This text was published under the reference:
Vailly, J., Ensellem, C., 2010, Informing populations, governing subjects: The practices of screening for a genetic disease in France, in *Assessing Life: on the organisation of genetic testing* (B. Wieser, W. Berger Ed.), Profil, München/Wien, 225-253.

Informing populations, governing subjects:

The practices of screening for a genetic disease

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Abstract

The autonomy of subjects in medicine, emphasised by the Nuremberg Code following the Second World War, is today one of the cornerstones of good practice. However, the practical and conceptual limits of this principle of self-determination are the object of debate in social sciences. Moreover, in the field of genetics, the conception of subjects making choices in an individual consultation ignores the fact that we have already entered into the era of mass genetics. The situation in France offers an interesting perspective on this issue, since screening of all neonates for cystic fibrosis, requiring the written consent of the parents (or mothers) was introduced in 2002. In this delicate combination of individualising procedures (the consent of each individual) and globalising techniques (screening of entire populations), what exactly is going on in this zone where the two intersect? Using the Foucauldian concept of government, we propose to study how government is exercised "at the bottom", in maternity units. On the basis of a field study conducted by observations and interviews in two Paris maternity units, in this article we first describe how information on screening is given to new mothers. We then analyse the way in which written consent is sought, and the logic of consent. We show that rather than true informed consent, what emerges here is a formality which derives from an assumption of self-evidence and rests on power relations, values and presuppositions. We conclude with a discussion of the political and moral configuration presented by this screening.

"The voluntary consent of the human subject", emphasised by the Nuremberg Code following the Second World War (Bayle 1950), is today one of the cornerstones of good biomedical practice in research and treatment[1]. In attempting to understand this politico-moral context, while we need to take account of the crimes perpetrated by Nazi doctors which are often, quite rightly, invoked (Boulton & Parker 2007), we should not forget the debates aroused by clinical trials conducted during the 1960s, which showed scant respect for persons (Beecher 1966). More broadly, this approach is integral to a movement which is organising a transfer of legitimacy, in order that each individual can take charge of her own health and feel "responsible" (Fassin 2004).

This issue of the autonomy of subjects is posed still more acutely in the field of genetics, a particularly sensitive area given the history of eugenics. Since the 1950s the norm in genetic counselling, frequently invoked in the discourse of professionals, has been non-directivity on the part of doctors with respect to those seeking advice (Dice 1952). Some social science studies, while rejecting the idea of any sharp distinction between imposition and acceptance, therefore emphasise the production of subjects faced with choices in relation to genetic tests (Lemke 2004; Novas 2000; Rose 2007). Moreover, a series of studies allow us to question this notion of autonomy in genetics. Some of them show how social and cultural constraints, including the influence of professionals, can influence the choices of parents (Kerr 2000); others highlight the dilemmas of professionals and those seeking advice when faced with a decision on prenatal diagnosis (Conrad 1999). In reality, it seems that such situations involve both values and injunctions based on the "free choice" of those seeking advice, contained in ethical discourses, and conditions of efficacy of choice which are much more complex, depending on the situation (Koch & Svendsen 2005). It means that the production of "subjects" should not blur the disparities between social groups, assimilate practices and rhetoric, and neglect both structural constraints and the effects of these changes. Moreover, the notion of individuals making choices when they seek advice from a genetic counselling service ignores the fact that we have already entered into an era of mass genetics, no longer simply targeting populations deemed at risk. More broadly, different studies, demonstrating the practical and conceptual limits of the principle of

self-determination in biomedicine (Corrigan 2003; Jacob 2007; Dixon-Woods 2007; Hedgecoe 2005) do not concern large populations. For this reason, this article addresses the question of the subjects of genetics as it intersects with the issue of management of populations.

On the theoretical level, the notion of the "government of bodies" (Fassin & Memmi 2004) is a particularly apt framework for analysing the notion of the autonomous subject in biomedicine. In previous work, one of us (JV) has offered an overview of the scope of the Foucauldian concept of government (Vailly 2006). To recall briefly, Michel Foucault introduced this concept by adding the dimension of freedom to his theories of power (Gros 1996). The term "freedom" immediately invites two remarks. Firstly, and crucially, the freedom in question is *internal* to power, for not only does power include freedom within its own techniques, but it needs freedom in order to endure. What reinforces the stability of this power is that it does not repress or forbid – hence the metaphor of the bee which rules without recourse to its sting: it incites and produces. Secondly, what Foucault (2001) analyses, rather than power or powers, is power *relations* exerted on an other who is recognised and maintained as a subject of action. Thus he defines government as the ensemble of more or less considered and calculated modes of actions intended to act on the possibilities for action of other individuals (Foucault 2001). As this conception of power no longer locates it only "at the top" (states etc.), this analytical framework incorporates a "microphysics" of power, made up of all the apparently minor processes of power diffused through the society. For the analyst it is therefore important to grasp not only the strategies and instruments of government as previously defined, but also the power "at the bottom", where it becomes capillary (Foucault 2001).

