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SECTION E

THE SOCIOLOGY OF ENTRENCHMENT: A CYSTIC FIBROSIS TEST FOR EVERYONE?

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Abstract—In this article we introduce the notion of entrenchment to conceptualize the processes in which new technological options, through the interactions between a variety of actors, become viable and established practices in society, both satisfying and modifying needs and interests. The notion of entrenchment we use as a framework for an analysis of developments and debates in the field of cystic fibrosis testing and screening in Denmark. On the one hand, it appears that the development and introduction of cystic fibrosis (CF) screening to some extent is predetermined both by existing networks of human genome researchers, clinical geneticists, patients (organizations), funding organizations, and regulatory agencies, and by existing practices like that of prenatal diagnosis. On the other hand, in Denmark, the content and future of CF screening is shaped in ongoing processes or articulation of demand for screening and of its cultural and political acceptability, processes which also involve political decision-making and which (may) result in new networks and regimes. Yet, what appears to be an inherent and undecided part of the process of entrenchment of CF screening in Denmark, is how to allocate responsibilities and authority to decide what is acceptable and what not.

Key words—genetic screening, cystic fibrosis, ethics, political regulation, sociology of technology

INTRODUCTION

In a comment on the ethical and social consequences of the international genome mapping effort, Sydney Brenner, a leading British molecular biologist and ardent promoter of the human genome project, argues that we should separate the discussion about the project into two parts: one concerning the acquisition of the knowledge, the other its application. He then goes on to explain that the knowledge itself can be only neutral and that "everything else that will stem from the knowledge, good or bad, will take place outside the laboratory in the social realm". So, it is society that should properly exercise the choices on the application of scientific knowledge. In advancing this view, Brenner opposes what he calls the "Pandora's box argument" of those who think we should stop the research before it is let loose on the world because opening the box will initiate an inevitable causal chain leading to future disaster [1].

Brenner is not the only scientist involved in the human genome project who, in response to fears about inevitable ethical and social implications, trustfully refers to society. Thus, in discussions of the implications of the project, Brenner, Gilbert and Watson all emphasize that it is society that should properly exercise choices, deal with the problems in a democratic way, and learn to use information only in beneficial ways [2–5]. A striking feature of this rhetoric is that both science and society appear as highly black-boxed and clearly separated entities. On the one hand we have 'science' or the 'laboratory' producing knowledge and technologies, on the other hand we have 'society' deciding upon, or setting limits to, the uses of new knowledge and technologies.* Thus, what is suggested in this rhetoric is a very simple model of the relationship between science and society (Fig. 1). In this article, we suggest another more complex model of this relationship (Fig. 2). Based on a more thoroughgoing sociological analysis of science and technology, the model implies that the development and introduction of new technologies in society take shape in complex interactions in which, on the one hand, many different actors are shaping technology and, on the other hand, technology becomes a means for actors to (re)shape society. Thus, of the two notions—'science' as Pandora's box simply forcing its products on society, or 'society' neatly deciding about whether and how these products should be used—neither does apply. Both these

*This rhetoric we do not only find among scientists, but also in political debates about human genome research and its implications. For example, when the European Commission proposed to add to the EC programme of Human Genome Analysis a special programme to study and evaluate the implications of human genome research, the Commission neatly distinguished science as a quest for pure knowledge from society as a body which should carefully consider the applications of this knowledge [6].

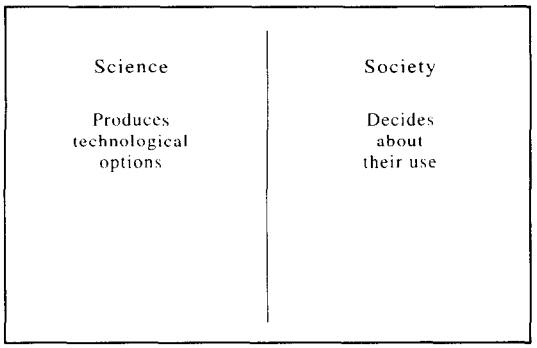

Fig. 1. A (too) simple model of the relationship between science and society.

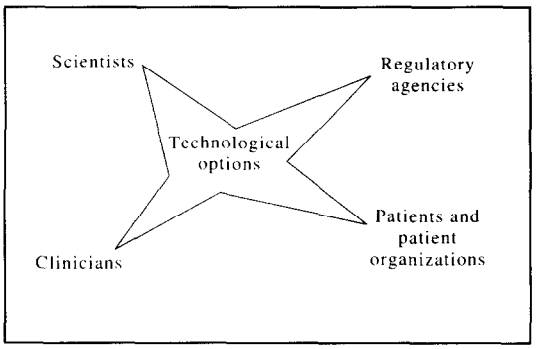

Fig. 2. A less simple model of the relationships between (biomedical) science and society.

notions are only taking to the extreme some simplified version of a complex process of socio-technical change.

