Shifting contraceptive policies in light of risk assessment and management – the French "pill scare" case

Mylène Rouzaud-Cornabas (mylene.rouzaud-cornabas@inserm.fr), *University of Paris*, *Sud (France)*

Abstract (about 150 words): In 2012-2013, an important public health crisis about thrombosis risks associated with new generations contraceptive pills has deeply transformed the French contraceptive model. Uncertainty and reassessment of risk about this gendered medication and consumed by healthy women, have destabilized medical and socio-political consensus on the predominance of the pill and its effective preventive action. The controversy has highlighted the issue of a new relation to contraception and, therefore, a new relation to the female risk-taking in matters of sexuality and reproduction. The objective of this presentation is to show how this recent controversy in reintroducing, in a particular way, the concept of risk came to undermine standards, paradigms and models on which were based contraceptive and health policies in general. We seek, more specifically, to understand how the centrality of this issue of risk has contributed to the introduction of an individualistic approach of the body and its uses. And, therefore, to what extent this is neutralizing the issue of social determinants in controlling reproductive bodies?

Keywords (5 to 8): sexual and reproductive health, risk assessment, medicines regulation, gender studies

Introduction and context

In December 2012, a French newspaper article entitled "Warning about the pill" publicized a complaint filed against a pharmaceutical company by a woman using a third-generation pill who had suffered a stroke that left her severely disabled. This gave rise to an intense debate, in France, over the following weeks, on the risk of deep venous thrombosis associated with new generations contraceptive pills. Those risks had however been demonstrated as early as 1995 in many other European countries and well known among the scientific community. The decision of the Ministry of Health to halt reimbursement of those pills and to momentarily withdraw the pill Diane-35, an anti-acne treatment with contraceptive properties reinforced this controversy. Renewing an old debate on hormonal contraception and health risks, it deeply changed the French contraceptive model that was mainly centered on the pill and on rigid contraceptive norms. Trends that very slightly began before the media debate – notably the decline in pill use observed since the mid 2000s– were thus reinforced, at a time when women were pointing up the constraints and side effects of combined contraceptive pills.

As a consequence, nearly one in five women reported having changed methods since the 2012-2013 controversy on the pill. Use of the pill fell from 50% to 41% between 2010 and 2013. It concerned almost exclusively types of pills that were targeted in the debate, the so-called third and fourth generation pills. Indeed, when 40% of the pills used in 2010 were third and fourth generation, this proportion fell to 25% in 2013. Women turned to other methods of contraception, notably intrauterine devices (IUD), condoms, and other methods such as the calendar method (fertility awareness method) and withdrawal. Even though the pill remains the most widely

used contraceptive in France, contraceptive patterns have become more diverse (figure 1).

Following this controversy, uncertainty and reassessment of risk about this gendered object, prototype of chemoprevention (Fosket, 2002) and consumed by healthy women, have destabilized medical and socio-political consensus on the predominance of the pill and its effective preventive action. The controversy has highlighted the issue of a new relation to contraception and, therefore, a new relation to the female risk-taking in matters of sexuality and reproduction. The objective of this presentation is to show how this recent controversy in reintroducing, in a particular way, the notion of risk came to undermine standards, paradigms and models on which were based contraceptive and health policies in general. We seek, more specifically, to understand how the centrality of this issue of risk has contributed to the introduction of an individualistic and biomedicalized approach of the body and its uses. And, therefore, to what extent does this new trend participate to the neutralizing process of social determinants such as race, class or gender and to a reification of sex differences in matters of reproductive health?

To this end, we will first show how contraceptive norms, models and policies since the 1980s have shifted with the definition of risk and its changes over time. We will then focus on how risk has contributed to further (bio)medicalization of public health issues and normalization of reproductive bodies and their uses.

This research project is based on quantitative and qualitative work. Interested in the making and changes in contraceptive policies, we conducted interviews (55) with decision makers (health agencies, ministerial offices) and other stakeholders (Planned Parenthood, patient associations, health professionals, industrials, media). We also used second-hand materials such as institutional archives, reports, working papers, meeting or media reports. Quantitative data has also been gathered through the 2010 and 2013 Fecond survey (INSERM-INED) to know, among other questions, the impacts of this particular crisis on women and their contraceptive practices and representations. We will be using the data on the perception of risk, on the uses and representations of contraception through different social affiliations (sex, occupation, origin, age, medical coverage). The results of these surveys help to contextualize and discuss speeches on risk assessment and contraceptive behaviors.