On the practical level, the situation where consent to a genetic test is required for the purposes of screening over entire populations is different from an individual genetic consultation. It was during the 1960s and 1970s, the period when the bioethical principle of autonomy was developed, that screening for genetic diseases in populations of neonates first appeared, using blood samples (known as Guthrie tests, after their inventor). The first screening was for phenylketonuria, a genetic condition which, if it

goes undiagnosed or is left untreated, inevitably leads to mental retardation. It was at this point that a tension emerged between two principles: on the one hand, protecting the health of babies by carrying out screening as widely as possible, and on the other preserving the autonomy and consent of parents. Nevertheless, because of their medical benefits, a number of neonatal screening programmes have come to be made compulsory (Mandl 2002). Today, the question of subjects is being posed with renewed urgency in the light of the rapidly increasing number of conditions for which neonatal screening is provided (in the US, testing for as many as 40 diseases is carried out at birth), changes in the aim of screening (there is no treatment for some of the conditions tested for), and the development of new techniques (DNA tests can now be used) (Clayton 2005). While medicine (Mandl 2002), bioethics (Kerruish & Roberts 2004) and law (Abbing 2004) have taken an interest in these developments, social sciences have so far paid them little attention. The sociological and anthropological literature which comes nearest to addressing this issue is that dealing with prenatal detection of foetal abnormalities (Press & Browner 1997; Rapp 1999; Williams 2005).

The situation in France offers an interesting perspective in this regard, since the launch in 2002 of screening for the genetic disease cystic fibrosis in all newborns[2]. France was one of the first countries to apply the test universally, at a time when it was still widely debated in the biomedical arena. These debates focused mainly on the balance of advantages and disadvantages of screening, the regime of proof relative to benefit and, to a lesser extent, on the articulation between neonatal and prenatal screening (MMWR 1997; Wagener 2001). However, in 2004 a consensus conference in North America concluded that the benefits outweighed the disadvantages, despite the lack of a treatment leading to cure (MMWR 2004). Moreover, the process chart for neonatal screening for cystic fibrosis (NSCF) includes, for the first time on this scale in France, research into DNA mutations. French law on bioethics provides a strict framework for such investigations, requiring the written consent of the individual tested or, in the case of children, their parents[3]. This provision does not apply to the study of all genetic diseases – such as those for which the test involves analysis of proteins – but only to those where the test involves direct analysis of DNA. Thus in France, screening at birth for other

genetic and non-genetic diseases does not require consent[4]. This subtle distinction needs to be considered in the light of representations around DNA, which have led to talk in the US of the DNA "mystique" (Nelkin 1998), where is apparently endowed with all powers, all dangers or all virtues. In France the situation is perhaps more nuanced than in the US, but these arguments reveal how the study of DNA never appears neutral. Nevertheless, when the written consent of the parents of newborns is required, the parents are constituted as subjects in law who, at least on the legal level, can have a certain maneuvering room.

On the basis of this analysis, the present chapter will examine what government means for a genetic disease, using the example of NSCF. To put it more precisely, the question at issue is the way in which government is both transmitted and relegated to "the bottom", i.e. to the maternity units. In the very delicate combination of individualising procedures (the consent of each person) and globalising techniques (screening of populations), what exactly happens in the zone where the two intersect? Going beyond the somewhat theoretical politico-moral injunctions, our concern has been to study concrete practices, through observations and interviews, when most of the studies cited above are conducted by interviews. We do not propose to discuss the validity of NSCF, but to clarify and interpret the issues involved in and expectations of consent procedures. The first part of this text presents the study; we will then go on to describe how information on screening is given to mothers in maternity units. We then analyse the way in which written consent is obtained and the logic of consent. We will show that rather than true informed consent, what emerges here is a formality proceeding from an assumption of self-evidence and based on power relations, values and presuppositions.

The study

This study forms part of a broader programme investigating the scientific, political and moral issues involved in NSCF in France, and seeking to relate them to more general changes in Western societies. Within this framework, one of us (JV) has shown that one of the peculiarities of NSCF is that this procedure has essentially become a means of

orienting patients towards specialist care centres and a technique of government (Vailly 2006). The technical procedures involved, making it clear that DNA testing is not carried out on all newborns, but only on those whose first test result is positive, have also been described (Vailly 2008). Nevertheless, for reasons beyond the scope of this chapter, those organising the screening, grouped under the umbrella of a professional organisation known as the French Association for Screening and Prevention of Disability in Children, (acronym AFDPHE in French), chose to seek the consent of all parents. This procedure brought with it questions about the content and the form of the information that needed to be provided to parents. In view of the particular concern about this issue, a working group on information for parents and professionals was set up, under the auspices of AFDPHE, to reflect on the subject. On the basis of the group's conclusions a set of recommendations on information provision was drawn up (AFDPHE 2001a)[5], a practical guide for maternity care professionals was produced (AFDPHE 2001b), together with an information sheet for parents headed "3 days: the age for screening" (AFDPHE 2001c). These various materials provided a practical and theoretical basis for the present study.