To substantiate our model we use the concept of entrenchment as a notion referring to the processes in which new technological options, through the interactions between a variety of actors, become viable and established practices in society, both satisfying and modifying needs and interests. In recent sociology and economics of technology we find attempts to create a comprehensive analysis of processes of societal entrenchment of technology [7]. Such attempts may help us to understand the intricacies of what is often so misleadingly called the 'diffusion' of technology through society*. In this article we will use the notion of entrenchment as a framework for an analysis of developments and debates in the field of cystic fibrosis (CF) testing and screening in Denmark. On the one hand, we will show that the development and introduction of CF testing to some extent is predetermined in our society both by existing networks of human genome researchers, clinical geneticists, patients (organizations), funding organizations, and regulatory agencies, and by existing practices like that of prenatal diagnosis. On the other hand, we will show how the content and future of CF testing is shaped in ongoing processes of articulation in which the demand for and acceptability of particular options for screening are negotiated among a variety of actors. These processes also involve political decision-making and may result in new networks and regimes. In other words, the history of CF testing is neither simply a question of 'society' deciding about the application of a test, nor simply a question of 'technology' forcing itself upon society. Only in the sense that existing socio-technical networks and regimes promote the entrenchment of a particular technology we may say indeed that technology forces itself upon society, but it is also the other way around. Just because technology depends for its entrenchment on elaboration of new networks and regimes it depends for its success on negotiations and decisions in society.

*For a critique of the model of diffusion see [8]. Some authors who use the notion of diffusion come very close however to an analysis which includes all the elements of what we would call entrenchment. See for example [9].

THE SOCIOLOGY OF ENTRENCHMENT

The concept of entrenchment of technology is used to emphasize that there is more to the introduction of new technologies than putting a new product into 'the' market and having it adopted by users (or not, as the case may be). Societal entrenchment is a process including further technological development, articulation of demand for specific applications of a particular technology, and, increasingly, articulation of cultural and political acceptability. In the domain of human genetics, we have seen in the past decade a rapid emergence of new technological options to diagnose genetic disorders, coupled with increasing demand for specific applications. Articulation of such demands is not automatic, however. It requires activities like arrangements to reimburse diagnostic tests, possibilities of counselling, education, training of doctors and social workers. Thus, application of a new technology requires the creation of an environment in which such applications can actually be realized, in which technology can be 'entrenched'.

In addition to articulation of demand, the introduction of new technologies in society more and more also needs efforts to insure its cultural and political acceptability, especially in view of potential adverse implications for society. This point is obvious in the case of the new human genome technologies (or indeed new genetic technologies in general). The development and societal entrenchment of these technologies meets with questions, concern and resistance and leads to reflection and debate involving various parties: researchers, clinical geneticists, patients and their organizations, ethicists, feminist groups, government and parliamentary committees, etc. Issues of cultural and political acceptability of human genome technologies, especially their use in testing and screening programmes (including CF screening), have been articulated in a great number of studies [10–16], and have become a special matter of concern in official programmes for evaluation of ethical, social

and legal issues as part of the international human genome initiative*.

Our analysis of entrenchment focusses on the way in which, in the interactions between actors like innovators, users, funding bodies, service organizations and regulatory agencies, a mutual attuning and alignment emerges between the development of new technological options, articulation of demand, and articulation of acceptability. Thus, in our discussion of the question of societal entrenchment of CF testing and screening, the following issues are of central importance.

Attunement of technical options and demand

Entrenchment of technology in society will result in, and be the outcome of, a mutual attuning of technical options and demand. This attunement involves on the one hand processes of technical specification, in which the content and meaning of a particular technical option (like a genetic test) becomes further specified in practice, and on the other hand processes of articulation of demand, in which producers as well as consumers further specify needs and demands in relation to available technical options [17, 18]. Technical specification and articulation of demand are the explicit aims of many of the pilot projects on CF screening that are going on in the US and elsewhere. Technical specification relates to the kind and number of mutations to be included in the test and to the procedures followed in conducting the test (to whom and in what way will the test be offered?). At the same time demand is articulated in these projects, identifying "factors that affect a couple's decision whether or not to be screened", determining "predictors of consent", determining "what proportion (of women of reproductive age) desires it", etc. [14, p. 16].

