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

1. Blaming the users in contraceptive development

Women’s health advocates and potential users should be represented in all decision-making mechanisms and advisory bodies that are established to guide the research process (Declaration 1993).

This recommendation was approved by the participants in the symposium on *Contraceptive research and development for the year 2000 and beyond*, held in Mexico in 1993. The participants included senior managers of all international and some national public sector agencies that undertake contraceptive research and development, and programme directors and senior staff of national and international agencies that are otherwise involved in the field of fertility regulation research. The symposium was organized in preparation for the United Nations International Conference on Population and Development (ICPD) in Cairo in 1994, where the recommendation was seconded. Since the early 1990s, there has been a growing consensus among researchers, policy-makers, funding agencies, and women’s health advocates that the future users of contraceptive methods should be involved in the developmental process. However, in practice the integration of the users’ perspectives into contraceptive research and development has proved very difficult. Why?

The 1990s witnessed a major shift in the field of contraceptive research and development. In the Program of Action adopted at the ICPD in Cairo, for the first time people’s reproductive health and rights were placed at center stage in the approach to family planning. The end-users of contraceptive technologies, virtually invisible in the previous paradigm of population control, came forcefully into focus. During this decade meetings between contraceptive developers and women’s health advocates were organized, policy was formulated and social scientific research into the needs and
preferences of users was intensified in order to develop what was called the integration of users' perspectives.1

At the basis of this new strategy lay the conviction that users had not sufficiently been taken into account by contraceptive developers (Bruce 1987, WHO/HRP 1992, Population Council 1990, Cottingham and Benangiano 1997). Indeed, numerous problems and controversies have surrounded the introduction of modern contraceptive technologies. Well known examples include the first generation of oral contraceptives, the DalkonR shield, surgical sterilization, the hormonal injectable Depo ProveraR, and the hormonal implant NorplantR. The women’s health movement has played a pivotal historic role in documenting and exposing these problems. In the 1960s a growing number of reports signaled blood clotting disorders among women taking the Pill, which at that time contained more than one hundred times the amount of estrogen in current oral contraceptives. The DalkonR Shield intrauterine device (IUD) had to be taken off the market in 1974 because it caused pelvic inflammatory disease, leading to infertility and in a number of cases to deaths. There were documented cases of women being sterilized without their knowledge, especially in Third World countries. Depo ProveraR, an injectable hormonal method, was suspected of causing breast cancer. The fact that until 1992 it was available in many developing countries, but not in the United States, contributed to the perception that there was something wrong with the method. The hormonal implant NorplantR provoked controversy about the importance of side-effects such as irregular bleeding and headaches. Researchers and policy makers rated these side-effects as "non-life-threatening conditions", but women’s health advocates saw them as profoundly affecting women’s lives and daily well being. Women in Bangladesh, Brazil, and Indonesia faced problems because the expertise and sometimes the will to remove an implant after its expiration, or on demand, was not available (Boston Women’s Health Book Collective 1984, Hartmann 1987, Mintzes 1991, Hardon 1992, Briggs 1997, Cottingham and Benangiano 1997).

The fact that difficulties with these contraceptive technologies invariably arose once they began to be used seemed to suggest that the introduction of new methods needed more consideration. Two major organizations in the field of contraceptive development, the World Health Organization in Geneva and the Population Council in New York, developed new approaches to the introduction of contraceptive methods into family planning programmes. Henceforth, the introduction of new methods would ideally be accompanied by acceptability studies and research into the service delivery setting (Cottingham 1997, Simmons et al. 1997, Population Council 1990). Such an approach was implemented for the first time with the introduction of the hormonal implant NorplantR in the 1980s (Beattie 1991, Zimmerman et al.
1990). But these acceptability studies and introductionary trials produced a peculiar effect: users became the problem, while the contraceptive methods remained unquestioned. The social scientists who studied the acceptability of contraceptive methods experienced great difficulty in defining who the (potential) users were, or specific views on what exactly should be studied. The results of users-studies were said to be extremely sensitive to the research methods employed, so that it was difficult to generalize (Shah 1995, Report of a workshop 1995, Cottingham 1997). A great many features of potential users and the contexts in which they plan their families could be studied, and were indeed studied. Crucially, the relation to technology development increasingly faded away. Instead of focusing on the user-technology interactions, attention shifted towards the users and away from the technologies. In the Norplant case, for example, the researchers found that the main reason why women discontinued the use of this method was menstrual disorders, such as frequent and long periods, or on the contrary, long intervals without bleeding. They then determined that there had been insufficient counselling to prepare women for such changes in their menstrual patterns. These studies concluded that Norplant was a very acceptable method, but that the method required that women be told on beforehand what side-effects they could expect, so that they wouldn’t worry (Hordon 1992, Hanhart 1993 and 1999, Fraser et al. 1998). As early as 1977, John Marshall from the WHO’s Task Force on Acceptability of Fertility Regulating Methods advocated "designing technology to fit people" (Marshall 1977) rather than the other way around, but this did not happen. Thus, two unforeseen tendencies evolved from the way in which studying users' perspectives on contraceptives had been approached. First, the users and not the technologies were blamed for any mismatches. And second, earlier stages of technology development, and the possible involvement of users in the trajectories preceding introduction, were not questioned.