Methodologically, this part of the project is based on a qualitative field study conducted in spring 2005. To find answers to the questions raised, we first studied the information given to parents of newborns, and the procedure for obtaining written consent in two maternity units in the Paris region. These units, located within hospitals, look after 1,800 and 2,400 births each year (unit 1 and unit 2 respectively), placing them at or a little above the national average in terms of activity, given that in France caseload at such units varies from a few hundred to over 4,000 births per year. The first unit has a neonatology service (classified as a level II unit in terms of equipment), and the second has a neonatology and neonatal resuscitation service (level III). We observed 34 interactions with health professionals in which information on neonatal screening was given to mothers and consent forms were obtained. We took extensive notes during our observations or, when this was not possible, immediately afterwards. In order to examine the logic of consent, we also conducted short interviews with mothers (38 interviews averaging 15 minutes in length), evenly distributed between the two units. The interviews focused on the way in which the mothers had dealt with the information card (whether

they read it or not), the information they had taken in from it, and their opinion on screening and their reasons for consenting (we met no mothers who refused consent). Their socio-professional status was above or around the national average in unit 1 (with a majority of professional/managerial staff and mid-level employees) and low or average in unit 2 (with a majority of service sector employees and mid-level employees); the average age was 29. All the observations were conducted with the agreement of those involved (health professionals and mothers). The interviews, which were all recorded and transcribed with the agreement of those interviewed, were conducted at the maternity unit on the day when consent was obtained. Finally, we analysed the documents given to parents at the unit or detailing guidelines for professionals. There was little difference between the two units in the results of the study, and here they are considered together unless otherwise stated.

Informing parents without alarming them

The first step in the consent procedure is to inform parents, but the way in which the information is delivered is obviously not neutral, since acceptance or refusal partly depends on it. So how is this information given in maternity units? The information card headed "3 days: the age for screening" is given to parents the day after the birth, which medical professionals call "D1". Written consent is obtained and blood taken from the baby between 72 and 80 or 90 hours of life, on the day known as "D3" or "D4"[6]. If parents leave on D2 (we observed two such cases), medical staff ask them to return for the test and telephone them, calling them back if necessary, if they fail to turn up. The interval of two days between D1 and D3 is designed to meet the technical conditions for the test (taking blood three days after birth) and to allow mothers or parents time to read the information card. Here there is a difference between the two units. In unit 1, a paediatric nurse simply hands the card over (one nurse was observed), saying something like:

> "Here is the information card for the Guthrie test, which we do at 3 days. Please take some time to read it" (paediatric nurse 1, observation 20.5.05).

Sometimes the exchange may run something like this:

> "That's for the Guthrie test that we'll do on Saturday (paediatric nurse 1).
> *What? What's that?* (mother 1).
> It's screening for certain diseases (paediatric nurse 1).
> *Oh, OK"* (mother 1, observation 1.6.05).

In unit 2, the card is given to parents by a paediatrician (four were observed), who makes reference to the legal requirements, saying something like:

> "Here's a little leaflet about screening for all the diseases you see on here, it's compulsory. But since last year, we've also had screening for cystic fibrosis. In the unfortunate event we find something, we do a genetic test and in France we can't carry out a genetic test on a person without their consent. So here's a form to fill in for that, for you to sign" (paediatrician 1, observation 16.5.05).

In half of the cases, the paediatrician added a comment on the importance of screening and/or the serious nature of the diseases:

> "It's important, it's so as to prevent disease" (paediatrician 2, observation 15.6.05).
>
> "These diseases are very rare, but very serious" (paediatrician 2, observation 15.6.05).

In unit 2, the form on which the blood test results will be recorded, and which the mother or parents are asked to sign, is given to them, along with the information card, by a paediatrician on D1. This contrasts with unit 1, where the form is given to the parents on D3, when the blood is taken. It should be noted that the brevity of the explanation given by the nurse and, to a lesser extent, the paediatricians, is out of line with the recommendations of the working group on information for parents, which state: "Information must be given verbally. Nothing substitutes for dialogue with the parents. […] Simply handing over the document is not sufficient" (AFDPHE 2001a: 7). On the other hand, the guidelines for professionals in maternity units, as detailed in a pamphlet addressed to them, are to "give the parents clear, accurate, concise and above all comprehensible information. Do not alarm them without cause (the diseases we are screening for are rare). Explain to them the advantages for their child of early detection in the event that s/he has one of the diseases screened for" (AFDPHE 2001b: 6). In the same

vein, the services manager in unit 1, where the information given verbally is more succinct, explained in an interview his concern not to worry parents unduly:

> "If we give the minimum of information, they are less anxious than if we give them a lot. So we make it very matter-of-fact […], they take it as something quite routine […] we also deliberately don't medicalise the test […]. And I think that the less we medicalise and the less we intervene, the less frightened they are. We have to find a good balance so that they get the information" (paediatrician 3, 15.6.05).

From this we can appreciate the difficulty of the exercise: there is a delicate path to negotiate between giving relatively complex information in order to obtain "informed" consent and the risk of causing parents alarm or even panic to no purpose, given the rarity of the condition. It makes more sense to inform people of the various aspects of a problem when they are "at risk" than when the risk of disease is low (in this case 1 in 4,600).