Attunement of technical options and acceptability

Entrenchment of technologies also needs activities directed to overcoming, or adapting to, concern and resistance. Here we can distinguish processes of articulation of cultural and political acceptability, in which potential impacts and issues of acceptability are defined, from the specification of technical and social practices as a means to cope with these impacts and issues. Articulation of cultural and political acceptability is taking place in professional and public debates or controversies, but is also shaped by evolving practices of regulation and assessment, including official impact studies like the recently published OTA report on CF carrier screening. Current pilot projects on cystic fibrosis screening also can be seen as a means to articulate acceptability and to specify practices in accordance with notions of acceptability. These projects include studies of 'psychological impact following testing' and 'responses to implications of the test results', and seek to specify procedures for screening in response to notions of acceptability [14, p. 16]. An interesting example of such attempts at specification of technical procedures is the introduction, in a British pilot project, of 'couples screening' to avoid the implications of knowing one's individual carrier status [14, p. 15]. Issues of cultural and political acceptability may also lead to attempts at regulation through institutional or legal means. In relation to genetic screening practices institutional or legal means are used or advocated for example to ensure quality control or to preclude discrimination.

The role of existing 'niches' and 'regimes'

New technological options cannot survive in society without being entrenched in networks of producers, users and various services. Thus, the initial steps taken in the development of some new technological option will often be strongly determined by existing networks in society which constitute 'niches' offering advantageous opportunities for particular applications. More in general we may speak of 'regimes', that is, mutually adapted and coordinated technological, organizational and societal practices which are the result of earlier processes of attunement between technological options, demand and acceptability. The existing regime of prenatal diagnosis constitutes for example an important niche in our society for the entrenchment of a rapidly increasing number of new genetic tests based on DNA-diagnosis. This is clearly illustrated by the design of the earlier mentioned pilot projects on CF screening. Many of these projects have started with women enrolled in prenatal diagnosis as their target population. Thus it is reported in the OTA study on CF carrier screening that "initially, routine CF carrier screening will likely occur in the reproductive context" since "the prenatal population has been the traditional entry point into genetic services for many people" [14, p. 14]. In this way, existing networks and regimes do not only shape the content and meaning of new technological options, but also predetermine the entrenchment of these options in society. That is, as far as, in the context of these regimes, questions of demand and acceptability can be taken for granted by the various parties in the network, such regimes will strongly facilitate the entrenchment of new technologies in society. Revealing in this respect is the conclusion of the earlier mentioned OTA study that "without offering judgment on its appropriateness or inappropriateness, OTA finds that the matter of CF carrier screening in the United States is one of when, not if" [14, p. 16].

*For the American Ethical, Legal, and Social Issues programme see the first five year plan of the US human genome project, US Department of Health and Human Services and US Department of Energy, 1990. For the European programme see the report of the Working Group on the Ethical, Social and Legal Aspects of Human Genome Analysis, 1991.

The relation between demand and acceptability

In processes of entrenchment of technology issues of demand and acceptability often will be inextricably related as is clearly illustrated by the questions examined in studies and pilot projects on CF screening. Yet, there are good reasons to distinguish processes of articulation of demand from processes of articulation of cultural and political acceptability. Although a variety of actors is involved in either process, there is general agreement about the authority of the 'autonomous' consumer or patient in deciding about questions of demand. The picture is far less clear however in dealing with issues of cultural and political acceptability. Here, the question who has the right to speak authoritively about these issues is often an undecided and controversial issue. Thus, articulation of cultural and political acceptability is often also a question of articulating who has the right to decide in which terms about what*. In the field of genetic diagnosis, governments in general will guarantee the availability of particular genetic services in the context of the national health system and, in doing so, may also introduce regulation which binds the availability of these services to certain conditions, especially in regard to costs. Governments usually will also be involved in quality control, for example in regard to reliability of diagnostic genetic tests. Finally, the issue of ethical and social implications may be a ground for regulation and government interference. This form of regulation we find embodied for example in the activities of national and local ethical committees. The question whether, and in what form, government interference is desirable and legitimate in regard to ethical and social implications of genetic technologies is far from decided however†.

