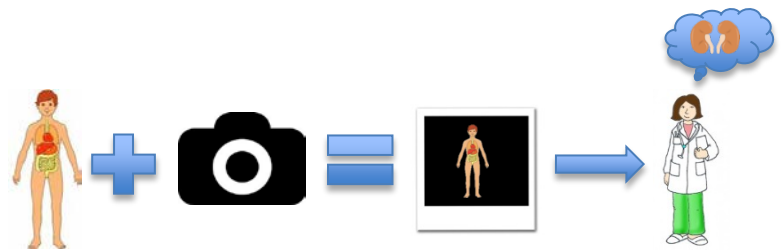


Figure 1: Medical imaging as photography, the naïve conception of technology in clinical practice

A less naïve representation of imaging is illustrated in figure 2. In this conception, an image is shaped in the interaction between the elements from the knowledge domain of doctors (here represented by the background knowledge, systematic theory, topical hypothesis, target and source of modification) and the elements from the knowledge domain of engineers (modeling of the apparatus, detectors, tools, data generators, raw data and data processing). We cannot expect of doctors to be experts in the domain of engineering, but they should nevertheless be aware that a complex system of elements make up the “technological” part of a measurement and with that shape the resulting outcome. Therefore, I think that a better understanding of the acquisition and processing of measurements will improve the quality of diagnoses. The interpretation of data can be better adjusted to the other elements when doctors have a

The Epistemology of Clinical Decision-Making

better understanding of how they are constructed. This requires a more accurate understanding of the role of technology in clinical decision-making.

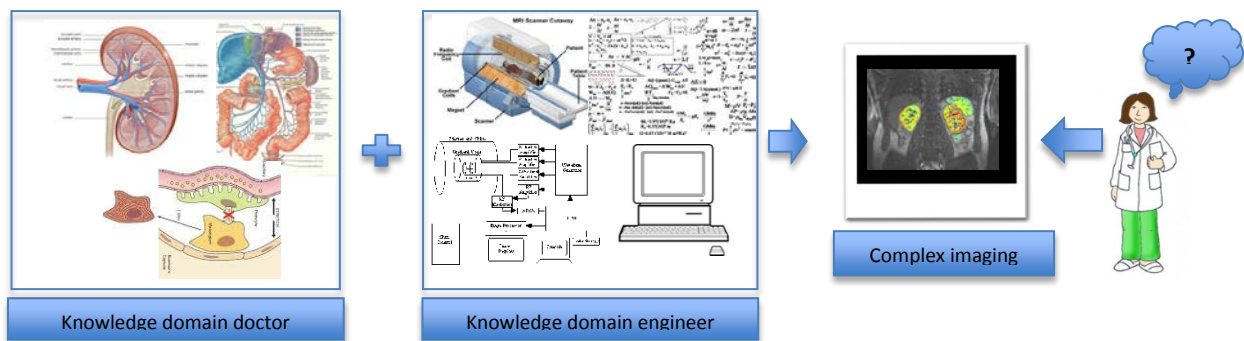


Figure 2: Complex image emerges in an interaction between technological and medical systems. Knowledge from both kinds of systems is required to understand and interpret the images.

4.2 Measurements and the epistemological responsibility of doctors

Measurements only provide a limited perspective on the patient's disease, omitting the aspects that cannot be measured. In contrast, the excessive reliance on "hard data" obtained from measurement and a dismissal of other "soft" information in EBM epistemology reflects a simplistic view of how information from measurements is obtained. In this simplistic view, measurements are facts that directly represent a property of the patient, organ or tissue under investigation. However, as illustrated by the taxonomy of clinical reasoning, the acquisition and use of data is affected by many aspects, including for example theories of how the instruments works and data processing. Hence, measurements cannot simply be considered a "fact." This simplistic view of EBM epistemology obscures the understanding of how "hard data" is obtained and with that how to correctly interpret and value this data when it is combined with other information.