Thomas Lemke (2004) argues that the notion of genetic "risk", and the uncertainty it brings with it (about whether one has a disease or not), mean that people are faced with choices (for example whether to terminate a pregnancy). Uncertainty and risk thus make a call on their autonomy and their responsibility. Here we need to go further, and point out how the low level of risk is a factor in the brevity of the information given and the resulting limits on the process of subjectivation. More generally, as illustrated by prenatal screening in the UK, this tension between delivering information and striving to avoid causing anxiety may be the source of ethical dilemmas faced by health professionals (Williams 2005). Hence the difficulties involved in adapting procedures for obtaining consent to entire populations, which result in a form of contradictory injunction within consent procedures (to inform without raising anxiety). Moreover, there is a further element that reinforces this effect. In their study of women's acceptance of a blood test to screen for developmental problems during pregnancy in the US, Nancy Press and Carole Browner (1997) show how the relatively matter-of-fact way in which the test is presented among other, more traditional monitoring practices leads to screening becoming routinised alongside the other practices of care. Similarly, the neonatal screening under discussion here is incorporated into the economy of care, but in such a way that the test

becomes still further routinised because there is no specific consultation, in contrast to the prenatal test. In short, a complex equation develops at this stage between consent, psychological support for parents, routinisation and the absence of a consultation.

The other aspect of information is the media used to convey information relating to consent. Marie-Andrée Jacob (2007) notes that documents given out to people are often "analytically invisible" in studies of consent, despite the fact that for those interested in practices, they are just as informative as the ideas or representations held by these individuals. The brevity of the explanations offered by the nurse and the paediatricians indicates that most of the information is contained in the card given to the mother, making it all the more important to take this question seriously. With its glossy paper, colour printing, photos of babies and its typography, this card is first and foremost meeting aesthetic criteria. Moreover, the question-and-answer form in which the information is presented, the typographical variations and the relatively simple style make it easy to read. As far as the substance of the text is concerned, the carefully designed folding of the card allows the information to be hierarchised. It highlights a paragraph giving a brief history of screening programmes and suggesting their positive impact:

> "The results of this screening are very positive. [Babies] who were ill were diagnosed and treated within the first weeks of life, and were thus able to develop normally" (AFDPHE 2001c).

There follows some information on the value of screening, and on the practical methods of testing and communication of results, notably:

> "If any of the tests shows an abnormal result you will be informed straight away. A control test will be done as soon as possible afterwards to allow us to determine whether your child really needs treatment" (AFDPHE 2001c).

This is followed by information on the diseases screened for; here the information on cystic fibrosis is highlighted, and points out:

> "Clinical diagnosis is difficult and often not possible until later, which can be to the disadvantage of the patient […]. With early and rigorous treatment, the frequency of

> clinical manifestations can be substantially reduced. This enables the patient to have a better quality of life, even though there is no specific treatment which can cure the disease" (AFDPHE 2001c).

While still pointing out that there is no cure for cystic fibrosis, emphasis is placed on the importance of early and rigorous treatment, and on the positive effects of NSCF ("manifestations can be substantially reduced", "a better quality of life"). The consent form, on the other hand, is couched in much more bureaucratic terms. With its standard format, it is located more in the space of law and technicality than that of aesthetics. In addition to personal data on the baby and parents, it includes the following formula: "Having received the information, we the undersigned (surnames, forenames)…, mother, father of the child… born on …. authorise □ do not authorise □ the physicians responsible for neonatal screening to conduct, if necessary, a genetic test to screen for cystic fibrosis. Date… Signatures…" It should be noted that the authorisation is thus limited to cystic fibrosis, protecting the patient from unethical and unregulated use of any other genetic tests.

All in all, the written information can be described as clear, well presented and persuasive: how could one not wish one's child to receive the best possible care, in the unfortunate event that he/she proves to be sick? The organisers of the screening and the *ad hoc* working group took great care over the written information. In its aesthetic and its readability, the information card follows the practice of "ethical bureaucracy", taking care over the form of consent documents (Jacob 2007). It is this that gives the card not only its respectability as a medium for moral values, but also its efficacy. To be more precise, its efficacy answers more to the aim of informing parents on the different kinds of neonatal screening and obtaining the maximum number of signatures than to that of offering genuine support for "informed consent" on NSCF. In fact, despite the reference to the possibility of a second test, the card gives no statistical data or diagrams to help parents understand or visualise the rate of recall, or the proportion of the general population suffering from the condition. In terms of the effects of screening, no mention is made of the notions of benefit/risk or advantage/disadvantage – notions that are admittedly complex, but which were at the centre of national and international debates

around the appropriateness of NSCF (Wagener 2001; Wilford, Parad & Fost 2005). Addressing this issue, Angela Raffle (2001) identifies differing aims for the information given in relation to medical consent (ensuring the maximum level of consent, or offering an informed choice by making clear the limits of screening), and the drawbacks of each option. In particular, the second option could mean that some people, particularly the more socially vulnerable, will be excluded from screening and access to care (Raffle 2001). Clearly, it is not always a simple matter to present medical uncertainty in a comprehensible form (Epstein 2004), all the more when the information needs to be addressed to an entire population. The most balanced solution would probably be to explain the advantages of screening, but without confining the information to this explanation, and without passing over its various limitations.