In the next part of this article we will use the analysis of societal entrenchment of technology as a framework for discussing the entrenchment of CF testing and screening in Denmark. As the following history will make clear, we are moving here along a path which started in 1987 with the straightforward and generally accepted introduction of CF-testing for high-risk individuals in a medical context, and then proceeded, after the localization of the CF-gene in 1989, with the establishment of a pilot screening programme which has become more and more controversial however. In regard to CF testing in the medical context, everything was 'in place', so to speak. Established networks and regimes gave actors a certain space and autonomy, questions of demand and acceptability had been negotiated and could be taken for granted. Yet, in the case of population screening, a situation has emerged in which questions of demand and acceptability cannot be taken for granted any longer and issues as well as actors have to be 'put into place' yet.

THE ENTRENCHMENT OF CF SCREENING IN DENMARK

Why Denmark?

For at least three reasons, Denmark is an interesting country for a study of the entrenchment of the genetic diagnostic test for CF which became available after the cloning of the most common mutation of the CF gene (Delta 508) in 1989. First, Denmark is probably the country in Europe with the highest prevalence of the Delta 508 mutation (88%) and also has a rather high frequency of CF in the population (1:4760). Second, Danish biologists were in the front line when the CF gene was localized on chromosome 7 in 1985 [21, 22] and lastly—perhaps influenced by these 2 previous factors—Danish CF experts have considered Denmark the ideal country to take the lead in CF screening: immediately after the cloning of the gene, in late 1989, a pilot programme was initiated by the section of clinical genetics at the University Hospital of Copenhagen to screen 7000 pregnant women in greater Copenhagen in order to "illuminate the technical, informational, psychological and ethical problems of a CF carrier screening" [23]. This step was facilitated by the existence of a publicly financed practice of prenatal care in Denmark, including broadly accepted prenatal diagnosis of a large section of the pregnant population. Since >99% of the pregnant population attent prenatal care and give birth in registered hospital clinics, total screening of virtually all pregnant women as well as centralized registration of their genetic data is possible. Thus, in Denmark, the initial steps in a process of entrenchment of CF screening took place in the reproductive context thanks to the existence of an elaborate regime of prenatal care in which new forms of genetic testing can be easily implemented. As we will see, the introduction of CF screening in this regime of prenatal care was further promoted by the existence of a strong and centralized CF network involving genetic researchers, clinicians and a CF patient organization.

In the following we will first discuss the features of this Danish CF network and show how in this network a practice was established of prenatal testing

*In the OTA report on CF screening the question "who serves as gatekeepers of a new technology" is mentioned as one of the controversial issues surrounding the growing practice of CF screening (p. 18). From a recent overview of the process of bioethical decision-making in the United States it becomes clear that there is a variety of actors involved and that one question to be resolved in the process is 'who will decide'. See [19].

†Illustrative in this respect is the discussion about the role of Congress in the OTA report on CF screening. See also Ruth Schwartz Cowan's discussion of genetic technology and reproductive choice, in which she strongly opposes government interference in reproductive decisions for reasons of personal freedom and autonomy, concluding that "if nothing else, the history of the twentieth century ought to have taught us that individuals can sometimes behave badly, but they can never behave as badly, or as destructively, as governments" (20, p. 263).

of high risk individuals. Then, we will show how the content and fate of CF testing in Denmark is being shaped in an ongoing process of articulation of demand and acceptability and a process of negotiation between a variety of actors making up an increasingly complex network. A network involving not only researchers, clinicians and a patient organization, but also different kinds of ethical evaluatory bodies, and the national health authorities.

The CF network in Denmark

The leading CF unit in Denmark, the centre for research and treatment of Cystic Fibrosis, is situated at the University Hospital of Copenhagen. Here a small group of biochemists, paediatricians and lung specialists have created a reknowned unit for CF research as well as the nation's most treatment-efficient centre for the diagnosis and treatment of CF. In 1990 the centre was converted into a national centralized unit by the National Board of Health after documentation had been provided that treatment efficiency was significantly lower in smaller regional centres than in the medically and technically more advanced Copenhagen unit [24]. The centralization process, which was thus supported by the national health authorities, was important for the process of creating a strong and coherent CF network, commanding the majority of the resources attributed to CF research and treatment in Denmark.