1. Shifting contraceptive models and policies

French contraceptive model has been constructed around a strict contraceptive norm (Bajos and Ferrand, 2002). This contraceptive norm is associated with the technical and social history of the contraceptive pill in France. The centrality of the pill and its progressive deconstruction inform us on norms and models that have predominated over time. Through a common aim of population control (regulating the abortion rate¹), two models have succeeded each other: one based on a universal access to contraception, another one based on a diversification of the contraceptive panel and on individual choice.

The construction of the centrality of the contraceptive pill

¹ On the contrary to United Kingdom, for instance, the main public issue in terms of population control is not unplanned pregnancies (among precarious populations) but abortion rate.

Contraception was legalized in France in 1967 by the Neuwirth law. Later on, in 1974, a law called "second Neuwirth law" allowed its reimbursement. Contemporary and entangled with the struggle for the right to abort, access to contraception has been a major social benefit for women, constituent to their emancipation. It has enabled women control over their fertility thereby contributing to a redefinition of the place and role of women, for a long time, confined to their reproductive function. This advanced social technology fed the path to gender equality by separating what concerns sexuality and procreation. In contrast to the legalization of abortion, birth control is of a certain social recognition to the point of talking about an "ordinary social fact" (Ferrand, 1982).

Successive innovations legitimized and contributed to a wider dissemination and democratization of medical contraception. Following the generalization of a first generation pill in 1967, a second generation appeared on the market in 1974 and third and fourth generations starting in 1982. Other hormonal methods came to the market such as the vaginal ring or the patch in the early 2000s. New generations pills however had a bigger success being consumed by nearly 2.5 million women in France, up to the controversy. Moreover, a woman out of two in France uses the pill and 80% of women aged 15-24, making France one of the greatest consumers of pills. This democratization of birth control among the general population is, at first glance, understood as the success of oral contraception, now more associated with what Watkins calls "lifestyle drug" (Watkins, 2012). It was this gradual dissociation between the product, a medicinal product having risks and benefits, and its social significance, a mean to separate sexuality from procreation, that will be at the heart of this controversy.

The new generations pills were greeted with much enthusiasm since they were supposed to be better tolerated than the first ones even though no scientific work had demonstrated it. Facing pressure from feminist organizations including Planned Parenthood association who thought that it was a challenge in terms of freedom of choice for women, the decision was even taken to repay some new generations pills in 2009. This constant biomedicalization of contraception was therefore at first sight, regarded as constitutive of women's emancipation. Whether it was the medical profession, public authorities in a population control objective or feminist associations², the different actors of contraception in France favored a model where the pill was considered as much a symbol as the most effective and safe method. The archives of the past fifty years confirm a constant concern, although cyclical, for potential risks associated with hormonal contraception (cancer, risk of venous thrombosis, fertility, libido). But these concerns did not prevent diffusion and democratization of hormonal contraception and even more so for the pill.

The predominance of the contraceptive pill may also be understood through the contraceptive norms, mainly framed by prescribers, and which regulate contraceptive uses. The medical institution has indeed contributed to create a specific contraceptive standard. This norm defines good practices in terms of fertility control (Bajos and Ferrand, 2002) and a certain temporality. It thus urges men and, more specifically women, to use condoms at first sexual intercourse and at the start of any new relationship because of the risk of infection to sexually transmitted diseases and

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² Which compared to movement for women health in other western countries (UK or US) is not in a rhetoric of de-medicalization.

more specifically to HIV. As soon as the women's emotional life gets stabilized, supposed to have a more regular sexual activity, contraceptive pill becomes the reference. Moreover, the French medical orthodoxy considers the IUD only when women reach a certain age or when they already had children. This no-prescription of IUD to young women and a fortiori to nulliparous refers to popular medical beliefs yet deeply rooted in France³. Other contraceptive methods, including hormonal implant or the contraceptive patch, are rarely offered by doctors (Gelly, 2006) or are limited to the young audience. As for sterilization for contraceptive purposes, authorized since 2001, it is little used in France for women as well as for men. This contraceptive norm thus makes the pill, the contraceptive method of first intention and contributes to the idea that it is the safer and more adequate method for women.