Obtaining consent

Having considered the information, we now turn to the way in which consent is obtained. In maternity unit 1, the blood is taken by a paediatric nurse in a small office, where the babies' files are also updated. Below are three examples of how consent was obtained:

> The paediatric nurse goes to fetch the mother, who is feeding the baby in her room. The nurse says:
> "When he's finished, come and see me for the Guthrie test" (paediatric nurse 1).
> When the mother comes into the office, the nurse gives her the form for the blood test and for signature and says:
> "On this form you need to fill in surnames, forenames and sign it there. The authorisation is just for cystic fibrosis" (paediatric nurse 1).
> The mother signs without saying anything and asks:
> *"Is that it?"* (mother 2).
> "Yes, you can go now" (paediatric nurse 1).
> *"Er…Yes, I haven't had lunch yet…* (mother 2, observation 1.6.05).

> The paediatric nurse goes to fetch the mother and baby from her room. When they come into the office, the nurse says:
> "Here's the form for authorisation, you fill in surnames, forenames, and sign there" (paediatric nurse 1).
> The mother signs, and goes with the nurse and the baby, but is very disturbed by the taking of the blood. She moves away from the baby, unable to bear the sight of blood. The nurse says:
> "So you won't get any results (paediatric nurse 1).
> *Yes, I read that on the information sheet, if there's a problem they tell us, but if not they don't…* (mother 3, observation 2.6.05).

The paediatric nurse gives the form to the mother and says:
"That's the three-day test, for all babies, you must have read it" (paediatric nurse 1).
"Yes" (mother 4).
So you put your surname here, your first name, the baby's first name…" (paediatric nurse 1).
The mother signs. She is very tired and short of breath, she takes a long time to fill in the form, has difficulty concentrating.
"You know you won't get any results (paediatric nurse 1).
Yes, I know, well, you know, I'd rather not get anything!... But I don't really understand why they need authorisation? (mother 4).
For cystic fibrosis it's a genetic test, and we always ask for permission for any genetic test (paediatric nurse 1).
Yes, but there are two basic principles that are in contradiction, aren't there – the interest of the child and the interest of the people! For cystic fibrosis it's best to know straight away. I don't know why they ask for permission, why some people refuse (mother 4).
Definitely for cystic fibrosis the earlier we know the better. Especially since we'll know sooner or later anyway. Have you got any other questions?" (paediatric nurse 1)
No, I read everything." (mother 4, observation 3.6.05).

In unit 2, blood is taken by a nurse (two nurses observed) in a room known as the "babies' room", which is only used for giving care. The nurses do not ask the mother to be there, in case she is disturbed by the sight of her baby's blood or the baby cries too much. Below are three examples:

The parents are in the mother's room. The nurse enters and says:
"Have you signed the form? (nurse 1).
Yes (mother 5).
The nurse takes the baby off to do the test. She comes back, saying:
"For the results, if you don't hear anything in two or three weeks, it means that everything's fine: no news is good news! (nurse 1).
[together] Yes! (mother 5, father 1, observation 20.6.05).

The nurse comes to the mother's room to fetch the baby for the blood sample, but the mother has not signed the form. The nurse points to the form and says:
"You know, it's for screening for diseases (nurse 1).
Oh yes, no problem (mother 6).
The mother signs the form and the nurse takes the baby off (observation 17.6.05).

The nurse comes to fetch the baby; the mother has not signed the form, and asks the nurse:
"What is cystic fibrosis? (mother 7).
A serious illness, very serious. It's a genetic disease, and whenever it's genetic, we need permission. So all the other tests are compulsory, so we'll do the test whatever for the other diseases, but cystic fibrosis isn't compulsory" (nurse 2).

> The mother signs the form. The nurse takes it and takes the baby off (observation 27.6.05).

It should be noted, further to these observations, that in interviews or informal conversations, some paediatricians highlighted the difficulties posed by the language barrier in the case of mothers from other countries. We observed three such cases (7% of all the mothers), where the mothers did not speak French. In two cases the mother filled in and signed the form without understanding; in one case it was signed by her partner, who understood that it was about screening for disease. In the first two cases, the procedure for obtaining consent ran as follows:

> The mother is African; she does not speak French and has difficulty writing her name on the form. As the paediatric nurse has been called away to an emergency, a nurse comes to replace her and says:
> "You know, it's the Guthrie test for metabolic diseases related to feeding problems and genes" (nurse 3).
> Guthrie, metabolic, genes… The mother signs without understanding (observation 13.6.05).

> The mother is African, she does not speak French. The paediatric nurse asks her to sign, the mother signs without understanding and the paediatric nurse fills in the form (observation 6.6.05).

A number of points may be made about the cases observed in the two units. Firstly, the exchanges are extremely brief and in the vast majority of cases a signature is obtained without any difficulty or discussion. There is no doubt that this can be explained in part by the information given on the card, which also contributes to the very high rate of consent to NSCF on the national level (99.7%; see AFDPHE 2004). In addition, every effort is made to ensure maximum rates of consent (a telephone call if the parents have left the unit before blood is taken, etc.). Beyond this, the broad level of agreement of mothers is evident, taking the form of incredulity or even irritation towards those who refuse consent ("I don't know why they ask for permission, why some people refuse"). In this last example, this moral condemnation of negligence of the health of one's family is part of a much more general phenomenon, in which health is a strong value and each individual is deemed "responsible" (Fassin 2000, 2004). In the case of breast cancer screening, for example, Patricia Kaufert (2000: 167) notes: "Being screened is a duty; evasion is tagged as irresponsible behaviour, a moral dereliction." The second point of