Furthermore, by promoting "objectivity" and equating objective data to numerical data, EBM epistemology prefers quantitative measurements over other measurements, observations or information. However, because there is no comprehensive understanding of what quantitative measurements are and how they are produced in EBM theory it overlooks two important and related aspects. First, the impact that the availability and use of instruments have on how we consider the concept "disease" and how doctors approach clinical decision-making. Second, the influence of multiple acquisition and processing steps on the outcome of a measurement.

I described the epistemological responsibility of doctors as "making the best possible judgment regarding diagnosis and treatment, using good quality data." Focusing on the epistemological responsibility of doctors enables overcoming the objective - subjective dichotomy and to emphasize that although clinical decision-making concerns individual doctors and patients, it is not necessary subjective and can still be systematic and rational. In this view, measurements and observations bridge the gap between general knowledge and a particular patient. In addition to Hacking's taxonomy in the clinical practice, other types of information are also available, for example, the patient's story, the outcome of the physical exam, questionnaires or diaries and standardized qualitative observations, like microscopic

analysis of a biopsy. Furthermore, Annemarie Mol argues that the type of information that is employed in thinking about a patient directs clinical decision-making (see Chapter 3). Therefore, in clinical reasoning, different types of information should be considered as an array of different ways of looking at patients and their disease.

The question is; is one way of looking at a patient (e.g. through instruments that produce “hard data”) more valuable than another way (e.g. through the patients story)? Khushf, following Flexner, makes a distinction between two types of data: “First, [...] the signs and symptoms that constitute the clinical data, and serve as a basis for the initial formulation of the hypothesis. Second, there are data that enable the assessment of the hypothesis, including laboratory and autopsy data, and the probabilistic data associated with effective management of the patient’s condition” (pg. 151). This distinction suggests that both types of data are valuable in clinical decision-making, albeit in a different role. Khushf therefore argues that clinical data should not be dismissed as more subjective or less reliable than “hard data”. However, the case of Anne and Betty shows that the distinction between discovery and justification cannot be drawn so strictly: diagnosis and treatment is an ongoing process. Within this process new information becomes available, it has to be included in the knowledge that was generated about the patient, adjusting the epistemic tool, in order to adjust questions and reconsider hypotheses. For example, Anne and Betty both initially presented with similar complaints, leading to similar hypotheses. However, during the process, the outcome for both girls changed. Therefore, regarding “clinical data” as the initial input for theory formation and measurement as data for confirmation does not do justice to the complex process of diagnosis and treatment.

Then, how to handle different types of information without establishing a rigid hierarchy? In my opinion, it is part of the epistemic responsibility of doctors to handle and value different kinds of information, which entails being involved in acquisition and understanding the applied methods. With that, doctors should understand the strengths and pitfalls of all methods that produce medical information. For some methods, like history taking and physical exam the methods are well known by clinicians, enabling critical assessment of the results. However, doctors usually have little knowledge of acquisition and processing of most technological measurements, resulting in the naïve conception that I have mentioned at the beginning of this chapter.

In short, I conclude that, regarding to role of medical measurement instruments in clinical :

- 1) Technological measurements are enabling but also directing and limiting. They enable to observe phenomena that would otherwise not be accessible, e.g. to hear heart sounds with a stethoscope. At the same time, they direct the course of decision-making by only enabling access to certain phenomena, leaving out others.
- 2) Data acquisition and processing has an impact on the resulting measurement outcome. The instrumentation is decisive for what data can be recorded, and subsequently the algorithms that are used to process data. The data processing algorithms simplify and interpolate the data, and with that partly determine the shape of resulting outcome.
- 3) The resulting outcome directs diagnosis and treatment, by making a one course of action appear more logical or applicable than another.

And therefore, for doctors to fulfill their epistemological responsibility of appropriately valuing medical information, a more elaborate understanding of measurement instruments, their methods and their impacts is needed. In the following paragraphs I will make a start with such an analysis for medical imaging devices, and for the development of innovative technologies for medical practice.