Moreover, up until the 1990s, contraceptive policies have aimed at democratizing the access to contraception through the democratization of contraceptive pills, the final objective being to guarantee the best contraceptive cover and, in that way, avoid, in a population control logic, the resort to abortion. Concretely, it has been materialized by reimbursement of several contraceptive pills, even newer generations in 2009, despite several scientific reports that have demonstrated an additional risk of thrombosis associated with those pills. There were also many information campaigns, measures to facilitate prescription or to guarantee anonymity for certain populations. But all those actions were based on the pill as a standard and depicted this method as a safe, easy to use but mostly easy to prescribe. This period is what we call the period of the "universalist model" characterized by a will to broaden and facilitate the access to oral contraception.

Towards a more diversified and emancipatory model?

For a long time, contraceptive policies therefore aimed at democratizing contraception with the objective of ensuring better contraceptive coverage and avoid what is prescribed as deviant, practice of abortion (Bajos and Ferrand, 2011).

But, in the early 2000s, a bill was discussed and voted to facilitate abortion in France but it also renewed the debate on the stability of abortion rate and led to the questioning of contraceptive policies. Facing the exhaustion of this universalist model, a model of diversity and differentiation seemed to emerge. Indeed, realizing that "contraceptive failure", the main cause of abortion (Moreau, 2011), was due to compliance difficulties, the focus has shifted from the access issue to the quality of use and, in other words, from socio-economic determinants to individual determinants of contraceptive practices. The notions of "choice", diversity and autonomy have emerged neutralizing the question of social distinctions and inequalities (gender, class, race, etc.). Information campaigns by the National Institute for Prevention and Health Education (INPES) presented this contraceptive choice as devoid of socio-economic constraints and adopted this "empowering" model, generalized otherwise to other public health issues (addictions, smoking, obesity, sexual health). This new model is thus based on incentive policies to "make

(IUD) related to age or parity (WHO 2010). This reluctance of the medical profession to offer women IUDs as long as they have not completed their reproductive life persists over time even though new information about this method has been

broadcast for several years by public health authorities (HAS, 2004).

³ There is indeed no medical indication against-the use of an intrauterine device

an individual choice" of a contraceptive method that would best fit individuals. It goes by information campaign called "choose your birth control method" or "sharp turn" to diffuse this message of a reasonable choice. It is also symbolized by an increased production of socio-epidemiological or psychological work, recycled by public authorities, on contraceptive choice and observance to find ways of making contraception taking effective. The characteristics of these contraceptive policies is thus to successfully transpose the notion of choice from an individual emancipation paradigm to one of public health.

But, it is only in a context of distrust for medicinal product in France⁴ and of a controversy on risks associated with contraceptive pills that those policies had a real impact. This notion of choice conveyed by both governments, feminist associations or media ended up impacting contraceptive practices thanks to this pill scare which has contributed to the incorporation of this new standard of contraceptive diversity and choice. For example, the use of the pill has declined more between 2010 and 2013 among women who consider they choose alone their contraception (35% of decrease against 14% among those who let their doctor make that choice for them). Just like the IUD: 29% of decrease in use for those who choose for themselves and only 16% for those who choose after the doctor had submitted their methods (table 1). We can certainly explain those changes by a greater awareness from a part of the population now informed and conscious of risks associated with oral contraceptives. It could also be analyzed as a prescriber awareness of the need to open the choice to women beyond the pills. Now, if indeed our results show that the "acting out" is facilitated when contraception is seen as constraining, other indicators show, firstly, that those changes in contraceptive uses are socially situated and, secondly, that beliefs and misconceptions persist, nuancing the relevance of this diversity and choice models. Interviews with several prescribers make us also think that if the precaution to take in prescribing new generations pills has been understood, the notions of choice and diversity might be interpreted differently depending on the woman (new contraceptive standards established, based on age, geographical origin, level of education, perception of the sexual/emotional life of the woman). If the contraceptive landscape has become more diverse, the question of the sustainability of these changes and their social implications remains.

2. The "quality of care": a socially neutral focus on individuals and their safety?

Shifting contraceptive policies is, according to us, not only related to different population control modalities but also to different qualification, quantification and ways of assessing risk in comparison to the benefits of the methods. Our aim is thus to better understand norms, knowledge and instruments used in the regulation of those contraceptive methods, and more generally medicines, and the production of public health policies, now mainly driven by safety concerns. Through the analysis of how risk assessment and management have transformed public health policies in the domain of sexual and reproductive health, we want to question their neutral action. Therefore, it is important to demonstrate how biomedicine, based on notions of objectivity and scientism, has reproduced social inequalities and reified social distinctions.