In this thesis I have turned the tables on the problem of integrating the users’ perspective into contraceptive development. Instead of focusing on users and their ideas about the acceptability of contraceptive methods, I will systematically trace the ways in which users were involved in the development of a new contraceptive technology, over its entire life cycle. Might it be that users are implicated in contraceptive development long before the methods appear in family-planning clinics? And couldn’t it be that problems have occurred over and over again, not because of the researchers’ lack of concern for users, but because of the specific ways in which users have been integrated into contraceptive development? Viewed this way, the issue becomes to make explicit the perspectives on users invoked in contraceptive development. My research questions are: What are the dynamics of users’
involvement in the development of anti-fertility vaccines? And what are possibilities and limitations for changing the ways in which users are implicated in this developmental process? In this thesis I will examine these issues empirically.

Various definitions of users have been suggested in the realm of medical technology development (Rose 1999). The demand structure for medical technologies is multi-layered. For example, Stuart Blume (1994) has argued that in the area of diagnostic imaging the demand for new medical technologies responds to the shared interests of both its industrial producers and the professional users of medical technology. Annetine Gelijns (1991) has proposed that in relation to demand for medical technology the term "user" should include various groups, among them patients, clinicians, hospital administrators, and the families of patients. However, this broad definition of users makes the dynamics between these diverse groups invisible. In this study I will examine the involvement of end-users, defined as those who potentially will be actually injected with anti-fertility vaccines to regulate their fertility. The situation of contraceptive innovation and marketing can be characterized by a relatively large number of intermediaries between the developers and the end-users. According to Charlotte Ellertson and Beverly Winikoff (1997), this is the case firstly because in prescribing drugs or medical therapies to end-users, doctors play an intermediary role. The views of these intermediary users are important to the developers of medical technologies, who often have little opportunity to gain a thorough knowledge of the situations in which their novel methods might be used. But the perspectives of the doctors can differ from those of the end-users. In providing contraceptives, doctors have historically played a policing role to regulate women's sexuality. Secondly, contraceptive development increasingly takes place in the public sector rather than in the private sector. The withdrawal of industry has led to increasingly significant investment by the international and U.S public sectors and by nonprofit foundations (Djerassi 1989, Bardin 1987, Gelijns 1991, Vemer and Bergink 1994). Notably, many of these public and nonprofit organizations are major players in the distribution and provision of contraceptives, especially to poor women in developing countries (Gelijns 1991, Zeldenrust, de Haan and Smit 1994). Ross and Frankenberg (1993) have estimated that ca. 80% of the contraceptive users worldwide are supplied by public sector programmes. This is the third reason why a focus on end-users' involvement in contraceptive development is especially important, according to Ellertson and Winikoff (1997). As compared to other consumer goods and even compared with other medical devices, contraceptive users have relatively little power to make their preferences known, not even by voting with their wallets. Contraceptives are often
donated to family-planning programmes. Decisions about which methods or brands to donate may be made for reasons unrelated to the end-users, such as the price, existing surpluses, or on political grounds. Among these political grounds are demographic concerns. Owing to this special institutional embeddedness, the involvement of end-users in contraceptive technology development requires special consideration. In addition, to label all these intermediary groups as users of medical technology might distract attention from the patients or end-users whose lives and well-being are very much affected by the medical treatment or therapy.

