Genetic screening programs for susceptibility to disease in Denmark?

Applying a socio-technical multi-level approach to study the co-evolution between morality and technology

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Abstract

Denmark is, with its extensive public healthcare system, the object of study. In Denmark, genetic technologies, as a means of preventing disease and improving on the health of the population, have been discussed in a variety of ministerial reports as a possibility in future scenario's of the healthcare sector. Internationally developments in genetics have been coupled with an agenda of 'Public Health Genomics' a term including not only genetic disciplines, but also disciplines of population sciences, humanities and social sciences.

One specific application of genetic technologies could be genetic screening programs for susceptibility to disease. No such screening programs, are as of yet, in operation in Denmark. In this report it is speculated that such a development would entail the combination of the two disciplines of screening and clinical genetics – two disciplines which are embedded in the Danish healthcare sector and which operate with their own goals as well as 'rules of behaviour'. With screening the goal is one of early detection of disease and thereby possibly preventing the outbreak of disease, while clinical genetics has the goal of providing individuals with genetic knowledge through the golden rule of non-directive counselling. Both disciplines however also have a history of provoking debate and as being associated with serious ethical issues. A new discipline of genetic screening programs for susceptibility to disease would embody the same moral issues as screening and clinical genetics to a larger or lesser extent. Thus genetic technologies in the shape of genetic screening programs for susceptibility to disease develop in interaction with societal or more specifically moral elements connected to specific practices.

I mobilize the socio-technical multi-level model and explicate the place of moral rules inside this model, in order to study the practices of screening and clinical genetics in Denmark. Using the terminology of this model it becomes possible to identify a moral framework of rules shaping each of the regimes of screening and clinical genetics; a moral framework of rules which is created through the interpretive action of social groups embedded in framework of moral rules at the regime and niche levels. In the terminology of the model the interpretive activities of the social groups, through which they create moral frameworks of rules, facilitate a co-evolution between technology and morality. To illustrate this co-evolutionary interaction the inventory of NEST-ethical patterns of argumentations has been used. On the niche level of prenatal testing and HNPCC (hereditary non-polyposis colorectal cancer), a blurring of the boundaries between the regimes of screening and clinical genetics could be uncovered. Analyzing the moral elements of this merge a possible emerging pathway to wards genetic screening programs for susceptibility to disease can be uncovered at the niche level.

In conclusion the research performed has with the help of the extended socio-technical model made it possible to show that moral frameworks of rules shaping screening and clinical genetics are continuously being interpreted on and re-created by social groups, which not only interpret on moral rules in earlier frameworks, but who also respond to changes in moral elements at the landscape level. In this way it is shown how any future development of genetic screening programs for susceptibility to disease in Denmark is dependent on and situated in existing moral frameworks and elements. At the same time the model opened up for uncovering the emergence of a pathway at the niche level which could lead to genetic screening programs for susceptibility for disease. A further development of this pathway was analyzed to be dependent on certain technological as well as moral elements, again pointing to the situated character of any socio-technical development.

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I would like to thank all my interviewees for their contribution and for taking time to see me. When an interviewee is quoted the first time they are mentioned by name and position. Pauses or words which are left out are marked by (…), and additions in parenthesis are made in order to clarify spoken statements. Quotations by interviewee's have been slightly edited to fit better into the written form. Following the first quotation of an interviewee, a code is used to identify each interviewee. More information as well as the codes can be found in appendix A. Transcriptions of the interviews are found in appendix A on the accompanying CDROM. Likewise appendix B can be fond on the accompanying CDROM.

In my research I have used a number of sources written in the Danish language. When these are used I have chosen to retain the original Danish titles in the main text, and mark them with an *, which indicates that they are translated in the bibliography.

Last but not least a sincere thank you to friends, family and my boyfriend, for loving, supporting and believing in me throughout this whole process.

Lise Bitsch

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1 Introduction

In this chapter I will introduce the prospect of a development towards genetic screening programs for susceptibility to disease and the international as well as national context of Denmark in which such a prospect arises.

I begin by introducing speculations on a future development of genetic screening programs for susceptibility to disease in Denmark and some of the questions which such a development would raise. This development is one which has been envisioned in a number of Danish reports. On an international level the contributions, which genetic technologies and knowledge might provide in terms of public health, is widely discussed under the theme of 'public health genomics'; a vision, which operates with the goal of applying knowledge of the genome into more effective preventative options as well as treatments for the individual. Public health genetics is part of the theme of public health genomics and I continue the chapter with an investigation of this discipline, which can be seen as including traditions from two disciplines inside public health; two traditions which have developed their own individual rules of behavior in this way embodying their own morality. In their book Petersen and Bunton (2002) discusses the application of genetic knowledge to manage the health of the public under the term 'the new genetics', which is seen as having the potential to change the way we perceive ourselves, society and health. Genetic screening programs for susceptibility to disease would in this perspective constitute one such application of genetic knowledge to manage the health of the public. A development towards such application is seen to take place through mutual interaction between technology and morality an interaction, which in this way can be termed as co-evolution between technology and morality. I end the chapter with the formulation of a main research question.

1.1 The prospect of genetic screening programs for susceptibility to disease in Denmark

Could you imagine if in 30 years all citizens in Denmark were routinely offered a genetic test which could identify them as being at risk of a developing Alzheimer, a cancer, a lung or heart disease? To know that this risk did not necessarily mean they would develop the disease? Would you like to be told, that you should not smoke based on a genetic risk which might not manifest? Or to be told you should refrain from certain foods, or have your breasts removed? Would you still want to pay collectively to insurance companies, knowing that your neighbor despite of having a genetic test showing increased risk of lung cancer, continued smoking? Could you imagine this would change the way you see the relationship between your neighbor, yourself and the rest of society? These are some of the questions which have and are being asked in connection with the current practice genetic tests. It is the expectation that the use of genetic test will rise, and that they will be used to test for individual pre-conditions to disease. Something which eventually could lead to population based genetic screening programs for susceptibility to disease. The worry is that genetic test offered through screening programs will change the way we perceive ourselves and our

fellow human beings. That we will come to see ourselves as potentially sick, and become dependent on medical experts to tell us that we are healthy. At the same time knowledge about a potential for developing a disease could lead to increased demands on us as individual human beings to take responsibility for our own health status. This could lead to discrimination in society of groups who fail to live up to their responsibilities, or groups identified as having a weak genetic make-up. On the other hand such a development could be seen as having great potential in terms of prevention and early detection of disease in order to improve the quality of life of the population, as well as saving the healthcare system from the increasing burden of having to treat lifestyle diseases. A development in this direction could also be seen as empowering the individual. Knowledge about ones disposition towards certain diseases could make it easier for the individual to take preventive action into own hands, and at the same time preventive programs could be efficiently targeted to the groups needing the most help.

1.1.1 Expectations to genetic screening for susceptibility in Denmark

Expectations towards the future development of genetic technologies were aired in several Danish reports in the years 2000-2004. Expectations in these reports included development of better medicines, diagnosis, treatments and preventions. The Ministry of Science, Technology and Innovation published three reports on biotechnologies in 2002, 2003 and 2004 respectively. Genetic tests were mentioned in all of these reports as having the potential of becoming an important tool in the future developments of the healthcare sector and the use of genetic tests were expected to rise considerably. (Ministeriet for Videnskab, Teknologi og Udvikling*, 2002/2003/2004) The Danish Council of Ethics published a report in 2001 on screening programs and a report in 2002 on presymptomatic testing, and in 2002 the Danish Board of Technology held a consensus conference surveying the citizen's attitudes towards genetic testing. (Danish Council of Ethics, 2001/2002; Teknologirådet*, 2002) In the report by the Danish Council of Ethics the expectation that the use of genetic test would rise and that this eventually would mean that the target group of genetic tests would expand from a small group of the population to possibly include the whole population, was also explicitly mentioned. (Danish Council of Ethics, 2002) Would this be the case, it would be a matter of interpretation if this kind of practice would start to resemble a screening program. None of these reports however touch the subject of the plausibility of such a development. These reports show the presence of expectations towards a development of genetic screening programs for susceptibility to disease, a development which would be dependent on the co-evolutionary interaction between society and technology and an investigation of the context of Denmark, the Danish healthcare system and in particular the practices within the healthcare system, which would be involved in genetic screening programs is therefore necessary for any assessment of the plausibility of such a development to take place.

1.1.2 Investigating 'the new genetics' and the discipline of public health

Scenarios of presymptomatic genetic screening programs arise within a context of what has been called 'the new genetics'. In their book, Petersen and Bunton (2002) define 'the new genetics', as the application of genetic knowledge to manage the health of the public. They identify a contingent relationship between 'the new genetics' and eugenic movements in their joint focus on human betterment. The two disciplines are however tried separated as the old eugenic movements became discredited after the Second World War. When advocates of this 'new genetics' try to separate it from the old eugenic movements, they tend to describe these as misguided and bad science, whereas 'the new genetics', contrary to this, is portrayed as advancing individual autonomy and individual freedom. The health of the public has traditionally been studied within public health studies, where there has been a division between the host, the environment and the agent. The new genetics threaten to transform all of these spheres. For the host this means changes in the way we perceive our individual self and populations, for the environment this means changes in the way we define and perceive the relation between environment and health and for agent this amounts to changes in the way we perceive that which makes us sick. (Petersen & Bunton, 2002) Genetic screening programs for susceptibility to disease would be one of the applications of genetic knowledge, which could bring about such a change. And as mentioned in the introduction public health genomics is the heading under which the application of genetic knowledge to improve on the health of the public is being studied and discussed internationally. This vision of public health genomic involves a whole cluster of activities and apart from discipline of public health it involves the disciplines of population sciences and the humanities and social sciences. (phg-foundation, 2008)

A development towards an increased application of genetic knowledge to manage the health of the public originates from complex interactions between disciplines and traditions. In end of the nineteenth century public health science incorporated a two different project: one with a focus on improving the public health through initiatives such as sanitation and hygiene thus improving public health through societal changes, and one focusing the hereditary conditions responsible for health, thus focusing on the conditions within the individual causing disease. The first project later became associated with the discipline of social medicine, which had a traditional focus on social and environmental causes of disease, while the second project become connected to the discipline of clinical genetics[1], which has a traditional focus on the genetic variation between humans. Both disciplines separate inheritance and environment and focus on disease prevention through early detection of disease and both disciplines use screening as a tool in disease prevention. Traditionally the knowledge within social medicine was clinically more useful than genetic knowledge, and within the area of public health science this was therefore the knowledge and discipline which took precedence. The two disciplines of social medicine and clinical genetics developed different approaches towards detecting causes for disease, and while social medicine develop a practice of issuing advise to people on the best way to live to stay healthy, clinical genetics developed a tradition for providing people with information on their genetic inheritance, while leaving decisions on what to do up to the individual. In recent years the development in genetics has taken off and developments in chromosome research,

[1] This is a simplified description as clinical genetics only entered the picture later. However for sake of simplicity I will not go into further details on these relationships, suffice it to say that the second project eventually became connected to clinical genetics.

molecular genetics and genetic technology has suddenly positioned genetics as potentially having a great clinical value. The determination of the shape of DNA by Watson and Crick in 1953 and the determination of the number of human chromosomal pairs into 23 by Tijo and Levans in 1956, paved the way for the mapping of the entire human genome. Technically this became possible during the 1970's and 80's and in "The Human Genome Project", which was carried out from 1990 to 2003, the whole of the human genome was mapped. With this technological development a new discipline of public health genetics has emerged, a discipline in where the old union of the two different projects could become a reality. (Koch, 2008) Public health genetics is a major part of public health genomics. The field of public health genomics thus incorporates a large complex of traditions and disciplines and it is within the context of this project that speculations of a development towards genetic screening programs for susceptibility to disease in Denmark should be seen.

1.2 Formulation of the main research question

The development of a discipline of public health genetics thus implies a merge of two different disciplines of social medicine and clinical genetics. These two disciplines, as it was touched on above, work with two different perceptions of how society and disease should be approached. Within social medicine there is made no distinction between individuals and the focus is on external environmental, as well as social conditions as the cause of disease. Genetics traditionally and here specifically clinical genetics, work with the basic assumption that humans are genetically unequal, and therefore focus on hereditary genetic patterns is explaining the cause of disease. These two disciplines have developed their own moral sets of rules of behavior. In social medicine therefore there is a tradition for issuing recommendations on preferred types of lifestyle and preferred choices in terms of health within the population, while clinical genetics has a tradition for providing patients with neutral information thus leaving the choice of action up to the patient. In this way two differing understandings of the morally right way to approach disease are embodied within the two disciplines. As was seen in the previous section, the technological development in genetics managed to shift the balance between social medicine and genetics to a point where a merge between the two is now expected. In this way technology shapes the dominant moral rules inside the discipline of public health. The merge of the moral rules belonging to social medicine and genetics will however also shape the forms in which new genetic technology will become available. In this way technology and morality mutually interacts in a process of co-evolution. The main research question can now be formulated in two parts:

1a. How does the co-evolution between technology and morality shape the moral rules of the practices of social medicine and clinical genetics?

1b. What does this co-evolution imply for the interaction between the practices as well as for a future development of genetic screening programs for susceptibility to disease in Denmark?

The following chapter explores the two disciplines of social medicine and clinical genetics, and the practices of screening and clinical genetics are used as a starting point.

2 Screening and clinical genetics in Denmark

In this chapter I will provide a brief introduction to the practices of screening and clinical genetics in the localized context of Denmark and the Danish healthcare system. Screening is a well established practice within the Danish healthcare system, and as social medicine prior was the tradition within public health, which had the most to offer in terms of clinical utility this practice it is to a certain extent expected to embody the moral rule-set belonging to social medicine[2]. Clinical genetics on the other hand was established in 1996 in Denmark and is therefore a newly established discipline within the Danish healthcare system. For a development towards genetic screening programs for susceptibility, it is assumed that the two practices of screening and clinical genetics will merge. In their own right the two practices are associated with ethical controversies, and a merge, facilitated by technological developments in genetics, would bring the ethical controversies associated with each practice on a collision course; a collision which might reproduce old ethical controversies or create new ones in the process of creating a practice of genetic screening for susceptibility to disease. I therefore briefly present the ethical controversies connected with screening and clinical genetics and their connection to and dependence on the localized context of the Danish healthcare sector. I end the chapter by expanding the main research question with a number of sub-questions.

2.1 Screening

In Denmark a number of screening programs are in operation. The best known examples are screenings every third year for cervical cancer offered to 23-59 year old women and mammographic tests for breast cancer, offered every two years to women between 50-69 years old. Every pregnant woman is also invited to prenatal check-ups, where the woman is weighed, has blood pressure measured and blood samples taken. After birth all children have blood extracted from their heel to have it tested for Phenylketonuria. Early after the child's birth, the parents will also receive an offer to have a healthcare worker come and check how the child functions socially, weigh and measure it and test its reflexes. Later the child and parents will be invited to various paediatric investigations. A list of future screening programs produced in a report by the Danish Council of Ethics, shows that a number of more than thirty diseases are considered for implementation in screening programs. The diseases fall in the areas of: prenatal screening, paediatric screening, cardiovascular diseases, cancerous diseases, metabolic disorders, infectious diseases and mental illnesses. (Danish Council of Ethics, 2001)

In 1999, the National Board of Health published a report on screening. The purpose of the report was to function as a tool for policymakers having to make decisions, but also as a tool to structure the debate

[2] This is however a little simplified as a whole bunch of practices, such as sanitation and hygiene movements, could be said to belong under the tradition of social medicine. In addition genetics is also identified as using screening as a means of early disease detection. An essential difference between screening in general and the way screening is being defined in this thesis is that screening is an offer from the healthcare authorities towards groups in the population identified as being at risk of developing a certain disease.

surrounding screening. In this report screening was defined as the search for the early stage of disease or for risk factors of disease. In all cases investigation is carried out on persons who feel healthy and screening is in these terms prevention aimed at identifying early stages of disease, not the causes of. (Sundhedsstyrelsen*, 1999) In a 2001 report on screening the Danish Council of Ethics also describe screening programs as targeted on persons who are not showing symptoms of the disease they are being screening for. The target of screening programs can be a whole population or specific groups within a population. Screening is compared to a sieve, where sick people are being isolated from the healthy. Depending on how big the holes in the sieves are, more or less people with early stages or risk of disease are found, but also more or less people will falsely be diagnosed as either sick or healthy. The defining feature of a screening program is that it is the health authorities which take the initiative to the screening, and that screening is a recurring routine event. (Danish Council of Ethics, 2001) As Lotte Hvas (LH) associated researcher at the Research Unit of General Practice, Copenhagen and Vice-president in the Danish Council of Ethics says:

"It is about whom goes to whom (...) with screening it is the healthcare system which comes to people (...)" (Appendix A, LH)

Screening programs have been accused of being problematic and a recent publication made by a group of doctors, was published as an alternative to a newly published folder on screening for breast cancer published by the National Board of Health; a publication which shows that the debate on screening programs is continuous. By surveying a report on screening by the Danish Ethical Council and the alternative folder by the group of doctors, it can be shown how they transform defining features of screening into problematic issues in a debate. One of the defining features of screening is the identification of a population group as being at risk of a certain disease. This feature is made problematic as the Danish Council of Ethics argues that a large population group in this way as potentially sick. In this way screening programs create a dependency between the population group and medical experts. Another defining feature of screening programs is the notion of being an offer from the healthcare authorities towards the population. The council of ethics as well as the group of doctors problematizes this notion, as the decision itself to take or not to take part in a screening program, can create anxiety and guilt. This is especially a problem if one chooses not to participate and then later becomes sick. On the other hand participation in a screening program is no guarantee, that you will not become sick, and therefore participation might create a false sense of security. The council of ethics also problematizes the notion of an offer of participation, by arguing that an offer of participation in a screening program can also be seen as either reinforcing or violating a person's right to self-determination. Reinforcing as an offer of participation in a screening program makes it possible for a person to decide on his or her own whether or not to participate in the program. On the other hand being given a offer of a screening program gives a person the information that he or she is identified as being at risk of a certain disease and this can be perceived as violating a persons right to determine on their own whether or not to want such information. This dilemma is often referred to as the right to know and the right

not to know. To problematize the right to self-determination makes an especially forceful argument, as the right to self-determination is formulated as a central guiding value for the Danish healthcare sector. The nature of the tests used in screening programs is also problematized, both by the council of ethics and the group of doctors. In their view screening programs chronically suffer from the problem of false negatives and positives. This means that if the sensitivity parameter is set high, a relatively high number of false positives will result, resulting in a group of people being treated for a condition which they do not have. Conversely if the sensitivity parameter is set low, a relatively high number of people will receive false negatives and go on with a condition that is not treated. (Danish Council of Ethics, 2001; Gøtzsche, Hartling, Nielsen, Brodersen*, 2008)

2.2 Clinical genetics

In Denmark it has been possible for a while to analyze for the monogenetic diseases, like Down's syndrome and Huntington's chorea. The gene for Huntington's chorea was the first to be identified in 1983, and since then more genetic tests have continuously developed. Today genetic tests in Denmark are primarily used to assist research in criminal cases, to test for rare monogenetic diseases (before and after birth as well as carrier testing) and to help determine parenthood in paternity cases (Ministeriet for Videnskab, Teknologi og Udvikling*, 2002).

2.2.1 Genetic tests

A genetic test entails investigating the base pairs that make up the strings of DNA which make up the genes, and were first made possible with the identification of the gene for Huntington's chorea in 1983 (Danish Council of Ethics, 2002; Ministeriet for Videnskab, Teknologi og Udvikling*, 2002). The genes are arranged on the 46 chromosomes, which can be seen under a microscope. The chromosomes are arranged in pairs, which are copies of each other. With one half stemming from the mother and the other half stemming from the father. The exception is the genital chromosomes where girls have two X chromosomes and boys have an X and a Y. Some diseases, like Huntington's chorea, are dominant and expressed even if mutations are only present on one of the genes in the chromosomal pair. In comparison cystic fibrosis is recessive and only expressed if the mutation is inherited from both the mother and the father and as boys only have one X chromosome, recessive diseases will be expressed in boys if the X chromosome is the carrier of disease. Some diseases are caused by a single mutation in the base pairs of a gene, while others are caused by larger changes in one gene, and again other diseases are caused by multiple mutations in several genes. Only relatively rare monogenetic diseases are caused by single or multiple changes to one gene and they have a much higher expression rate than diseases caused by multiple mutations. Diseases caused by multiple mutations on more than one gene are termed multifactorial diseases. The expression of these diseases is amplified though environmental influences as well as certain lifestyles, and are much more common than the monogenetic diseases. They differentiate themselves from the monogenetic diseases in that their

manifestation in the affected individual is less easy to predict. (Ministeriet for Videnskab, Teknologi og Udvikling*, 2002)

2.2.2 The practice of genetic testing in clinical genetics

Tests for monogenetic diseases and hereditary cancers are performed inside the practice of clinical genetics (Region Hovedstaden Specialebeskrivelser*, 2006; Teknologirådet*, 2002). Examples of monogenetic diseases which are tested for are Huntington's chorea and cystic fibrosis. Testing for these is usually only offered to families with a history of the disease. All women are routinely offered prenatal testing, which can determine their risk of carrying a child with Down's syndrome[3].

Examples of hereditary cancers, which are tested for are colon and breast cancer.
For the hereditary cancers a number of at risk families are registered and are continuously monitored. To gain access to a genetic test for a hereditary cancer condition a referral from a general practitioner to a specialist in clinical genetics is needed. Here the whole family will be involved in counselling sessions and a pedigree of the family will be drawn up. However it rests on the person which originally came to the clinical geneticist to inform other family members about the possibility of participating in this process. Based on this pedigree the family will, if estimated as being at risk, be offered a mutation screening, to locate the mutation specific to their family. To perform the mutation screening a blood test needs to come from a sick family member and again it is up to the person who originally came to the healthcare system to require this. Based on the results of the mutation screening individual members are offered genetic tests to determine their individual risk as well as offered participation in monitoring programs. An exception to this practice is the practice of HNPCC (hereditary nonpolyposis colorectal cancer). Here family members estimated to be at risk are automatically contacted by the clinical genetic departments. (Lægeforeningen*, 2002; Bojesen et al., 2007)

In this way the specific practice of HNPCC makes an offer of participation in counselling and of genetic tests, an offer which could be seen as an offer made in the same way as the screening programs make them. There is a continued speculation on the future development of the use of genetic test. In a report from 2002 the National Board of Health wrote about these tests;

"Today it is being discussed if analysis of DNA should be used to be used in the same way as other biochemical analysis to trace persons with an ***increased risk of developing disease****. In this way there is no difference between genetic diagnostics of healthy people and other analyzes used to screen parts of or the whole of the population" (Sundhedsstyrelsen*, 2002; 124, original emphasis)*

At the same time the development in the field of genetics has also escalated, as mentioned in section 1.1.2 and through for example the information obtained in the Human Genome Project (1990-2003) more is

[3]The first tests offered to all women measure the amount of certain proteins in the blood of the mother and produce ultrasound imaging of the child, are as such not genetic tests, but the final test, which provides a certain result, is.

known about the connections between genes, health and disease. In addition technologies used for DNA analyses have become more and better, resulting in the availability of more reliable and faster means of analysis. (Ministeriet for Videnskab, Teknologi og Udvikling*, 2002)

Clinical genetics and the use of genetic tests is thus a practice which is envisioned will grow in the future, however as with screening the practice is problematized in debates. In a report by the Danish Council of Ethics as well as in a health technology assessment made by a group inside the National Board of Health, the principles of the right to know and not to know are made central in discussions on genetic testing. Due to the nature of genetic information a test will provide information not only about the person tested but also about family members. In this way a decision made by an individual person can cause other to obtain information which they did not want in the first place. On the other hand family members might want such information, and withholding it then denies them information they would wish to have. The nature of genetic information obtained through a genetic test thus makes it difficult to retain the right to self-determination of the individual. Here it is the kind of information obtained though a genetic test which is made problematic and a parallel is again made to the central value of the right to self-determination.

