Conceiving contraceptives: the involvement of users in anti-fertility vaccines development
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Summary

Since the early 1990s, a consensus has been growing among researchers, policy-makers, funding agencies, and women’s health advocates that the future users of contraceptive methods should be involved in the process of their development. However, in practice the integration of the users’ perspectives into contraceptive research and development has proved very difficult. Most studies of users and contraceptives have focused on the introductory stage, where problems generally surface. Earlier stages of technology development, and the possible involvement of users in the trajectories preceding introduction, have not been questioned. In this thesis I have traced the ways in which users were involved in the development of a new contraceptive technology over its entire life cycle. The research questions are: What are the dynamics of users’ involvement in the development of anti-fertility vaccines? And what are the possibilities and limitations for changing the ways in which users are implicated in this developmental process? The character of the relation between representations of users and technology development is subject to debate. This study provides an empirical and theoretical contribution to this discussion. In contraceptive technology development, precisely because it has been such a contested area, a number of initiatives have been undertaken by international organizations to promote broader participation and dialogue about social aspects in earlier stages of technology development. Therefore, those interested in technology assessment may find that this study provides important insights into the effects of such endeavors upon technological development.

In the Introduction, the literature on users and Science and Technology Studies is discussed. The Social Construction of Technology approach conceptualizes users as a relevant social group, but the effects of ideas about the envisioned users in earlier stages of technological development are not systematically included in such analysis. The script approach proposed by Akrich (1992, 1995) assigns an important role to representations of future users held by the developers of a technology. Technologies, she has affirmed, contain a script: together with the actors and the settings in which they are
supposed to act, technical objects define a framework of action. Technical objects can distribute responsibilities and assign positions to other participants in the sociotechnical network, including the potential users. The innovators’ projected users are anticipated in the script. In this thesis, I have adopted this approach in order to understand how anti-fertility vaccines evolved with a particular script. Akrich’s procedure has been to examine situations of mismatch between the anticipated users and the actual (non)users, and in this way she has made visible how the designers’ representations of users had been solidified in the artefact by their design decisions. But I am interested in understanding users’ involvement in the preceding trajectories, before they are solidified or go awry. And I am concerned with developing a perspective on changing the ways in which these technologies evolve in the pre-market-stage, so that problems might be prevented. Therefore, I have proposed two extensions to the script approach. First, it is important to analyze where certain representations came from, who articulated them, and how some of the implicit and explicit images of prospective users became more powerful than others in certain circumstances. Second, I have explored various ways to learn about the prevailing representations of users before the script is performed. I have examined how evolving scripts can be made explicit in earlier stages by contrasting the representations of users held by the scientists involved with those held by other actors concerned in technology development. In anti-fertility vaccine development, the international women’s health movement provided me with a suitable point of contrast. I was able to study the representations of future users that the scientists and women’s health advocates invoked in their negotiations about what the technology and its concomitant script should look like. The clinical trials with immunocontraceptives provided me with another opportunity to study the evolving script before the product is introduced. Given the potential agency of the trial participants, it is interesting to see what we can learn from their encounters with the expected users inscribed in the anti-fertility vaccines.

The chapters in this book follow the developmental trajectories of anti-fertility vaccines. Immunocontraceptive development started in the early 1970s, when the concept of immunological approaches to fertility regulation became articulated in initial research programmes at the Human Reproduction Programme of the WHO and at a national research institute in India. Chapter 1 is about this agenda-setting stage. From a perspective on change it was interesting to examine who was entitled to bring representations of future users to the fore, and what their contents were. The WHO/HRP enrolled its member states, biomedical scientists, and clinicians in framing the research programme. Social scientists, family-planning organizations, and women’s health advocates were not involved in the process in this stage. I have discussed how representations such as populations, non-Pill users, and finally
"everybody" were generated and came to bear upon the initial research programme in immunocontraception. Importantly, representations of users had more functions to accomplish than that of simply guiding the innovators in their technology development, such as legitimizing the research and development. In order to develop a research programme, agreement had to be reached about a "doable research problem" (Fujimura 1987), involving the alignment of the laboratory work, the clinical practice, and the world of policy-making and financing. In this endeavor, ideas about who might use the methods were left implicit. The WHO/HRP and the member states wanted to avoid the suggestion that research into this particular method could be interpreted as a statement about the politically sensitive relations between population growth in Third World countries and development. The idea of users as "everybody" was not as politically neutral as it might appear at first sight. Aligning the technology development with more specific user profiles might have deferred the doability of a quick and universal technological fix for fertility control.