4.3. Medical imaging

In medical imaging, to produce an image a value is measured for each pixel that represents a location in the organ tissue under investigation. The value is based on the properties of the instrument and the tissue (e.g. Hounsfield units in a CT scan or T1/T2 relaxation for MRI). Therefore, I understand an image as a “map of measured data”. Doctors usually use this map in a qualitative way: not by assessing the exact values of the pixels, but examining properties like size, shape, and relative intensity of the organ. In some cases, images are used to obtain quantitative data as well: lengths can be measured (kidney size, bladder size, etc.) The same (obtaining qualitative and quantitative information) goes for graphs, like the uroflow and urodynamic examination graphs.

In order to produce images from technologically produced data, the data is processed. Data processing entails methods that simplify and interpolate data, based on models and theories about the interaction of the measuring device and what is measured. What is made visible in the resulting image is therefore not a direct reflection of the patient. Ian Hacking (1981) analyzes the role of the microscopic images in science in his essay *Do we see through a microscope?* He argues that observing an object through a microscope is something different from seeing a tree: “the image must be a *map of interactions between the specimen and the image radiation*” (pg. 137). However, in the end Hacking concludes that we could still speak of “seeing” with a microscope, if the map is a good one. With that he means that there is a direct interaction between “a wave source, an object, and a series of physical events that end up in an image of the object” (pg.151). and that there is excellent reason to believe that what you see is not an artefact of the technology. In other words, there is a *causal* relationship between the object and the image. Furthermore, Hacking argues that in order to see through a microscope, one first needs to learn how to handle the instrument (which is a skill) and how things look under a microscope (which, according to Hacking, requires theoretic knowledge and entails manipulating the object under investigation, “you learn to see through a microscope by doing, not just looking” (pg. 136)). In other words, even though observations using a microscope is different from unaided vision, in some cases researchers “see through” a microscope, but only when certain criteria are met.

Images in the clinical practice differ from seeing through a microscope by a less direct interaction between the source, the object and physical event that result in an image. In most imaging techniques, the raw data that is the result of a direct interaction is processed using mathematical algorithms that model the interaction in order to reconstruct an image. For example, in ultrasonography, a model of the interaction between sound waves, tissue and transducer is used to reconstruct the image on the screen. Yet, doctors would usually regard using these images as “looking” inside the body, similar to Hacking’s idea of “seeing with a microscope”. Joseph Pitt (2011) questions whether these kinds of imaging techniques (Pitt focuses on the scanning tunnel electron microscope, abbreviated STEM) can be compared to microscopic imaging. “Instead of dealing with the physics of light and the properties of

specimens as we do with an optical microscope, with the electron microscope we get a 'picture' of that surface through the use of various computer programs which take the input from the stylus running over the surface and using the physical theory of the properties of matter 'interpret' the results, producing an image" (pg.194). In other words Pitt argues that there is no direct causal relationship between the object and the resulting image. I think that this also agrees with how most medical images are produced (except perhaps X-ray images, although CT, based on the same wave source, is more comparable to STEM.) The problem with STEM is, according to Pitt, that there is no way to verify that what image shows "In the case of the electron microscope, when asked to accept what it produces as a representative image, we are also asked to accept the fact that the assumptions built into the manner in which that image is constructed are correct and reliable." In medical images, this is only partly true: doctors generally know the shape and physiology of organs and have related images to what they see in the operation room. However, intact organs of living and awake patients can only be visualized using medical imaging, making verification a relevant issue.