These two actors also problematize genetic tests by focusing on their potential impact. One potential impact which worries these actors is social stigmatization of person who has been told of an elevated risk of developing a certain disease. This discrimination could develop both from family members in terms of isolation or from society in terms of difficulties in the insurance and job market. Stigmatization of individual, familial and societal relations is also often mentioned as a consequence of genetic testing. (Danish Council of Ethics, 2002; Bojesen et al., 2007)

These two practices of screening and clinical genetics operate in the context of the Danish healthcare sector. I will therefore use the next section to briefly introduce the Danish context, the healthcare sector as well as place some of the central values which guide this system.

2.3 The context of the Danish healthcare sector

Denmark is a small country of 5.4 million citizens and the healthcare sector, and the whole political system, is based on a model referred to as the Scandinavian Welfare model. Employment, education policy and social and health policy form the cornerstones of this system (Ministry of Foreign Affairs of Denmark, 2007a). In Denmark this means that healthcare is conceived of as a public matter. The public authorities are accepted as, and expected to be responsible for healthcare. As an example of this all citizens have a basic healthcare insurance which is secured and organized by the state. This public healthcare system is exclusively financed through taxes (Ministry of Foreign Affairs of Denmark, 2007b). Currently the demographic development, which resembles that of other Western countries, with a relatively large amount of the population consisting of elderly people, poses the greatest challenge to the system, as it is financed by active working citizens. (Ministry of Foreign Affairs of Denmark, 2007c)

Traditionally there has been a strong focus on the rights of the collective and the duty which every citizen has to finance the system through taxes is deeply entrenched. Recently however a focus on individual rights has emerged, and in the new law on health, which was initiated in January 2008, much was done in terms of explication the rights of the individual to self-determination. Equal access and opportunities for treatment is a value related to self-determination and is also emphasized. The debates surrounding screening and clinical genetics should be seen in the context of this system. Remembering the debates in section 2.1 and 2.2, it can be recognized how the general principle of the right to self-determination is transformed and made problematic in connection with the practices of screening and clinical genetics[4].

In terms of organization the Ministry of Health and Prevention is directly placed under the central government. Below this ministry one finds the National Board of Health, the Danish Council of Ethics and various Patients' complaint boards as well as a Danish National Committee on Biomedical Research Ethics. Another Ministry, which is not directly involved in healthcare as such, is the Ministry of Science, Technology and Innovation which finances The Danish Board of Technology. (Strandbjerg-Larsen, Nielsen, Vallgårda, Krasnik, Vangbæk and Mossialos, 2008) In addition various institutions exist among other the Danish Medical Association, which is a lobby organization for Danish doctors and at the same time recognized as an expert advisory body for the government (Danish Medical Association, 2008). In addition there are six clinical genetic departments in Denmark. Four of these are placed within hospitals, and of the last two, one is placed at a Research Institute and one at Copenhagen University (Sundhedsstyrelsen*, 2002). As Denmark is part of the European Union this organization forms and outer frame for the organizations in the Danish Healthcare sector.

In Denmark, new biomedical technology or treatment methods can be initiated locally as research projects, as long as they are approved by the Danish National Committee on Biomedical Research Ethics. This has previously shown to be able to lead to a diffusion of the methods used in a specific research projects to the rest of the healthcare sector. The use of ultrasound and the use of measuring cholesterol numbers were initially local practices. However a demand for access to these methods and technology arose and this created pressure on the authorities to subsequently introduce these programs. Even a publication by the National Board of Health, which demonstrated that there was no documented effect of using ultrasound, stopped the diffusion of this technology. However the opposite is also possible. A research program, which offered testing to all pregnant woman for cystic fibrosis did not lead to a national offer of this test to all pregnant woman. (Koch & Stemerding, 1994) This sums up the introduction and leads to the formulation of the general research questions as well as a presentation of the build-up of the rest of the thesis.

[4]The right to self-determination is not the only central value guiding the Danish healthcare sector, and other such examples how general guiding principles are made problematic in connection with specific practices are made in the following chapters.

2.4 Research questions and build-up of the rest of the thesis

What becomes clear through this chapter is that the development of presymptomatic genetic screening programs is not only about what technological possibilities are available. It is as much about the way we perceive ourselves, each other and our societies. Will it be permissible to smoke in the future knowing that you have a genetic disposition to lung cancer or to eat fast food knowing you have the genetic disposition towards obesity? Will it still be possible to apply for any job that you want, or will you have to provide your genetic data, and what about insurances? Will we still want to finance in solidarity the treatment of each others diseases, and what about bank loans or adoptions? How will you feel about your neighbor if you and he both had a disposition to lung cancer and you stopped smoking and he did not? As mentioned in the previous chapter the interaction between technology and morality is perceived as co-evolutionary and by using this as a guiding notion I aim to find out what this co-evolutionary interaction in the practices of screening and clinical genetics implies for a development towards genetic screening for susceptibility. This gives rise to the main research question as well as sub-questions:

Main research question:

1a. How does the co-evolution between technology and morality shape the moral rules of the practices of social medicine and clinical genetics?

1b. What does this co-evolution imply for the interaction between the practices as well as for a future development of genetic screening programs for susceptibility to disease in Denmark?

Sub-questions:

2. What moral frameworks of rules guide the practice of screening and the practice of clinical genetics and how are they created?

3. What moral elements guide the governance of the Danish healthcare sector?

4. How does the co-evolution between technology and morality take place inside the practices of screening and clinical genetics and how do the moral sets of rules inside each practice interact with moral elements at the level of the Danish healthcare sector?

5. What interactions can be traced between the practices of screening and clinical genetics?

6. What elements become essential, through the co-evolutionary interaction between technology and morality in the practices of screening and clinical genetics, for a future development of genetic screening programs for susceptibility to disease?

In chapter 3 a theoretical model is developed. This model conceptualizes the co-evolution between technology and morality, the notion of moral rules as well as technology, all of which are central concept in this research. This results in an analytical tool which can be used to explore the co-evolution between technology and morality in the practices of screening and clinical genetics in a more structured way. The chapter ends by rephrasing the research questions using the developed model. In chapter 4 and 5 the conceptual model developed in chapter 3 is mobilized to analyze the co-evolution between technology and morality in the practices of screening and clinical genetics in detail. In chapter 6 an analysis is made of common and diverging themes within the moral set of rules belonging to each practice and a moral set of rules belonging to an emerging practice of genetic screening programs for susceptibility to disease is created. In chapter 7 conclusions to the research questions are drawn and these are discussed along with the approach and results of the research performed.

3 Conceptualizing the co-evolutionary interaction between technology and morality

In this chapter I will develop a conceptual model which allows for a more structured exploration of the creation of moral frameworks of rules shaping screening and clinical genetics through the co-evolution between morality and technology in the practices of screening and clinical genetics. As co-evolution is a central concept in my research I begin by making a general conceptualization of co-evolution between technology and society. Following this I will use the socio-technical multi-level model to develop a more precise conceptualization of the co-evolution between technology and society. I will then use the case of the discovery and introduction of BRCA testing in the US and the UK is used to illustrate the conceptual model. By the help of this case I am able to show the importance of moral rules as well as to make explicit the place of morality inside the socio-technical model. This results in a conceptual model where the socio-technical model is used to analyze the co-evolution between technology and morality as moral rules have now found a specific place in the model. Following this example, the NEST-ethical framework is developed into a tool, which will help make visible the co-evolution between technology and morality in the practices of screening and clinical genetics. The extended socio-technical model is illustrated by the example of the practice of screening and clinical introduced in chapter 2 and the chapter ends with a re-formulation of the research questions.

3.1 The co-evolution between technology and society

The previous chapter introduced the context of the Danish healthcare sector and specifically the practices of screening and clinical genetics. Further it was shown how actors problematize the practices of screening and clinical genetics by referring to general principles, which are defined as central for the Danish healthcare sector. In this section I develop a first general conceptualization of the co-evolution between technology and society.

Traditionally either technological development is used to explain societal development or societal development is used to explain technological development. In the first perspective of technological determinism society is exclusively shaped by the technology. In this way society is stripped of agency and possibilities to influence technological development. In the other perspective, technology is exclusively

shaped by social and political choices and the agency which was granted technology in the previous account is completely taken away by this process of deconstruction. (Misa, 2003)

"A concise way of making the same point is to say that while philosophers and social theorists "asserted the technological shaping of society" historians and sociologists countered with the "social construction of technology"" (Misa, 2003;10)

Recently a new perception on this interaction between technology and society has emerged. This approach has been called co-evolution or co-construction[5]. This approach tries to bridge the gap between the 'technological shaping of society' and the 'social construction of technology' by uniting these. As Misa writes:

"One can see, of course, that these two rival oppositions are not logically opposed ones" (Misa, 2003;10)

Therefore in the approach of co-evolution, neither society nor technology is reserved the role as the one which decisively shapes the other, rather their shaping takes place in an interactive process of change or more precisely society and technology mutually shape each other through a co-evolutionary interaction. The co-evolutionary perspective therefore proposes that we see technology as inherently embodying social, political and economic decisions[6], while at the same time the social context is shaped by the technological options available at a given time. (Misa, 2003; Moors, Rip and Wiskerke, 2004)

It is this perception of the interaction between the technology and the society, which informs the approach used to study the co-evolution between technology and morality in the practices of screening and clinical genetics. However, more is needed than just a conception of the interaction between the technology and the society, taking place in a co-evolutionary fashion, to investigate the co-evolution between technology and morality, and to arrive at moral and technological elements necessary for a development towards genetic screening programs for susceptibility being a plausible one in Denmark. To be able to do this in a structured way, a conceptual model, which both operates with a conception of co-evolution between technology and society as well as a model which has room for giving moral rules an explicit place in this co-evolution, is needed.

[5] These two terms of co-construction and co-evolution can be perceived slightly different with co-construction seen as referring to the mutual deliberate construction of the social and the technical contexts while evolutionary implies a development that is related to and dependent on earlier occurrences. The term of co-evolution is intentionally used throughout the rest of this thesis due to this difference in interpretation.

[6] This is not an exclusive list other social decisions can be added to the list.

3.1.1 Conceptualizing the co-evolution between technology and society by use of the socio-technical multi-level model

The socio-technical multilevel model[7] operates with a perception of an entangled network of the society and technology. Co-evolution takes place at three different levels (macro, meso and micro) and socio-technical change can occur when these co-evolutionary processes at the different levels become linked. (Geels, 2005) In this perspective technology consists of heterogeneous elements and not just the artifact in itself. The functioning of technology is in focus, and for technology to function heterogeneous elements need to be interlinked. This interlinking of heterogeneous elements also includes social elements. Socio-technical systems, according to Geels (2004):

"Consist of a cluster of elements, including technology, regulation, user practices and markets, cultural meaning, infrastructure, maintenance networks, supply networks." (Geels, 2004; 19)

Returning to the three levels in the socio-technical multi-level model, the model develops a nested conception of the organization of the social and the technical contexts, and operates at the landscape (macro), regime (meso) and niche (micro) level. At the regime level, the socio-technical networks take the form of social groups which are embedded in a framework of semi-coherent rules. This framework of rules is separated into three categories: regulative (law, standards, regulations), normative (role, relationship, values) and cognitive (belief systems, innovation agendas, guiding principles, search heuristic). Important to notice is that the framework of rules is not static but dynamic, and the social groups actively participate in the formulation and negotiation of the rules which make up the framework of rules. Nested inside the regime level is the niche level. The characteristics of the niches are the same as for the regime, with social groups embedded in a framework of rules. However, this framework of rules is even less coherent and stable than at the regime level. The regime and niche level are nested inside the landscape level, which forms the overall structure, and is seen as constraining or enabling certain opportunities for action at the regime and niche levels. (Geels & Schot, 2007)

This then leads to another important characteristic of the model, namely its perception of how interaction between the different regimes and niches at each level as well as between the levels in the multilevel model. As mentioned the social groups are active inside the regimes and niches in terms of active processes of interpreting, re-inventing and re-producing the rule-framework, but at the same time the social groups are also subject to pressures from the landscape level. Characteristic for the pressures arising at the landscape level is that these pressures arise outside the organized socio-technical regimes and niches. To have influence the pressures arising at the landscape level therefore need to be taken up and acted upon by the social groups

[7]The socio-technical model is a perspective which has developed in recent years and a number of scholars have been working on it. The version presented here is mainly taken from a 2007 article by Geels and Schot and a 2005 article by Geels. To give an overview of the work done, a number of important articles, which have developed on the perspective, are listed separately in the bibliography.

to have influence. Pressures can also arise at the regime and niche levels. These pressures arise from the constant processes of interaction between and inside the socio-technical networks at the regime and niche levels. Again these pressures can eventually lead to changes at the landscape level. The landscape level is however characterized as being of a slow changing nature, and in comparison with the regime and niche levels change here happens slowly and is difficult to induce. (Geels & Schot, 2007; van den Ende & Kemp, 1999; Berkhout, Smith and Stirling, 2004)

The socio-technical model then constitutes an analytical tool, which allows for a conceptualization of the interaction between technology and society as taking place though a co-evolutionary process at multiple levels. This co-evolution is further specified as being facilitated by the action of social groups embedded in socio-technical networks at the regime and niche levels.

3.2 Extending the socio-technical multi-level model with moral elements

The socio-technical multi-level model now represents a conceptualization of how co-evolution takes place between technology and *society*. The desire however was to develop a conceptualization of the co-evolution between technology and *morality* in order to explore this in the practices of screening and clinical genetics. This section therefore first uses the case of the introduction of BRCA testing in the US and the UK to illustrate the co-evolution between technology and society at multiple levels. This illustration of the co-evolution between society and technology is then used to show the importance of moral rules, as well as to explicate their place within the socio-technical model and thereby also developing a conceptualization of co-evolution between technology and morality. Finally the NEST-ethical patterns of argumentation are used to more specifically conceptualize this interaction.

3.2.1 The case of the introduction of BRCA testing in the US and the UK

Parthasarathy (2007) has developed an account on the discovery and introduction of the BRCA1 and 2 genes[8] in the US and the UK. In her account she shows how the discovery and introduction was shaped by what she terms the 'tools in the cultural toolbox'. Each country has its own cultural toolbox with tools specific to each country. The purpose of Parthasarathy's account is to show how social and cultural aspects (the tools in the cultural toolbox) shaped the introduction of the technology of BRCA testing. (Parthasarathy, 2007) The account given by Parthasarathy can however also be explained in terms of a co-evolutionary pattern between technology and society. Using the socio-technical multi-level model, the context of the US and UK can be divided into landscape, regimes and niche levels.

[8]The BRCA 1 and 2 genes are identified as some of the genes responsible for the development of breast cancer in men and women and for the development of ovarian cancer.

Using BRCA testing in the context of the US and the UK to illustrate the co-evolution between technology and society in the socio-technical multi-level model

As it is the goal of Parthasarathy to show how cultural and social settings shape what she calls 'technological architectures', she provides a description of the cultural and social setting of the US healthcare system. (Parthasarathy, 2007) In terms of the socio-technical multi-level model, this setting of the US healthcare system can also be conceptualized in terms of the landscape level of US healthcare system. This landscape level consists of a tradition for private health insurance, a system which had been in place since the 1930's. This social element is explained by reference to 'America's entrepreneurial history and decentralized government structures'. In addition American physicists were strongly against the creation of such a system as they feared to lose their autonomy in a state controlled system. These social and cultural elements in the words or Parthasarathy 'made it both unlikely and difficult for a national healthcare system to emerge; or in the terminology of the socio-technical multi-level model the social elements at the landscape level enable certain developments while they disable others.

Parthasarathy then continues with a description of the technological architecture of genetics in the US, and how this architecture was shaped towards a final configuration of BRCA testing in the US. In the final configuration the actor group of Myriad Genetics manage to build a technological architecture which outlasts the architectures build by the other actor groups. The winning architecture of Myriad Genetics offers BRCA testing as a purely commercial product, which anyone can obtain through their local practitioner. In explaining how this final architecture develops we follow the struggle of various actor groups, and their attempts to build a technological architecture, which would prevail in the context of the cultural and social setting of the US, the success of the architecture developed by Myriad Genetics is explained by referring to its fit with the social and cultural setting of the US as well as the configuration of the system of genetic services. (Parthasarathy, 2007)

In the terminology of the socio-technical multi-level model, the actors groups and their struggles to develop a successful technological architecture can however be conceptualized in the terminology of regimes and niches. Before the discovery of the BRCA genes, genetic clinics existed within hospitals, which were connected to universities. During the 1960's and 70's the genetics services changed, when technological opportunities for analysis of chromosomal and DNA anomalies emerged, and lead to the emergence of private laboratories and clinics separated from the hospitals as well as the counselling which had taken place there. In terms of the socio-technical multi-level model this shows how social groups at the regime level of genetic services facilitate a co-evolutionary interaction between technology and society. In interpreting both on new technological development as well as the social context of a tradition for entrepreneurship and private insurance systems, the actions of the social groups facilitate a development where commercial laboratories become the dominant providers of genetic services at the regime level.

As the BRCA genes are discovered, four social different social groups (Myriad Genetics, University of Pennsylvania's Genetic Diagnostic Laboratory, OncorMed and the Genetics and IVF institute) develop socio-technical networks around BRCA testing. Again, using the terminology of the socio-technical multi-level model, these four groups develop four niches on BRCA testing. As the various social groups at the niche level interpret and re-work their socio-technical network, they facilitate a co-evolutionary interaction between the technology of BRCA testing as well as the regulative, normative and cognitive rules. In building and maintaining this network the social groups constantly had to interpret on the effort by various working groups to develop recommendations for regulations on the area, but also on messages coming from media and activist groups. The way the social groups interpreted these regulatory efforts and messages thus shaped the way the technology of BRCA was built. An example is the system built by the Genetics and IVF institute. Their interpretations of the social technological context lead them to define BRCA testing as the search for the 185delAG mutation, which was specific to members of the Ashkenazi Jewish population. Everyone had in principle access to a test, which was sold commercially, but the genetic test performed searched for this specific mutation. On the other hand social groups which interpreted on the technological context lead to a continuous effort by these social groups, such as the US government, NAS (National Academy of Science), FDA (US Food and Drug Administration) and the American Medical Association to, throughout the 1980's and 90's, develop guidelines and recommendations as well as to the continued efforts by activists groups to influence the socio-technical networks build around the BRCA testing. In the end only the socio-technical network build around the BRCA testing by Myriad Genetics however managed to link up to the regime level of genetic services. Again the successful link made between the niche developed by Myriad Genetics and the regime level of genetic services can be explained in terms of the better fit between this socio-technical network and the socio-technical network developed around genetic services at the regime level. At the same time the elements of landscape of the US healthcare system enabled the developments at the regime and niche levels through its tradition of private health insurances, entrepreneurial history and physicians fight for autonomy.

The UK

As with the US, a landscape level consisting of social and cultural elements can be identified. This landscape consists of a long tradition of state involvement in medical care in the UK. Early in the twentieth century national social welfare programs were initiated with the primary goal of providing acute emergency care to the low-income class of workers. The state took full responsibility for healthcare services with the creation of the National Health Service (NHS) in 1948. This landscape level, in style with the US landscape level thus enables certain developments while disabling other. On the regime level a regime of genetic

services was, as in the US, also present. When the technological opportunities for genetic services grew, the organization of this regime in the 1960's and 70's had the configuration that obstetricians and pediatricians offered prenatal and newborn screening while genetic clinics with testing structures where built in NHS teaching hospitals. All of these activities where however under the sole control of the NHS. As technological opportunities grew the social groups within the regime started to interpret on the socio-technical network which surrounded genetic services. Through the actions of social groups the genetic services in the UK developed into a system of regional genetic clinics where access was granted to anyone who was considered to be in need of genetic services. For evaluating need extensive evaluation procedures were developed in the form of guidelines to general practitioners on how to evaluate if patients should be placed in the low, moderate or high risk groups.

This end configuration can again be explained by the co-evolution between technology and society facilitated by social groups and the enabling character of the specific landscape of the healthcare system in the UK. Social groups at the regime level of genetic services emphasized the cost-saving potential of genetic testing and argued that it could help streamline healthcare and cutting costs by prevention of disease. When BRCA testing then became available social groups in niches developed suggestions of socio-technical networks in where BRCA testing could be implemented into the existing NHS network. In the end BRCA testing was incorporated into the socio-technical network at the regime level in a model where BRCA testing was only available through extensive evaluation procedures. In this way the social context shaped the technological contest of BRCA testing, but the social context was likewise shaped in the creation of specialist regional genetic centers to which equal access was designed as access based on need and provided through selection procedures.

In sum these two illustrations of the socio-technical multi-level model show how elements at the landscape of the healthcare systems in the US and the UK enabled a certain development in the regimes of genetic services, while disabling others. The elements at the landscape level become interpreted by social groups in niches as well as regimes who interpret and re-work these elements in the creation of their own socio-technical network. The illustration also show how the social groups, in the process of creating their socio-technical networks facilitate a co-evolution between technology and society. In the following section I take a closer look at the elements at the landscape level as well as the rules in the regimes and niches in order to show how moral elements and rules are part of these.

3.2.2 The importance of moral rules in the socio-technical multi-level model

As mentioned in the introduction to this chapter the example of the implementation of BRCA testing in the US and the UK serve both the purpose of illustrating the socio-technical multi-level model, but also the purpose of illustrating the importance of moral rules as well as to give them a explicit place in the multi-level model.

When considering the elements at the landscape level and the interpretation of these by the social groups into rules for how the socio-technical networks of genetic services as well as BRCA testing should be made, at the regime and niche level it is immediately evident that these elements concern more than just the trivial elements and rules on society and technology. Instead these elements contain moral judgments on the right way to organize the healthcare sector and the right way to provide medical care, as well as genetic services. They contain moral judgments on the just distribution of medical goods and health in a society, how to avoid causing harm as well as conceptions of the good life.

Defining a moral rule

Morality is very generally concerned with rules of behavior and more specifically with rules of behavior that pertain to the right thing to do, the good way to live or how to avoid causing harm. A common example is the moral rule "you should not kill". Following Swift (2006), this general rule can be considered a moral concept[9]. This general concept, we can all agree on, we all want to do the right thing, live good and avoid causing harm to our surrounding, which in this broad understanding means that you should not kill. However, when we try to define, to create a more specific conception of this general concept, different people, nations and groups tend to come up with very different answers. For example one group would argue that it could be morally right to kill one person in order to save the lives of a hundred, while others would argue that it can never under any circumstances be morally right to kill. The different conceptions which can be made on the basis on one concept already make morality confusing. How can both positions be moral ones when the outcome of the action is the totally opposite? On this question Beauchamp (2001) argues that a moral judgment must necessarily be founded on an acceptable moral theory. An example of such an acceptable moral theory is utilitarianism or deontological theories. So generally morality is about how we behave towards each other and moral theories help us to explicate exactly what constitutes morally right behavior.

The openness of general moral concepts to individual interpretations is something which is illustrated in the above example of BRCA testing in the US and the UK. In general both countries have healthcare system based on the general concept of 'helping the sick', however when conceptualizing what it means to help the sick the US defines it as morally right to bye and sell medical services, while the UK defines the right way to provide medical services as one of equal access, provided on the basis of need. This struggle over conceptions and their justification is the area of ethics and three traditional theories in this area is utilitarianism, which is broadly concerned with maximizing utility for the largest group of people, deontology, which is broadly about acting out of respect for moral principles and virtue or good life ethics,

[9] Specifically 'the 'concept' is the general structure, or perhaps the grammar of a term like justice, or liberty or equality. A 'conception' is the particular specification of that 'concept', obtained by filling out some of the detail.' (Swift, 2006;11)

which broadly is concerned with using criteria of the good life lived by the virtues person, to make moral judgments[10].

In terms of the theoretical model developed so far, using the notion of co-evolution as a guiding notion for investigating the interaction between technology and society, there is however no mentioning of moral rules. Since moral rules seem to pertain to important questions, which, as it has just been shown, play a part in the co-evolutionary pattern of socio-technical interaction, they should be given an explicit place inside the theoretical model. In other words moral rules need to be made an explicit part of the framework of the regulative, normative and cognitive rules in where the social groups at the regime and niche level act, as well as a part of the slow changing factors at the landscape level.

3.3 Conceptualizing and distinguishing moral elements in the socio-technical multi-level model

The co-evolution between technology and morality has now been conceptualized using the socio-technical multi-level model. This co-evolutionary process is conceptualized as taking place at multiple levels, which are nested inside each other; the landscape level frames, the regime and niche levels, and consist of slowly changing elements and now explicitly also moral elements, which enable certain developments at the regime and niche levels while disabling others. The regime and niche level consist of social groups embedded in a framework of rules, a framework of rules which is now explicitly extended with moral rules, which are part of the regulative, normative and cognitive framework at these levels.