In chapter 2 I have examined the circumstances in which appropriate antigens were selected, and the concomitant representation of users’ bodies that evolved. The scientists’ indeterminacy about the envisioned users included their sex. Users’ bodies came to be represented at the level of target substances. However, the sexless representation of users’ bodies did not correspond with the work that the reproductive scientists carried out in practice. A technology evolved with a clearly gendered script. Therefore, I have argued that even if innovators do not always have users in mind, we cannot conclude from this that users do not matter. The concept of "implicated users" (see Clarke and Montini 1993) is meant to make this form of involvement visible.

Next, in order to account for the asymmetric presence of male and female bodies in anti-fertility vaccines development, I have analyzed the researchers’ room for manoeuvre to develop certain vaccines and not others. The distribution of opportunities for developing anti-fertility vaccines was not merely contingent, but embedded in a certain context that evolved over years of doing reproductive research. The availability of research materials decisively structured the course of the research and development of immunological contraception. The purified placental hormone hCG was readily deliverable, and animal models of proven utility existed for studying the female reproductive tract. This "gynecological infrastructure" (Oudshoorn 1994) for doing reproductive science encouraged the development of vaccines to be used by women more than research into male methods. International policy debates also forcefully impinged on the co-construction of anti-fertility vaccines and future users. Particularly influential were the policy debates on abortion, on male partnership in contraception, and on reproductive rights. I

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have also examined the factors conducive to research into male immuno-
logical contraceptives.

The involvement of the international women’s health movement with
anti-fertility vaccines development is analyzed in chapter 3. The inclusion of
women’s health advocates in the analysis of contraceptive development raised
the question of whether and how women’s health advocates could be con-
sidered spokespersons for future users of anti-fertility vaccines. I have
approached this issue by analyzing how the question was handled by the
actors involved. The women’s health advocates did not claim to speak in the
name of users; but based on their differing experiences and analysis, women’s
health advocates could contribute more contextualized images of future users
to the discussions with contraceptive developers. Influenced by the policy
shifts in the early 1990s under the banner of reproductive health and rights,
their alternative perspectives were recognized as valuable by the contraceptive
developers. Crucially, for members of the women’s health movement this
meant that they were not restricted to the essentially impossible task of
voicing the supposed needs and preferences of people wanting to plan their
families. Instead, they could relate to contraceptive technology in other ways,
as researchers or as advocates. Room was created for women’s health
advocates to introduce different frames of meaning, such as exploring the
kinds of relations that one or another technology might constitute.

I also have examined the possibilities and limitations involved in
integrating women’s health advocates’ alternative perspectives into the design
of anti-fertility vaccines. The scientists aimed to develop a contraceptive that
would be long-acting and easy to administer, and they expected that such a
method would then meet users’ needs and preferences. From their perspective
on users-in-their-contexts, the women’s health advocates questioned the
practicality of certain features of immunocontraceptives. In particular, they
were concerned about the occurrence of a lag-period of three to six weeks
after injection to build up sufficient immune response, the unpredictable
duration of effectiveness, and the impossibility of switching off the immune
response on demand. Given the history of recurrent situations of coercive and
not fully informed administration of contraceptive methods, they also were
concerned that these methods might be prone to abuse in population-control-
driven family-planning programmes. According to the researchers, these
issues were not part of developing the vaccine itself, but should be addressed
in family planning programmes in the application stage. The researchers
proposed providing a bridge method to cover the lag period, a test-kit to
monitor the antibody response, and thorough counselling by health-care
providers on the possible duration of effectiveness. I have analyzed these
proposals as a mixture of "boundary work" (Gieryn 1983 and 1995, Jasanoff
1995) and the attempts of the scientists to align the developing artefact with
the users (Akrich 1992, 1995). Women’s health advocates also questioned the efficacy and safety of the developing product for users with differing genetic dispositions, or suffering from stress, malnutrition, or disease that might affect immune responses, or in contexts of marginal health care. The researchers argued that these concerns of the women’s health advocates were irrelevant, since what they had developed was only a prototype and not a product that would be used by users-in-their-contexts. But at the same time, measurements made on the basis of these prototype vaccines in clinical trials were cited in support of the safety and efficacy of the new method. As a result of this way of mobilizing the prototype status of the developing method, the women’s health advocates’ different understanding of safety and efficacy could not be taken into account. All of their concerns were postponed to later stages of technology development.

Users’ involvement in the clinical testing of anti-fertility vaccines is studied in chapter 4. I have examined the roles that were assigned to the clinical trial participants in the researchers’ papers. The scientists viewed trial participants as "test-users" and referred to the trial participants as the forerunners of the future user population (see Epstein 1995). In the enrollment and in the conduct of the trials, the participants were present as embodied agents. Their embodiment endowed them with the capacity to foot-vote. It also endowed them with vulnerability to pain and ethical abuse. It was at this stage that international differences between women’s options came most clearly to the fore. Because of women’s differing possibility for action in various countries, it was easier to recruit and keep women in the trials in India than in Sweden. For poor women in India, the clinical trials could provide a welcome opportunity to obtain better access to superior health care, an extra income, and a social space outside their homes.