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⁴ The Mediator affair in 2011 in France has, for instance, deeply changed perception of risks associated to medicinal products.

En-gendering risk and its assessment

In this controversy, the nature of this drug is central since it refers directly to the gendered production of standards, knowledge, practices and representations. Science studies have been largely influenced by feminist studies, highlighting gender bias in the production and dissemination of knowledge (Harding, 1991). Therefore, if one looks at the history of the pill and hormones, one realizes that this is the story of a major biomedical innovation as well as the chemical construction of sexual differences. E. Martin (1987) has thus shown how the medical discourse and the emergence of the idea of "reproductive body" have contributed to the naturalization of gender differences. N. Oudshoorn (1994) has pointed out the gendered representations of the hormonal body in biology and medicine. L. Marks (2001) has, as for her, realized a socio-history of the pill by showing that it was primarily thought as a mean to "normalize" the female body. In France, Gaudillière (2003) talks about "molecularization of sex characteristics" by relating the history of "sex hormones" and their involvement in the treatment of female infertility and menopause. In that matter, the contraceptive pill should be thought of as an artifact that materializes gender relations among other social relations and as a chemical substance having both been shaped by biomedicine and society.

We want to further those thoughts from the production of a biotechnology to its regulation by scientific experts and public health authorities. We can take the example of the benefit-risk assessment, which is a standard in the marketing authorization process or to set reimbursement rates. Its evolution over time, the methodologies and subsequent reassessment reflect the advance in scientific knowledge in this area but also to the development of therapeutic strategies. But these strategies are also closely linked to the socio-political context in which they are developed. Therefore, for contraceptive medicinal products or devices, the criterion of effectiveness (the Pearl Index) has long dominated as part of the "population" control" vision of contraceptive policies. Thus, contraception had to be effective without taking into account individual contraceptive strategies, preferences or intolerances. Moreover, this was linked to a minimizing of health risks since the contraceptive method was systematically evaluated against the risk of unplanned pregnancy. If this criterion does not completely disappear from the risk assessment argument, with the new contraceptive strategies of diversity and quality, problems of intolerance are now more considered and the concept of efficiency is enhanced by an approach in terms of "acceptability". However, this acceptance remains measured through iatrogenic risks proven by pharmacoepidemiological studies that may cause women to stop treatment, such as cardiovascular risks. Other factors having also an impact on the (dis) continuity of contraceptive treatment such as decreased libido. weight gain, mood swings, the need to regularly visit a doctor, however, remain excluded from the assessment process because they are considered as "female" invalid scientifically or "not yet scientifically proven". In a more general perspective, this "quality of care" approach takes a medico-economic definition of quality (what makes a more effective contraceptive than another) and does not legitimize the inclusion of "quality of life" criteria, yet central to acceptability.

Furthermore, if we adopt a gendered critique of this instrument, we see both that what is the subject of attention (for scientists and decision-makers) is efficiency and not what women may feel because it is considered as a private matter and superfluous. Secondly, the pursuit of efficiency refers to a reproductive norm that

bans contraceptive failure and strengthens the lack of social recognition and legitimacy of abortion practice. It also contributes to put a harder pressure on women and their constructed responsibility in birth control and reproductive matters. Finally, the question of social interactions and power relations is removed. Indeed, social factors affecting adherence are not taking into account such as socio-economic status, level of education, emotional life, male partner involvement or power relations among the couple. Moreover, there is no comparative studies on the risks and benefits of contraceptive methods according to sex and this is thus reinforcing the fact that the way of assessing risk in the domain of sexual and reproductive health are driven by gendered concerns and stereotypes (Van Kammen and Oudshoorn, 2002), female risk-taking being apparently less problematical than male risk-taking in that domain.