The above conceptualization of the co-evolution between morality and technology however raises the question of how to distinguish the moral element and rules, which should have an explicit place inside the model. At the landscape level they should be part of the slowly changing elements that are positioned here, and at the regime level they should be part of the framework of rules in where the social groups are embedded. Specifically these will, as mentioned in the previous section, concern the right thing to do, the good way to live or how to avoid causing harm to others.

"We become aware of moral routines when people disobey them, when conflicts between routines emerge and a moral dilemma arises, or when they are no longer able to provide satisfactory responses to new problems" (Swierstra & Rip, 2007;3)

Defined in this way moral elements and rules are invisible rules of behavior, and only when the rules are broken or challenged is their existence noticed. This observation informs the approach to distinguish moral elements and rules which will be taken here. As visibility of a moral rule or element entails that it has been broken or challenged, it is reasonable to expect that struggle and conflict can be observed in connection with this.

[10] These will be briefly explained in the following section.

"Emerging technologies and the accompanying promises and concerns, can rob moral routines of their self-evident invisibility and turn them into topics for discussion, deliberation, modification, reassertion" (Swierstra & Rip, 2007;4)

In this sense technology development as well as introduction of new technologies, seem to effect and challenge moral rules and elements. Again the illustration of the implementation of BRCA testing in the US and the UK can be used as an example. In the US for example four different niches developed, each building their own socio-technical networks around BRCA testing, which had different implications for who could get access to a test. In this way the emergence of BRCA testing prompted social groups to re-interpret the moral rules for access to genetic services; a rule which become moral because it concerns the right way to provide a medical service as well as the functioning of the good healthcare system.

3.3.1 Conceptualizing moral elements and the co-evolution between technology and morality using the NEST-ethical pattern of argumentation

As noted in section 2.2.2 and 3.2.2, ethics enters the picture as soon as certain conceptions of a moral rule are tried justified. Or as Swierstra and Rip put it *"Ethics is 'hot' morality and morality is 'cold' ethics"* (Swierstra & Rip, 2007;3-4). For the moral elements at the landscape level this means that they at first glance will seem self-evident and established, as they are slowly changing factors. But due to their moral nature these elements will be surrounded by the remains of earlier struggles; in other words as they have come out of a struggle they will be justified and emphasized when mentioned. This instability will be even clearer at the regime and niche levels, where the moral rules are less stable, and struggles and debates over the moral rules become possible to observe directly.

In their 2007 article Swierstra and Rip shows that there is such a thing as a pattern of ethical argumentation surrounding new and emerging technologies. They name these patterns of argumentation about new and emerging science and technology (NEST-ethics). In the framework of NEST-ethics certain patterns of argumentation can be recognized in debates over new and emerging technologies. This pattern contains a list of various arguments which can be connected to each their traditional ethical theory: consequentialist arguments will concern debates about the costs and benefits of emerging technologies. Such consequentialist arguments serve to point out the main areas of concern. These areas of concern will typically be addressed in terms of deontological arguments, which center around principles such as autonomy, or in terms of justice arguments, which center on distributions of benefits and costs or virtue ethical arguments focused on the good way to live and how to perceive this.

Meta-ethical patterns, which concern the understanding of technology that participants in a debate have, are also distinguished. One such understanding is that technological development can be influenced, which leads to perceptions of technological determinism or sociological determinism. Secondly one can understand technology in terms of previous experience, which can be seen as legitimizing or de-legitimizing new technology development. Thirdly technology can be understood in terms of its possibility to change our

morals, which can be seen as inevitable, something that we will get used to or as a treat that should be meet. These meta-level understandings of the interactions between technology and society form the background for patterns of argumentation, which arise at a practical level. (Swierstra & Rip, 2007) However, a fourth way of understanding technology development is in terms of a co-evolution of technology and morality or more specifically as a co-evolutionary process between technology and morality; seen in this way the argumentative patterns above turn into patterns representative of a co-evolutionary development between the technology and the morality. The inventory of NEST-ethical patterns of argumentation can now be used as a tool to make visible the co-evolutionary interaction between technology and morality in the socio-technical multi-level model.

3.3.2 Distinguishing more or less stable moral elements and rules

In the socio-technical multi-level model the three levels are distinguished by their degree of structuration and their openness to change, with the landscape level being the most stable level. In section 3.2 these levels were extended with moral elements and rules and in section 3.3.1 the NEST-ethical pattern of argumentation was developed into a tool able to analyze the co-evolutionary interaction between technology and morality. This however does not say anything about how to distinguish between more or less robust moral elements and rules at the three levels? One way to solve this is to use the distinction made between a concept and its conceptions as done in section 3.2.2. To apply this one would say that moral elements at the landscape level are moral concepts such as autonomy. Moral rules are then conceptions of how autonomy should be integrate in a specific practice. The concept of autonomy is so to say translated at the regime level to for example meaning informed consent. Moral rules at the niche level will then be made up of translations of how informed consent as formulated on the regime level apply to their specific regime.

3.4 Re-phrasing the research questions using the conceptual framework of the extended socio-technical model

To sum up, we now have a conceptual model for the co-evolutionary interaction between technology and morality. In this model the co-evolutionary process is conceptualized as taking place at multiple levels (landscape, regime and niche), which are nested inside each other. The landscape level consists of slowly changing socio-technical elements, which now also explicitly contain moral elements and the regime and niche level consist of social groups embedded in a framework of rules, explicitly extended with moral rules, which are part of the regulative, normative and cognitive framework at these levels. Finally the NEST-ethical pattern of argumentation is used as a tool to make visible the moral elements and rules in the regimes of screening and clinical genetics and to illustrate the co-evolution between technology and morality. Moral elements at the landscape level are slowly changing, but as they are the results of struggles, they will when mentioned be emphasized as their position on the landscape level has not always been self-evident. Moral rules at the regime and niche level are translations of these moral elements resulting in more and less stable

rules pertaining to the right thing to do, good way to live or how to avoid causing harm in connection with the functioning of a certain regime. Figure 1 illustrates the model.

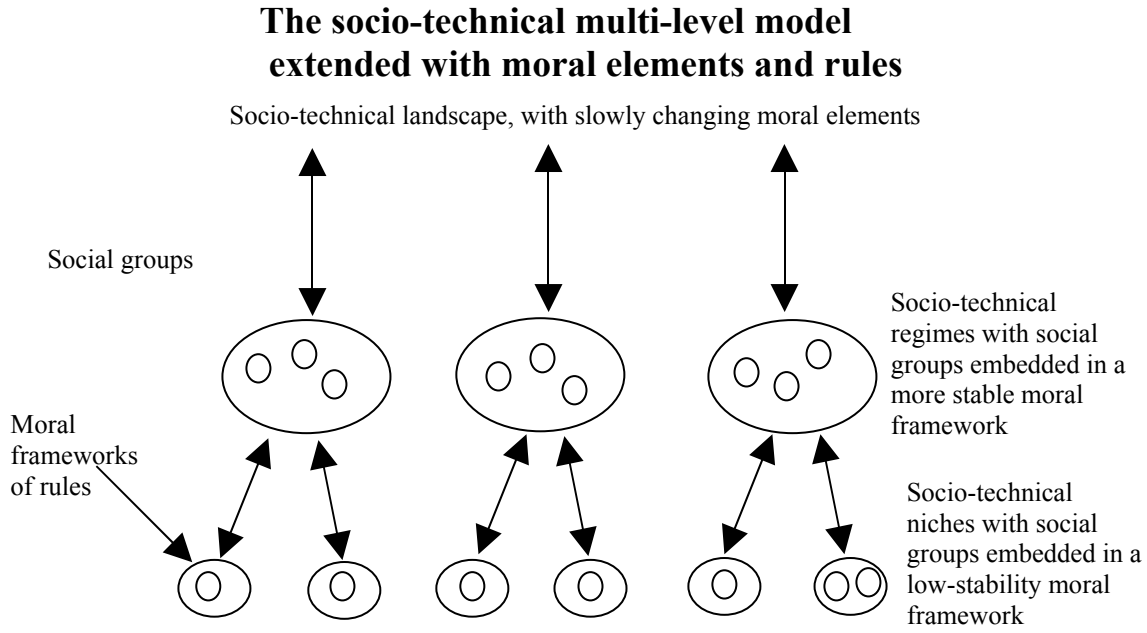

Figure 1 *Shows the conceptual model of the extended socio-technical model, where the social groups facilitate the co-evolution between technology and morality at the regime and niche levels, which are nested inside the landscape level with its moral elements. The moral frameworks of rules, which are emphasized in the figure only form part of the socio-technical network which make up the regimes and niches in where the social groups are embedded.*

In the terminology of the extended socio-technical model, the practices of screening and clinical genetics now become two regimes nested inside the landscape level of the Danish healthcare sector. On the landscape level some moral elements which can already be identified for the Danish healthcare sector were briefly mentioned in chapter 2; specifically the elements of a focus on the rights of the collective and a focus on the right to self-determination. On the regime level of screening and clinical genetics the moral frameworks of rules shaping these regimes can be already be partly identified in the descriptions of the goal and approach of these practice and the problematization of these moral frameworks of rules by groups such as the Danish Council of Ethics show how social groups continuously interpret on and rework the frameworks. On the niche level can be identified a niche inside the regime of screening, which concern itself with the specific practice of mammographic screening for breast cancer. In the next chapters the following research questions together with the extended socio-technical model, will guide a more detailed investigation of these landscape, regime and niche levels.

The main research question as well as sub-questions can now be reformulated into:

1a. What moral framework of rules are created for the regime of screening and the regime of clinical genetics through the co-evolution between technology and morality?

1b. What does the co-evolution between technology and morality imply for interactions between the moral frameworks of rules shaping the regimes of screening and clinical genetics and what do these interactions imply for a future development of genetic screening programs for susceptibility to disease in Denmark?

Sub-questions:

2. What moral frameworks of rules shape the regime of screening and the regime of clinical genetics and how are they created?

3. What moral elements can be identified at the landscape level of the Danish healthcare sector?

4. How does the co-evolution between technology and morality take place inside the regimes of screening and clinical genetics and can the NEST-ethical patterns of argumentation help to male this co-evolution visible?

5. What interactions can be traced between the regimes of screening and clinical genetics?

6. What moral and technological elements become essential for a future development of genetic screening programs for susceptibility to disease in Denmark?

4 The creation of a moral framework of rules shaping the regime of screening

In this chapter I use the conceptual model developed in chapter 3 to explore the co-evolution between technology and morality in the regime of screening as well as the creation of a moral framework of rules in the context of the Danish healthcare sector. The aim of the chapter is to illustrate how a moral framework of rules is created for the regime of screening and to show how this creation takes place through the co-evolutionary interaction between technology and morality. A first step towards this aim is to identify the moral framework of rules which shapes the regime of screening. This is done by investigating written sources by the social groups, which have the power to issue recommendations and guidelines at the regime level of screening. Next the moral elements at the landscape level as well as their historical dependency are identified and their interaction with the regime of screening is shown. This is done by investigating written sources of the history of the Danish healthcare sector as well as current legislation on healthcare services. Further it is shown how social groups, which do not have the power to issue recommendations and laws, interpret and rework the moral framework of rules shaping the regime and how interactions occur at this level between the niche and regime level. This interaction, between niches and the regime of screening, show how technological development at the level of practice on the niche level becomes important for the interaction between the regimes and niches and thereby also the landscape level. An investigation of written sources by social groups participating in the debate around screening forms the basis for this part of the chapter. Finally the inventory of argumentative patterns from NEST-ethics is used to make visible how the moral framework of rules is created through a co-evolutionary interaction between the technology and morality facilitated by the social groups belonging to the regime of screening.

4.1 Identifying the moral framework of rules which shape the regime of screening, and investigating its historical dependency

In this section I identify the moral framework of rules which shape the regime of screening. This section focuses on health laws issued in Denmark, recommendations made by the Danish National Board of Health, guidelines by the WHO and recommendations made on screening by the European Union. The mapping of the moral framework serves to identify the framework as well as to position the social groups inside it. This section also identifies moral elements at the landscape level of the Danish healthcare sector and their historical dependency and interactions with the regime of screening.

4.1.1 The moral framework of laws, guidelines and recommendation shaping the regime of screening

The National Board of Health and the WHO

A first important social group in this context is the National Board of Health. In a report from 1999 The National Board of Health recognized and accepted guidelines developed by the WHO in 1968[11]. (Sundhedsstyrelsen*, 1999) The guidelines developed by the WHO specify the right way to behave in a screening program as well as the design of the good screening program and focuses on a few points; that the disease should be an important health problem, the disease should be recognizable on a latent or early symptomatic stage, the natural history of the disease should be known, there should be an effective treatment, there should be a suitable test that recognizes the disease in its early stages, the suitable test should be acceptable by the population, it should be agreed on who treats the disease, facilities for diagnosis and treatment should be available, case finding should be an ongoing process and costs of the screening program including diagnosis and treatment should be evaluated against other expenditures to medical care. (Wilson & Jungner, 1968; Sundhedsstyrelsen*, 1999)

These guidelines are generally accepted by the Danish Health authorities, but as the National Board of Health comments in the report, considerable technological developments had occurred since the formulation of the guidelines and they could therefore no longer be considered sufficient. The WHO guidelines were developed with the vision of the healthcare system performing screening in the interest of the individual. As the report from the National Board of Health writes screening programs can however be performed for different purposes such as; to protect the individual from disease which this individual is not aware of, to protect society or others from harm or to save money. (Sundhedsstyrelsen*, 1999) One example of using the second motivation is when donor blood is screened for HIV, even though there is no cure for this disease. Here the interests of the greater society are prioritized above that of the individual. However the comment as well as the additions made by the National Board of Health in the report, is also testimony to the technological development occurring between 1968 and 1999, a development which obviously makes it necessary for the National Board of health to expand on the guidelines by the WHO. This observation is one which will be returned to later as it is important for the perception of a co-evolutionary development between the technological and moral contexts. Added to the WHO guidelines by the National Board of Health were considerations of the validity, effectiveness and predictive value of the screening activity, that an estimate of ethical and psychological consequences and of stigmatization and of the consequences of false positive and false negative results should be made, and that an economic evaluation, including cost-benefit analysis, as well as a detailed description of the organization of the screening program should be made. Apart from this the National Board of Health worries about the emergence of what they call 'grey-zone' screening programs. These screening programs are initiated locally as research projects which then diffuse into practice.

[11]The WHO is in itself an important social group. Here however the guidelines developed by this group will be treated under the social groups of the Danish National Board of Health.

Examples are ultrasound and cholesterol measurements. (Sundhedsstyrelsen*, 1999) The purpose of screening is clearly stated in the guidelines by these two social groups as being disease prevention. That is the prevention of as much disease as possible, as effectively and with as much value for money as possible. Mette Hartlev (MHa) is professor in Health Law and Director of Studies at the Faculty of Law, Copenhagen University and describes screening as:

"With screening interests evolve both around the society and the individual. The interests of the individual in the sense of having an interest in preventing and treating conditions, but also the interest of the individual in being afflicted with nervousness, anxiety and so on, (....) the interests of the society is in using some funds on investigating a larger group of society to prevent them from becoming sick, which can increase the level of health and possibly save some expenses on treatments. (....) seen from the point of the individual it is clear that for the ones who had an actual risk of becoming sick and now do not become sick because they were screened, the screening is in accordance with their own interests. On the other hand there is also a lot which are inflicted potential suffering and nervousness, so in this way it is (screening) potentially infringing on the integrity of the individual." (Appendix A, MHa)

From this description it becomes clear that the purpose and interest involved in screening programs can be interpreted from various angles, a point which will be returned to in section 4.2. To sum up the guidelines developed by the National Board of Health and the WHO point to effectiveness as the right way to measure if a screening program is the right method for disease prevention. The purpose of disease prevention which comes forward in the guidelines defines what is perceived as the good way to live, which becomes a life free from disease. Furthermore the guidelines explicate the areas to which concern should be directed as not to cause harm to involved individuals. An example is the attention which should be paid to social, psychological and ethical consequences of screening programs. What also already becomes clear here is that one social group (the National Board of Health) takes up and slightly reworks a moral framework of rules developed by another social group (the WHO). Illustrating how social groups move around in the moral framework of rules, and how they use each other to legitimate their own perceptions of the moral framework shaping the regime of screening. In this sense the National Board of Health uses the WHO as an authority which justifies the guidelines and focus developed by the National Board of Health.

The European Council

A third social group is the European Union, which Denmark is a member of. The European Council developed guidelines on screening in 1994, and they too are part of the moral framework of the regime of screening. The recommendations are more elaborate than the guidelines by the WHO and are described by MHa as:

"In addition the European Council has made some recommendations on genetic testing and screening and the WHO have also made some, but the European Council is one of the places where they have been most precise in writing down recommendations for genetic testing and screening" (Appendix A, MHa)

In eight sections the recommendations made by the Council of Europe spells out introductionary reflections, ethical and legal values, criteria for selecting diseases suitable for screening, economic aspects, quality assurance, organization, research and general remarks which should be taken into account by each member state before implementing screening programs. In these recommendations, screening programs are defined as testing applied to a defined group, before this group would otherwise have sought treatment. They mention that screening is just one method to reduce the burden of illness to society and the individual, and that a decision to implement such programs should be taken in co-operation with the medical profession in each country to take into consideration ethical and legal differences. The recommendations also put emphasis on awareness around disadvantages of screening programs and here stigmatization, discrimination, social pressures, psychological stress, physical and psychological risks, raising expectations which cannot be fulfilled as well problems surrounding false positives. Effectiveness is mentioned as an essential and necessary feature in making a screening program ethical, where ethical here is used in the sense of right action. Information obtained in screening programs should be treated as private, no one should be forced into screening programs and holding back information on advantages or disadvantages conforms to infringements on the autonomy of persons. Again criteria around choosing a disease as suitable for a screening program involve that the disease be a serious burden and that treatment and diagnosis, which have to live up to certain quality standards, be available. Economical considerations are mentioned as playing a role in evaluating the efficient use of resources to combat disease. The screening programs should continuously be evaluated for their ability to be both effective as well as for their disadvantages mentioned earlier. (Council of Europe, 1994)

These recommendations are thus both similar and different from the guidelines developed in 1968. The moral rules developed there can still be recognized, but the new rules introduced by the National Board of Health are also visible. A screening program is still defined in the same way, but there seems to have been some development in terms of what should be fulfilled and contained within a screening program. The recommendations made in the guidelines from the WHO are still visible, the focus on effectiveness, and quality and availability of suitable diagnosis as well as treatment. However much more is here done in terms of putting emphasis on the autonomy of the individual and the providence of information as well as the private nature of the information obtained from the individual through a screening test as well as the social and psychological consequences of screening programs.

These three social groups thus create a moral framework of rules, which shape activities in the regime of screening. The moral framework spelled out by these social groups is similar in the sense that it contains an

emphasis on disease prevention, efficiency, quality and availability of diagnosis, treatment and organization surrounding screening. However the National Board of Health as well as the Council of Europe also expands the moral framework by adding emphasis to social, legal, ethical and psychological consequences, to the private nature of the data obtained and the importance of individual autonomy.

It is however also clear that the moral framework created by these social groups is developed in different time periods. Keeping the nested as well as dynamic character of the socio-technical multilevel model in mind, it becomes interesting to identify moral elements at the landscape level of the Danish healthcare sector, the historical dependency of these moral elements as well as niches nested inside the regime of screening; an identification, which can be used to point to possible connections between the moral elements at the landscape level and the moral rules at the regime and niche levels.

4.1.2 Connecting the moral framework of rules shaping the regime of screening with a historical moral landscape of the Danish Healthcare sector

In the previous section a moral framework of rules shaping the regime of screening, made up by three social groups, was identified. This moral framework of rules is nested inside the landscape level of the Danish healthcare sector and the moral elements present here. To explore this landscape and the moral elements and historical connections, a new general law on health, historical descriptions as well as the 2008 structural reform of the healthcare[12] sector is investigated.

The Ministry of Health and Prevention and the general law on health

A central social group at the landscape level is the Ministry of Health and Prevention, which issued a new general law on health in January 2008. This law serves to lay down the general framework of rules, which any regime in the healthcare services is expected to follow. Through reading this law it becomes clear that there are some key areas where the law specifically points to the right way to behave as well as to the values which should guide the good healthcare system.

To begin with a general purpose of the healthcare system is spelled out as insuring the respect, integrity and self-determination of the individual. Specifically the healthcare system should insure easy and equal access to treatment, treatment of high quality, a good connection between services, freedom of choice, easy access to information, a healthcare system which is easy to maneuver in and limited waiting list for treatments. Following this it is stated that informed consent should be obtained before any treatment, and that the patient should be informed of the consequences of not consenting to treatment or denying the healthcare authorities certain information. The law further states that information about a patient cannot be passed on without the consent of the patient. This principle however is complimented by a list of exceptions which

[12]This structural reform involved more than the healthcare sector, but in the light of this thesis only change affecting the healthcare sector is interesting.

make passing on information without consent possible if it for example is in the interest of the patient. Again in connection with collecting information on patients, this is only permissible if it has a professional purpose. That is the collection needs to be based on a professional medical purpose. (Retsinformation*, 2008)

Regarding insurance and employment regulation also exists, which prohibits insurance companies from collection information regarding the patient's risk of future disease, but allows them to collect information on current conditions, employers can only collect information on current or symptoms of conditions which could have importance in a certain working environment. (Bojesen et al., 2007) Clearly this law on health points to the right way to behave in certain situations and the good healthcare system thus spelling out the moral of the healthcare system.

The following section explores the historical dependency of the moral elements at the level of the Danish healthcare. As elements on the landscape level are in general slow changing, it is expected that it is possible to trace a certain historical dependency between historical and current moral elements. At the same time interactions between the moral landscape and the regime level are expected.

The historical connections at the landscape level of the healthcare sector

Historically[13] philanthropy in various forms was practiced through the 18th, 19th and 20th century. One expression of this were the artisan groups, which established their own help funds to provide mutual help in the case of illness and other groups which organized help funds for the poor. A motivating factor for the practice of philanthropy was a focus on a healthy and industrious population. To achieve this goal, good access to healthcare was therefore essential to keep a large working force. It was a common conviction that good health of the population would reduce public spending and be good for the national economy. Early on public spending and effectiveness therefore became an issue in the management of the sector. Measures such as improvement of the education of surgeons and physicians, smallpox inoculations, education of midwives and state-employed doctors to take care of the poor were initiated. Hospitals were built, but people were extensively treated at home. Public health boards were formed, which were to take care of sewage, water, food and working conditions controls. In 1929 sterilization laws were enacted, to ensure that people judged mentally disturbed did not procreate (Dikötter, 1998). In the 1930's and 1940's free healthcare examinations were introduced for pregnant women, infants and preschool children. Medical services were implemented into the schools and all children under 18 had free access to dentists. Today all of these practices continue to exist. (Strandbjerg-Larsen et al., 2008)

In 1970 and 1973 healthcare reforms were initiated and the state took the full responsibility for the sector, and at the same time health insurance became exclusively financed by the state through taxes. Since the beginning of the 1970' the state has therefore been sole responsible for the organization and running of the

[13] A proper historical investigation would of course entail a more thorough investigation using original historical sources to show how people at the time described the healthcare sector and their own activities. The source here is however a HIT report written by acknowledged experts in the field public health history.

healthcare sector. The public system is complimented by a few private hospitals and private insurances. Many citizens take out additional private insurances and companies increasingly offer additional insurances to their employees. This insurance market is unregulated and remains a cause for continued political conflict. (Strandbjerg-Larsen et al., 2008)

The structural reform

Currently a new structural reform is being implemented, which was initiated on January 1 2008. The Law on Health is part of this reform. The reform is seen as giving the state larger possibilities for controlling the healthcare sector. Decentralization which is traditionally valued is still retained, but the division of tasks inside the sector was changed and the regions lost their rights to collect taxes. Most visibly the reform reduced the 14 counties to 5 regions and the 275 municipalities to 98. A central reformulation, which connects to the value of decentralization, is the change in focus from prioritizing the rights to self governance by the municipalities and counties/regions to a focus on securing equal standards of healthcare throughout the country. (Strandbjerg-Larsen et al., 2008)

The moral landscape of the Danish healthcare sector and its connections to the regime of screening

What can be recognized in this section are some moral elements, which are again and again brought to the fore to justify a certain build-up and organization at the landscape level. The goal of a large healthy industrious population, about which it is believed that it will improve the economy of a country, can be recognized in the perception of the good life being one lived without disease. An expression of this perception of the good life can be recognized in the offer of free healthcare examinations of pregnant women and children and the implementation of healthcare in school.