Since contraceptive methods are developed mostly by public agencies, the early and middle stages of the developmental trajectories are relatively open to scrutiny. In drug development by the pharmaceutical industry these stages are usually cloaked in with secrecy. Anti-fertility vaccines provide a particularly suitable occasion to study the ways in which users are implicated in the development of a novel contraceptive technology while it is still in the making. In the late 1980s and early 1990s, when women’s health advocates first learned about the development of these new methods, their introduction was still far away. Nonetheless, many women’s health groups were concerned about the development of anti-fertility vaccines. These groups also began to sense that the developmental trajectories preceding the introduction of contraceptive technologies needed further analysis. One major women’s health group in India stated: "First it was NET-EN [an injectable hormonal method, jvk], now it is Norplant and the next is going to be the anti-fertility vaccine (...) we have to stop reacting in a piecemeal fashion to every new method that is being introduced (...) [we have to] critically examine the research processes and methods (...)" (Forum for Women’s Health 1994, 40). The German women’s health advocate Judith Richter wrote: "This is a unique opportunity to take part in a scientific and socio-political discussion about a new contraceptive while it is still being developed, drawing from experiences with long-acting contraceptives, such as hormonal implants or injectables" (Richter 1993, 7). The involvement of women’s health advocates with anti-fertility vaccines development, in the same period when the contraceptive developers became committed to taking their concerns and those of potential users into account, makes this case especially interesting. Anti-fertility vaccine development was at the forefront of experimenting and learning about different ways to accomplish "the integration of users’ perspectives" into earlier stages of technological development.

The development of anti-fertility vaccines began in the 1970s. Unlike hormonal methods, the immunological mechanism of action causes temporal infertility by provoking the production of antibodies against substances necessary to human reproduction, such as certain hormones and molecules of the sperm and the ovum. About ten percent of the public funding available
for research on new contraceptives is spent on anti-fertility vaccines (WHO/HRP 1993). The researchers involved are located in various contraceptive research institutions, predominantly in India and the United States. Their activities are coordinated by the World Health Organization (WHO), the Indian National Institute of Immunology, the Population Council in the U.S, and the American National Institute for Child Health and Development/National Institutes of Health (NICHD/NIH), which sponsors a consortium of university-based research groups in the U.S. The research is supported by national and international public resources, and by philanthropical private foundations, most notably the Rockefeller Foundation (Richter 1996). Funding from the pharmaceutical industry for research on contraceptives in general, and for immunological methods in particular, is rather small. Research institutions do seek collaboration with pharmaceutical companies, especially at the time of phase II clinical trials when production needs to be scaled-up.

Those engaged in health care technology assessment and forecasting have much to learn from the case of immunocontraception development. Recently, Stuart Blume (1998) has signaled changes in the relations of patients and users vis-à-vis medical innovations. Influenced by demographic developments and the concomitant increasing prevalence of chronic and disabling conditions, patients increasingly organize and demand to be taken into account in decision-making processes surrounding the development and implementation of medical technologies. The role of the state in technology development has also changed, from a generally benevolent and distant posture to actively introducing new regulatory requirements and demanding proof of the need for new treatments. These changes affect both the medical innovation processes and the study of these processes. Therefore, Blume has argued, it is no longer sufficient to look at medical innovation through the eyes of scientists. According to Blume, health care technology assessment should no longer ignore the social and political issues, the multitude of actors involved, and the complexities that arise from the changing involvement of the state and the end-users. Many of the dynamics in anti-fertility vaccines development that I will discuss might be exemplary for these tendencies. The discussion by Arie Rip, Thomas Misa, and Johan Schot in their book Managing technology in society (1995) points in the same direction. These authors signal that most current assessments of medical technologies are done only after they are ready for introduction into clinical practice, or later. To be able to produce desirable technologies and positive impacts, design practices should be broadened. They suggest that "Realistic strategies for managing technology in society (...) must consider impacts already during the development of technology, involve users and other impacted communities, and a certain element of societal learning on how to coproduce technology and its
impacts" (1995, 5). In contraceptive technology development, precisely because it has been such a contested area, a number of initiatives have been undertaken to promote broader participation and dialogue on social aspects in earlier stages of technology development. Therefore, this study provides important insights into the effects of such endeavors upon technological development.

In the remainder of this introduction, I will first discuss the literature on users in Science and Technology Studies. In particular, I will outline the script approach, developed by the French sociologist Madeleine Akrich as an analytical tool to study user-technology relations. Subsequently, I will introduce my contributions to this approach, which I will elaborate in this thesis. And next I will describe the scope of this study and provide an overview of the following chapters.