The national CF unit is working in close cooperation with the section of clinical genetics at the University Hospital of Copenhagen which has developed fruitful contacts to international research centres, including genetic research associations such as the CF genetic analysis consortium. Here the molecular-biological findings of CF genetics from 80 labs all over the world are pooled and coordinated for everyone to use freely, a structure that has been conducive to the development of CF genetics. The CF unit also works very closely together with the Danish association for the struggle against CF—officially a patient association but actually rather a national organization of medical doctors, patients and patients relatives characterized by great expectations to medical and genetic research. The CF association is unique among patient organizations in Denmark for its energetic lobbying for easier access to prenatal diagnosis to avoid the birth of handicapped children, for its international orientation and its efficient fundraising practices. The funds raised by the association finance several research projects at the CF unit in the University Hospital, including a study of the reproductive function of CF patients, microbiological studies of lung infections and most recently a study of public acceptability of CF screening. In almost all outreaching activities do the CF unit and the CF association act in harmony, often countersigning each others actions. The combined

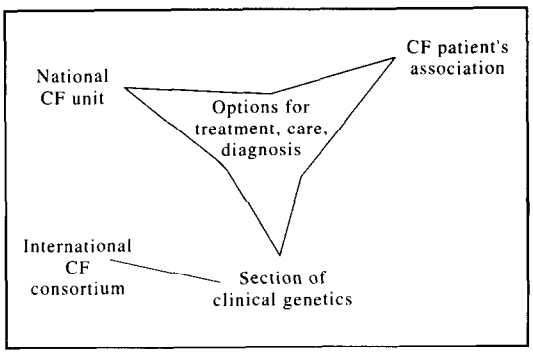

Fig. 3. The Danish CF network before 1989.

efforts of the three groups—the CF unit, the section of clinical genetics, and the CF association, could in several respects be said to form a seamless web (Fig. 3).

Prenatal testing of high risk individuals

With the advent of the first findings of markers of the CF gene in 1987, the unified network, including enthusiastic CF parents wanting another but unaffected child, supported the introduction of prenatal diagnosis in people with a family history of CF. Since the advent of prenatal diagnosis for CF >90% of those offered the test (riskpersons consulting the CF unit) have chosen prenatal diagnosis for CF and virtually all of those with an affected fetus have aborted [25].

The development and introduction of the first CF test on a genetic level has taken place in a medical context of research and care for CF patients and their relatives. The fact that research has required the cooperation of patients and their families, and the fact that patients have obtained important benefits from research in the form of information, prenatal diagnosis and a sense of being partners at the frontline of science, has contributed to the convergence of the CF network. Within the network, the introduction of CF testing among high risk individuals has been a rather straightforward matter, and consistent with the dominant practice in the Danish health service system that people with an increased risk of a hereditary disease have automatic and free access to prenatal diagnosis. There has been no public discussion about the use of the CF test in this high risk group, since prenatal diagnosis and abortion enjoy a high degree of public acceptability. In other words, when the option for CF testing in high risk individuals came within reach, questions of demand and acceptability were taken for granted. At this point in the history of entrenchment of CF testing in Denmark, the development and introduction of a CF test in prenatal diagnosis as provided to individuals with a family history of the disease was indeed predetermined by the existence of a CF network of genetic researchers, clinicians and patients and an existing regime guiding access to prenatal diagnosis.

From testing to screening

As mentioned above, the section for clinical genetics at the University Hospital in Copenhagen launched a pre-planned carrier screening pilot study of pregnant women in greater Copenhagen as soon as the CF gene was cloned in late 1989. The pilot project was exclusively funded by the University Hospital after failed attempts to obtain external funding. The screening programme offered a CF test to all pregnant women consulting the hospital in the period 1990–1992: if a woman was found to be a carrier, her partner was offered the test; if both were carriers, they were offered prenatal diagnosis. Almost 7000 women were screened; 172 hetorozygotes were found; eventually one fetus was found to be affected and was subsequently aborted [25].

Although CF testing of high risk individuals might be considered quite a different thing than a general screening of the population, questions of demand for and acceptability of CF screening have been articulated from within the CF network as quite a straightforward matter and completely comparable to the current practice of testing of high risk individuals. In the eyes of the leading geneticist at the section for clinical genetics there is a direct link between testing in high risk families and screening of low risk populations. "Almost all families with a CF child ask for prenatal diagnosis if they want more children and ... choose to have an abortion if the fetus appears to have CF. On this background I find it natural that you do not want to have your first child with CF if that can be avoided". And the head of the national CF unit adds "The moment the gene was found I said: Now we must start carrier screening programme as soon as possible. I didn't really discuss it with anybody because our experience with prenatal diagnosis in families with a CF child was so good. So I found that the rest of the population should be offered a carrier test so that they could avoid having a child with CF" [16, p. 24]. Thus, the demand for CF screening in Denmark was articulated first of all by those highly involved in the existing CF network, whereby the current practice of CF testing of high risk individuals served as a model for the design and justification of the intended pilot project.