The difference observed in the guidelines from the WHO and the European Council which was partly visible in the additions made by the National Board of health can be traced in a historical development where focus has gradually shifted from society in general to the individual. The sterilization laws enacted in 1929 can be seen as an extreme expression of the rights of the general public coming before the individual. These forms of eugenic sterilization were presented as an essential part of the socially desirable welfare state and people judged mentally disturbed had no rights legally deny sterilization. The low resistance both from the public and the Lutheran church demonstrates the weight put on collective rights and before 1970 individualism, individual choice and freedom was seen as dangerous ideas and as harming the collective rights of society. (Dikötter, 1998) However in the 1999 publication from the National Board of Health Self-determination and freedom of choice were presented as one out of four basic values which characterized the Healthcare sector. (Sundhedsstyrelsen*, 1999) One might speculate that this change was initiated by the increased focus on human rights which emerged after the Second World War, or as MHa puts the development around the individual rights:

"It is most clear that a development has taken place around the individual rights, where self-determination and integrity of the individual, or especially self-determination have become a principle which was introduced rather late. Previously there is no doubt that the purpose was to improve the health of the population and for that purpose you had a doctor, who probably knew what was best, and who was obligated by "Lægeloven" and then society would provide a system within which the doctors could practice. The idea that the individual could have some rights in relation to the public system is a relatively new thought. (...) It is difficult to say what has caused it, but it probably relates to a general tendency in society to focus more on individual rights. It is visible that this development starts to happen at about the same time as talks of human rights began, and it is not only on this area (of health) but in all other contexts as well where this concept of individualization and individual rights is showing" (Appendix A, MHa)*

Clearly a development has taken place around the individual rights, a development which can thus be traced in the formulations of the main values of the healthcare system. In connecting these moral elements from the landscape level with moral rules in the framework surrounding screening, the formulations of the social groups in become interesting; interesting in an investigating of how and if social groups translate moral elements from the landscape level.

Characterizing the moral elements at the landscape level, one moral element which has persisted through a long period of time is the perception that the good life is a life lived without disease, and that it is the responsibility of the state or at least the public authorities to provide the public with opportunities to reach this goal. In addition a moral element is the belief that there is money to earn on a good an industrious population. Another moral element, which has been dominant until recently is the weight put on the good of society coming before that of the individual. Recently this moral element has been challenged with an emerging focus on the individual human being and the rights of the individual. The social groups have taken up these moral elements in various ways. At the regime of screening social groups have translated the moral elements of a state being responsible for healthcare, for example the National Board of Health, translating it into a need to implement state initiated screening programs of defined groups in the population. Efficiency in terms of economic feasibility as well as predictive value of test and diagnosis are translations of the moral element of saving money and having a healthy population, as the goal is to get as much health for as little as possible. With the emerging focus on self-determination and the rights of the individual, we see how social groups at the regime level take up these moral elements and start formulating rules on the importance of adequate information on advantages and disadvantages of participation, the private nature of information obtained as well as social and psychological problems. This change can be seen in the 1968 guidelines by the WHO to the 1990 recommendations by the National Board of Health and the 1994 recommendations by the European Council. This change in the way social groups translate and take up the moral elements is noted in the following comment by Maja Horst (MHo), who is an associate professor at the Department of

Management, Politics and Philosophy at Copenhagen Business School and Director of the Doctoral School in Knowledge and Management:

"The idea with screening is to find the ones which would benefit from the treatment at as early a stage as possible. But it is also about a targeting of resources that is kind of like the point with screening, of course the point is also to help the people who have a disposition for a disease, but as a societal activity it is much more targeted. I (MHo) studied prenatal diagnosis in the beginning of the 90's, and back then it was clearly a cost-benefit analysis which was behind it (the screening program). (....) It was interesting in the beginning of the 90's because you had a public offer build on an analysis, which if exposed, would be completely unmoral. In 1994 new guidelines then emerged which put the emphasis on autonomy. There is clearly a fear of using economic arguments as a basis. Instead arguments should be based on what is the best for the individual." (Appendix A, MHo)

Interaction thus takes place between the moral framework shaping screening and the moral landscape of the Danish Healthcare sector. This interaction arises when social groups take up the moral elements from the landscape level and translate these into moral rules which apply to the regime of screening. What can also be seen is the historical dependency of the regime of screening itself. Rather than being developed at one point in time this framework has continuously developed through the action of the social groups embedded in their socio-technical network. This is also a point for moral elements at the landscape level of the Danish healthcare sector, which can indeed be characterized as changing more slowly than the moral framework of rules surrounding screening. While the moral elements at the landscape level of philanthropy, social and individual interest change over centuries the moral framework surrounding screening change through a couple of decades.

This brings us to the social groups which do not have the power to independently issue laws, guidelines and recommendations, but which instead rework and reinterpret the moral framework of rules developed by the three social groups in section 4.1.1.

4.2 Following the struggle of the social groups in the moral framework of the regime of screening

Having identified the moral framework produced by the National Board of Health, the WHO and the European Council it becomes possible to move on to the social groups which do not have the power to issue laws, recommendations and guidelines. Instead the moral framework of rules is re-worked and re-interpreted in order for the social groups to position themselves within the regime. Following these social groups the niche level and the interactions between the regime and niche level become visible. What we are looking for here are thus social groups which are directly involved in taking up, interpreting and re-arranging the moral framework of rules which is laid out by the National Board of Health, the WHO and the European Union. An opportune place to start looking for these social groups is in the debates on screening.

The Danish Council of Ethics

A social group which has contributed vastly to the debate on screening in Denmark is the Danish Council of Ethics which published a report on the issue, in 2001, and which trough various hearing answers have contributed to the debate. In the 2001 report the council points out four key areas of concern. The first key area of concern are if screening programs represent a "pathologization" of people, understood in the sense that people will become dependent on doctors to tell them they are healthy or if they represent a good offer for a few sick people while at the same time act as reassuring for a large group of healthy people. Elaborating on this key issue the council points to the ambiguities in how different people perceive invitations to participate in screening programs, which can be either scaring or reassuring. The problems here is that a diagnosis does not rest on a distinction between being ill or sick, but on a knowledge of groups with a potential, thus creating a dependency to experts as the ones which are needed to guarantee that you are not sick, because otherwise you always might potentially be. This dependency might lead to people feeling less and less responsibility for their own health and continuing unhealthy lifestyles or the opposite could happen and healthy people could be informed and motivated to make an effort towards staying healthy. Being approached by the healthcare system with an offer to take part in a screening program can also create feelings of guilt if one chooses to say and even worse if one then later becomes sick. This feeling might even be increased by the practice of the healthcare system to send reminders to people who do not respond. Of course there are advantages for sick people who are treated early, and healthy people who have their health confirmed. However the council stresses that screening should be viewed as only one method of preventions and that it might even be misleading to call screening prevention as preventing something from happening would for many people entail avoiding disease all together. The council stresses that there is more to prevention than informing people about their risk of disease such as informing about healthy lifestyles and improving the environmental conditions under which people live and work more or less voluntarily. (Danish Council of Ethics, 2001)

Secondly the council points to the problem with false negatives and false positives which inevitably follow the operation of a screening program and whether or not the consequences of these are outweighed by the people who can be helped by a screening program. Elaborating on this key issue the council investigate the difference between going to the doctor and participating in a screening program. Going to a doctor the doctor does not plan to diagnose you wrongly or inflict you with unnecessary pain. With a screening program however it is already known that this will happen. Screening programs single out people with a risk and who might not be at risk at all and in this way over-treatment becomes a problem not known to the same extent from traditional doctor visits. The problem is then that the tests make a lot of healthy people feel ill when they are not and the health service should primarily be about curing people not making healthy people feel ill. Finding out false positives can be perceived at over-treatment and result in long term anxiety. Again

also false negatives are obviously also a problem as some people will be reassured and then disappointed. (Danish Council of Ethics, 2001)

A third key area of concern is prioritization of resources, where the council stresses that there is a limited amount of resources available which might, seen in the amount of lives saved, could have been spent better. There is a conflict between using resources on the people who are actually sick and the ones who possibly become sick. Another viewpoint stresses that the people who might possibly become sick also need help as it provides better chances of survival and this expands they idea of who are in need and should therefore be helped. The success of a screening program depends on how many participate and this could be an argument for saying there is a duty to participate. Finally the council argues for the necessity of calculating how many people actually need to be screened to safe one life. (Danish Council of Ethics, 2001)

Finally a last key area of concern is pointed to as being if the is a difference between being told that one is sick for certain and between being told that one has a risk of developing a certain disease. Here the council points to the principles of the right to know and the right not to know. This question comes down to evaluating if an offer of screening violates a person's self-determination and integrity or if such an offer reinforces these rights. The council concludes by stressing that the recommendations made are in line with the recommendations by the European Council from 1994, the WHO guidelines from 1968 and the report by the National Board of health from 1999. Further the council concludes that none of the existing screening programs currently live up to any of these recommendations or guidelines. (Danish Council of Ethics, 2001) The final conclusion made by the council is evidence to two interesting interactions between the regime, niche and landscape levels. First the council draws attention to moral elements at the landscape level, by pointing to the European Convention on Human Rights and Biomedicine, thus highlighting the moral element of self-determination and integrity. Secondly the council uses examples from specific practices at the niche level to support its general arguments, a point which will be returned to in the following section.

The main focus of the council of ethics is on the social and psychological consequences as well as the individual rights of persons. This place the Danish Ethical Council in the moral framework of rules at a position which is inline with the recommendations made both by the National Board of Health as well as the European Council. In elaborating on their four areas of concern the ethical council also refers to the National Board of Health as well as the Council of Europe as authorities, exactly in the same way as they National Board of Health referred to the WHO, showing that internal power relations exist between the social groups.

Niches inside the regime of screening

As was shown above social groups debating at the regime level use examples from specific practices to support general arguments and in Denmark especially the niche of screening for breast cancer receives attention. In the report on screening by the Danish Ethical Council mentioned above, they specifically evaluate and criticize existing screening programs and one of these are the mammographic screening

program for breast cancer. Further the council was asked by the minister of health to evaluate a suggestion to make screening for breast cancer a national offer. In their answer the council expresses its concerns on especially three areas; it asks for a more thorough investigation of available literature on possible harmful effects of screening, urges the minister to review the letters of invitation sent to women and brings to the minister's attention that inviting people for screening on a less than fully informed basis is against the law on the rights of the patient. (Etisk Råd*, 2005) This answer again serves to place the Danish Ethical Council in the area of the moral framework which but emphasis on individual rights and individual autonomy.

A second social group in the niche of breast cancer is a group of doctors who in January 2008 published an information folder on mammographic screenings for breast cancer, despite the fact that an information folder published by the National Board of Health already existed. The group of doctors justified their decision to publish an alternative folder by referring to the folder from the National Board of Health as "one-sided", as putting emphasis on benefits and not informing adequately about the risks and dangers associated with screening. In the folder the group of doctors emphasize that it can be a good idea to participate in a screening program but that it can be an equally good idea not to participate. As advantages of screening the folder mentions that there is a greater chance of survival as out of 2000 women screened 1 can be saved. As disadvantages the folder mentions; that many women will be diagnosed with a risk they do not have as many small lumps never start growing into cancers and out of every 2000 women screened over 10 years 10 will mistakenly be treated as cancer patients, that more women will unnecessarily have their breast removed or reduced, over a 10 year period of screening 2000 women 200 of which will experience a false positive test and be summoned to unnecessary follow-up investigations, there can be pain involved with the investigation and investigation can create a false sense of security as false negatives are also a problem. (Gøtzsche et al*., 2008)

This social group thus places itself in line with the areas of concern noted by the Danish Council of Ethics however they focus even more on informing of the advantages and disadvantages which can be calculated in numbers instead of more moral issues of social and psychological consequences. Informing their approach is the idea of the autonomous informed individual.

The National Board of Health now also becomes a social group at the niche level of screening through their publication of an informational folder on breast cancer. In their folder the National Board of Health recommends mammographic screening based on a collected weighing of advantages and disadvantages. The folder goes through advantages and disadvantages. Of advantages is focused on better survival rates, the possibility to catch cancer early, more sensitive treatment and less follow-up treatment. Of disadvantages the focus is on over-treatment, false negatives and positives and the pain that can be experienced during the mammographic screen. The folder encourages women to talk to others if they feel any anxiety around the screen. It gives some information on breast cancer and available treatment as well as the procedures followed around diagnosis. This social group thus recognizes disadvantages in connection with screening but argues

that they are of minor importance in the light of the advantages. The social group recognizes that there can be anxiety connected to the screening but evaluates that the problem is not greater than it can be handled by others. (Sundhedsstyrelsen*, 1999)

4.3 A moral framework of rules shaping the regime of screening

Throughout this chapter it has been shown how a moral framework of rules shaping the regime of screening is created through the action of social groups. The framework is dynamic and is constantly re-created through the interaction between the regime, landscape and niche level; an interaction that is facilitated by the interpretative activities of social groups. The social groups respond to pressures arising inside or outside a level while interpreting and re-creating the moral framework of rules. As the social groups are embedded in a socio-technical network, some of these pressures will arise from technological development. The moral framework of rules shaping the regime of screening is illustrated in Figure 2.

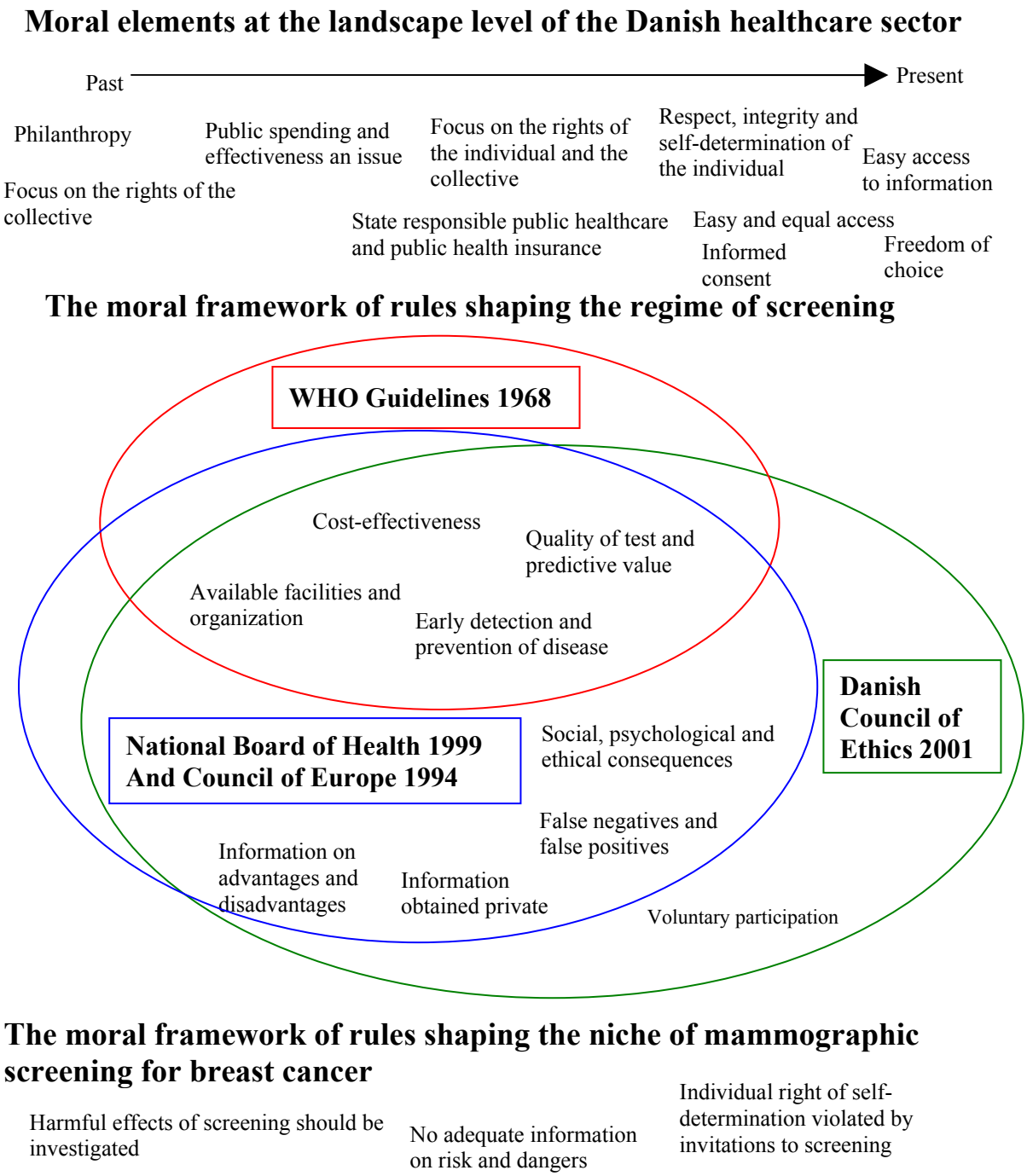

Figure 2 *illustrates the moral framework of rules created by social groups. The figure shows the social groups embedded in the moral framework of rules shaping the regime of screening. The rings symbolize the social groups and encircle the areas of the moral framework which the particular social group places emphasis on. The historically dependent moral elements at the landscape level in which the regime and niche levels are nested are illustrated as well as are the moral framework of rules from the niche of mammographic screening fro breast cancer.*

Clearly the most outspoken social groups on the regime of screening place themselves differently within the moral framework and disagree on how to interpret the moral framework of rules. An interesting characteristic of the debate, which takes place, is the interaction which takes place between the regime and niche level. Examples from the actual practice in different niches is used as examples on the regime level for supporting general arguments and on the niche level general moral rules shaping the regime of screening is used to argue for rules connected to a specific practice. Now this constant interaction between the social groups and the moral framework of rules and the technological context of possibilities for screenings should take the form of a co-evolutionary process of interaction. In the following section the NEST-ethical pattern of argumentation is used to make the co-evolution between technology and morality visible.

4.4 Co-evolution between technology and morality in the regime of screening

According to chapter 3section 3.3.1 the co-evolution between technology and morality can be made visible by the use of the tool of NEST-ethical patterns of argumentation. As the social groups are part of a socio-technical network embedded in a moral framework of rules their activities inside the network become the starting point for revealing this co-evolutionary interaction. In terms of the NEST-ethical pattern of argumentation the consequentialist strand is easy recognizable in the above sections on the moral framework of rules surrounding the regime of screening. Effectiveness is one term which is often mentioned. In this way effectivization is evaluated as being an advantage that is big enough to outweigh any disadvantages. One example of this consequentialist way of reasoning is when this effectiveness is evaluated as outweighing the disadvantages of identifying a large group of the population as potentially sick and when this effectiveness is also more important than a few people being anxious or wrongly diagnosed and or treated. All the social groups participating in the debate on screening list advantages and disadvantages some just do it in a more speculative way than others. The National Board of Health makes a list of advantages and disadvantages but at the same time also makes a clear recommendation stating that the advantages of screening (specifically in this case mammographic screening for breast cancer) outweigh the disadvantages. The social group of doctor's which published the alternative folder applies the same method of listing advantages and disadvantages, but do not make any recommendations. The way they present their listing of advantages and disadvantages is clearly consequentialist in its direct calculations. However instead of making recommendations they make a move toward a more deontological form of reasoning by moving the focus from the actual decision of whether the advantages or disadvantages point towards implementing and recommending screening programs towards the informational basis on which the decision to participate is made. They state that it can be equally rational to take part or not take part in the mammographic screening programs. However the important point for them is that the decision whether or not to take part in the screening program is made on an informed basis. Thus they appeal to the moral element of self-

determination from the landscape level, making self-determination possible only when the individual is fully informed.

In the contributions by the Danish Ethical Council this line of consequentialist argumentation can also be recognized. This is especially when the council discusses reasons for prioritization of resources, where the council speculates on using calculations as a basis for evaluating the benefits of implementing a screening program. The speculative approach to advantages and disadvantages is also obvious when the council discusses the first key issue of social and psychological consequences as well as the second key issue on false negatives and positives. The previous social groups only recognized the possibility of social and psychological consequences and put them on the side of disadvantages, the council of ethics also recognizes these as consequences but instead of listing them as advantages or disadvantages the council speculates on how these consequences can be perceived as either advantageous or disadvantageous thus opening up for deontological or virtue ethical reasoning on how evaluate what if something is the one or the other. When we reach the fourth key issue of the consequences of the uncertainty of the diagnosis the council however immediately point to the principle of the right to know and the right not to know. This concept is inherently tricky as it is both recognized that the individual has a right to be informed about its own state of health while at the same time it also has a right not to be informed about its own state of health. To say no to certain information however requires that one is made aware of the possibility of receiving this information. However the offer itself can be seen as inflicting on the persons right not to know.

The offer of participation in a screening program can thus be seen as inflicting on a persons right to know. In this sense the council is appealing to a deontological weighing of which principle should take precedence. In speculating about the possible consequences of letting one principle take precedence over the other, the council does more than point to a deontological principle, it also frames different perceptions of the good life and with these perceptions of the good life comes differing perception of what constitutes harm as well as just distribution of costs and benefits. Different framings of the good live appear when the council speculates on the implications of screening programs. This can be seen in the speculation whether screening will bring about a ' pathologization 'of people so they will need experts to reassure them they are healthy or if screening represent a good offer to for the few people who are actually sick or on their way to becoming sick as well as a good reassurance of the healthy. The argumentation is of course speculative but brings to the foreground the question whether the good life is one where a few sick people will rightly benefit from participating while a large group of people might possibly be wrongly diagnosed or made dependent. There are of course different responses to this speculations one which would answer that it would be just to possibly harm a larger group of people for the benefit of smaller group and one which would see it as unjust to infer possible harm to a large group of people for the benefit of a few. The argument here even goes further than the individual human and extends to the healthcare system in general when the council speculates whether or not the good healthcare system is one that provides for the sick or the possibly sick.

4.5 The creation of a moral framework of rules for the regime of screening, through the co-evolution between technology and morality facilitated by social groups

Through this chapter it was shown how social groups create a moral framework of rules which shape the regime of screening. This moral framework of rules is created through the co-evolution between technology and morality facilitated by social groups. This co-evolution can be illustrated by the help of the NEST-ethical patterns of argumentation. This moral framework contains a common goal of disease prevention and defines the approach towards this goal as one of seeking out groups in the population evaluated to be at risk of a certain disease. To carry out this approach and reach the goal the moral frameworks contains rules which emphasizes efficiency, quality and availability of diagnosis, treatment and organization surrounding screening, social, legal, ethical and psychological consequences, the private nature of the data obtained and the importance of individual autonomy. This moral framework is nested inside the landscape level of the Danish healthcare sector which contains moral elements. These moral elements have a historical dependency and a moral element which has emerged relatively recently is the importance put on the rights of the individual human. One such right is the right to self-determination, which should be exercised on the basis of adequate information. This element has been translated and taken up by the social groups at the regime level, which can be seen in the emergence of a focus on the individual and the importance of information in recent recommendations and guidelines on screening.

The social groups in the regime of screening however do more than just create a moral framework of rules. The framework is dynamic and due to pressures arising at all level the social groups constantly interpret and rework the framework and as such certain rules on how to reach the goal of disease prevention become contested when taken up by these social groups. Examples of this interactive process is when social groups at the regime level use examples from specific practices at the niche level to support general arguments and when social groups at the niche level use general rules from the regime to develop rules for specific practices. This constant process of interaction between the moral framework of rules at the socio-technical regime and niche level and the moral elements at the landscape level as well as technological development is facilitated through the action of the social groups. A direct comment on this interactive process, which shows the importance of the technological context, can be read in the comment on the WHO guidelines made by the National Board of Health. Here they argue for introducing additions to the WHO guidelines based on the considerable technological development, which had taken place since the WHO principles were formulated. The NEST-ethical patterns of argumentation are used to make the co-evolution between technology and morality in this interactive process visible. In this way the aim of showing how a moral framework of rules shaping the regime of screening is created through the co-evolutionary between technology and morality is reached.