2. Research on users in Science and Technology Studies

Users have become an area of mutual interest for both Science and Technology Studies and for Gender Studies. In recent years Science and Technology Studies have contributed convincingly to the view that technological development is a sociotechnical process (Bijker, Hughes and Pinch 1987, Law 1991). Technologies are constructed by actors with particular perspectives, at certain historical places and moments. In traditional approaches to technological development, technological innovations were thought to evolve linearly, automatically, and as if inevitably from advances in scientific knowledge. Social constructivist approaches emphasize the non-linear character of technological developments, and the agency of the people involved. Technologies are developed by actors who actively take decisions and make commitments towards some technological developments and not towards others. These actors also include the users, and many recent studies include an analysis of the roles of users. In particular, feminist Science and Technology scholars have suggested placing the end-users at the analytical center of their work. Initially this was proposed as a strategy to enhance the visibility of women’s contributions. The extent to which women had become invisible in technological development was succinctly summarized by the American historian Jan Zimmerman, who remarked that "Technology is everything that women don’t do" (Zimmerman 1986). According to the Dutch historian of technology Ruth Oldenziel (1995), the focus predominantly on the work of innovators and engineers in the design and production stages of high-tech, capital intensive technologies, and the relative neglect of studying end-users’ involvement in technological development has led to an unintended genderblindness in much of the work in Science and Technology Studies.
Many feminist authors have noticed that merely conforming to Bruno Latour's famous methodological adage to "follow the actors" (1979) may lead to following only the most powerful and visible actors (Star 1991, Fujimura 1991, Clarke and Montini 1993, Summerton 1996). Susan Leigh Star has called this "the executive approach" (Star 1991), and it has its gender implications as well. Star has signaled that such an approach negates the work of less visible actors, and reflects only one perspective among many. The work of "invisible actors" such as technicians, wives, and secretaries is obscured (Star 1991, Shapin 1989). These invisible actors also include "actors that are silenced but implicated" by the practices of the designers (Clarke and Montini 1993). The users of technologies are an outstanding example of such invisible but implicated actors. Aspiring to retrieve the users, Ruth Schwartz Cowan proposed that the analyst should study technological development from the users' point of view. In her programmatic 1987 article on The consumption junction: a proposal for research strategies in the sociology of technology, she argued that the success or failure of technological development depends to a large extent on a positive decision at the consumption junction, the place and the time at which the user does or does not employ the technology. Focussing on the consumption junction invites the analyst to think through the considerations of users and the contexts in which they adopt, modify, or reject a technology. Therefore, Schwartz Cowan suggested, this junction might provide an excellent strategic research site for understanding technological development.

The fruitfulness of such a user-centered approach to technological development was subsequently illustrated by various authors (Callon 1986 and 1987, Cockburn and Omrod 1993, Chabaud-Rychter 1994, Berg 1994 and 1996, Pinch and Kline 1996, Bergman and Frissen 1997, Lie and Sorensen 1996). Roger Silverstone and Eric Hirsch (1992) have coined the term "domestication of technology" to highlight the processes of cultural appropriation by which users make technologies meaningful in their everyday lives. Drawing upon the methods of history and anthropology, these authors examined various instances in which users were genuine co-producers of technological artifacts, in ways sometimes overlooked by previous analyses. For example, Ronald Kline and Trevor Pinch (1996) have described how rural people in the first half of the twentieth century in the United States were active participants in the social construction of the automobile. Farm men and women defined the car as more than a transport device; they saw it as a general source of power. These families used the car for many different purposes, such as running agricultural machinery, grinding, sawing, and pumping, and for powering washing machines. In the usage stage, they adapted the car and thereby became agents of technological change. Partly in response to these novel interpretations of the car, manufacturers developed
new artifacts such as tractors and pickup trucks. Kline and Pinch (1996) have demonstrated how the usefulness of the concept of interpretative flexibility can be extended to the usage stage. Interpretative flexibility is a core notion from the initially design-oriented Social Construction of Technology approach (Bijker and Pinch 1987). According to this approach, different social groups attribute different meanings to the same artifact. Therefore, what counts as a working artifact or what counts as a problem to be addressed is subject to different interpretations among different social groups. Also, certain meanings that specific social groups assign to an artifact can become embedded in new artifacts, and this process can help us understand technological development, as in the above-mentioned example of the car. Of course, not all flexible interpretations are consequential.