In the clinical trials in India and Sweden in the 1990s, special organizational efforts were required to overcome the problem of unpredictable individual variation in immune response, involving well-equipped laboratories, motivated health care personnel, and frequent access to the trial participants for blood tests and booster injections. Part of the effort to make the vaccine work was in the reporting of the trial findings in scientific texts. The researchers applied a specific distribution of competencies, in which high antibody responses were attributed to the vaccines, while side-effects and lesser immune responses were assigned to the women. In the Indian trial, the efficacy results were expressed not in terms of the number of pregnancies among the trial participants, but of the number of pregnancies per menstrual cycles in which the immune response was above the threshold value. The outcomes produced in this way played an important role in legitimizing further research. I have indicated that the status of "promising technology" (Van Lente 1993) that had been assigned to anti-fertility vaccines helps to
explain how the new contraceptive method could continue to receive the benefit of the doubt for many years.

In 1994, the WHO discontinued their clinical trials in Sweden, when two of the first seven participants left the trial because of the severe side-effects they experienced. The scientists then proceeded with research into the causes of these side-effects. At the same time, the research group in India postponed their clinical research and continued with additional laboratory work to make their preparation more suitable for wide-scale use in family-planning clinics. Concerns about the side-effects of anti-fertility vaccines and the practicality of the method had been among the issues raised by women’s health advocates before the trials had begun. I have therefore concluded that if people voicing user-centered perspectives had been involved in the early stages of anti-fertility vaccine development, the socially costly, expensive, and time-consuming detour of the scientists might have been prevented.

In the concluding chapter the highlights of this story are summarized and some implications for policy-making in the field of contraceptive development are outlined. The method that the researchers proposed to develop contained a script: a low-cost anti-hCG vaccine that would provide long-acting protection against pregnancy following a single injection, and one that could be used surreptitiously, would be suitable for a particular category of users: women with poor access to low-quality health care and relatively little decision-making power over their reproductive lives, in casu poor women in Third World countries. I have therefore proposed that "implicated users" is an important addition to the instrumentarium for conceptualizing users in the pre-market stage of technology development. To make visible how users are implicated in the technical choices of the innovators is particularly important in understanding the possibilities and limitations involved in changing user-technology relations in early stages of development.

My analysis of who was entitled to represent future users, and in what circumstances, enabled me to understand the power of implicit and unarticulated notions of users, such as "everybody". From the perspective provided by the women’s health advocates, of users attempting to plan their families in their daily lives, a number of incoherences became apparent in the script of anti-fertility vaccines. Women’s health advocates doubted that the method being developed would actually meet the needs of poor women in developing countries. I have argued that the lack of definition of those for whom the method is deemed suitable allowed the technology to develop in this inefficient way. I propose that invoking better defined user profiles from the beginning would help one to thematize users and to detect dysfunctional user-scripts early on.

Constructing more specific representations of future users might not be enough to achieve a more user-centered approach to contraceptive develop-
ment. Technological development is structured not only by imagined notions about envisioned futures; and future users of technologies are defined not only by the representations of users that designers bring into the process, but also by early technical choices that in turn are shaped by existing institutional infrastructures, material possibilities, international policy-making, etc. Therefore, the script approach should be extended to include an analysis of what enables and what constrains certain technical choices with implications for the eventual users.

A contraceptive technology evolves with a particular script that could have been otherwise. I have shown how the script of anti-fertility vaccines has evolved from a composite of population-control ideology, the workings of the immune system, funding opportunities, the availability of certain target substances, measurements made in the lab and the clinic, health-care infrastructures, international policy debates and campaigns, and more. I have argued that, according to this understanding of technology, contraceptive abuse is not a problem of application, but one related to technological design. Abuse can therefore not be addressed satisfactorily in the health-care delivery system alone. Action to prevent abuse should involve all the actors involved in the coproduction of technology and social (dis)order, including the contraceptive developers.

To policy-makers in the field of contraceptive development I have suggested that, in addition to the initiatives already undertaken by the WHO/HRP, strong linkages should be created between technological innovation and the practices in which contraceptives are used. Contraceptive developers have asserted that users cannot be involved as long as there is no tangible product to talk about. While they might be right that views on users’ involvement with non-existent methods are necessarily speculative, it does not follow from this that alternative perspectives cannot be taken into account before the introductionary stage. Speculations on possible futures are part and parcel of any technological development, and the hypothetical character of imagined user-technology relations cannot serve as a basis for excluding the envisioned futures provided by some actors and not those of others. Taking into account user-centered perspectives is a major challenge, because restoring the contexts in which people plan their families means restoring the political dimension to technological development.