The aim of the following chapter is to identify the moral framework of rules which is created for the regime of clinical genetics as well as to make the co-evolution between morality and technology visible.

5 The creation of a moral framework of rules shaping the regime of clinical genetics

The aim of this chapter is similar to the aim of the previous chapter, specifically to identify the moral framework of rules shaping the regime of clinical genetics and to show how this is created through the co-evolution between technology and morality. A first step is again to identify the moral framework of rules which shape this regime. This is done by investigating written sources by the social groups, which have the power to issue recommendations and guidelines at the regime level of screening. The regime of clinical genetics is also nested inside the landscape level of the Danish healthcare sector. As the moral elements of the landscape level were established in the previous chapter the focus here will be on the historical dependency of the regime of clinical genetics and the connections which can be made between the moral framework of this regime and the moral elements at the landscape level. This is done by investigating written sources on the history of the genetics as well as clinical genetics. Further it is shown how social groups, which do not have the power to issue recommendations and laws, interpret and rework the moral framework of rules shaping the regime and how interactions occur at this level between the niche and regime level. Interaction between niches and the regime of screening, show how technological development at the level of practice on the niche level becomes important for the interaction between the regimes and niches and thereby also the landscape level. Written sources by social groups participating in the debate around clinical genetics and genetic testing again form the basis of the investigation. Finally the inventory of argumentative patterns from NEST-ethics is used to make visible how the moral framework of rules is created through a co-evolutionary interaction between the technology and morality facilitated by the social groups belonging to the regime of clinical genetics.

5.1 Identifying the moral framework of rules shaping the regime of clinical genetics, and investigating its historical dependency

A first step is an identification of the moral framework of rules created by the social groups which have the power to issue laws, guidelines and recommendations. This section focuses on recommendations made by the European Council and the Danish Medical Association. Again the mapping of the moral framework serves to identify the framework as well as to position the social groups inside it. This section also establishes the historical dependency of the moral framework of rules shaping the regime of clinical genetics and makes connections between the regime and the moral elements found at the landscape level.

5.1.1 The moral framework of laws, guidelines and recommendations pertaining to the regime of clinical genetics

The Council of Europe

A first social group is the Council of Europe. In 1992 recommendations were made by the Committee of Ministers to the member states on "Genetic Testing and Screening for Healthcare Purposes". In 1997 the "Convention on Human Rights and Biomedicine", which Denmark has signed, was finished. The protocol on "Genetic Testing for Health Purposes" is an addition to the 1997 convention and was finished in 2007. These recommendations all evolve around genetic testing, but where the 1992 recommendations concern genetic tests done for a variety of purposes the 2007 recommendations only concern genetic tests for health purposes[14].

The 1992 recommendations define a genetic test as one that is carried out with the purpose of either diagnosing a genetic disease, to identify a carrier of genetic disease, to detect serious genetic disease before the onset of symptoms to improve the quality of life of that person and/or to avoid giving birth to child with the genetic defect and to identify persons at risk when the disease both depends on genetic make-up and life-style conditions. The recommendations make a distinction between genetic diagnosis and genetic screening. Genetic diagnosis refers to a test which is carried out to test for a presumed genetic defect found in individuals or members of a family, and genetic screening refers to tests which are carried out on populations or groups within this population without there being any previous suspicion that they should be carriers of the trait investigated for. Recommendations are made on: rules for good practice; which includes informing the public, the quality of the genetic services and counseling and support facilities, mentioning that all counseling should be non-directive. Access; which include equality of access, where no discrimination based on economic or personal choices should take place, and commercial offers of genetic tests should be subject to strict licensing under national law, there should be respect for self-determination based on free and informed consent, the non-compulsory nature of genetic tests, insurance, where insurers should not be allowed to require tests or ask about previous test results. Data protection and professional confidentiality; which include data protection, professional secrecy and, samples should be stored separate form other personal information and unexpected findings which can only be communicated if they are of clinical interest to the individual and family. In the case that the tested person do not wish to let family members in on information on unexpected findings they can only be included if the information is of vital interest, and research; which include rules on supervision and handling of data. (Council of Europe, 1992)

For "The convention on Human Rights and Biomedicine" it is mentioned in the convention itself that discrimination on the grounds of a person's genetic heritage is prohibited, that any genetic test including tests for susceptibility to disease may only be performed for health purposes and should always be followed by appropriate counseling. (Council of Europe, 1997) The additional protocol on "Genetic Testing for Health

[14] The additional 2007 recommendations do not cover research on embryos in vitro or research on embryos or fetuses in vivo.

Purposes" specifically concerns itself with genetic tests for health purposes and therefore excludes issues of genetic testing of the human embryo and fetus. The focus in these recommendations is in this way narrower than in the 1992 recommendations. The protocol states as its purpose the protection of the dignity and identity of human beings and the guarantee that these will be respected for everyone without discrimination. In its general purpose the protocol states the primacy of the individual human above societal or scientific interests. In addition the protocol contain chapters on: genetic services; which should be of a certain quality, clinical utility should be an essential criteria for offering a test and individual supervision should be the standard, information. Counseling and support; appropriate information should be given, entailing information on the purpose, nature and implications of the test and counseling should be non-directive and consent should be free and informed. Test on persons not able to consent; protection of persons not able to consent, and information and guidelines on authorization, counseling and support. Test for the benefits of family members; tests on persons not able to consent, persons who cannot be contacted and deceased. Private life and information; respect for private life and right to information, rules on storage of biological samples and the person tested should be told if the information could be relevant to family members. Objective information on genetic tests should be made available to the population and the population made aware on how to access such information. (Council of Europe, 2007) Finally the protocol is concluded by these words:

"In order to monitor scientific developments, the present Protocol shall be examined within the Committee referred to in Article 32 of the Convention on Human Rights and Biomedicine no later than five years from the entry into force of this Protocol and thereafter at such intervals as the Committee may determine." (Council of Europe, 2007; article 23)

Reading this quote it becomes clear that the council point directly to an interaction between technology and moral rules. In their perception however moral rules can be used to monitor scientific progress; that is to control in some way. However the formulation also seems to imply that scientific development might have the power to change moral rules, and as lay in the perception of monitor/control moral rules also have the power to influence scientific development, thus pointing to a co-evolutionary interaction between the two.

Summing up on the recommendations made by the Council of Europe they point out some key areas of concern in connection with genetic testing which focus on informing the public, both of the existence of genetic testing possibilities and in terms of education, the qualifications of staff and laboratories, the non-directive nature of counseling as well as its availability, the importance on information on purposes, facts, and consequences of genetic testing, the private nature of the data obtained and the right of the tested to say no to information, self-determination, free and informed consent as well as the primacy of the individual human and respect for its integrity and identity.

The Danish Medical Association

The second social group here is the Danish Medical Association, who in 2002 laid down general guidelines for counseling in connection with clinical genetics. The focus of these recommendations is even narrower than the focus in the recommendations made by the council of Europe and solely concerns the right way to balance counseling and genetic testing in practice. A first emphasis is on the way genetic counseling and diagnosis is different from other types of professional medical activities. Specifically the amount of choice available for the individual patient as well as the fact that genetic information and therefore also counseling involves not only the individual person seeking advice but also extends to involve the family of this person, makes it different from other professional medical practices. As the guidelines explain, it is to a higher extent the person seeking advice which makes the decisions. In the guidelines it is mentioned that the medical information available should be made the basis for the decision made by the person seeking advice. (Lægeforeningen*, 2002)

The rights of the person seeking advice involves the right to know what counseling contains before a diagnosis is made. The person seeking advice has both the right to seek information about own state of health, as well as the right to, at any time during counseling and diagnosis, deny wanting this information. The person seeking advice should be made aware of the kind of information that counseling and diagnosis can provide and the consequences. The information should be given in a considerate manner and should be adapted to the perceptional framework of the individual. Any investigation on children (under the age of 18) for late-onset diseases should not be carried out, unless there are really good reasons to carry out such investigation. (Lægeforeningen*, 2002)

The person seeking advice should be informed on; the uncertainty of diagnosis and counseling, about the possible necessity and consequences of involving family members. In cases where blood samples are needed from relatives, these relatives should be included at an early stage in the counseling process. The person seeking advice should contact the relevant family member and figure out if the family member wishes to participate. This family member should be informed in the same way as the person seeking advice on the range and consequences of consenting to participation. In cases where the person seeking advice and the relevant family member are not speaking, the doctor should contact the hospital where the family member is admitted and ask the doctor's there to achieve an informed consent from the relevant family member. If the identity of the person seeking advice is hereby revealed this person should give consent to this revelation. If information is sought of diseased person the close relatives to this person has a right to know the particulars about the disease of this person unless it goes against the wish of the diseased. If it is found that the person seeking advice is in risk of developing the disease of the sought genes the person is informed of this unless the person has had a change of heart in the meantime. If the information could be relevant for other family members, it is up to the person seeking advice to inform these family members. If the person seeking advice does not wish to transfer this information and there is a possibility for preventing a life threatening disease

the doctor must carefully weigh the duty to remain silent against the duty to save lives. It is emphasized that doctor's cannot on their own initiative give people information that they do not want. Therefore doctors should perform a weighing of the potential psychological consequences against the possibility of preventing the disease. Further the disease needs to be serious, foreseeable, have serious consequences for the health of the person and the diagnosis leading to the establishment of risk needs to live up to certain quality standards. (Lægeforeningen*, 2002)

In 1999 the Ministry of Health formulated five criteria, which should be used as guidelines for specialists considering whether or not to contact family members against the wishes of a patient. The first criteria states that the disease needs to be a serious genetic disease with grave consequences for the health and life of the individual, that the probability that the relatives are affected should be reasonable, that the connection between predisposition and development of the genetic disease should be certain, that the tests used to show the genetic predisposition are certain and that the disease can be treated and prevented. (Nordahl-Svendsen & Koch, 2006)

The guidelines created by this second social group are different in focus than the guidelines developed by the Council of Europe. The focus is here on the specific process of counseling. However there is again a continuing focus on the specific rights of the persons involved in relation to information and specific rights in terms of decisions that has to be made. The relations evolving around information are the ones that take up central space in the guidelines and an effort is made to protect the rights to and from information of both the person seeking advice as well as relatives. However these rights can be overridden in case the doctor evaluates that a life can be saved. Taken together these two social groups create a moral framework of rules for the regime of clinical genetics. Within this moral framework emphasis is put educating and informing the public on genetics and genetic testing possibilities, the quality of staff and laboratories, non-directive counseling and the inseparability of counseling and genetic testing, the importance of information on purposes, facts, and consequences of genetic testing, the private nature of the data obtained and the right of the tested to say no to information, self-determination, free and informed consent as well as the primacy of the individual human and respect for its integrity and identity.

As mentioned in chapter 2, genetic tests are in Denmark performed inside a regime of clinical genetics, which is a relatively new discipline with historical connections to the discipline of genetics. This historical connection, as well as connections between the moral framework shaping the regime of clinical genetics and the moral elements at the landscape level of the Danish healthcare sector, will be the subject of the following section.

5.1.2 The historical dependency of the moral framework of rules shaping the regime of clinical genetics and connections to moral elements at the landscape of the Danish healthcare sector

As the historical dependency of the landscape level and the moral elements found here were explored in the previous chapter in section 4.1.2 they will not be repeated here. Instead this section focuses on the historical dependency of the moral framework of rules shaping clinical genetics of today, and connections which can be made to the moral elements at the landscape level of the Danish healthcare sector.

The historical dependency of the regime of clinical genetics

Traditionally genetics is a discipline, which is preoccupied with understanding hereditary conditions and today Mendelian genetics form the basis for our understanding of how characteristics are inherited from parent to child. According to this theory a random combination of the parent genes make up the genotype of the child. The genotype however is different from the final expression or appearance of the child. The genotype is thus the basis of the gene, whereas the phenotype is the part of the gene which is expressed under certain circumstances. At the end of the 19th century, when genetics became a distinct discipline, it became associated with various eugenic movements, which only common characteristic was a preoccupation with human betterment (Petersen & Bunton, 2002). The focus on hereditary conditions within genetics could be used by eugenic movements of racial hygiene to argue for the separation of weak and strong individuals and for introducing voluntary sterilizations of genetically weak members of society. Following World War Two and the genocide and medical experimentation which took place during it, eugenic practices and thereby genetics became discredited. It became connected with bad science in being value-laden, a politically distorted project abusing neutral science and belonging to totalitarian regimes (Petersen & Bunton, 2002). Genetics, through its focus on hereditary conditions, also provided a basis for the development of prenatal diagnosis – a practice which has long been discussed and which has been connected to discussions on abortion. A connection which is recognized by MHo:

"A theme which keeps reoccurring is the discussion on abortion and inside prenatal diagnosis all discussion can be traced back to discussion around abortion. It goes back to a discussion of which lives can be born and even further back to a Kantian discussion of if a human can just be a means and not a goal in itself." (Appendix A, MHo)

Technological options were not at first interesting in the debate on abortion, but technological developments in genetics made it possible to conduct prenatal diagnosis through the investigation of actual samples from expecting mothers and with these possibilities discussions of prenatal diagnosis became entangled in discussions of abortion. As MHo puts it:

"The debate about abortion in the last century was not about technology. That then changed and at a certain time it became a technological discussion. (…) In the 70's the left wing would say that the fetus is

just a dead thing, and they would not say the same thing 20 years later, you cannot say anything like this in the parliament any more. In that way perceptions change" (Appendix A, MHo)

All of these factors; the eugenic movements, genocide and discussions on abortion thus have some historical connection to the regime of clinical genetics. The degree and influence of each factor is difficult to determine, but during the 1950's and 60's medical genetics made an effort to separate itself from accusations of being value laden and bad science aiming at preventing the birth of disabled humans and non-directive counseling in connection with genetics and genetic counseling was made the golden standard. (Koch, 2008) As MHo put it:

"It (non-directive counseling) is and old story about racial hygiene and this, that we are all in someway afraid of discriminating, but in truth it is difficult to understand. As parents we would think that it is wrong to do something genetically to improve on the intelligence of our children, but at the same time it is completely fine to enroll them into elitist schools to improve their abilities. We have some funny issues around things where the effect is the same but the means are evaluated differently" (Appendix A, MHo)

As this quote shows the origin of the moral rule of non-directive counseling is complex and the interviewee mentions both racial hygiene as well as fear of discrimination, while at the same time adding that the principle is difficult to understand the rationale of the rule in itself. The difficulty in understanding the principle of non-directive counseling is one which will be returned to in section 5.2. Before genetic tests were available, specialists within the discipline of medical genetics thus counseled people on hereditary conditions and drew up pedigrees over families and possible hereditary patterns of disease, but refrained from advising patients in any way on what to do with this information. Genetic test enters the picture of genetics in 1989 with the first genetic test for Huntington's chorea and, as has been written earlier, the development of genetic tests has increased with an enormous speed ever since (Danish Council of Ethics, 2002). The goal of the practice is still to inform people of their genetic make-up and on hereditary disease patterns and the principle of non-directiveness is still, as it will become clear in the following section 5.2, a central principle. In Denmark clinical genetics, using genetic tests, became a special field in 1996 and is practiced at six highly specialized clinical genetic centers throughout the country (Region Hovedstaden Specialebeskrivelser*, 2006).

Interactions between the regime of clinical genetics and the landscape level of the Danish healthcare sector

The golden standard of non-directive counseling which emerged in the 1950's and 60's can be traced today in the moral framework of rules shaping the regime of clinical genetics as non-directive counseling is still the main principle which informs this regime. In addition essential moral rules are; informed consent, and the rights, integrity and autonomy of the individual human being. On the landscape level of the Danish

healthcare sector the good of society and the collective was for a long period the main focus and this focus can be recognized in the goals of the eugenic movements to obtain human betterment through selection and here the theory of hereditariness from genetics lends itself to this purpose. The emergence of moral elements at the landscape level emphasizing self-determination and focusing on the rights of the individual where translated in the discipline of genetics and the emerging regime of clinical genetics into the golden standard of non-directive counseling. A translation which is clearly visible in the guidelines issued by the Danish Medical Association as well the recommendations from the European Council. Here self-determination is even further translated as self-determination on the basis of genetic information. Self-determination is thus taken up by the regime of clinical genetics and translated into a necessity of having all the available information which genetics can offer before one can be able to make any informed decisions. The focus put on the rights of the individual human being is translated into the right of the individual not be discriminated or stigmatized due to genetic information.

This review of moral framework of rules, the moral elements at the landscape level, their historical dependency as well as their connection lead us to the social groups which are embedded in the socio-technical network that is the regime of clinical genetics and who move around in the moral framework of rules changing and reworking it as they go along.

5.2 Following the struggle of the social groups in the moral framework of the regime of clinical genetics

Having identified the moral framework of rules created by the Council of Europe and the Danish Medical Association, it becomes possible to move on to the social groups which do not have the power to issue laws, recommendations and guidelines with the same power as the social groups mentioned here, but who instead re-work and re-interpret these rules to position themselves within the regime. Here the focus is on the Danish Council of Ethics, the Danish Board of Technology, BIOSAM and the National Board of Health.

Danish Council of Ethics

A social group is again the Danish Council of Ethics which in 2002 published a report on presymptomatic genetic testing of healthy subjects. In this report the council reviews the purpose and implications of presymptomatic genetic tests. In this way the council identifies for main issues; the right to know and not to know, presymptomatic testing of minors[15], social and psychological effects and prioritization. As before the council tries to argue for different perspectives before developing recommendations. On the first main topic of the right to know and the right not to know, it becomes a tricky concept because of the nature of information which is obtained by a genetic test. Through a genetic test knowledge obtained contains information, not only on the individual tested, but also on the family of this individual. One can therefore speak of a duty to pass on such information with regards to right to know of the relatives, and one speak of a

[15] As the topic of this project is the plausibility of a development of genetic susceptibility testing for disease of adults the issue of genetic testing of minors will not be dealt with here.

duty not to pass on such information with regard to the relatives right not to know. Here the council recommends that it be the tested individual who judges whether or not to pass on information as this individual is the best judge of the wishes of relatives. On the other hand there might be situations where an individual refuses to pass on any information to relatives and in these situations doctors might consider breaking their duty to confidentiality. Here the council recommends that guidelines specific to all the types of diseases which are tested for are drawn up, because risk, prevention and therapy potentials vary within these and because the rights of the tested individual are not sufficiently protected when it is solely up to the doctor to make decisions on breaking confidentiality in special cases. The council further discusses if there can be such a thing as the duty to know and under what circumstances such a duty should be in force. The council does not make any recommendations on this issue, but proposes a possible solution of a central register where general practitioners can inquire into if persons are registered as at-risk individuals and then the individual person can decide whether or not to receive this information. The council emphasizes that right to know of one person should never be used to control the choice's of relatives but recognizes that the law cannot prevent this from happening in practice. (Danish Council of Ethics, 2002)

On the third issue of social and psychological effects the council speculates on consequences pertaining to the individual, the family and society. Psychologically people essentially react differently, and a positive test can result in anything from relief, clear headedness, disappointment, uncertainty of process of disease, hopelessness, fear, grief, despair, depression and altered sense of identity, and having a negative test can leave people feeling relief, but also guilt and sorrow of the ones who were not so lucky. The type of response is connected with the type of genetic disorder one is tested for. Being told you do not have the genetic disposition for Huntington's makes it certain that you will never develop the disease, while being told that one does not have a certain disposition for breast cancer does not mean that one will never develop the disease. Socially stigmatization individually between family members and on a societal level might be felt. In terms of society there might be discrimination on the labour market/insurance/pension or in connection with adoptions. On these issues the council recommends research into long-term psychosocial effect for the individual and the family that pension funds as well as adoptive authorities should not be allowed to request genetic information and that research into societal effects should be put in place. (Danish Council of Ethics, 2002)

On the fourth issue of prioritization it essentially comes down to how the objectives of the healthcare system are perceived. If the healthcare system should be devoted to helping the sick or the possibly sick, and if the healthcare system can be perceived as having a duty to offer presymptomatic tests once they are there and finally how one should define the target group offered access to presymptomatic genetic tests. On this issue the council recommends open public debate on the use of presymptomatic genetic tests. Before any introductions of testing programmes finances should be secured and the decision-making process by which

introduction of genetic testing would be made should be intensified and qualified. (Danish Council of Ethics, 2002)

In marking out these four key areas of concern the social group of the Danish Council of ethics then places itself in area of the moral framework of rules which emphasize the rights to and from information of the individual and which but special emphasis on the rights of the person seeking advice. This area also contains wider speculations on psychological, social effects, duties of the tested individual as well as involved medical staff and speculations on how presymptomatic genetic testing should be prioritized in the overall healthcare sector.

The Danish Board of Technology and the consensus conference

A second social group is represented through a conference held by the Danish Board of Technology. At this conference randomly chosen members of the public were invited to comment on the issue of genetic testing and experts were invited to present on specific issues. In this way this social group is put together of both an official board of technology, members of the public and experts. From the conference eight main areas of concern appeared on which the citizen panel made several recommendations. Under the heading of status and perspectives the panel worried about patenting of genes, and recommended that this development should be followed closely, and they saw research into multifactorial diseases as having health improving potential, and therefore recommended that more resources be transferred to this area. Economy was the heading of the second issue and here the panel recommended that citizen's should not pay for treatment in the system of public healthcare and at the same time speculated that offers of genetic screening could be reasonable seen in perspective of a public ally funded healthcare system, where such might be able to save money. Counselling and practice was a third heading where the panel recommend that similar practices should be in place on the six genetic centres. At the same time they worried about the burden of informing family members which was put on the tested person and they recommended a campaign of information to the public at large. For registration the panel recommended that the identity and private life of people should be respected and protected and that anonymity should be the norm. For co-operation and co-ordination the panel recommended that formalized plans for co-operation between the national centres be made. On the issue of law, the panel recommended minimum demands on how a test should be performed, method, equipment, education and treatment of results. Counselling should be made obligatory for private companies and just insurance schemes should be prepared. Ethics was an area the panel thought to be large and recommended it to be brought into all aspects concerning genetic testing. Finally on goals and the future development the panel wished that society should try to counter negative effects such as stigmatization, discrimination and the development of a disease society. Self-determination and ownership of ones own body should be respected. Further the panel again emphasised the need for developing future insurance methods and standard guidelines for testing. (Teknologirådet*, 2002)

Through reviewing the classification made by this social group it becomes clear that it places itself in an area of the moral framework of rules, where there is emphasis on the protection of the individual and its access opportunities to healthcare which should not be compromised by economic consideration. At the same time however this social group keeps an eye on the larger society and argues an offer of participation in genetic screening programs could be justified and a socio-economic basis. The panel worries on patenting of genes and the private sale of genetic test as well as the selling of genetic information, but would allow these as long as no conditions of monopoly arise or if counselling are made obligatory and as long as information is kept anonymous. This however shows how the panel has a preference for a healthcare system provided by the public authorities in order to ensure that for example economic consideration do not become determining for ones access.

BIOSAM

Another social group called BIOSAM was organized as a council on biotechnology and ethics during the years 1998 to 2004 (BIOSAM, 2008). This organization published some newsletters on genetic tests. Through one newsletter with the title "Use of Genetic tests – fear of misuse can keep people from seeking the right treatment" the emphasis is laid on conflicts arising due to the uncertainty whether or not a disease will manifest itself in an affected individual and the fact that information is obtained about family members as well which raises the conflict of the right not to know. The article warns against genetic tests bought on the internet because they are not connected with counseling and states that the development of a suitable model for insurances is a challenge. The development of such a model should however always take as a starting point the need to protect the individual against discrimination as well as the individual's right not to know. (BIOSAM*, 2002)

A second article with the title "Doctor how are my genes doing" focuses on the use of genetic and how the use of these are experienced at the clinical genetic centers. Pedigrees are still the most important tool at the clinics and tests are only used when there is a reasonable suspicion. The clinics do not experience any problems with informing patients about risk but rather feel that there is a problem if they do not. It is the experience that people only want to use genetic test if there is a real gain by using them and the general practitioners are mentioned as important gatekeepers in making sure that it is only people in need which gain access to the specialized clinic. At the same time the private market of genetic tests seem to have regulated itself and has slowly suffocated as the tests were expensive to develop and the amount of customers to small. (Andersen*, 2004)

Again this focus is on preserving access for the group which is identified as being in need. Keeping genetic tests in a public healthcare system is seen as the way to ensure this access and counseling is again seen as intimately connected to genetic tests.