As Nelly Oudshoorn (1998) has noted, it is no coincidence that the role of users in the area of reproductive technologies such as contraceptives has become an important theme in feminist Science and Technology Studies. Many of us have our own histories of engagement with the women’s health movement, a node in the network that seems to be situated close to, and have a complicated relation to, Schwartz Cowan’s consumption junction. In addition, current contraceptive technologies have a special relevance to women’s health and lives. They are designed to prevent a condition that can be both intensely desired and profoundly resisted. Indeed, the analysis of users’ roles in the field of reproductive technologies has contributed greatly to our insight into the diverse ways in which users, far from being victims, incorporate these technologies into their understandings and adopt, modify, or reject them correspondingly (Hardon 1992, Franklin 1997, Saetnan 1997, Rapp 1998). One example of users acting as agents in the realm of reproductive technologies is the development of the so-called Yuzpe-regimen for fertility regulation. The Pill was designed to be taken daily as an oral contraceptive. Women in countries where abortion is not safely and legally available started to use the Pill improperly: post-coitally in a different dosage, as an emergency method of fertility regulation. The safety and efficacy of this use of the method was tested, and in 1995 experts on fertility regulation from around the world produced a consensus statement in which they encouraged this use of hormonal contraceptives (WHO/HRP 1996, 40-41). Thus, end-users put the Pill to an alternative use and thereby became co-producers of technology. In sum, studies of the domestication of technologies have confirmed that users as a social group engage in processes of attributing meaning and modifying technologies. There is a growing body of scholarship supporting the claim that users are a relevant social group that co-construct technologies in the usage stage.

The above-mentioned studies have analyzed the ways in which end-users in their encounters with technological artifacts adopt or reject them,
submit them to alternative uses, and insert them into frames of meaning that are radically different from those foreseen by the designers. But what about users’ involvement in the preceding stages of technological development? How can we study the involvement of users in the development of a technology that is not (yet) ready for use, such as anti-fertility vaccines? The Social Construction of Technology approach does not suffice for dealing with these questions. In a SCOT analysis, users come into view as a relevant social group only ex post. Other forms of involvement of users, for example the effect of ideas about the envisioned users in earlier stages of technological development, are not systematically included in such an analysis.

3. The script approach

The script approach, proposed by the French Science and Technology scholar Madeleine Akrich, seems very promising for studying other forms of users’ involvement (Akrich 1992, Akrich and Latour 1992, Akrich 1995). In her analyses, Akrich presents innovators as deeply interested in the future users of the developing technology from the very beginning. They inscribe their hypotheses about users into the technical content of the new artefact:

Designers thus define actors with specific tastes, competences, motives, aspirations, political prejudices, and the rest, and they assume that morality, technology, science, and economy will evolve in particular ways. A large part of the work of innovators is that of "inscribing" this vision of (or prediction about) the world in the technical content of the new object. I will call the endproduct of this work a "script" or "scenario" (Akrich 1992, 208).

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. Crucially for my purpose, these participants also include potential users. The designers’ projected users are anticipated in the script. Steven Woolgar (1991) has introduced the term "configuring the user" to indicate this process of defining the identities of potential users and setting constraints upon their likely future actions. In the realm of contraceptive technologies, Oudshoorn (1998) has analyzed one example of a script that assigns a specific position to the users: that of the hormonal implant Norplant®. This contraceptive consists of a number of small hormone-releasing rods that have to be implanted under the user’s skin by the means of a small operation by a trained health worker in aseptic circumstances. The same conditions are needed for removal of the
contraceptive. According to Oudshoorn, this form of administration entails a prescription for use that is incorporated in the artifact. The script of Norplant® enforces a specific relationship between the user and the health care provider, namely one of dependency. This example also nicely illustrates the simultaneously social and technical character of the links between users and technologies. The script approach allows one to analyze and describe the contraceptive method as both a constructed and an embedded technology and as a social phenomenon.