Anamaria Carusi (2012) argues for a new understanding of the epistemological role of visualizations "as playing a crucial role in the formation of evidence for scientific claims" (pg. 107). In current science, vast amounts of data are translated into "qualitative visual renderings" by mathematical algorithms. According to Carusi, "the resulting visual rendering is a hybrid of the causal and the computational" (pg. 109). These computational modes of visualization entail new ways of connecting data, information and the object. Therefore, Carusi argues that we should rethink or even give up three central distinctions in the epistemology of science. First, the distinction between the qualitative and the quantitative: "during the process of developing the technology, there will be continuous interplay between data in quantitative form, the algorithms for processing that data and producing the visualization, and the qualitative visual evaluation of the progress of the algorithms formation" (pg. 109). Second, the distinction between objective and subjective: although visuals are frequently used in science, it is still seen as subjective and therefore less reliable. The third distinction is the distinction between the causal and the non-causal. Carusi argues that "embodied in the algorithm for image processing, there is a hybridity of causal factors (the way in which the algorithm organizes shapes and contours in the image) and intentional/ informational factors. The resultant images that are viewed for further interpretations are a hybrid of causal and non-causal factors" (pg. 111). In other words, the image is not the result of a chain of causal factors, but of causal factors combined with factors like processing algorithms, that are programmed with an intention to filter, simplify or interpolate data.

Carusi's analysis of computational visualizations has several implications for the understanding of the role of images in medical practice. In my view, medical imaging methods are similar to the computational image processing methods that Carusi refers to. Therefore, the distinctions that Carusi investigates should be studied for specific cases of medical images as well. For the causal relationship between object and image is different for photographs, the microscope, STEM and multiple types of medical imaging methods. Carusi shows that these types of images are of a distinct class and can be considered as a hybrid of causal and non-causal factors. Therefore, to better understand their role in medical epistemology, imaging technology should be studied regarding the complex interrelationship of these factors and the resulting image. In the previous chapters I have often referred to the other two distinctions,

between quantitative and qualitative and subjective and objective, and argued that they are not fruitful in medical epistemology. Carusi makes plausible that these distinctions are also not fruitful to understand the role of visualizations in the epistemology of science. Therefore, to understand the role of medical imaging technology in clinical decision-making, the appropriateness of distinctions need to be settled.

4.4. Innovation

A second reason to study the role of measurement instruments in clinical decision-making is to improve the quality of innovations. A naïve understanding of the role of instruments, like the photographic conception of medical imaging technologies, is unhelpful for innovation in medical practice, because it omits the complexities of medical practice and of the technology, first, and with that, in the first place, hinders the integration of knowledge about the intended medical practice in an early stage of technology development. Secondly, it hinders the translation of a new technology from the “ideal situation” that developers envision to the more complex medical practice. Understanding and interpreting the images that are produced by new technologies require medical knowledge of the anatomy, pathology and physiology - the knowledge domain of doctors - and technical knowledge of the physics and mathematics of the instrument and data processing - the knowledge domain of engineers.

Therefore, for successfully embedding new technologies in medical practice, a close collaboration between doctors and engineers is needed. Currently, most engineers focus on delivering a device that functions well in technological terms, yet without studying the specific application of the product in medical practice. As a result, new technologies do not anticipate the complex clinical reasoning, that I have illustrated in chapter 2b with the cases of Anne and Betty. In contrast, they are designed with an algorithmic use in mind: a technology will provide an unambiguous answer to a clinical question. If this is not (yet) the case, it is considered a design flaw that can be fixed by technological improvement. Furthermore, technology is designed for an “ideal situation”, an ideal representation of the patient and context. However, this “ideal patient” is rarely encountered by doctors.

As I made plausible with the analyses by Hacking, Pitt and Carusi, technologies that produce medical images consist of complex systems. In these complex systems, data is both simplified and interpolated using build-in assumptions to translate digital data into an interpretable image, introducing uncertainty. When a doctor uses images in a clinical context, the interaction between his theoretical and practical knowledge and information from the images will result in diagnosis or treatment decisions. As such, the built-in processing steps required for producing interpretable images steer medical practice in hidden ways. For clinical practice, it is therefore important to ensure that images steer in a desirable way. Hence, the knowledge domains of doctors and engineers need to be integrated. This requires a better understanding of the epistemology of clinical practice, and the role of technological measurements within that practice. Therefore, it is the epistemological responsibility of the engineers that develop technology for clinical practice and of physicians that will use them to improve this understanding and integrate it in the development process.