Niches inside the regime of clinical genetics

As in the previous chapter social groups also act on the niche level and inside the regime of clinical genetics the niche of HNPCC testing becomes interesting through the a report evaluating the current practice surrounding hereditary non-polyposis colorectal cancer (HNPCC). This report was written for the National Board of health and in this way they become a fourth social group acting at the niche level of HNPCC testing inside the regime of clinical genetics. In this report the group develops recommendations for the counseling process. By going through issues pertaining to the relation between the individual and relatives, personal experiences on dealing with knowledge on risk and the principle on the right to know and not to know, the group reaches a list of recommendations for the counseling process. Going through the issues of relations between the individual and relatives and personal experiences in dealing with knowledge on risk, the group shows how the knowledge obtained through genetic testing and counseling is used to control anxiety and uncertainty. At the same time opportunities for genetic testing and counseling are often perceived as individual projects by people and they are surprised when the whole family needs to become involved. The perception that a genetic test is an individual project is recognized by Anne Marie Gerdes (AMG) who is a senior consultant at the University Hospital Odense:

"Most people are not aware that the family needs to become involved and most become very surprised at this, they think they can just come in for a consult and then that is the end of it. Some people back out when they find out that they need to include the whole family." (Appendix A, AMG)

Clearly the experience in practice is that people are surprised when they find out that they cannot regard finding out their genetic status as an individual project and clearly some find this very uncomfortable, uncomfortable to a degree where they give up on having the genetic test. Especially the duty placed on the person seeking advice to contact other family members is experienced as troublesome and as can be read in the following quote by AMG:

"(….) often it is the case that people are not in contact with this and that person, they do not know where they live or people say that they know that others are not interested in participating, or their aunt is sick with breast cancer and they cannot bring themselves to approach her with the request. People really feel it is an uncomfortable task, because they somehow start something that also is going to make other family members aware that they might be sick" (Appendix A, AMG)

These issues are not specific to the Danish context but recognized in a recent Dutch study on genetic testing for dispositions to breast cancer. Through a case study Boenink (2007) shows how the obligation placed on the person seeking advice by having to seek out and ask relatives to participate in counseling and screening programs is a task that is experienced as very troubling task (Boenink, 2007).

The opportunities for testing and counseling also have the ability to change relations between the individual end relatives. Sick relatives identified as carries of a hereditary mutation are inflicted with feelings

of guilt and sorrow and the set-up of genetic investigations as exploring biological connections in a family can redefine relations between persons and affect the choices of the individual. In this way idea of the rationally thinking autonomous individual, who makes informed decisions on is or her own is an illusion. At the same time individuals are shown to operate with differing framework of understanding risk. This is clear when persons accept preventative investigations but deny genetic testing. These persons do not speak of their personal risk but refer to it as something that there is no sense in worrying about, and they are quite certain that they do not have the mutation anyway. At the same time however they feel they are in good hands by going to the preventative follow-up investigations. The group shows how the standard of non-directive counseling is in practice modified by available preventative treatments. The observation of a modification of the moral role of non-directive counseling is recognized by AMG from her own practice:

"That is to deny your responsibility (to let all choice be up to the patient). You have to in some way look at it as a communication process, where it is my (AMG) most prominent job to sense how to best help the specific patient in question, and I (AMG) know that I (AMG) then form an opinion on what would be best for the patient and that it is not certain that it is the right decision, but that is how things are today and that is how they should be" (Appendix A, AMG)

The 'difficulty' of the moral rule itself as it was referred to in section 5.1.2 is shown on the level of practice in a statement by LH:

"I do not know if someone will start to say that now we need some counselors who will stand at the side of their patient when choices need to be made. Because there is a definite need for someone who dares to take responsibility and in someway say that they respect the choices of their patients, but who will still give an estimate of what they think would be the right thing to do. It is insanely difficult how it should be done, but it in some sense it just does not work, first to say to people that you have an offer for them, and then, when choices need to be made, you cannot help them" (Appendix A, LH)

Clearly the principle of non-directive counseling, which is again mention in the 2007 recommendations made by the European Council as well as the Danish Medical Association, is not experienced as unproblematic on a practical level. Again this is testimony to the activities of social groups which take up and interpret moral elements and rules, causing interaction to take place between the moral elements at the landscape level and the moral framework of rules on the niche and regime level of the regime of clinical genetics; a process which is influenced by and influences possibilities arising through technological developments.

By showing that non-directive counseling is modified in practice by available preventative treatments, this social group wants to show how the purpose of counseling is changed into a project of prevention, registration and information of at-risk individuals. In this way the group identifies a regime of prevention which influences the niche of HNPCC on the level of practice and in this way genetic knowledge becomes a tool to prevent disease. That technological options influence the moral framework of rules at the level of

practice in specific niches, in such a way that choices, which would seem to lead to prevention of disease being privileged, is shown in an article by Koch and Nordahl-Svendsen (2005). Here they identify an imperative of disease prevention through which notions of informed consent, non-directiveness and autonomy are transformed in the process of transferring knowledge from the clinical genetic specialist to the person seeking advice. During this transfer process disease prevention becomes the choice which the fully informed autonomous person seeking advice should take. (Koch & Nordahl-Svendsen, 2005) Where the social group in focus draw their conclusions based on practice in the niche of HNPCC Koch and Nordahl-Svendsen draw their conclusions based on counseling for hereditary cancers in general. This is again testimony to interactions between the regime and niche levels.

On commenting on the dilemma of the right to know and the right not to know, this social group inside the National Board of Health argues that this dilemma makes visible the inherent contradiction between a genetic understanding of familiarity and ideas of self-determination and individual bodily integrity on the other. The group concludes that if prevention of HNPCC is still to be a goal within the healthcare service then individual autonomy cannot be preserved. At the same time it is clear that unwanted pressures arise between family members when these are set to inform each other and therefore the group recommends that information of relatives is done by the clinical genetic counselors. The group recognizes that the right not to know is in this way marginalized but justices this by referring the condition that society finds it relevant to pass on information and to the principle of equality. (Bojesen et al., 2007)

In the niche of HNPCC we see a social group which takes up on the descriptions of genetic counseling and relates it to the practice of HNPCC. In this way they manage to show how a regime of disease prevention gains influence in the regime of clinical genetics and how the healthcare service itself find the passing on of information legitimized by technologically mediated available options for prevention. Further they show how moral rules of self-determination and autonomy formulated at both the regime and landscape level collide with basic understandings in genetics of the biologically intertwined and interdependent family. However what is also shown throughout this section is that the emergence of the technological possibility of performing genetic test does more than make it possible to establish a mutation with certainty; it also strengthens the "difficulty" of preserving the principle of non-directive counseling and provides the possibility for an imperative of disease prevention to enter into the regime of clinical genetics: An imperative which threatens to undermine the moral rules now shaping the framework of rules of the regime. By giving way to this imperative this social group create a niche where it becomes legit to marginalize the right not to know as well as the principle of non-directive counseling, when the goal is disease prevention. The moral framework of rules pertaining to the regime of screening is illustrated in Figure 3.

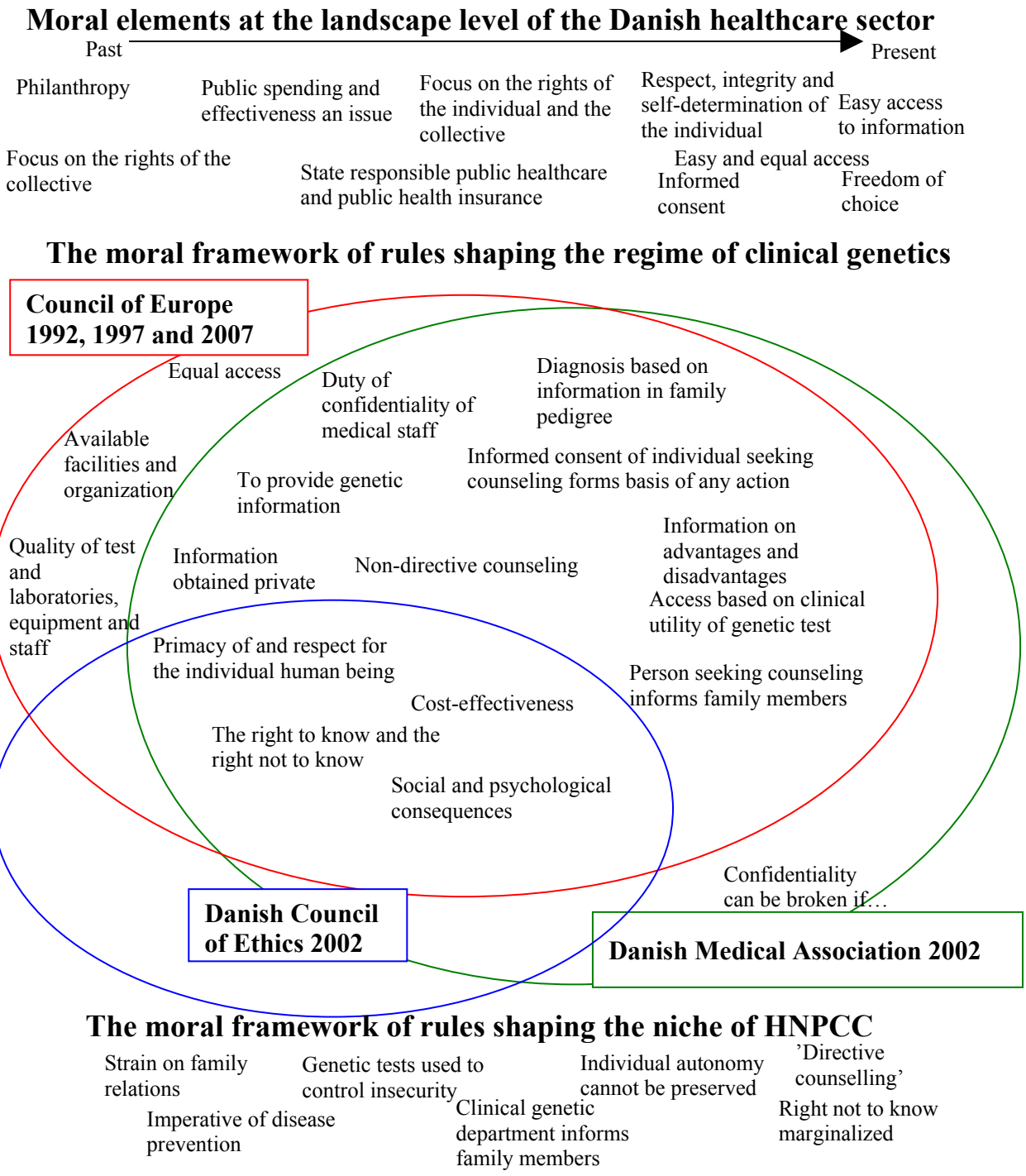

Figure 3 *illustrates the moral framework of rules created by social groups. The figure shows the social groups embedded in the moral framework of rules shaping the regime of clinical genetics. The rings symbolize the social groups and encircle the areas of the moral framework which the particular social group places emphasis on. The historically dependent moral elements at the landscape level in which the regime and niche levels are nested are illustrated as well as are the moral framework of rules from the niche of HNPCC.*

Now this constant interaction between the social groups and the moral framework of rules and the technological context of possibilities for genetic testing should take the form of a co-evolutionary process of interaction which follows a NEST-ethical pattern.

5.3 Co-evolution between technology and morality in the regime of clinical genetics

The consequentialist line of reasoning is recognized in the arguments by all the social groups, but advantages and disadvantages are not as clearly listed here as with screening. As benefits of clinical genetics and genetic testing is the possibility to inform people of their genetic makeup and especially to inform on hereditary diseases; a mission which is central to clinical genetics. This mission has coupled with technological developments created the claim that genetic counseling coupled with genetic testing will lead to effective disease prevention, that it will save lives and therefore improve the quality of life of the individual families as well as the society as a whole at the same time as it will safe the society costs of treating these diseases. This promise is countered with claims of genetic counseling and genetic test creating a whole group of new problems, for the individual, the families and society in terms of stigmatization, discrimination and psychological problems. To deal with these problems it is obvious how the social groups move into a deontological line of reasoning when they focus on the right to know and the right not to know. All of the social groups, except for the citizen's panel mention these principles as equally important. The principle of non-directive counseling is not mentioned directly but at the same time all the social groups mention the choices that the individual will have to make as well as the respect which should be exercised towards these choices. Fundamental to the choices of the individuals are the principle of informed consent. This principle is mentioned as one that should be respected along with the private life and integrity of the individual.

From these consequentialist and deontological ways of reasoning the argumentation turns to more good life ethics argumentation when social groups start speculating on the impacts of making the one or the other choice. In the report by the HNPCC group it is shown how people operate with different frameworks of perceiving information on risk from genetic counseling and from genetic tests. The group finds it important that counselors are aware of these different responses to information on risk so that individuals can be allowed to deal with given information within the boundaries or their own perceptions. At the same time they point to a picture of the life that will be result if prevention of HNPCC is the goal. The conclusion is then that the autonomy of the individual cannot be uphold in the context of HNPCC and therefore they go on and recommend that relatives can be contacted without the consent of the family member which in the first place came to the healthcare system. The group also recognizes that clinical genetics work within framework of disease prevention where all counseling is given with this aim and counseling therefore becomes intertwined with this aim. This results in a framing of the good life which arises within the context of HNPCC. In this way a perception of the good life is framed as one where you are informed about your risk for developing

certain diseases and where the imperative of disease prevention becomes the most important criteria for judging what action is the right one to take. Again the speculative approach taken by the Danish Ethical council also frames differing perceptions of the good life this is for example seen when discussing the principles of the right to know and the right not to know. Arguments favoring the right to know point to the fact that the relatives should be given the same options for action as the person who initiated genetic counseling pointing to a good life being one where any information one ones health should be passed on and where this information should lead one to consider acting upon it. Arguments for the right not to know on the other hand argue that passing on information to relatives on their health infringes on their right to privacy and burdens them with information and choices which they might not want. In this way pointing towards a good life where it is completely up to oneself what kind of information on ones health one wants to have and where it does not become seen as necessary to be informed about every aspect of ones health. Again speculations on the distribution of cost and benefits can be traced, when the council speculates on the possible social and psychological effects as well as individual consequences of having to pass on and receive information on possible disease.

5.4 The creation of a moral framework of rules for the regime of clinical genetics, through the co-evolution between technology and morality facilitated by social groups

Through this chapter the moral framework of rules shaping the regime of clinical genetics was identified and it was shown how social groups constantly re-work this moral framework of rules and in doing so facilitate a co-evolution between technology and morality. This moral framework contains a common goal informing individuals of their genetic makeup and on uncovering patterns of hereditary disorders, and defines the approach towards this goal as one where individuals approach the healthcare system on their own initiative and then on the basis of evaluations of their family history are referred to genetic counseling. To carry out this approach and reach the goal the moral frameworks contains rules which emphasizes educating and informing the public on genetics and genetic testing possibilities, the quality of staff and laboratories, non-directive counseling and the inseparability of counseling and genetic testing, the importance of information on purposes, facts, and consequences of genetic testing, the private nature of the data obtained and the right of the tested to say no to information, self-determination, free and informed consent as well as the primacy of the individual human and respect for its integrity and identity.

On the landscape level of the Danish healthcare sector, a moral element which has emerged relatively recently is the importance put on the rights of the individual human. One such right is the right to self-determination, which should be exercised on the basis of adequate information. This element has been translated and taken up by the social groups at the regime level, which can be seen in the emergence of a focus on the individual and the importance of information in the recommendations on genetic testing inside clinical genetics. Further the social groups facilitate interactions between the niche, regime and landscape

level, through the uptake and interpretation of these moral elements of self-determination and a focus on the rights of the individual, along with responding to opportunities arising due to technological developments. This multi-level complex of moral rules and elements, technological opportunities and social groups interact in a way which problematize the principle of non-directive counseling and makes it possible for an imperative of disease prevention to gain access an influence in the regime of clinical genetics. The influence and importance of the technological development and again be read directly in the comment made by the Council of Europe in the 2007 recommendations, where they, due to developments in the sciences, find it necessary to review the moral framework of rules within a five year period.

The NEST-ethical patterns of argumentation are used to make the co-evolution between technology and morality in this interactive process visible. In this way the aim of showing how a moral framework of rules shaping the regime of clinical genetics is created through the co-evolutionary between technology and morality is reached.

In the following chapter I will investigate whether the two moral frameworks of rules, which shape the regimes of screening and clinical genetics, contain any common and diverging themes, in order to uncover a possible emerging framework of moral rules, which would shape a regime of genetic screening for susceptibility to disease.

6 Investigating a possible merge between the regimes of screening and clinical genetics

In this chapter I begin by re-stating the sub-research questions to create an overview of the ground covered so far as well as the ground which remains to be covered. I then continue by investigating the two regimes of screening and clinical genetics, which co-exist at the regime level nested within the landscape of the Danish healthcare sector. The aim of this investigation is to explore how these two regimes relate to each other.

In chapter 4 and 5 it was shown how moral frameworks of rules shaping the regimes of screening and clinical genetics were created through the co-evolutionary interaction between technology and morality, facilitated by social groups. On the niche level of HNPCC, inside clinical genetics, the emergence of an imperative of disease prevention was shown to have gained access. An access facilitated by the interpretation of the socio-technical network by the social groups. The aim of prevention is one, which can be recognized from the regime of screening, and the speculation now turns to the possibility of a further merge between the two regimes of screening and clinical genetics. One speculation is that a further merge between the two regimes could lead to the development of a new practice of genetic screening programs for susceptibility to disease. Such genetic screening programs would be initiated with the focus of disease prevention recognized within the regime of screening and could use the language of self-determination and individual rights. I therefore use the analysis of common and diverging themes to construct a possible moral framework of rules which could shape a regime of genetic screening for susceptibility to disease.

6.1 Re-stating the sub-research questions

The first three sub-questions were:

2. What moral frameworks of rules shape the regime of screening and the regime of clinical genetics and how are they created?

3. What moral elements can be identified at the landscape level of the Danish healthcare sector?

4. How does the co-evolution between technology and morality take place inside the regimes of screening and clinical genetics and can the NEST-ethical patterns of argumentation help to male this co-evolution visible?

All of these questions were dealt with in chapter 4 and 5 and it was shown how moral frameworks of rules shaping the regime of screening and clinical genetics were created through the actions of social groups. It was also shown how moral elements of the rights of the collective as well as a focus of the rights of the individual could be found at the landscape level of the Danish healthcare sector. And finally it was shown that the NEST-ethical pattern of argumentation indeed could be distinguished and used to show the co-evolutionary interaction between technology and morality in both the regimes of screening and clinical genetics. Sub-question five and six were:

5. What interactions can be traced between the regimes of screening and clinical genetics?

6. What moral and technological elements become essential for a future development of genetic screening programs for susceptibility to disease in Denmark?

Sub-question five will be dealt with in the analysis of the common and diverging themes between the regimes of screening and clinical genetics, while the identification of an emerging moral framework of rules for a regime of screening for susceptibility to disease partly deals with sub-question six. Sub-question six will be returned to in chapter 7, section 7.2.

6.1.1 Common themes in the moral frameworks of screening and clinical genetics

Common to both regimes is an emphasis in the moral framework of rules on the voluntariness of participation and actions. This voluntariness is however differently emphasized within the frameworks. In the moral framework of screening, the moral rules emphasize that only an *offer of participation* is made, while it in the moral framework rules of clinical genetics is emphasized that the *choice of the individual* is the core concept around which participation as well as every subsequent step in diagnosis and treatment is centered. In this way individuals when accepting an offer of participation into a screening program consent on an already prefabricated package; their consent in this way is more passive than the active individual decision-making process which persons seeking advice within the regime of clinical genetics have to perform. Both moral frameworks are concerned with negative psychological and social effects, and are both concerned with avoiding these. Psychological effects include feelings of grief, despair, depression and hopelessness. Social effects include individuals feeling stigmatized by a diagnosis of a disease or of carrying a certain mutation or risk of discrimination in terms of access to employment, insurance or adoption. In both moral frameworks information receives attention in two ways. One; information obtained through testing is private and should be protected and two; information on the process in which the individual either consents or decides to be a part of, is also the basis on which individuals should make their choices. As decisions, especially within clinical genetics need to take the shape of an informed consent, this last condition provides for a preoccupation within both regimes of providing participants with information on both advantages and disadvantages of participating as well as consequences of making certain choices. The preoccupation, with the consent of the individual being informed, supports an idea of the individual only being able to make autonomous decision after being provided with sufficient information. In both frameworks there is a focus on the quality of equipment used as well as reliability of tests and diagnosis. The understanding of the diagnosis itself within the moral frameworks is also something common to both disciplines in that it does not rest on a traditional understanding of being sick or healthy but on knowledge of potentially becoming sick.

6.1.2 Diverging themes in the moral frameworks of screening and clinical genetics

The primary purpose differs within each of the regimes. Within the regime of screening the purpose is one of catching disease early by screening groups in the population identified as being of risk of developing a certain disease. This is different from the purpose of clinical genetics, which is one of informing people on their genetic make-up in connection with the mapping of hereditary diseases. The different purposes of each regime also facilitate differing understandings of the right way to reach the goal within each regime. For the regime of screening the right way towards prevention of disease, is defined within the moral framework of rules, as being when the healthcare system actively seeks out groups in the population, and offers these tests to reveal early stages of disease. Within the regime of clinical genetics however, the right way to approach the goal of informing on hereditary disease patterns, is defined as being one where an individual who him or herself being aware of being at risk of developing a certain hereditary condition, approaches the regime of clinical genetics. The individual is then subsequently offered opportunities, including genetic testing to deal with suspicions of being at risk for developing a certain condition. The moral framework shaping the regime of screening openly focuses on testing large population groups, in order to catch the individuals inside a group, which display early signs of disease. The consequence of this is that large population groups are made into at-risk groups and exposed to a test where false positives as well as false negatives will appear. This is different from the framework surrounding genetics, where the goal is not the investigation of a large group to find the few individuals who display early signs of disease, but rather the diagnosis of the individual on the basis of family information. The consequence of this approach is that the right way to arrive at a diagnosis of the individual, becomes based on family information, and the results obtained do not only contain information of the individual but about family members as well.

The consequences of the approach deemed to be the right one within each regime bring out the issue of weighing the moral principle of the right to know and not to know. This principle is problematized differently within each regime. In the regime of screening the offer of participation is seen as problematic in itself as it already provides people with information they might not wish to have. In the regime of clinical genetics the very approach of having to involve family members into the process of obtaining a diagnosis brings forward the dilemma.

Screening is defined as a recurring event, and this feature is problematized by speculations of population groups becoming dependant on medical experts to tell them that they are healthy, which would create a worry culture. For screening effectiveness also becomes a moral rule within the framework, as it is explicitly mentioned as a condition that needs to be fulfilled before a screening program can be initiated. This is not a condition that is mentioned in connection with the use of genetic tests. Instead the moral framework of rules

surrounding genetic test specify, that these are only offered to persons on the basis of extensive mapping of family relations and focus is explicitly on the primacy of the individual human being, and the importance of the informed consent of the individual.

Remembering the characterization of the new genetics from chapter 1, the moral framework of rules shaping the regime of screening carry the burden of easily being associated with being a state controlled healthcare program, whereas the moral framework shaping the regime of clinical genetics is more easily associated with the language connected to the new genetics of empowerment, individual choice and freedom of the individual.

As has become clear through this section the moral frameworks of rules shaping both regimes contain both common and diverging themes. A merge of the moral frameworks of these two regimes into a practice of genetic screening programs for susceptibility to disease would in some way or other incorporate moral elements from both of these frameworks. The aim of the next section is to analyze whether a merge between these two moral frameworks of rules can already be observed.