Akrich (1992) developed her approach by searching for a way to analyze the structuring action of technical objects that would be neither deterministic nor voluntaristic. If a set of prescriptions for use are solidified in a technical object, artifacts definitely may have politics that affect potential users. Of course, as Akrich (1992, 208) has noted, "it may be that no actors will come forward to play the roles envisaged by the designer. Or users may define quite different roles of their own". For example, Akrich (1992) has described how the photoelectric lighting kit was designed to provide cheap electricity and to work under all circumstances, without people interfering with and potentially damaging the kit. Therefore, the designers decided to make a kit with direct current, a standard length of wiring, watertight batteries, and nonstandard plugs. A specific role and responsibility was allocated to the users, namely not to tamper with the artifact. But in spite of this inscription, some users found ways to adapt or modify the kits. Another example that Akrich has described is the use of electricity meters in Ivory Coast. These were designed to control and measure the users’ consumption of electricity. But some users found ways to block the meters and to establish illicit connections. Another way of putting this is that not all electricity users matched the representations of users inscribed in the kit or in the meter (Akrich 1992). In such situations of mismatch between the foreseen users and the actual (non)users, the designers’ representations of users, solidified in the artefact by their design decisions, will become especially apparent. This enables the analyst to de-scribe the script. Another example of such "subversive use" is provided by Oudshoorn (1994). A contraceptive hormone prepare was developed in the 1950s. The prepare was marketed as a drug to stabilize irregular menstrual cycles. One of the side-effects mentioned in the package insert of these pills was that women would not ovulate when using these preparates. In practice the pills were soon prescribed and used as a contraceptive method. Thus, these users did not conform to the formal script of this technology. Characteristically, the extent to which the possible actions and relations of users were inscribed into the design became apparent in its use.

Clearly, the potential future users of anti-fertility vaccines exist in an infinite variety of social, cultural, and personal settings. Ruth Schwartz
Cowan has signaled that the fact that users "come in many different shapes and sizes [is] the single most worrisome complicating factor" (1987, 263) of focusing on users. And Akrich (1995, 174) has noticed that "(...) 'the user' is not a single entity taken on board when the project is launched, but a set of disparate characteristics which will not necessarily merge into a tight configuration ready to accommodate the definitive end-user". In what ways are representations of users constructed, and how do they come to bear upon technological development? Technology developers and their associates had to do a lot of - more or less visible - work to represent users in such a way that they can properly accomplish the function of guiding the innovators in the process of developing new technologies. Akrich (1995) has described different techniques by which representations of users are generated. She has distinguished explicit techniques, legitimized by a formal scientific and conceptual basis, from implicit techniques of a more empirical kind, lacking such a basis. Explicit techniques include marketing surveys, consumer testing, and feedback on experience through after-sales services. The less formal techniques that Akrich has described include: the designers' reliance on personal experience, the reliance on expert consultants, and the adoption or rejection of representations present in products considered to have something in common with the innovation at hand. These representation techniques produce a whole set of particular aspects of "users", each of which may or may not be displayed in specific situations. For the successful development of a new technology, these disparate representations should be combined and superimposed to achieve alignment. Akrich found three strategies that technology developers employ for the purpose of reconciling the various facets of users. The first is the strategy of delegating the reconciliation function to the artefact itself. This can be done by endowing the artefact with a number of features that would enable it to cope with different situations, expectations, and requirements of users. One variant of this is the 'range of products' strategy: developing a number of similar, but not identical, products tailored for a specific user type. In the area of family planning, this would equal the 'cafeteria approach': the differentiation of contraceptive methods offered to users. The second strategy that Akrich found was to delegate the reconciliation work to intermediaries, who then make the necessary adjustments between the technological system and disparate representations of users. An example of such intermediaries in the area of reproductive technology would be the service delivery system or the providers of family planning. This happens, for example, when health care providers instruct and counsel the visitors of family-planning clinics on how to use condoms. In this way methods and users are brought together. The third strategy that Akrich describes is partly to omit the need for reconciliation by creating a new user together with the new technology. One example is the prescription of hor-
effective in medical technology development, as illustrated by the Dutch physician and philosopher Rein Vos in his book with the telling title Drugs looking for diseases (Vos 1991). Vos developed a model for understanding drugs development in which he highlights the importance of medical practices. According to Vos, drugs development can be conceived as a process of rapprochement between profiles of drugs on the one hand and profiles of diseases on the other. Vos does not point out the eventual role of representations of users in drugs development or in medical practices. Paraphrasing Vos, Akrich’s third strategy would be that of drugs (or medical technologies) looking for users.