interest is the limiting cases represented by the mothers or parents who do not speak French. On the one hand, they cannot be overlooked as people at risk of transmitting a disease in a routine procedure which is applied to an entire population; on the other, it goes without saying that while they are still constituted as subjects in law, they are completely emptied of their meaning as subjects. Thirdly, it should be noted that in maternity unit 1, the father is not usually present on the morning of D3, and the mother signs alone. Here it is the mother who plays the role of subject in law, rather than "the parents" or "the family" usually referred to in legal texts or information cards. In unit 2, however, the form is given on the first day, when the father is present, and the forms are often signed by both parents. Thus we see the extent to which subjectivation is constituted as much in apparently trivial practices as in general principles. Finally, the verbal information about results, the social effects of which have not yet been studied, indicate that if the parents are contacted after the test it means the baby has "a problem". However, this verbal information, unlike the information card, fails to point out that control tests may be necessary at the screening stage, but this does not mean that diagnosis of the disease will be subsequently confirmed. This information may thus generate the anxiety it seeks to minimise, at least among the parents who are recalled.

Overall, the consent procedure, being at once formal and routinised, becomes a *formality* in both senses: on the one hand an operation prescribed by law, and on the other an action that is required to be performed but has no importance. We might even say that it is part of a well-established mechanism which derives from something that seems self-evident, as indicated by the very high level of consent. And as Mitchell Dean (1999) notes, analysis of social sciences in terms of government seeks to show that what appears to go without saying in our ways of thinking and acting is not necessarily completely self-evident or inevitable. So what is this sense of self-evidence based on? This question draws us to analyse the logic behind the assumption.

The logic of consent

On the basis of the interviews conducted with mothers of newborns, we can establish the conditions of and reasons for their agreement. The interview looked firstly at the information they gained on screening, secondly at why, in their view, they were asked for their signature, and thirdly on their reasons for consenting. We should recall that in 7% of cases no interview could be conducted because the mothers did not speak French. Leaving aside these cases, 60% of mothers said in interview that they had read or "skimmed through" the information card (i.e. 53% of all the mothers, if we include those who were unable to read it):

> "I read the card that explained it" (mother 8, business executive, age 27, 2.6.05).
>
> "My husband read the leaflet out to me" (mother 9, business administrator, age 31, 20.6.05).
>
> "I read it – well, I skimmed through it" (mother 10, shop assistant, age 22, 16.6.05).
>
> "I didn't read all of it" (mother 11, domestic assistant, age 41, 27.6.05).

Thus 40% of mothers who were able to read it say they did not read the card (i.e. 47% of all mothers did not read it). Half of these explain that this was because they were tired or had lost a lot of blood, sometimes after Caesarian sections or birth complications; others said that they had not had time to read it. Nevertheless, the possibility that in fact some have difficulty reading or are not in the habit of reading cannot be dismissed. Others said that they knew about screening because they have other children (often unaware that NSCF has been introduced more recently); and some explained that they had not received the card:

> "To be honest I didn't have time to read it […] I'm so drained" (mother 12, interior designer, age 21, 2.6.05).
>
> "I didn't have time to read the leaflet" (mother 13, telesales operator, age 28, 17.6.05).
>
> "I didn't look at it" (mother 14, care assistant, age 22, 30.5.05).

When asked about why they were asked for their consent, two thirds of the mothers thought that consent was sought in relation to all the diseases screened for, or, conversely, that cystic fibrosis was the only disease screened for (incorrect responses).

One third understood that the consent sought applies only to cystic fibrosis, but that screening also relates to other diseases (the correct answer). Moreover, although, as we have seen, the consent form states that its purpose is to authorise "doctors responsible for neonatal screening to conduct, if necessary, a genetic test to screen for cystic fibrosis", only half of mothers understood that they had signed to give permission for a potential genetic test should it prove necessary, while the other 50% were unaware of this. The following extracts from interviews illustrate this latter situation, which arose in both units:

> *"In your opinion, what was it exactly that you signed for?*
> It was cystic fibrosis.
> *Why more for cystic fibrosis than for other diseases, do you have any idea?*
> No.
> *Did you read the information card, or did you just tick 'yes' to give your authorisation?*
> No, I read the card, it's to give permission or not to the paediatrician and the person whose going to do the tests for cystic fibrosis. I read the paper before I signed it" (mother 15, radiologist, age 31, 2.6.05).

> *"Did you read the information card, or did you just sign?*
> I read that I was giving permission for them to take a blood sample from my child. […]
> *So was the signature for any kind of blood test?*
> For those diseases.
> *Does the term 'genetic test' mean anything to you?*
> Is it for Down's syndrome?
> *No.*
> I don't know, then" (mother 16, operations manager, age 25, 29.6.05).

> "*What did you just sign?*
> That I was giving the hospital permission to take a blood sample and screen for this disease, if it's found. […]
> *So you signed just to give permission for a blood sample to be taken?*
> Yes.
> *Does the term 'genetic test' mean anything to you?*
> No, no-one said anything about that" (mother 13, telesales operator, age 28, 17.6.05).