Within the CF network only one important controversy seems to have arisen in the context of the screening programme, i.e. concerning the relative importance of a semistructured interview survey among the participants. The CF patient association and its managing director had taken the initiative to include such a survey to determine public acceptability in the screening project, but for financial and other reasons the clinical geneticists did not manage to integrate this survey into the overall plans. The study proposed and eventually financed by the patient association was put off and instead only a very limited psycho-social study was included in the programme. The population of this study does not include all those screened, as planned in the original study, but only the detected carriers as well as a similarly sized group of women screened but not found to be carriers*. The failure to do the overall study led to major frustration in the CF association, though the fact that a study managed to be decided upon at all was considered a positive turn of events. Furthermore promises were made to try to make a follow-up study of the people interviewed, and this as well as the good will of the association has contributed to the solution of the controversy [26]†.

Though the CF patient association had been frustrated by their fruitless attempts to obtain a comprehensive survey of user acceptability, there is a close congruence of view between the association and the medical CF community regarding the desirability of a screening programme. According to the association: "This is something we have been hoping for for many years". Access to prenatal diagnosis is necessary it is claimed if "families shall have the possibility to decide for themselves after counselling if they want to give birth to a CF child or not". And, as the association further states, it is "very grateful that also pregnant women outside the already known risk groups will now be able to benefit from this offer" [16, p. 27]. But how can the CF association with a knowledge limited to the experience of affected families evaluate the acceptability of screening to the population as such? In an interview the manager-general of the CF association admits to this difficulty: "As an association representing risk families we are not able to decide whether a general screening should be introduced. This is the opinion of opponents in our organisation as well as of supporters ... In our organisation it is crucial that the test is voluntary. You must decide for yourself whether you want the test" [16, p. 27].

Thus, in conjunction with the medical CF community, the CF patient association has been active in articulating both demand and acceptability of CF screening in Denmark. Ths ability to decide for yourself appears in this process of articulation as a basic value, explicitly or implicitly implied in the statements of those involved in the CF network. However, as is demonstrated by the controversy about the CF association's proposal to study public acceptability of CF screening, questions of demand and acceptability are not conceived of in identical terms by the section of clincal genetics on the one hand and the CF association on the other. The association airs doubt about the direct link between

*The limited scope of the present study will probably make it difficult to redeem the purposes of the screening programme which were to illuminate "the psychological and ethical issues related to carrier screening".

†Eventually the CF association has managed to obtain financing of a retrospective interview study covering all the groups included in the pilot programme. This study will show whether non-risk families share the view of CF-families on CF screening.

testing and screening and needs confirmation by a study of acceptability before the process should continue. Although, in the network, the tension about this issue was resolved, this is not the end of the study. With the advent of the screening programme new actors appeared on the stage, and issues of acceptability became part of negotiations in an increasingly complex network.

Scientific and ethical evaluation

Although, in Denmark, the National Board of Health is the supreme authority in health matters, it has not been necessary to officially consult it, neither has it played any role in the planning or decision-making processes related to the CF screening programme. The Board has however for a number of years been warning against the initiation of screening and other preventive programmes without proper documented health or economic benefits. This policy of 'rational health care', in which a utilitarian cost-benefit approach is employed to many new medical technologies, has only had little success, because of the decentralized organizational structure of the health services in Denmark. Initiation of a screening programme as this one is completely within the domain of the leading medical doctor of the clinical department, who has so-called 'methodological freedom' of research and treatment of his patients. The pilot programme is a research programme, and thus within the bounds of methodological freedom. Where innovative research ends and routine practice begins is however an open-ended question, which leaves room for de facto entrenchment of new technologies and practices without any formal official decision.

What every biomedical research project needs however, according to Danish practice, is a 'start-permit' from the scientific ethical committee system, originally a professional control system but given legal status by law in 1992. The necessity of obtaining a permission from the regional Scientific Ethical committee was relatively easily fulfilled (and probably made easier since the application included a letter of recommendation from the CF association). The committee only required a minor change in the letter to the participating individuals before the permit was issued, plus reassurance that the waiting period between testing and disclosure of result was minimized. The ethical problems related to introducing, for the first time in Danish medical history, a prenatal screening programme to detect carriers rather than sick or potentially sick people were mentioned. They were however not addressed directly, but were rephrased as cost-benefit issues concerning the proper weighing of the cost of (un)necessary worries among the tested individuals and more provoked abortions vs the benefit of a almost total eradication of CF. The basic criterion here was the degree of medical seriousness of CF. "In the face of such serious diseases it was found justified to perform a comprehensive screening of the total population". Only in the case of serious disease though and it was added, "in the interest of the preservation of biological diversity, one had to accept that individuals might have to live with a reduction in the quality of life, when these reductions were not seriously debilitating" [27, pp. 29–30]. Thus, with this recognition of the acceptability of the CF screening project, the CF network had gained another associate*.