4.4. Conclusion

The role of measurements and of medical images in particular in clinical decision-making is poorly understood. In EBM epistemology, quantitative measurements have the reputation of being objective and therefore more reliable than other types of information. However, Carusi, Pitt and Hacking make plausible that looking at images is not similar to looking at a photograph, and hence that a naïve conception of measurement is not accurate. Because measurement outcomes direct diagnosis and treatment decisions, the complex systems that produce measurements steer clinical practice in hidden ways.

I would not argue that doctors need to understand all aspects of a measurement system to be able to use the outcome to reason about diagnosis and treatment. However, I would argue that, for epistemologically responsible clinical decision-making, doctors at least need to be aware of the fact that these measurements, especially images, result from complex systems that shape the outcome. Doctors need to cultivate skills that enable them to realistically assess the outcomes of measurements and to value them in relation to other information they have at hand. Realizing that technological measurements are not as “objective” as they seem, but rather provide another perspective on a patient and their disease among other perspectives would be a more epistemologically responsible attitude towards technological measurements than the undue reliance put forward in EBM epistemology. In contrast, in relation to the development of innovative technologies for clinical practice, a detailed understanding of the role of measurements in clinical decision-making and the impact of the complex technological systems that produce the measurements is needed. In order to develop technologies that produce information that is relevant and fitting for clinical decision-making, not only the technological accuracy of an instrument should be considered, but developers should anticipate the expected uses of the technology and the measurement outcomes.

References

Carusi A. (2012) Making the Visual Visible in Philosophy of Science *Spontaneous Generations: A Journal for the History and Philosophy of Science*, 6(1), pp. 106-114

Pitt J. C. (2011) When is an image not an image? In Pitt J. C. *Doing philosophy of technology: Essays in a pragmatist spirit* (pp. 199-207) Dordrecht Heidelberg London New York: Springer

Hacking I. (1981) Do we see through a microscope? In: P.M. Churchland and C.A. Hooker (eds.) *Images of Science*, pp. 132-152, The University of Chicago Press, Chicago

5. Conclusions

The goal of this thesis was to understand clinical decision-making regarding diagnosis and treatment and the role of different types of information, including measurements using technological instruments. From the history of medicine, I concluded that the development of medical practice is intertwined with the development of science and scientific methods, for example the advancement of knowledge of human anatomy in the 16th century. Over time, two opposing approaches to medical science developed: the nosography approach, aiming at an a-theoretical description of disease, much like botany, and the “Flexner approach”, which is highly informed by scientific theories and models of physiological and pathological mechanisms. Furthermore, throughout history, medical practice appeared to be intertwined with the conception of disease and health, with societal norms and with the organization of care. Therefore, the context in which clinical decision-making takes place is extensive and can be divided (at least for analytical purposes) into four dimensions: the dimension of the patient-physician interaction, the dimension of organization, the material dimension and the intellectual dimension.

Reviewing the current epistemologies of medicine, two opposing views surface: evidence based medicine (EBM) and the art of medicine. EBM was developed in the 1990’s as a response to the then ubiquitous expert-opinion based medical practice. The goal was to secure the scientificity and objectivity of decision-making in clinical practice. Therefore, it promoted the development of scientific methods that produce clinically applicable and unbiased data, such as clinical epidemiology and randomized controlled trials (RCT’s). For a better application of the results, a “hierarchy of evidence” was formulated, with RCT’s on top and “expert opinion” on the bottom. To facilitate clinical decision-making based on EBM research, guidelines based on the highest available evidence are produced.