It should be noted that these results do not appear to be specific to the maternity units involved in this study, since they are corroborated by a doctoral thesis in medicine based on a survey conducted in eight maternity units in south-west France (Lunardi-Laval 2004)[7]. As far as the conditions of acceptance are concerned, there is a range of situations, among which failure to read the information or poor understanding of why consent is required figure in a substantial number of cases (at least half of the

respondents). It is worth pointing out that the particular moment when consent is sought, just after giving birth, is not ideal in the case of the most exhausted mothers. As has been shown with people who have recently suffered from a cardiac problem (Corrigan 2003), neglecting this circumstantial aspect runs the risk of restricting subjects' capacity to constitute themselves as subjects. But a more general issue is raised here. A number of studies indicate that a relatively large proportion of informants fail to read consent forms, in situations ranging from epidemiological genetic research in France (Ducournau 2005) to gynaecological surgery in the UK (Akkad 2004) and organ donation in the US and Israel (Jacob 2007). In the case under consideration here, the reasons for agreement help us to understand at least part of the logic underlying this failure. These reasons for consenting appear to be similar and common to all mothers, whatever their socio-professional origin and the extent to which they have read the information card. They are based on the idea that the earliest possible diagnosis is best, in order that any disease that might be present can be treated: the mothers were unanimous in their view that it is better "to know", so that, if necessary, treatment may begin as soon as possible:

> "It is better to know your child's state of health in the first few days than later.
> *So you think screening is a good thing?*
> Yes, at least for me, I want to know as early as possible, because if not afterwards I'll feel I wasn't warned […], how come the hospital didn't tell me anything. So I think it's the right time, they're doing it the right way" (mother 18, finance company accountant, age 30, 27.5.05).

> *"Do you think screening is a good thing?*
> Oh yes.
> *Why?*
> Because it's reassuring for parents to know their child probably doesn't have this disease. And for the test to be done as soon as possible.
> *In case there is…*
> In case there is anything wrong.
> *Why is early screening good?*
> Maybe to get treatment more quickly. It's a disease that can't be cured, but to get it treated as quickly as possible. To have a better quality of life afterwards" (mother 15, radiologist, age 31, 2.6.05).

> *"So if I said to you, for example, that they're screening for ten other diseases, you'd be pleased?*
> I think that anything that can be detected as early as possible in my opinion it's one more chance that's given to the baby. Earlier is better, in my opinion" (mother 18, legal secretary, age 32, 1.6.05).

The reasons for consent derive from a general assent to screening, which is based on two elements. On the one hand, for mothers who have read the information, consent is based on a transfer of information from the information card, manifesting a high level of confidence in neonatal screening policy, as demonstrated by the second interview here, which takes up some of the ideas in the card ("it can't be cured", "a better quality of life afterwards"). But as Mary Dixon-Woods et al. (2007) explain, in relation to consent to epidemiological research, those who give consent are not simply passive receivers who may or may not be able to understand the information given, they also bring with them their own experiences, values and assumptions. In our case, the group of mothers who had neither read the information card nor received the information verbally allows us to assess these elements, some of which coincide with the logic or discourse of biomedical actors. In the first place, from the structural point of view, since it forms part of a logic of care, this screening needs to be located in the context of the high level of sensitivity to health issues in the West. It enjoys what Didier Fassin (2000) calls "biolegitimacy", which places health at the centre of concerns within our societies and ensures that a range of problems are recognised on the basis of health issues. Secondly, screening is based on the idea of early intervention, with the temporal inversion between diagnosis and the appearance of symptoms that this principle conceals. This idea is rooted in the medical obsession with early diagnosis, which has also become virtually structural today (Grimes 2002). Going beyond medical reasoning, it has the power of common sense, for everyone can point to examples from their own experience of cancer diagnosed too late, lesions which become infected and are more difficult to treat later. Hence what Paul Atkinson (1984), following Alfred Schutz, calls a "natural attitude" consists of advocating as early as possible diagnosis and treatment of patients as a matter of course. This idea is founded on a kind of inductive reasoning (Chalmers 1988); in other words, it draws on the example of other cases or other diseases, assuming that what was true in the past will be so in the future: early diagnosis of a particular disease allows for improvement in health, therefore *all* diseases should be diagnosed and treated early. It should be pointed out that this inductive approach does not negate the value of the argument, for after all, most actions in life, validated every day, are based on such reasoning. Thirdly, this common-sense theory also contains implicit statements which may not be problematic as they may

weaken the arguments of those who believe in them. These implicit statements are based on the idea that screening carries no disadvantages, although one could point in particular to the impossibility of predicting the seriousness of the disease and to negative conjunctions between post-screening treatment and risks of morbidity. While the North American consensus symposium in 2004 ended by recommending NSCF, the risk of cross-infection between babies diagnosed with cystic fibrosis and older cystic fibrosis patients in care centres was a central issue in the debate. Although the disease is genetic, it manifests in respiratory infections which patients have difficulty fighting off, and *some* North American centres showed higher infection rates among children diagnosed by screening than among those diagnosed on the basis of symptoms (Farrell et al. 2003). Professionals in French treatment centres are aware of this problem (data gathered by Joelle Vailly, forthcoming). This shows up clearly how the notion of informed consent raises issues other than the simple rational choice of subjects, with the entanglement of power relations, values and assumptions.