6.2 Indications of a merge between screening and genetic testing

As has been shown through the last section the moral frameworks of rules shaping the regimes of screening and clinical genetics both have their common as well as diverging themes, themes which are often problematized when social groups interpret and re-work the moral framework shaping the two regimes. HNPCC is located at the niche level of clinical genetics and prenatal diagnosis is located at the niche level of screening. These locations are however not easily made as both practices harbour elements of the opposite regime than of that to which they are located. That is; the niche of HNPCC harbors elements of moral rules which belong to screening and the niche of prenatal testing harbors elements of moral rules which belong to clinical genetics. This makes these niches an interesting starting point for the investigation of a merge between the regimes of screening and clinical genetics, as developments on the niche level can be a starting point for future developments leading to change at the regime level.

6.2.1 The niches of HNPCC and prenatal diagnosis

Counseling on HNPCC as well as diagnosis and testing is mainly carried out at Hvidovre Hospital in Denmark, however counseling is also carried out at the five other clinical genetics centers in the country. Hvidovre Hospital harbors the national register on HNPCC patients and mainly council individuals from the east of Denmark. (Region Hovedstaden Specialebeskrivelser*, 2006)

On the level of practice the process of investigating for HNPCC begins when the clinical genetic department receives a referral[16], which can come from general practitioners, hospitals and private clinics or when someone walks in from the street. A pedigree of at least three generations is drawn up. This pedigree is

[16] The referral received by the clinical genetics departments can be of two types; either it is a referral on a person suspected to be at risk of, but nor yet suffering from a hereditary condition, or it is on a person who is already sick and the condition is suspected to be hereditary.

used as a first assessment of risk. The person seeking advice is informed about the whole process of counseling and diagnosis and gives consent to the collection of relevant information about themselves and family members. In case information from living family members is necessary the person seeking information collects consent to collect this information from these family members. The person seeking advice is informed that the process can be stopped at any time. If family members do not wish to participate this is respected and can sometimes mean that the initial risk assessment cannot be carried out. The initial risk assessment is used to evaluate if mutation screening is an option[17]. In the counseling session, where the initial risk assessment is communicated, information is also given about; the pedigree and relevant diagnosis, genetic conditions in connection with the genetic disease, heredity, involved genes, the risk of developing cancer, the risk of passing the mutation on to offspring, genetic tests, controls and preventive operations, information of family members, information about the HNPCC register, social and legal aspects and patient organizations. This counseling is typically carried out in two to three conversations. When mutation screening is carried out the family is called in for counseling. If the result is negative, it is emphasized that HNPCC is still most likely, as risk assessment is based on the pedigree. All of the at risk persons are referred to preventive controls, and summaries of the results are sent to the family's general practitioner, the place from where the original referral came, the person seeking advice and, if agreed with the person seeking advice, to the HNPCC register. If a mutation has been found all family members are offered presymptomatic genetic tests. The result of this test is communicated through a counseling session, and the depending on the result the person is referred to preventive controls.

The clinical genetic counselors place great emphasis on the fact that genetic testing is combined with counseling. In Denmark there are no written guidelines for achieving informed consent, instead a "consent-declaration" is used. Written down American guidelines exist and the aspects relevant for the Danish context are used in the context of counseling. These include; the professional indication for the use of a screening for mutations, the pro's and con's of mutation screening including psychological and family aspects, the practical process of mutation screening that is the blood sample needed for mutation screening, might need to come from other than the person seeking advice, the possibility to save a blood sample for later analysis, what genes the mutation screening analysis for, which laboratory to use for analysis, the probability and consequences of a possible disease causing mutation, the probability and consequence of an indecisive mutation, the probability and consequences of negative mutation screening, the difference between mutation screening and presymptomatic genetic tests, agreements on the way the answer to the test is communicated, information of family members, the possibilities for prenatal genetic tests as well as social and legal aspects. (Bojesen et al., 2007)

[17] Mutation screening is different from presymptomatic genetic tests. When screening for mutations one searches for the specific mutation pertaining to a specific family using blood from an already sick family member. Presymptomatic genetic testing is then used to look for this mutation in family members interested in this.

In addition to this summary of the actual practice surrounding counseling and diagnosis of HNPCC, some recommendations made are; that all genetic testing is carried out in connection with counseling and that this counseling should be performed by specialized professionals and that it will be preferable if general guidelines for the attainment of informed consent were established. (Bojesen et al., 2007)

Subsequently recommendations for national guidelines for diagnosis and counseling in connection with HNPCC were made. Some of these recommendations resonate with the summary of the actual practice while others add to the existing practice. On a general level informed consent is emphasized as the basis for any medical treatment and both written and oral consent is considered legitimate by the law. Specifically in connection with HNPCC it is recommended that after a counseling session, the person seeking advice should be sent an overview of what has been consented to. The recommendations add that it should be possible to collect information from relatives without their consent, and that it should be possible for the doctor to contact high risk relatives on own initiate as long as there is good medical reasons for this. In addition it is recommended that it is made clear what the advantages and disadvantages of participating in preventive controls are, and how much they reduce the risk of disease. The at-risk person should also be informed that refusal to take a presymptomatic test does not influence offers of preventive treatment. (Bojesen et al., 2007) The report has been long underway and the recommendations made have been implemented in practice during the writing of the report, as AMG says:

"That report (the medical technology assessment of HNPCC) has been many years underway and many of the changes proposed have already been implemented. One area which was hotly debated was whether one could only get access to a genetic test following genetic counseling. Most people in Denmark think so, that one needs to go to a counseling session by a specialist in clinical genetics, who know what information should be given. On the other hand one could imagine that for example surgical department would order a blood test on a patient without informing this patient. On that subject we have not reached agreement, and the solution has become a compromise, so that it now has to be a person with special insight into the problem who orders the test. That then is something we will have to accept, but if you look to Norway or Sweden only clinical geneticists can order genetic tests. (…) At the clinical genetic departments no one is registered unless they have given their permission to be registered, and with diseased person the person seeking advice needs to consent to the registration. (…) but HNPCC has a special status here, as they began as a research database, and therefore they were allowed to register individuals who had not been asked. (…) an issue which has been discussed a lot is the allowance which the HNPCC register has to on their own initiative send letters to individuals. Here they again have a special status as they have been allowed by the National Board of Health to be the ones which inform. (…) that is the HNPCC register on their own initiative sends out letters to everyone who is evaluated as being at-risk for hereditary colon cancer." (Appendix A, AMG)

Apart from the report being long underway this quote also reveals the special status of HNPCC, with regards to informing family members of potential risks. In fact HNPCC is a practice within clinical genetics, which on its own initiative sends out letters to at-risk family members of the person seeking advice. Traditionally this is exactly the distinction used to set screening apart from genetic testing inside clinical genetics, that the defining feature of a screening program is, that the healthcare system approaches the individual on its own initiative. In this way clinical genetics suddenly harbors a moral rule which previously belonged exclusively to the moral framework surrounding the regime of screening. The practice of HNPCC is however not defined as a screening program and thus we find ourselves in a grey-zone area where something resembling a screening program but not labeled as such is taking place.

The niche of prenatal diagnosis

For prenatal diagnosis the National Board of Health published new guidelines on this practice in 2004. Following these guidelines, all women should be offered access to prenatal diagnosis and should, with the aid of counseling sessions with healthcare staff, make their own free informed decisions on whether to participate and what prenatal tests to accept. The development of an individual risk profile for each individual is the goal of the prenatal tests. In the guidelines emphasis was put on that these prenatal tests should be seen as assisting pregnant women in making their own choices. Assisting in this sense meaning to help the women make decisions about their pregnancies on an informed basis. The intension is therefore to assist pregnant women in making informed decisions, and not to prevent the birth of children with serious defects. Non-directive objective counselling is emphasized in the guidelines as forming the basis for this assistance. (Sundhedsstyrelsen*, 2004)

Before their publication the guidelines were sent to a list of organizations and authorities, among others organizations for disabled, and organizations such as the Danish Council of Ethics. The Danish Council of Ethics criticised the proposal for lacking ethical reflection on a number of points, among others on what could be calculated to lead to an increase in the number of accidental miscarriages following invasive diagnosis, an increase in the number of provoked abortions, the neglect to inform of the risks of prenatal diagnosis by solely focusing on the benefits, problems surrounding the notion of an informed and autonomous decision and the changed perception of the nature of the program from a screening program to a free choice program. (Etisk Råd*, 2003) This last comment made by the ethical council, which criticises the re-naming of pre-natal diagnosis is recognized by LH:

"(...) here I am (LH) thinking about prenatal diagnosis, where it is typically set up so that women have a right not to know and therefore the choice should be up to them (whether or not to have prenatal diagnosis). The problem is that no one chooses not to know something about something which they have been told they might want to know about. This National Board of Health then writes that prenatal diagnosis is not a screening program but a free choice program, but all screening programs should be free choice programs,

because then it becomes visible that everyone is allowed to say no, which is just sometimes difficult because the choice is not free" (Appendix A, LH)

The Danish Cystic Fibrosis Association was differently positive and warmly welcomed the new guidelines. At the same time they argued that now was the time for the health care service to finally offer genetic tests for cystic fibrosis to all pregnant women. This argument was backed by reference to the attitude among the members of the association, earlier research program of offering a test for cystic fibrosis to all in a group of pregnant woman, as well as based in the ability of the woman to make a decision on an informed basis. (Landsforeningen for bekæmpelse af cystisk fibrose* , 2003)

What we see here is something which was earlier labelled as a screening program being redefined in a language, which is described by Petersen and Bunton (2002) as belonging to the new genetics, a language which can be recognized from the regime of clinical genetics. A language which emphasizes the right to self-determination by the pregnant woman and her ability to make a free informed decision based on information on all her available medical options, which is exactly the same language used about the situation of the person seeking genetic counselling. In this way moral elements from the moral framework surrounding the regime of clinical genetics are used to redefine the practice of prenatal diagnosis. In this way developments in both the practice of HNPCC and prenatal testing are blurring the borders between the regimes of screening and clinical genetics.

6.3 Uncovering an emerging moral framework of rules, which would shape a regime of genetic screening

Having established that a blurring of the boundaries between the moral frameworks of the regime of screening and clinical genetics can be identified at the niche level of HNPCC and prenatal diagnosis we turn to an investigation of the moral framework of rules which could shape an emerging practice of genetic screening programs for susceptibility to disease. In the report by the Danish Council of Ethics on presymptomatic testing of healthy subjects the council speculated on the development in the use of genetic tests, from the first test for Huntington's became available in 1983 to genetic testing spreading to include all of us:

"In the process the target group for presymptomatic genetic testing is being expanded so as potentially to include all of us; and the ethical issues of personal relevance to a limited number of people in 1983 will be issues that concern us all" (Danish Council of Ethics, 2002;10)

An example of an expansion of the target group for genetic testing is exemplified by the practice of HNPCC. Here family members are approached by the clinical genetics departments with offers of counseling, genetic testing and follow-up programs. As screening was defined as an offer made by the healthcare services towards individuals, these genetic testing programs are strictly speaking turning into screening programs of groups in the population. The programs are however not labeled as such, and are therefore operating in a grey-zone area between screening and genetic testing. However if a regime of

genetic screening programs is to emerge from the regimes of screening and clinical genetics the moral framework of rules shaping this regime will have to contain moral rules from both regimes. It is therefore not straightforward, as proposed in the above quote, that an expansion of the target group for genetic testing will expand exactly those ethical issues which are found inside the regime of clinical genetics.

As both regimes of screening and clinical genetics contain their own problems, the mapping of the common and diverging themes become a good starting point for pointing towards how such a merge of the two moral frameworks could proceed. However it should be kept in mind that a merge between these two regimes rests just as much on opportunities arising through technological developments as opportunities arising through the merge of two moral frameworks. In addition to using the mapping of the common and diverging themes as guidelines, the guidelines for genetic screening programs, which have been developed by the Council of Europe as well as the WHO, will also be used. The acceptance of these guidelines in any future genetic screening program for susceptibility to disease is fair to expect, as the National Board of Health generally accepted the guidelines on screening from the WHO and is a member of the European Union.

In the WHO guidelines the main purpose of genetic screening is stated as being one of preventing disease and securing early diagnosis. The guidelines state that genetic screening should be voluntary and not mandatory, that adequate information on purpose, possible outcomes and choices to be made should precede the genetic screen, that anonymous screening for epidemiological purposes can be carried out as long as the population to be investigated is informed beforehand, that discrimination should be avoided by not disclosing results, to employers, insurers, schools or the like without the consent of the individual, that in rare cases disclosure might be in the interest of the individual or society and that in these cases a health provider should work with the individual towards such a decision, that counseling should the disclosure of test results and particularly if the results are unfavorable, that treatment and prevention if available should be offered without delay and that screening of newborns should be mandatory and free of charge if early treatment and diagnosis will help the newborn. (Godard, ten-Kate, Evers-Kiebooms, Ayme, 2003)

Further the guidelines from the Council of Europe on genetic screening programs state that they should be recognized for health relevance to whole or parts of the population, the scientific validity and effectiveness should be recognized, there should be appropriate treatment or preventative measures should be available, measures to ensure equitable access should be in place and the program should plan how to inform the public of its existence, purpose, how to gain access as well as its voluntary nature. (Council of Europe, 2007)

A review article from 2003, which surveys the professional and scientific views on the issue of potential genetic screening programs state that:

"Today, genetic screening programs may be defined as any kind of test performed for the systematic early detection or exclusion of a hereditary disease, the predisposition to such a disease or to determine

whether a person carries a predisposition that may produce a hereditary disease in offspring." (Godard et al., 2003;49)

What should be noted in the above broad definition of a screening program is the weight put on the investigation being carried out for the early detection of hereditary disease. This definition does not as such include the genetic screening programs for susceptibility to disease, but depending on how hereditary is defined the word 'predisposition' opens opportunities for such screenings. However with this definition, the guidelines from the WHO, the Council of Europe and the common and diverging themes from screening and clinical genetics in mind, we begin to glimpse a moral framework of a regime of genetic screening programs. In the moral framework of this regime the imperative of disease prevention and focus on early detection of disease, which was found to be emerging at the niche level of HNPCC has become even more visible. Still the voluntary nature of participation, which was a common future to both regimes, is emphasized. The problems and fears of psychological and social consequences in terms of stigmatization and discrimination still exist as well as the focus on the private nature of information obtained, the importance of providing participants with information on advantages and disadvantages as well as a focus on quality criteria towards, equipment, test and laboratories. All of which are common themes to both screening and genetic testing. The difference between the formulations in the guidelines for genetic screening and guidelines for other types of screening is the increased focus on the necessity of providing participants with information, and the necessity of protecting the information obtained in the interest of the individual. Defining the moral framework surrounding genetic screening in this way, it becomes fitted to what Petersen and Bunton (2002) call the language of the new genetics, which focuses on empowerment of the individual, autonomy and freedom of choice, a language, which they evaluate seems to fit the present political environment in our Western societies. (Petersen & Bunton, 2002)

6.4 An emerging moral framework shaping genetic screening programs for susceptibility to disease

Through this chapter it was shown that the moral of rules pertaining to the regimes of screening and clinical genetics contain both common and diverging moral rules. An essential difference is the approach taken towards reaching the goal of each regime, which was disease prevention within screening and providing information on hereditary conditions within clinical genetics. As a consequence of the difference between the purpose of each regime, moral rules in the framework shaping screening defines that a whole at risk population group have to identified and tested to reach the purpose of disease prevention, whereas the moral rules in the framework of clinical genetics defines that a whole family needs to have their risk status evaluated in order to diagnose an individual. At the niche level of the practice of HNPCC and prenatal diagnosis a blurring between the boundaries of moral frameworks of screening and clinical genetics can be identified. In the niche of HNPCC it has become practice that clinical genetic departments contact at-risk relatives to the person seeking advice, and inform them of their risk status as well as their options. For the

niche of prenatal diagnosis, this practice was in 2004 redefined from a screening to a "free choice" program offered to all expecting parents as a means of enhancing their opportunities for making informed decisions concerning their pregnancy. This discovery together with guidelines on genetic screening programs from the Council of Europe as well as the WHO then formed the basis for an emerging moral framework of a regime of genetic screening programs. In this framework the goal of genetic screening programs would be the early detection and prevention of disease. The moral rules to be followed to reach this goal would emphasize that voluntary participation, as well as a focus on the primacy of the individual human being should take precedence. Another moral rule within the framework of this regime would emphasize that information is a crucial feature of genetic screening programs. That is information about the advantages and disadvantages of participation in order to facilitate the individual in making an informed decision as well as information in the sense that information obtained through genetic screening program should be protected. This moral rule of protecting the private information obtained on the individual can be compromised if the data is annonymized or if it is evaluated to be in the interest of the individual or society. Figure 4 illustrates the moral framework.

A possible moral framework of rules, which would shape an emerging regime of genetic screening programs for susceptibility to disease

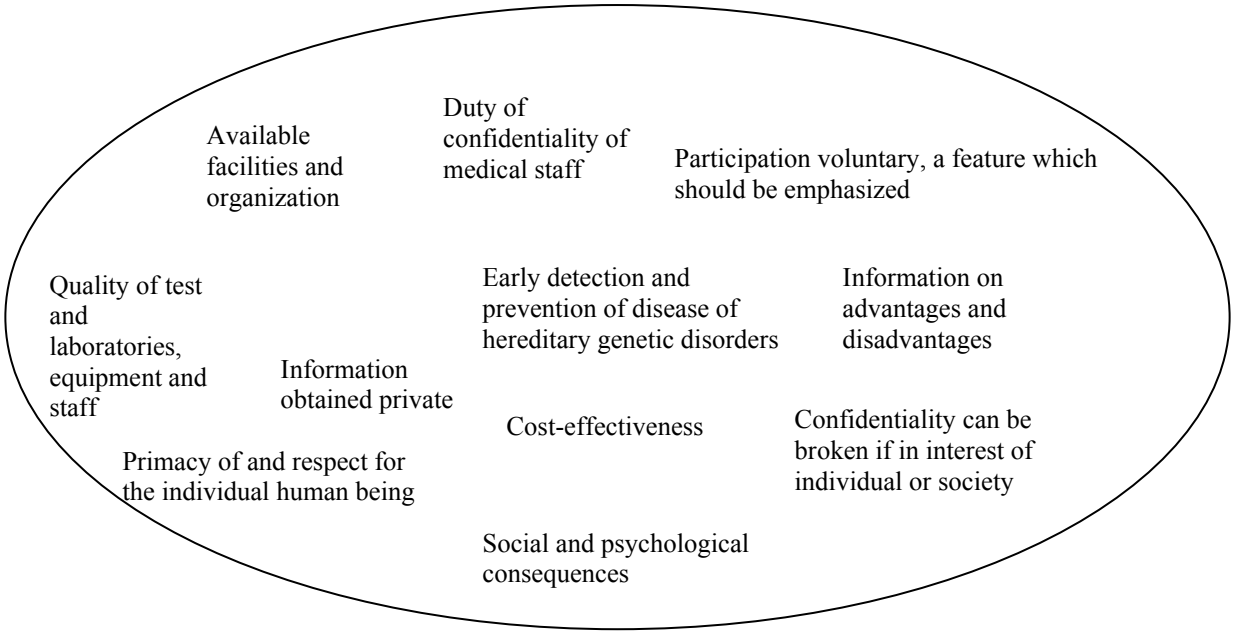

Figure 4 *illustrates a possible moral framework of rules, which would shape an emerging moral framework of rules belonging to a regime of genetic screening for susceptibility to disease.*

In the following chapter conclusions to the research questions will be drawn and these are discussed along with the approach and results of the research performed.

7 Conclusions and discussion

7.1 Conclusions

I began this report by giving an introduction to expectations of a development towards an increasing application of genetic technologies and genetic tests in Denmark and internationally to manage the health of the public. Subsequently I developed the idea of a development, which could lead to genetic screening programs for susceptibility to disease in Denmark. At present in Denmark there are no genetic screening programs, and one can still only gain access to a genetic test through an extensive evaluation procedure. A natural question now becomes; why genetic screening programs for susceptibility have not developed in Denmark? Part of the answer can be found in the analysis of the regimes of screening and clinical genetics in chapter 4 and 5, about which it was speculated would have to merge for a development of genetic screening programs. Through analyzing the regimes of screening and clinical genetics it became clear that these two regimes are shaped by each their moral framework of rules; frameworks which contain their own distinct moral rules. The moral framework shaping the regime of screening contained a goal of early detection of disease in order to prevent the disease. To reach this goal the moral rules shaping the regime of screening explicated the necessity of identifying a larger group in the population as potentially sick, and offers this group screening, in order to find the few actually sick. Within the moral framework of clinical genetics the goal is to inform individuals of their genetic make-up in order for them to be able to make informed decisions on their way to live. To reach this goal the framework the moral rules shaping the regime of clinical genetics specifies the necessity of providing non-directive counseling of individual who have identified themselves as in need of counseling. To be able to decide whether or not individuals qualify as in need of non-directive counseling on their genetic make-up, an extensive evaluation and monitoring system has been developed. Once inside this system, individuals themselves, on the basis of information obtained through counseling are seen as capable of determining their own course of action.

These moral frameworks, which are part of the socio-technical networks which make up the two regimes, are problematized by the social groups embedded in this network. This problematization is the result of the interpretive actions of these social groups, and through this process the social groups facilitate a co-evolutionary interaction between technology and morality in the regimes of screening and clinical genetics. In this way ethical problems become associated with both practices, providing part of the answer to why genetic screening programs for susceptibility to disease have not yet become a reality in Denmark.

The moral elements, which could be identified at the landscape level of the Danish healthcare sector, form another part of the answer to why genetic screening programs for susceptibility have not emerged at the regime level. In the problematization of the regimes of screening and clinical genetics, made by the social groups, the moral elements which could be identified at the landscape level come to play an essential role. These landscape moral elements act as enabling and disabling factors for certain developments. For example

the emergence of an increased focus on the rights of the individual at the landscape level could be analyzed as influencing both the regimes of screening and clinical genetics, which both developed in a direction where the rights of the individual became more clearly articulated. The social groups at the regime level extensively refer to landscape elements in their problematization of the regimes. This can for example be seen when the Danish Council of Ethics (and others) point to the dilemma of the right to know and the right not to know and connecting their problematization of these principles with the right to self-determination, which is an essential moral element at the landscape level of the Danish healthcare sector (see chapter 4, section 4.2 and chapter 5, section 5.2). The moral elements at the landscape level therefore form an important external structure, in which regimes can develop, and in where social groups can phrase their arguments and problematize present regimes. For the regimes of screening and clinical genetics this means that they become dependent on the opportunities, or in other words, the enabling as well as disabling moral elements at the landscape level of the healthcare sector for their development.

The analysis of the regimes and their niches, showed an extensive interaction between the regimes and actual practices located at the niche level. In this way, social groups at the regime level used examples from actual practices on the niche level to support arguments on made on the general regime level, and social groups at the niche level applied arguments from the regime level to argue for actual practice. This could be a trivial observation; however what the analysis also showed was that niche social groups not only used arguments from one regime, in which they should be placed according to the socio-technical multi-level model, but instead niche social groups took up and used arguments belonging to other regimes (see Chapter 6, section 6.2). In this way a path towards a possible merge between the regimes of screening and clinical genetics could be identified as emerging at the niche level. A pathway created and facilitated through the interpretive work performed by social groups. What at first glance would seem like a development which would not take place, due to persistent moral problems, can now at the niche level, be shown to be possible through the co-evolutionary interaction and mutual change of both technology and morality. A co-evolution between technology and morality which the use of the inventory of NEST-ethics patterns of argumentation helped make visible.

In conclusion; by making explicit the place of moral rules inside the socio-technical multi-level, and applying it to study genetic screening programs for susceptibility to disease in Denmark, it became possible to identify two distinct moral frameworks of rules for the screening and clinical genetics. These moral frameworks form part of the socio-technical network, which any social groups involved in these two regimes will have to interpret and rework when finding their place inside the regimes. At the same time it became possible to show how moral elements at the landscape level of the Danish healthcare sector, play an essential role in their ability to enable and disable developments at the regime levels. By applying this conceptual model it also became possible to uncover an emerging moral framework of rules, created though the interpretive actions of niche social groups, an emerging framework which could point to a pathway leading

to a merge of the moral frameworks of screening and clinical genetics and the development of genetic screening programs for susceptibility to disease. In the socio-technical multi-level model change is perceived as happening through a co-evolutionary process between technology and society and specifically after the extension with moral elements between technology and morality. By using the inventory of patterns of argumentation from NEST-ethics it was possible to make this co-evolution between technology and morality visible.