Critiques on the epistemology of EBM mainly concern the gap between population-based research and the treatment of individual patients in the clinic. Furthermore, in the formulation of clinical guidelines, there is no good account of how to apply them to individual patients with all their specificities. For this, EBM relies on doctors’ experience and “clinical skills” without explaining what this means. In other words, EBM epistemology can be characterized as rule-based reasoning based on a-theoretical clinical evidence, in order to warrant objective decision-making. Some authors that criticize the epistemology of EBM refer to the “art of medicine” which emphasizes soft skills, for example communication skills, the patient-doctor relationship and empathy. Hence, this approach seems to promote “subjectivity” over objectivity and scientificity. However, by focusing on the art of medicine, clinical decision-making becomes a vague and mysterious process whereas my goal was to better understand this process.

Therefore, following Loughlin’s point, I reject a strict dichotomy between “objective” and “subjective”. I argue that this is the result of a narrow view of science that is put forward by EBM epistemology. This results in a mismatch between the *knowledge* provided by EBM methodologies and the various kinds of knowledge used in clinical reasoning. Furthermore,

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there is a mismatch between the type of *reasoning* presupposed by EBM, algorithmic reasoning, and actual reasoning in clinical practice, which is much more intricate. George Khushf provides an account of clinical decision-making based on Kant's distinction between determinative and reflective judgment. He argues that clinical reasoning is a two-step process, analogous to the scientific method. Doctors use a different kind of judgment for each step. The first step is the formulation of a hypothesis, which is the propaedeutic practice of clinical decision-making. Crucial for this practice is the interaction between patient and physician, in which initial clinical information is gathered and a theory is formulated in such a way that it enables understanding and controlling disease, thereby enabling the practice of medicine as a science. This first step of initial theory formation requires *reflective judgment*, in which a concept is sought out for a particular. This happens by cultivating a feeling of accord with the scientific ideal of medicine, the current knowledge base and an awareness of the way clinical decision-making proceeds. The second step is verification, in which tests are used to confirm or reject the theory. In the second step *determinative judgment*, which entails bringing a particular under an already specified universal.

From Khushf's analysis, I identify several philosophical aspects of medical reasoning for diagnosis and treatment that are not sufficiently recognized in EBM epistemology.

- 1) The role of theory formation and its creative aspects. An important part of clinical reasoning consists of more complex and imaginative processes than the formal logic that EBM epistemology envisions.
- 2) The information gathered by history taking and physical exam is crucial in Khushf's account, for the initial formation of a working hypothesis. Hence, Khushf recognizes that this type of information is valuable for clinical reasoning and should therefore not be so easily dismissed as "subjective", as in EBM epistemology.
- 3) The scientific ideal of modern medicine is not in agreement with the a-theoretical empiricism advocated by EBM, but assigns a larger role to basic medical sciences, like anatomy, pathology and physiology.
- 4) Khushf highlights the purpose of medicine: understanding and controlling the disease of an individual patient, as opposed to the more general understanding of disease and the efficacy of treatments in the general population.

Based on these point and an analysis of two cases of girls with urine incontinence, I claim that, although it cannot easily be formalized in rules and algorithms, aspects of reasoning in clinical practice that are considered "subjective" are sometimes highly systematic, scientific and should not be so easily dismissed, as in EBM, or brought under a vague notion as "the art of medicine". Clinical decision-making is an complex process, in which hypotheses are continuously formulated and adjusted, and in which information from many different sources is used. EBM epistemology cannot account for these intricate decision-making processes, and therefore I argue for an alternative approach.