Conclusion

Raising what Ian Hacking (2005) calls a philosophical "node", in other words a problem resulting from contradictory tendencies (in this case the imposition of constraint versus freedom of action), this political configuration adapted to a population reveals three characteristics. Firstly, in a policy of neonatal screening which initially appears relatively consensual – it relates, after all, to the care of sick children – it is important to be clear about the way in which conceptions of the individual and the collective, power relations, types of domination and spaces of freedom may be interrelated. And indeed, as we have seen, on one level screening proves to be largely a way of directing patients towards treatment centres and a technique of "government" (Vailly 2006). On the other hand, the very high rate of consent and the genuine agreement observed in interviews, which extends to seeing the tests as self-evident, are part and parcel of a power which runs through the social body in positive mode. What we have here is not the imposition of a test but rather, in the Foucauldian sense, a productive power network based on the approval of those locally concerned: "[Power] needs to be seen as a productive network

which runs through the whole social body much more than a negative instance whose function is repressive," says Foucault (1984: 61). In this sense, government at work is indeed a mode of acting on others who themselves act, in more or less active or detached manner, and their positive response is based on a norm which posits that the earliest possible diagnosis and treatment have no disadvantages. In this way, screening has put in place a mode of operation which establishes a link between the development of techniques (the DNA test) and the history of techniques of government.

Our second remark relates to the fact that the value of this assent is diluted by the inherent limits in the situation (exhausted mothers, etc.). Although we should note the special care devoted to drawing up written information, individualising procedures come up against the practical difficulties raised by generalised policies. The legislator, who stipulates that "a test of genetic characteristics may only be prescribed within the context of an individual medical consultation […] carried out by a doctor […]"[8] zealously institutionalises good practice, but could hardly have envisaged the problems of mass screening. He institutes what Marie-Andrée Jacob and Annelise Riles (2007) call a "bureaucracy of virtue". Thus, the effects of the injunction to ensure individuation, expressed by the legislator to the organisers of screening, are adapted to concrete practices. For the sake of completeness, we would emphasise that this initial study needs to be extended to examine the way in which the organisers of screening and the medical professionals, particularly those working in maternity units, explain and justify it (the fear of generating anxiety and the complexity of the equation to be balanced, as we have seen, but also organisational constraints, lack of time, etc.). Under any scenario, it would be unreasonable, if only for reasons of cost, to mobilise a huge medical arsenal in order to obtain consent to a test which, given the incidence of the disease, detects 180 cases each year.

Our third remark relates to the type of subject produced (Fassin & Memmi 2001). One of the theoretical interests in the mode of analysis used here relates to the fact that in the Foucauldian conception, in contrast to the Cartesian and Sartrean traditions, subjects do not result from an intrinsic given which is constitutive of persons, but are formed through

processes (Foucault 1984). Thus these subjects change, adopt different forms or see their powers as subjects eroded in relation to the experiences they undergo. Hence this analytical model allows us to study how different types of subject are constituted. From this point of view, it would be of value to continue this study, with the aim of identifying a likely stratification in the reading of the information related to the socio-professional origin of the mothers in the two units, which is suggested by the randomly selected examples above. Whatever the case, all mothers in maternity units have a specific form of power, the choice to sign or not to sign. They constitute subjects who are admittedly convinced, but are restrained, acting under the influence of an idea that appears self-evident, contrasting markedly with current debates in the international biomedical arena. It is as if the more screening becomes part of a routine of care on the level of population, the less women's power as subjects is mobilized.

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[1] The present study was generously funded by the GIS-Institut des Maladies Rares. Our warm thanks to the members of the Iris for the valuable exchanges on our work. We are grateful to the various persons in the field for making themselves available for the study. The text was translated by Rachel Gomme.

[2] Cystic fibrosis is characterized principally by usually serious respiratory and digestive problems, though the severity of these disorders varies greatly. The life expectancy of sufferers in France is around 37 years.

[3] Law no. 94-654 of 29 July 1994, decree no. 2000-570 of 23 June 2000 and law no. 2004-800 of 6 August 2004.

[4] The other diseases for which neonatal screening is carried out in France are phenylketonuria, hypothyroidism and adrenal hyperplasia. Screening for sickle cell anaemia is universal in France's overseas dominions and territories, and restricted to black and Mediterranean-basin populations in the French mainland.

[5] This document relates equally to the information to be given to professionals in order that they may inform parents, the information to be given to parents before the test, before communicating the result of the test, and after the molecular biology (DNA) test, and the information to be given to parents of a child diagnosed as having the disease or carrying a mutation (AFDPHE 2001a).

[6] If the baby is born late in the evening, it is not yet 72 hours old by day D3, and parents who leave the unit on D3 are asked to return the next day (D4) for the test and the baby's health card (we did not observe any situation of this type).

[7] This thesis was written on the basis of a survey of 246 mothers, of whom 53% responded that they had read the information sheet (Lunardi-Laval 2004). In response to the question on the reasons why consent was needed, the thesis shows that one third of mothers did not know the answer, one third gave an incorrect answer (consent to the blood sample being taken, etc.), and one third gave the correct answer (for cystic fibrosis and/or for a genetic test, etc.). Of those who gave a correct response, half (or 13% of the total) gave a fully correct answer (genetic analysis for cystic fibrosis).

[8] Decree No. 2000-570 of 23 June 2000.