However, after publication of the project plans and a certain newspaper interest in the programme, a public controversy gradually developed, placing the issue of genetic screening programmes on the health political agenda. The major critic was the Danish Council of Ethics, an independent public body equally composed of laymen and scientists created by parliament in 1987 to monitor the developments in genetic and reproductive medicine. Attempts of this body to position itself in the genetic screening network would turn out to be a matter creating considerable controversy.

An ethical controversy

Already in 1990 the Council of Ethics issued critical views of the CF programme [28, p. 54]. Later in 1993, in a widely distributed pamphlet on genetic screening, the Council proposed two major changes for the implementation of future screening programmes, proposals that were articulated in general terms, but with indirect reference to the CF project. One concerned the quality of the ethical evaluation of the necessary pilotprojects. The Council characterized the scientific ethical evaluation, performed by the Scientific Ethical Committees as 'insufficient' and proposed an extra evaluation of "the general ethical issues related to genetic screening" performed by the Council [29, p. 65]. Second, after the effectuation of such a pilot project the Council required to be consulted for another comment before the relevant authorities decide on the implementation of the project proper. Thus the Council of Ethics has made a bid to participate in the general genetic screening network, using CF as a wedge—just as the CF screening programme functions as a wedge for genetic screening as such—by claiming a position for itself as the relevant authority on "general ethical issues related to genetic screening" in opposition to what was defined as more specific scientific ethical issues, to be decided by the scientific ethical committee system. What is at stake then in this discussion of acceptability is not only the question according to what ethical principles decisions should be made, but

*Although the Scientific Ethical Committee, like the National Board of Health, can be seen as a supporter of a utilitarian viewpoint, their evaluation of costs and benefits did not include the overall health economical interests which predominate in the Board of Health.

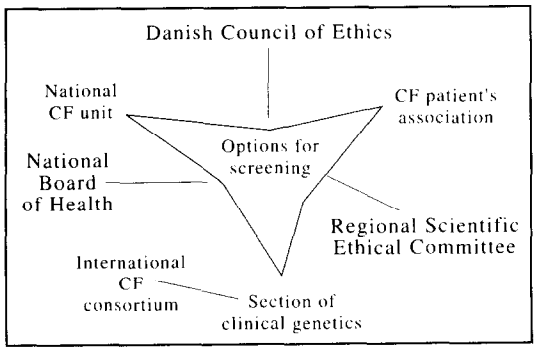

Fig. 4. The extended Danish CF network after 1989.

also the question who should have the authority to decide*.

At this point it is difficult to determine whether the viewpoints that separated the Council of Ethics from the Scientific Ethical Committees are of principle or not. The Council repeatedly refers to a more deontological ethics and underlines the importance of respecting individual autonomy in the decision-making process (in addition to the WHO guidelines), but whether this forms the content of the general ethical issues that the Council wants to have included in the evaluation of future screening programmes is not clear. If the authority claims of the Council of Ethics gain acceptance, we may witness however a significant restructuring of the ethical-regulatory authority beginning in the area of genetic screening. A new regulatory regime may then emerge in the field of human genetics, implying a further extension of the CF network (Fig. 4).

The public health authorities

A new regulatory regime in the field of human genetics may not be the only hurdle to be taken in the process of entrenchment of CF screening in Denmark. In the foregoing we already mentioned the National Board of Health as the supreme authority in health matters. In this quality, the Board lays out guidelines on prenatal diagnosis that are relatively binding for hospitals and practitioners. The present guidelines limits prenatal diagnosis to high risk individuals such as women above 35 years of age (at risk for Downs Syndrome) and women with a family history of hereditary disease. These guidelines are now under revision because of strong pressure to admit new diagnostic test methods and also to allow for a more individually oriented admission practice (e.g. anxiety-indication, individually determined risk status), though the Board of Health is extremely reluctant to abandon its restrictive practice. The policy is twofold: only admission of high risk women, and no increase in costs. Thus, although the current regime of prenatal diagnosis in Denmark has been very helpful for the initial steps in the process of entrenchment of CF testing and screening, it may also become a barrier for the entrenchment of CF screening on a grand scale. CF screening may however find another way into the health care system that evades this barrier.