This alternative approach should be able to account for specific aspects of clinical reasoning, such as the gathering of relevant information, the integration of different types of relevant knowledge, the use of different types of reasoning styles, and the local and context-specific nature of clinical decision-making, while at the same time securing the desired "scientific" quality. To warrant this quality, I claim that doctors have a responsibility in 1) gathering and using *good quality information and knowledge*, 2) valuing types of *reasoning* for specific

situations, and 3) making the *intellectual effort* to use these types of knowledge and reasoning so as to come up with good diagnoses and treatment plans and warrant the quality associated with “scientific”. Therefore, I propose that in an appropriate to medical epistemology there should be a central role for the *epistemological responsibility* of doctors, which I interpret as *making the best possible judgment* regarding diagnosis and treatment, using *good quality data*.

A central role for the epistemological responsibility of doctors shifts the focus from the “general” and objectified, represented by guidelines, algorithms and rule-based reasoning, to the specific, the individual doctors and patients. With this shift of emphasis, the four dimensions of the decision-making context that I have mentioned at the beginning of this chapter appear as important elements of the epistemological responsibility of doctors. They are highly intertwined but by analyzing them individually the impacts of the different dimensions on clinical decision-making become clear. Part of the epistemological responsibility of doctors is then to navigate within, and account for, all four dimensions.

The first of these four dimensions, the patient-physician interaction, is extensively analyzed in the “art of medicine”. As a source of information, this dimension was also mentioned by Khushf; according to him, history taking and physical exam are crucial aspects for the propaedeutic practice of theory formation. The second context is the *organizational dimension*, structured by protocols and guidelines, of which the epistemological aspects are put forward in the epistemology of EBM, by providing information about the efficacy of treatments and the sensitivity and specificity of diagnostic tools for the general population. Hence, the first two dimensions are extensively analyzed by the two “traditional” but opposing views on medical epistemology. The other two dimensions are often overlooked and can be better included in a medical epistemology by a referring to epistemological responsibility. These dimensions are the *material dimension* and the *intellectual dimension*.

The relevance of the material dimension of clinical decision-making can be clarified by using the conceptual framework from *the body multiple* by Annemarie Mol. Mol’s “praxiography” makes plausible that the specific instrument that is used for clinical measurements and the resulting presentation of the measurement steer decision-making. According to Mol, diseases cannot be considered separately from the instruments, settings and people that are used to investigate them. As a result, the treatment decisions made based on these measurements are pushed in a certain direction by the instruments that are used. The material context can therefore be understood as a context that steers clinical decision-making, in ways that are not so evident in the everyday practice.

To understand the intellectual context, I assume that doctors generate knowledge about each individual patient, analogous to the step of “theory-formation” in Khushf’s theory. I understand this knowledge as a coherent and consistent “picture” of a patient that is constructed by fitting together all relevant information (both general, theoretic and specific, empirical) by mutual adjustment. Therefore, I argue that instead of understanding epistemology as “objective truth finding”, this generated knowledge should be considered as an *epistemic tool* that allows doctors to ask questions and formulate hypotheses about their patients. This allows understanding clinical decision-making as a process, in which the epistemic tool is continuously adjusted by newly available information that has to be included in the epistemic tool. Furthermore, it enables considering the epistemic uses of the

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constructed knowledge, instead of its relation to reality. This allows considering the constructed picture in relation to the purpose of medicine: understanding and controlling disease (as stated by Khushf.)

To understand the process of fitting together and the roles of different types of elements, I use Ian Hacking's analysis of the laboratory sciences. Hacking provides a taxonomy of the elements that are mutually adjusted in the practice of theory formation in laboratory sciences, divided into three groups: ideas, things and marks. Elements of clinical reasoning can be identified analogous to Hacking's taxonomy. Important elements from the group "ideas" are, for example, the *question*, which is initiated by the patients but continuously adjusted by doctors when new information becomes available, and the *topical hypotheses* that doctors formulate to make predictions about what they will find in observations and measurements, connecting general knowledge to the observation of specific patients.