This leads us to further a final argument that is that risk has made possible a reification of social groups and risk management a way of neutralizing social determinants in public health policies. We are thus adopting the same approach of risk as Shapin (1994). We consider risk construction as the result of interactions between science and politics and a way to materialize social relations. As Van Kammen and Oudshoorn (2002) say: "He has shown how the tacit rhetorical constructions of the social order help to constitute risk, trust, and knowledge, and how this knowledge helps to shape social order"

Producing inequalities and shaping social order through risk assessment

Through the Fecond survey, we have been able to measure those changes in terms of contraceptive practices, representations and risk perceptions. A major conclusion is that, despite the fact that the French contraceptive model appears to be way more diversified than before (letting us think that women got more emancipated for that question), major social distinctions and inequalities remain.

The following results thus show how socially distinct were the changes in contraceptive practices. Compared with other categories, a higher proportion of women with no educational qualifications abandoned recent pill types in favor of the least effective methods (calendar, withdrawal), whereas those with a lower secondary education preferred condoms, and those with higher levels of education (four or more years of higher education) preferred IUDs. Women in higher-level occupations, who were previously the main users of third- and fourth-generation pills, replaced the pill with IUDs, and, in some cases, with "natural" methods (calendar, withdrawal), no doubt through disaffection for hormone-based contraceptives of all kinds. At the other end of the social hierarchy, female manual workers, who were initially less inclined to use the newer generation pills, did not change their contraceptive practices. Women in intermediate occupations and female technicians switched from third and fourth-generation pills to second-generation contraceptives and condoms; female clerical workers opted to use condoms. More broadly, while a portion of women without financial difficulties switched from newer pills toward older oral contraceptives, some of those in a difficult financial situation switched to "natural" methods. This is the case notably of women born in sub-Saharan Africa, who substantially reduced their pill use (-39%), turning to natural methods instead (26% in 2013 versus 5% in 2010). It thus seems that higher educated and wealthier women switched to more effective contraceptive methods whereas lower educated and more precarious women either did not change their contraceptive behavior or switched to

less effective but mostly cheaper methods and methods that do not induce women to be seen by a doctor and thus, pay for that consultation. There is indeed a real issue of free access to contraceptive methods and hence of universal access to the most effective methods.

As we previously said, contraceptive efficacy accounts for most of the regulation of medicines and medical prescription processes. This notion should be deconstructed, as did it medical anthropology (Etkin, 1988), and should thus be seen as the imposition of expected and legitimized results by the scientific and medical communities. Indeed, contraceptive efficacy has been established as a standard both in epidemiology and clinical research as well as in demography. The pill scare has thus also revealed a relation to risk associated with contraception as ambiguous and highly differentiated according to the socio-economic and cultural environment. Side effects reported and identified to be related to the pill use are indeed quite diversified from effects on the skin, on the periods, on sexual desire to broader health effects (cancer, the risk of thrombosis). The degree of knowledge and risk perception changes depending on social groups. If the pill may be considered, in a strict medical way, as a medication, it is not in the eyes of the majority of its consumers. If the health standard of self-monitoring expected from the individual, as homo medicus (Peretti-Wattel, 2009), it postulates a rationality that is distorted by various injunctions, sometimes contradictory, that the individual has to face. In our survey, we thus notice that higher educated women often think that their contraceptive method has an effect on their health (40% against 35% for the least educated) and that it is negative (16% for higher educated women against 9% for those without qualification). The effects on sexual desire, on the contrary, are more often detected among the least educated (27% against 20% among the most educated).

A last but not the least argument for putting this notion of risk in perspective is how people react to risk. In our survey, we notice another major social gap between higher educated women and women with lower or no qualifications (and similarly for socio-professional categories) on the reaction to risk that we measure by the fact of mentioning it to a doctor or to see a doctor for that reason (table 2). Higher educated women or with a highly qualified job are more disposed to see a doctor or to talk about that matter and, thus, to potentially change of birth control. Whereas, more precarious women will less get seen and will be more probably living with a contraceptive method that do not fit them, potentially dangerous or change of contraceptive method and switch for a less effective one without knowing the other options. We are thus underlying that hormonal methods are not only rejected, as it is commonly thought, by well-informed or activist women but also by women electing a "more natural" contraceptive method by their own, not for a matter of choice but for a matter of a medical interaction, socio-economically or culturally difficult. Changes in contraception towards non-hormonal or natural methods are thus not only the impact of a more critical patients flow but also of a part of disadvantaged populations or lessintegrated to biomedical Western culture, with a different understanding of risks and benefits or experiencing an antagonism with other cultural references (Whyte et al, 2002). Those differences in risk sensitivity should make us think that what accounts in risk assessment and management underestimates major social determinants and individual strategies defying the rational choice logic.