The Board of Health recently issued a publication on screening, out of a certain desperation that more and more screening initiatives cropped up from the decentralized hospital system in Denmark without any documented effect [24]. Recent Danish medical history has provided several examples. Ultrasound was introduced locally as a prenatal diagnostic test and gradually spread without any documentation of its effect in routine screening of pregnant women and even after the Board of Health had issued a publication documenting the lack of effect of routine screening it seemed extremely difficult to curb this diffusion process. Also AFP-maternal serum screening for fetal defects has spread uncontrolled by national authority in Denmark. AFP-tests were initiated by a medical doctor in one Danish county and when the National Health authorities finally tried to intervene, >40,000 Danish women (of a population of 5 mio) had been screened [30]. Now a tremendous pressure exists to offer the AFP test to all women. Thus the mere initiative of a pilotproject may in itself create both a stepping stone for further screening-projects and a knowledge and demand that may become difficult to limit. What is interesting here is the relationship between the issue of authority and the issue of acceptability. With the National Board of Health being strongly opposed to new routine screening programmes such as CF screening, but at the same time being a formally weak institution with access to only few means of enforcement, the issue of authority seems to be an inherent and yet undecided part of the ongoing process of the articulation of the acceptability of CF screening in Denmark.

CONCLUSION

What does the story about the introduction of CF screening in Denmark tell us? Did we see a 'society' deciding upon the acceptance of a new genetic technology, or a 'technology' forcing itself upon the Danish society? Neither of both. What we tried to reveal in our story of entrenchment is a process in which the development of CF screening in Denmark is advanced and shaped by various conditions including, first of all, a strong CF network and an elaborate regime of prenatal care, and further a high public acceptance of abortion and a culture emphasizing personal freedom and autonomy. Seen from this

*In this case the question of authority became particularly controversial in the context of a recent debate in Denmark on the legal status of the Scientific Ethical Committees, in which it was proposed by the Council of Ethics that the Council and the Committees should become more or less parallel institutions.

perspective, the argument that the matter of CF screening is one of 'when' not 'if', might well apply to Denmark too. But it is not simply technology that forces itself upon society. At work here is, to use a term of the historian technology Thomas Hughes, the 'momentum' of a whole constellation of technology, networks and regimes [31]. At the same time, as our story shows, such constellations change. When new technological options are introduced, we will see the articulation of new demands and new issues of acceptability. New actors enter the stage, claim authority, interfere with networks and attempt to redefine regimes. It is in this sense indeed, that the success of new technologies depends on negotiations and decisions in society. Seen from this perspective however, we talk about a complex process of socio-technical change rather than straightforward political decision-making.

What are the implications of this general conclusion? First of all, in thinking about the question how to deal with the implications of human genome research, solemn references to our democratic society are not enough [32]. What we need are answers to the questions:

(1) what actors, networks and regimes predetermine processes of entrenchment of human genome technologies in society; and
(2) how is articulation of demand and acceptability taking place, who is involved and in what way?

Our sketch of the Danish situation might be compared, in the light of these questions, to what is going on in other countries, as for example the Netherlands, in which the issue of CF screening is discussed with far more reserve. It would be interesting to see whether such differences can be understood in terms of differences in networks and regimes, or different ways in which articulation of demand and acceptability is taking place*.

In relation to these empirical and comparative questions, we might also raise more normative and political issues. What about the role of various actors—researchers, clinicians, patients and patient organizations, public interest groups, regulatory agencies, governments—in processes of articulation of demand and of acceptability? The case of CF screening in Denmark highlights some issues relating to this question that have a more general relevance. A first point is that articulation of demand for CF screening in Denmark has been more in the hands of the medical community and its constituency—geneticists, doctors and patient organization—than in the hands of the target population of potential users. Of course, we might see the pilot project as a means to involve potential users and, as the proponents of screening will say, users are free to choose whether they accept the offer or not. On this point, indeed, the experiences with pilot programmes like that in Denmark are extremely important. What about the 7000 women that have been screened, how did they decide upon the offer that was made to them, how 'free' did they feel about their decision? A second point is that while questions relating to the acceptability of new technologies are articulated in studies, debates and sometimes controversies, there is often a strong pressure to proceed even in the face of serious uncertainties and questions. Two findings from the Danish case are significant in this light. First, the reluctance of the medical community to make evaluation of acceptability a substantial part of the pilot programme. Second, the struggle for authority on these matters. Indeed, the question of how to deal with the implications of new technologies in society will often become also a strongly contested question of how to allocate responsibilities and authority to decide what is acceptable and what is not.

*We intend to proceed with our study according to such a comparative approach in the framework of a European programme for comparative studies of processes of entrenchment and regulation of human genome technologies in Europe. See [33].

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