More importantly, the taxonomy emphasizes the entanglement of the material dimension and the intellectual dimension, because both are an important source of elements mutually adjusted in theory-formation. For example, the *modeling of the apparatus*, bridging the material dimension and the intellectual dimension. The application of the taxonomy to the case study reveals that the other two dimensions are also involved. For example, for the two elements mentioned above (the question and the topical hypothesis), the intellectual dimension and the patient-doctor relation are intertwined. Other relations are found in the elements *target*, in which the patient is adjusted to the instrument to enable measurements and the *source of modification*, in which all contexts are relevant to determine which treatment options are feasible. In the group "marks and manipulation of marks" the *interpretation of data* also ties all contexts.

However, in latter group, there are three "missing links" when comparing the elements of the taxonomy and the four dimensions: the inclusion of *data* from the doctor-patient interaction as real data in a similar sense as data from instrumental measurements, and the awareness of doctors of the raw data and data processing underlying the resulting measurements (numbers, graphs, images). These should be included in clinical decision-making more pronouncedly as an aspect of the epistemological responsibility of doctors. Hence, Hacking's taxonomy shows that the material dimension is intertwined with the three other dimensions of the clinical reasoning context, through several elements. In short, knowledge about individual patients is generated in the process of mutual adjustment of the elements in Hacking's taxonomy, resulting in an epistemic tool that allows doctors to ask questions and formulate hypotheses, making connections between the general and the specific, the material and the intellectual contexts, the social interactions and technological findings.

The "missing links" revealed by the analysis of the relationship between the taxonomy and the four dimensions of clinical decision-making, illustrate two opposing tendencies regarding the role of technological measurements in clinical decision-making. First, in EBM epistemology, information obtained by technological measurements is preferred over other information because it is considered "objective" and quantitative and therefore more reliable than other types of information, like information obtained by history taking or physical exam. However, doctors have only a limited understanding of how data is acquired and processed to produce the measurement outcome. The relationship between the measured object and the

resulting outcome or image is not straightforward, as Hacking and Pitt argue for the microscope and STEM. Carusi makes plausible that the relationship of modern (computational) imaging can best be understood as a hybrid of causal and intentional factors and that from visually assessing the image the causal and intentional aspects cannot be separated. Therefore, the algorithms that are applied have an impact on the resulting image in, for doctors, hidden ways. Doctors are epistemologically responsible to gather, assess, interpret and apply different types of information and to fit together heterogeneous elements in a process of mutual adjustment. However, to value each piece of information, either obtained by physicians themselves through history taking or measured by a radiographer, an honest consideration of the information is necessary. In order to do this, doctors need to be aware of the hybrid status of measurements and should be careful with a too strong preference to base their decisions on measurement outcomes over other types of clinical information.

However, current medical epistemologies, like EBM and the art of medicine place either too much reliance on objective or quantitative measurements, or are too skeptical of the use of technology which hinders a detailed understanding of the roles of different kinds of information and for doctors to appropriately value them. In my view, philosophy of science can play a large role in improving this understanding. First, by analyzing presuppositions about the objective - subjective and qualitative - quantitative dichotomies in medical epistemology. Second, by analyzing the epistemological value of the different types of information for clinical decision-making, and their relationships. To understand how the outcomes of, for example, imaging technologies relate to clinical decision-making, individual technologies should be studied within the context of clinical practice and in relation to other types of information. In addition, the technology itself should be studied in detail at multiple levels: the interactions between the object and detecting phenomenon, the algorithms processing the technology, the models and assumptions build into algorithms, the physical make-up of the technology and ultimately the information that the images yield.

Such an approach will also have implications for the development of innovative technologies. A better understanding of the epistemological role of technologies in medical practice enables developing technologies that are more appropriate for the medical practice, for example by producing data that fits in better with other types of information or by producing data that is really relevant for the clinical decisions that doctors make. Therefore, in the development of technology for medical practice, doctors and engineers share an epistemological responsibility. An epistemological analysis of the role of measurement technologies in clinical decision-making can be fruitful to enable and support the interdisciplinary collaboration between doctors and engineers.