Conclusion – Towards a reproductive rights approach?

With these diversification policies and a focus on contraceptive choice, the universalist model seems to have been completed by a model of "quality of care" (Van Kammen and Oudshoorn, 2002). But contrary to what its name might suggest, it is more in the perspective of reducing costs and risks (unplanned pregnancies ending by abortion and/or iatrogenic side effects) than in a potentially emancipatory sight (reproductive rights approach). The emancipatory scenario of the controversy and contraceptive policies focusing on the notion of choice and diversity should indeed be very critically analyzed. There is a question of social inequalities being reinforced through this process but also a focus on the individual which paradoxically looks at individualizing responsibility but also at controlling them through the eventuality of a danger. Some anthropological and sociological works have focused on what we could call, in a Foucaldian perspective, a new form of governmentality exercised on bodies for which one individual autonomy and self-management are the cornerstone (Pickstone, 2000; Clarke, 2010) and where social control is certainly more diffused but has not disappeared (Memmi, 2003). The emergence of a "quality of care" approach (Van Kammen and Oudshoorn, 2002), completing a population control objective, has consequently settled the ground for an individualistic and riskcentered approach in sexual and reproductive health policies which contributes to further bio(medicalization) in this domain. As Clarke said « health is thus paradoxically both biomedicalizaed through such processes as surveillance, screening, and routine measurements of health indicators done in the home, and seemingly less medicalized as the key site of responsibility shifts from the professional physician/provider to include collaboration with or reliance upon the individual patient/user/consumer. » (2003, p.173)

A reproductive rights approach may indeed differ from a quality of care approach by producing a critical analysis and position to this process of (bio)medicalization by thinking the impact of social relations, for example gender, on the production of knowledge, the production of biotechnologies, their evaluation, their risk-benefit balance assessment and their role in therapeutic strategies. A reproductive rights approach may also lead to a better understanding of contraceptive preferences, women's and men's feelings, perceptions of the methods and own assessment of risks but mostly to a real differentiation between sexuality and procreation, free of gender stereotypes and norms such as the equation womanhood-motherhood.

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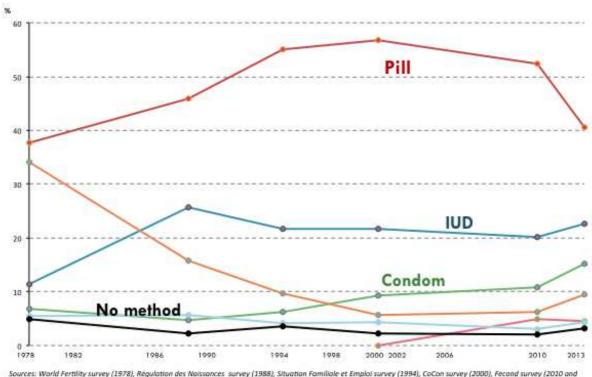
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Appendixes

Figure 1: Evolution of contraceptive practices in France (1978-2013)



Sources: World Fortility survey (1978), Régulation des Naissances survey (1988), Situation Familiale et Emploi survey (1994), CoCon survey (2000), Fecand survey (2010 and 2013).

Papulation: Women aged 20-44 living in metropolitan France who are not sterile or pregnant, who have sexual relations and do not want to have a child

Table 1: Contraceptive pill, IUD, condom and "natural methods" use (relative risks 2013-2010 age-adjusted)

	Pill	IUD	Condom	Natural methods
	0.82***	1.09*	1.26***	1.57***
Choice of the contraceptive method				
Choose alone	0.65	1.29*	1.25**	1.46**
The doctor presents the possibilities and then choose	0.78***	1.16*	1.18	1.35*
Let the doctor choose for themselves	0.86***	0.91	1.45**	1.59**

Table 2: Discussing health risks with their prescribers (percentages)

Diploma	49.9 (2897)
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No diploma	36.9 (232)
Baccalaureat (high school level)	54.2 (691)
Undergraduate	52.7 (836)
One deserte	F0.0 (000)
Graduate	56.3 (600)
Professional situation	
1 Totossional situation	
Executives, professors,	58.8 (521)
accredited professionals	
Clerical workers	49.1 (1229)
Manual workers	49.3 (138)
Total	49.8 (2886)