7.2 Further speculations on the socio-technical multi-level model and the development of genetic screening programs for susceptibility to disease in Denmark

The emerging moral framework of rules, which could be uncovered in the niches of prenatal diagnosis and HNPCC in the previous chapter, has implications for which technological as well as moral elements would be essential for a continuous development of the pathway leading to a merge between screening and clinical genetics. In the socio-technical multi-level model the regimes are interdependent and can affect each other through the action of social groups. However very little direction is given in the theoretical model on how such interdependency and interaction between regimes should be made concrete. In chapter 6 the analysis of a merge between the regimes is made by speculating on common and diverging themes in the two regimes. Such a merge is of course dependent both on technological development, but also on the ways in which social groups take up and interpret moral rules belonging to the two regimes, and how they interpret their place in the practice of genetic screening. In this way it may very well be that the emerging moral framework will be modified in other ways by existing or upcoming social groups. As change in the socio-technical multi-level model occurs through the co-evolutionary interaction between technology and morality facilitated through social groups, this creates three interdependent variables. The necessary technological developments are equally dependent on the moral conditions and vice versa and these two variables are dependent on the social groups responding and interpreting their development. An independent assumption on the necessary technological and moral conditions is inherently difficult, however for the sake of simplicity, they are separated in the following and a speculation is made on which technological and moral elements are necessary for a development towards genetic screening for susceptibility being a plausible one in Denmark. This of course raises the question if it is at all plausible that these technological and moral elements will indeed emerge? A question which is an important question, but which also contains material enough for another project.

7.2.1 Necessary technological conditions

The technology to perform genetic tests already exist, but the expectations are that in the future DNA analysis can be made faster and more efficient by the use of chip technology (Ministeriet for Videnskab, Teknologi og Innovation*, 2002). Expectations to the development of this technology can be found in various reports on the future development of the Danish healthcare sector can be found in reports from the

Ministry of Science, Technology, and Innovation (2002, 2003, 2004). Analysis of DNA is however only one part of the technology, another is the interpretation of this analysis, and as AMG says:

"Where I think we are moving towards is where you can start to make individual risk evaluations on the more common diseases, based on the genetic profile of the individual. Knowledge about the interaction between many different genes will form the basis of these risk evaluations. (…) but there are a lot of hurdles to overcome; we do not know all possible genetic combinations, what kind of diseases different combinations increase the risk for, or how different combinations effect each other, and we do not know the interaction between genetic combinations and environmental factors or other things like hormones, but if we imagine that all of these problems are solved in 50 years, and one then can go to ones general practitioner with a blood or saliva sample, then of course it would also be necessary to know exactly what the result of such a test would mean, and what the patient could be offered. There would be no use in letting someone know they had a high risk of a disease without being able to prevent this disease." (Appendix A, AMG)

The technology development needed is thus not just the development of faster and more efficient equipment for analysis, but also knowledge on how to interpret the results of such analysis. In addition it can be difficult to see the use of being told that one has a slightly higher susceptibility for Alzheimer, if nothing can be done to prevent or treat the condition. As Klemens Kappel (KK), who is an associate professor and Director of Studies at the Institute for Media, Cognition and Communication at Copenhagen University says:

"You have to remember that most of us will live very long, and when we are 80-90 years old or older, then most of us will be suffering from some of the "big diseases" like cancer circulatory diseases or Alzheimer's. We know that, and we know that to a certain extent these diseases are genetically determined. How much would one gain from knowing more? If I (KK) had my genetic profile analyzed, and was told that when I am (KK) 90 then there is a 10 percent chance of prostate cancer, 10 percent chance of stomach cancer, 10 percent chance of a bad heart or 10 percent chance of Alzheimer (…), well that is the kind of risk profile you would be able to get by analyzing the whole genome. What you would find out is pretty much what one already knows, and then it is suddenly not very interesting information. It is like being told that ones car is broken, when one already knows it. What one would be interested in being told is if one has a specifically elevated risk of for example Huntington's, where you would die being 40 years old. That would play a role for how one would plan ones life (…) There are specific conditions where the risk of developing the condition are specifically high, but that concerns very few people, and the large majority just has a normal distribution of disease, and to be informed of this normal distribution is not very interesting" (Appendix A, KK)

Necessary technological conditions for a development towards genetic screening programs for susceptibility to disease are then the development of new analytic possibilities, and increased abilities to interpret DNA analysis as well as possibilities for prevention and treatment need to be better developed before testing for genetic susceptibility to disease would become an interesting opportunity. The difficulty of

separating technological conditions from moral ones can already be seen in this section. The reasoning behind imagining certain technological conditions rests on moral arguments. When AMG says, that there would 'be no use' of letting someone know of a high risk unless this condition was preventable, she implicitly refers to a moral rule of not causing harm to others. Here it again would have been useful to have heard arguments from individuals working with development of genetic technologies.

7.2.2 Necessary moral conditions

The regime level

On the regime level some essential moral elements are; a continued appreciation of the early detection of disease, a belief in the imperative of prevention and continued focus and belief in the rights of the individual. These moral elements need to be translated in a specific manner for genetic screening programs for susceptibility to be plausible. A screening program needs to still be seen as the most effective means of achieving early detection of disease, as well as prevention of disease. The rights of the individual needs to continuously be translated as the right to information in order to be able to make informed decision and receiving information on ones individual health condition needs to be seen as empowering the individual. Following the rights of the individual, participation in genetic screening programs is expected to be presented as voluntary. If the organization of the good screening program is still defined is currently the case, then there will be demands made on facilities, organization and quality of laboratories and tests. However as it was observed in the 2001 report by the Danish Council of Ethics, none of the current screening program live up to these demands, and therefore these elements are not deemed essential.

The landscape level of the Danish healthcare sector

As the regime level is nested inside the landscape level there are certain moral elements present here which will facilitate a development on the regime level as sketched above. Currently the moral element of self-determination of the individual is in focus on the landscape level. The emergence of this moral element at the landscape level could be interpreted as important for the formulations of non-directive counselling and the importance put on information and informed decision making by the individual. For genetic screening programs, to be perceived as a tool to provide the individual with empowering information, this moral element need to keep its influence on the landscape level of the Danish Healthcare sector. However before the emergence and establishment of the moral element of the rights of the individual human being, another moral element with a focus on the collective and the rights of the collective existed at the landscape level of the Danish healthcare sector. This moral element was in chapter 4 shown to be important for the development of screening programs. For genetic screening programs to develop it would therefore be essential that the rights of the collective would still be interpreted as important in relation to the rights of the individual. Currently it seems to be the case in Denmark that these two moral elements co-exist on the landscape level. As it was observed by Mette Hartlev (MHa):

"But how much there is an actual clash between these two kinds of values is difficult to say at the current point in time. The way the thinking about rights is legally put together individual rights will always have to be weighed in relation to the interests of the community and other persons. The Human Rights are not only individualistic. One has the right to self-determination and a private life, but these rights can be encroached on if there are reasonable considerations to be made to public health or to other people, so in this way they are not ultimate. Really what one can say is that the individual rights have been made clearer than they were earlier." (Appendix A, MHa)

For the development of genetic screening programs for susceptibility to disease to develop it is thus essential that a continuous balance between individual and collective rights becomes established. On the landscape level it is also important that the public authorities keep being accepted as and seen as responsible for the healthcare sector. This is important as screening is defined as an offer made by the public healthcare system towards the individual, which is identified as being part of a group at increased risk of developing a certain disease. Furthermore, it is important, that the public authorities keeps perceiving themselves as responsible for the health of the population, and as responsible for providing the public with the most advanced technological means of diagnosis. If developments at the landscape level turn in the direction of more and more individual responsibility in terms of duties to be informed on and responsible for ones own health, the public authorities might change their perception and start giving the individual more and more responsibility for their own health status. In this way the public authorities could define the goal of the public system as one of treatment of disease. Prevention would be a task for the individual citizen and genetic tests for susceptibility would become available exclusively through the private sector. Offers of genetic tests to the population through private companies might also be seen as screening, but this screening would no longer be an offer made by the public authorities, which is one of the defining features of screening in Denmark.

The niche level

On the niche level several developments of moral rules are essential for the development towards genetic screening. It is essential that information obtained from a genetic test keeps being perceived as essential in order to prevent disease in the niche of HNPCC. The rule that the autonomy of the individual can be compromised in the name of prevention is new, and it is only established at the very unstable niche level. Prevention needs to become even more established at the niche level as the goal of performing genetic tests, and it needs to become acceptable to provide individuals with guiding instructions on how to use genetic information in order to prevent disease. A consistent and successful combination of genetic test and prevention would help induce change in this direction in more niches, which would diffuse into the regime level, where the goals of clinical genetics would have to be redefined. Clinical genetics would have to be redefined into a regime performing systematic screenings of the population in order to inform individuals on their genetic make-up and in accordance with this information guide them towards preventative options.

7.3 Discussing the application of the extended socio-technical multi-level model

In chapter 3, the socio-technical multi-level model was used as the basis for developing a conceptualization of the co-evolution between morality and technology, facilitated by the activities of social groups. For conceptualizing how change takes place, the model operates with three levels on which developments occur, which lead to socio-technical change. On two of these levels; the regime and niche level, social groups are embedded in a framework of regulative, cognitive and normative rules, a rule-set which is constantly interpreted and re-worked by the social groups. By making explicit that moral rules are part of the regulatory, cognitive as well as normative framework of rules, the scope of the socio-technical multi-level model is narrowed, in the sense that moral rules are only part of the framework of rules at these two levels. Narrowing the scope of the socio-technical multi-level model in this way, has the advantage that it becomes possible to explicitly study the co-evolution between morality and technology, and in this way focus explicitly on how social groups interpret and rework the moral framework of rules in which they are embedded. The need for developing methods to explicitly study the maintenance and change of the framework of rules embedding the social groups can be read in a recent review of the multi-level perspective (MLP). Here Genus and Coles (2008) argue that a convincing account for the way in which rules are 'made and unmade' still needs to be made:

"Yet the making or unmaking of the various types of rules constraining or enabling actions and the reproduction of related practices central to maintenance or transformation has not yet been an explicit object of systematic study in MLP research (…)*" (Genus & Coles, 2008;7)*

The extension of the socio-technical multi-level model with moral rules is a step towards enabling the 'making and unmaking of various types of rules' to become an explicit object of study within the multi-level perspective. Through identifying the moral frameworks of rules, which are created through the actions of social groups and which shape the regimes of screening and clinical genetics in chapter 4 and 5, shows a way in which the 'making and unmaking' of certain rules and here explicitly moral rules, which constrain and enable certain types of moral as well as technological developments, can be done.

When applying the extended socio-technical multi-level model to the Danish context it proved difficult to apply the separation between landscape, regime and niche levels in practice. The landscape, regime and niche levels are described as nested inside each other, where the landscape level is perceived as an outside exogenous factor, which influence the regime and niche level through pressures, but which is in itself of a slow changing nature. The regime and the niche level are described at consisting of the same elements only distinguished by the degree of robustness of the elements found at each level. In this study the separation between regime and niche level is purely made on the basis of individual choice and justified by arguing that niche practices are the ones in where moral rules are translated into concrete rules of behavior relating to one specific practice. An example is the translation of individual autonomy in the niche of HNPCC. On the regime level of clinical genetics individual means that it is completely up to the individual itself if family

members should be contacted on their risk status. On the niche level of HNPCC testing however, this moral rule is translated differently. Here individual autonomy is preserved unless there are important reasons for a specialist to contact family members, a contact which could be contrary to the wishes of the individual, who initially came to the clinical geneticist. One of the arguments for allowing such an action is the argument of a prospect of prevention. This difficulty of empirically applying the levels was also experienced in the development of the analysis in chapter 6. Here the moral frameworks of rules identified as shaping the regimes of screening and clinical genetics, were used to uncover an emerging moral framework which could come to shape a practice of genetic screening for susceptibility testing. This emerging moral framework is based on a speculation on how interaction between the regimes could proceed and how niches could come to have influence. As mentioned above the boundaries of a regime as well as the distinction between the regime and niche level are not very specifically conceptualized in the socio-technical multi-level model. For analytic purposes screening and clinical genetics were chosen as two separate regimes and niches were subsequently placed them. It can of course be discussed if these analytical distinctions are indeed appropriate. Alternatively the Danish healthcare sector could be perceived as an regime in its own right, and the landscape level could be Denmark and all the elements of societal, cultural and technological nature which defines this landscape and niches would then be specific practices of for example screening or clinical genetics. The division of social groups into regimes and niches is thus a relatively arbitrary process, a critique which can also be found in the review by Genus and Coles (2008).

In chapter 4 and 5 it was shown how social groups create a moral framework for the regimes of screening and clinical genetics, and how the development of these moral frameworks of rules was dependent on available technological options. This is for example seen in the regime of screening where the availability and reliability of tests becomes one of the factors on which the moral rule of effectiveness is based. And in the regime of clinical genetics it can be seen especially in the niche of HNPCC, where technological opportunities for prevention, compromise the moral rule of non-directive counseling and individual autonomy. What is however not sufficiently explored in the two chapters is the influence that the moral framework of rules has on the development of technology in the regime of screening and clinical genetics. The analysis showing the co-evolution between technology and morality in chapter 4 and 5 therefore lacks input from social groups involved in technology production and development.

The account of the historical dependency of the moral elements at the landscape level of the Danish healthcare sector is partly made using second hand historical information and a more accurate and detailed account would use original historical sources in establishing the moral elements found at this level. In addition the historical dependency of the moral framework of rules established in the regimes of screening and clinical genetics would benefit from a more thorough investigation, which would even further open up the details of the moral framework of rules and its historical dependency in the regimes.

In sum; the application of the extended socio-technical model, focusing specifically on the co-evolution between technology and morality, to study the subject of genetic screening programs for susceptibility of disease made it possible to show how any future practice of genetic screening is dependent not only on technological opportunities, but on a continuous mutual interaction between technology and morality. Through the model it became possible to show the importance of moral elements, formulated as guiding values for the healthcare sector in Denmark. An importance which could be traced by showing how social groups associated with screening and clinical genetics drew on these general moral elements when formulating moral rules in both general and specific practices. Furthermore it became possible to show how social groups not only use general moral elements to formulate general and specific rules, but also to show that these social groups through their interpretation and translation of these moral elements managed to create moral frameworks of rules for their general and specific practices. A creation of a framework which not only depended on translation of general moral elements but also on earlier formulations of moral frameworks made by other social groups. The model thus helped uncover the situated character of the moral frameworks of rules into which both new technology as well as new morality for genetic screening programs for susceptibility of disease would have to be introduced, and showed why such an introduction could be difficult. At the same time the model could however also be used to uncover emerging patterns in specific practices, which could be seen as forming a pathway towards a merge of the moral frameworks of rules shaping the general practices of screening and clinical genetics, a pathway created by social groups on the level of the specific practices of prenatal diagnosis and HNPCC.

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9 Appendix A - Interviews and information on interviewees

The interviewees where selected on using the criteria's that they should preferably be involved in one ore more projects on screening or genetic testing, be active in debates as well as being recognized experts in their fields. In the following a brief introduction to the interviewee is made, followed by a standard interview protocol. The interviewees are identified in the report using the following codes:

Anne Marie Gerdes = AMG

Mette Hartlev = MHa

Maja Horst = MHo

Lotte Hvas = LH

Klemens Kappel = KK

Transcripts of the interviews (In Danish) are to be found on the accompanying CDROM.

9.1 Anne Marie Gerdes (AMG)

Anne Marie Gerdes is senior consultant at the University Hospital Odense. She specializes in clinical genetics and especially the area of hereditary cancer diseases, where she has many years of experience in counselling. Anne Marie Gerdes was a member of the project group which planned the 2002 "Testing our genes" consensus conference which was arranged by the Danish Board of Technology and presented on "Genetic counselling and practice". In addition she is actively participating in the debate on clinical genetics and was a member of the group publishing the report "Hereditary nonpolyposis colorectal cancer in Denmark – a health technology assessment".

9.2 Mette Hartlev (MHa)

Mette Hartlev is professor in Health Law and Director of Studies at the Faculty of Law, Copenhagen University. From 2003 to 2005 she was a member of the Danish Council of Ethics. She presented at the 2002 "Testing our genes" consensus conference on "Registers and registration" and "The legal situation concerning genetic tests" which was arranged by the Danish Board of Technology and she was member of the expert group which published the report "Hereditary nonpolyposis colorectal cancer in Denmark – a health technology assessment". In addition she is an active participant in the debate on data protection and human rights.

9.3 Maja Horst (MHo)

Maja Horst is Associate Professor at the Department of Management, Politics and Philosophy, Copenhagen Business School and is Director of the Doctoral School in Knowledge and Management. She

presented at the 2002 "Testing our genes" consensus conference on "Information to citizen's on genetic tests" which was arranged by the Danish Board of Technology. Her research concerns the relationship between science and society, with particular emphasis on public communication about science and technology.

9.4 Lotte Hvas (LH)

Lotte Hvas is Associated Researcher at the Research Unit of General Practice, Copenhagen and Vice-president in the Danish Council of Ethics. Lotte Hvas is very active in the debate on screening, risk, prevention and medication to healthy people.

9.5 Klemens Kappel (KK)

Klemens Kappel is Associate Professor and Director of Studies at the Institute for Media, Cognition and Communication, Copenhagen University. He presented at the 2002 "Testing our genes" consensus conference on "How does genetic testing affect our perception of the concepts of sickness and health?" and "What is the purpose of genetic testing and what are the vision for the future (positive and negative) nationally and internationally?" which were arranged by the Danish Board of Technology. In addition he has been a member of the Danish Council on Ethics.

9.6 Interview protocol

Only AMG and MHa, where asked the questions under 9.6.3. HNPCC and genetic screening

Introduction

Introduce yourself (previous and current education) and the subject

Ask for permission to record, anonymity, transcription, the finished report and possible follow-up contact

The subject: Interaction between moral values and technological development

Clinical genetics and screening

Operating with two different moral sets of rules

Possible collision/merge between moral sets of rules, which would reveal something of the dynamic between technological development and moral values

Focus on three levels; the Danish healthcare sector, clinical genetics, screening, HNPCC and genetics screening of adults

Happy that you would participate

9.6.1 Guiding questions – The Danish Healthcare sector:

1. Are there specific values which the healthcare sector is built around?

   Probes:

   - Public healthcare, solidarity in financing, right to self-determination, equal access
2. Do these values affect the build-up of the healthcare sector?

   Probes:

   - Decentralisation**,** the state as the main responsible, a focus on what is good for the society, a focus on the possibilities of the individual, effectiveness and cost-benefit analysis
3. Do you perceive these values as stable? Are they historically founded?

   Probes:

   - Decentralization, state responsibility, public and financed in solidarity, focus on the individual and individual rights
4. How do you interpret the future development with regards to these values? Are there any tension around them, are they under pressure and if so in what way?

   Probes:

   - Public/private, decentralize/central government, treatment/prevention
5. How do you view the interaction between these values? Are they neutral or a cause for conflicts?

   - Possibly covered under the previous question

6. Which institutions are important (laws and regulations) for the formulation and shaping of these values?

   Probes:

   - government/parliament, Ministry of Health and Prevention, National Board of Health, Ministry of Science, Technology and Innovation, Danish Medical Association, media

9.6.2 Clinical genetics and population screening:

1. Is there a specific set of guiding rules connected to the practice of clinical genetics, and what are these?

   Probes:

   - For example the one from the Danish Medical Association, focus on information to the person seeking advice, weighing between the right to know and not to know, informed consent, the law on health, situations European convention on human rights and biomedicine

2. Is there a specific set of values, guiding rules connected to population screening and what are these?

   Probes:

   - 1968 WHO guidelines, offer of voluntary participation, disease needs to be treatable and important healthcare problem, suitable test, cost reasonable compared to collected costs of the healthcare sector, expansion with; ethical aspects, economy, detailed descriptions of the process

3. What is the difference between the values for clinical genetics and population screening, how are they formulated and who is responsible for formulating and shaping these rules?

   Probes:

   - To actively seek out vs. not actively seeking out, the importance of counselling in connection with treatment, can, should, laws and recommendations

4. Are the rules for clinical genetics different than the general rules for the Danish healthcare sector, and if yes in what way? Are there any connections between the rules?

   Probes:

   - Focus on the individual and free choice, self-determination and autonomy, consideration to others and to the rest of society, self-sufficient units connected to decentralization, equal access, financed through solidarity and general practitioners as gate-keepers

5. How stable are the identified values? Can any tensions be identified around the values for clinical genetics and how do these become expressed?

   Probes:

   - Like the right to self-determination of the person seeking advice, right to and from knowledge (connected to the conflict between society/individual), non-directive counselling, tensions from demands of prioritizing, effective use of resources, any change/development around the right to know, not to know (example that is becomes seen as more legitimate to seek out relatives), tensions

can also be seen around the individual not perceiving itself as a part of a family in the same way it is perceived in genetics

6. What are the most important/visible ethical conflicts in connection with clinical genetics?

   Probes:

   - Right to know, not to know, stigmatization, fear, psychological issues, uncertainty in diagnosis, prioritizing, effectiveness

7. Does genetic testing challenge values in clinical genetics, or values in the Danish healthcare sector?

   Probes:

   - For the sake of the collective you should seek treatment/prevention; in this way the genetic test in itself could challenge the non-directive counselling, right not to know; the test changes our picture of what it means to be an individual, changes in solidarity and perception of society, selective access challenges idea of everybody's right to knowledge and equal access as access is based on estimated need

8. How do ethical conflicts become discussed and how are ethical conflicts solved in practice?

   Probes:

   - Are ethical conflicts emphasized or kept quiet, are the same values used differently in different arguments; autonomy, then you will choose to undergo treatment if you are a rational thinking human being, or then you have a right to say no, without this being irrational, effectiveness and cost-benefits used both as pro and con's, what makes genetic knowledge special

9. What are your expectations to the future development in clinical genetics and genetic testing? Could presymptomatic genetic screening programs on a population development become a reality and why and why not?

   Probes:

   - No, the methods are not effective enough so it would not pay off, yea there could be great economic benefits for society in a few years

9.6.3 HNPCC and genetic screening

Recently a report was published on the practice of HNPCC and as you participated in the writing of this report I would like to ask some questions about this.

10. Can certain values for the practice of HNPCC be identified? How is the connection between these values and the values for clinical genetics?

    Probes:

    - Differences between how the right not to know is practiced with testing for predispositions to breast cancer and colon cancer?

11. Do you experience conflicts/tensions between values for clinical genetics in general and specific practice, and how are these solved? Are any changes desirable?

12. Is the practice of HNPCC/clinical genetics affected by values from the Danish healthcare sector and if yes, in what way?

    Probes:

    - Prioritising who is tested and who is not, carried out inside the public sector and the demand for counselling

10 Appendix B – Laws, guidelines and recommendations

The following can be found on the accompanying CDROM:

Council of Europe (2007), "Additional Protocol to the Convention on Human Rights and Medicine, concerning Genetic Testing for Health Purposes"

Council of Europe (1997), "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine – Convention on Human Rights and Biomedicine" *European Treaty Series*, Nr. 164

Council of Europe (1994), "Of the Committee of Ministers to the Member States on Screening as a tool of preventative medicine", Recommendation No. R (94) 11, Council of Europe, Committee of Ministers

Council of Europe (1992), "Of the Committee of Ministers to the Member States on Genetic Testing and Screening for Health Care purposes"

Wilson, J. M. G. & Jungner, G. (1968), "Principles and practices of screening for disease" Geneva, the WHO, 1968

Principles for genetic screening can be found in the article on page 51; Godard, Bèatrice, Leo ten Kate, Evers-Kiebooms, Gerry and Ayme, Ségolène (2003), "Population genetic screening programmes: principles, techniques, practices and policies" *European Journal of Human Genetics* 11, suppl. 2. pp. 49-87, on p. 51.

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These are to be found on the accompanying CDROM