In sum, the script approach assigns an important role to the representations of future users, the implicit and explicit images of prospective users held by the developers of a technology. The studies of Akrich (1992, 1995) make very clear that a range of different user representations are produced in designing a technology, and that these representations have to be made compatible in the course of the developmental process. In order to study the making of the script, the analyst has to elucidate what these representations look like, and examine how they are inscribed. In other words, the approach does indeed provide me with methodological tools to study the ways in which representations of users are involved throughout the technological development process. Other scholars who have adopted Akrich’s script approach and confirmed its appropriateness for studying interactions between users and technology include Nelly Oudshoorn (1996), Margo Brouns (1998), Marta Kirejczyk (1999), Els Rommes (1999), Jelsma and Popkema (1998) and Jaap Jelsma (1999), and Anne Jorum Berg (1996). However, using this approach is not sufficient for answering my research questions. Akrich does not analyze how some specific representations of users become more powerful than others in certain circumstances. Insight into this last issue is important in the light of my research question about the possibilities and limitations for changing the ways in which users are actually integrated into contraceptive technology development. In addition, problematic scripts are identified only once a technology was already being implemented. Might it not be possible to study the script set out by the designers before it is acted out? Could the inscription of representations of users be influenced at earlier stages of technology development? In the following paragraph I propose two extensions to the script approach that enable me to address these issues.
4. Extensions to the script approach

4.1 The embeddedness of representations

Why were certain representations of future users of anti-fertility vaccines adopted while others were excluded? And why did certain representations persist while others disappeared? These are important questions for understanding the development of immunocontraceptives, and for a perspective on change. Representations of users are not free-floating entities hovering above the real world. The ability of researchers to generate representations of users and to integrate these into their technical choices is not merely contingent. The material and political specificities of research practices both enable and constrain the range of possible configurations of users. Representations of users are produced and reproduced in specific historical situations, that have evolved over years of doing reproductive science. Nelly Oudshoorn (1991, 1994) has investigated the search for male and female sex hormones and the development of the Pill. She has analyzed how the availability of research methods and materials for female sex hormones, and the existence of a powerful institutional context of gynecological clinics to care for the reproductive functions of the female body, resulted in the making of hormonal drugs for women and not for men. Oudshoorn has called this "the power of structures that already exist" (1994, 138-151). Pre-existing power structures also have a cognitive dimension. For example, Oudshoorn (1991) has argued that the conceptualization of certain hormones as male or female sex hormones echoed common-sense notions on masculinity and femininity, and conformed to pre-scientific ideas about the localization of sex in the testis and the ovaries. This dualistic categorization was by no means self-evident. Oudshoorn has shown the uncertainties scientists faced in trying to bring their experimental findings, such as the discovery of oestrogenic hormones in the urine of stallion and ovaries secreting male hormone, into line with their ideas concerning sexual duality. Many studies confirm that gender has been a remarkably persistent feature of such pre-existing structures (van der Ploeg 1998, Brouns 1998). The American sociologist Adele Clarke has also noted, in her comprehensive cultural history of the reproductive sciences in twentieth-century America, that earlier occurrences delineate the possibilities for future developments in the field. The availability of laboratory techniques, the structure of the funding of the field, and the strength of social movements such as the birth control movement and the eugenics movement, turned out to have definite consequences, and to be deeply gendered. The development of the reproductive sciences was also culturally prestructured by the "controversial status" of the discipline, due to its association with sexuality (Clarke 1998). These pre-existing power-structures not only co-produce specific
technological developments; they also affect the cultural construction of user representations and the likelihood of their alignment. The researchers' room for manoeuvre is constituted by factors including earlier choices, the availability of research material, institutional constellations, the political climate, and cognitive notions.

For a perspective on change, it is therefore necessary to include a detailed analysis of the room for manoeuvre in which certain representations of users are conceivable, and in which they come to bear upon technological development (van Kammen 1999). The reproductive researchers involved in anti-fertility vaccine development did not start from scratch. One should examine where certain representations came from, who articulated them, and under what circumstances. Such an analysis, in addition, will shed light upon representations of users that were not adopted, and on path for technological development that were not taken. Indeed, it will elucidate how "things could have been otherwise" (Star 1991), or not. For example, when the initial research programme for immunocontraception was set up, the development of such a brand-new approach to fertility regulation promised to be a lengthy, expensive, and uncertain process. The contraceptive developers therefore had urgently to agree on a proper definition of the problems to be addressed. Not all representations of future users were equally adequate for this purpose. What kinds of representations of users were suitable for making immunocontraception into a "doable research problem" (Fujimura 1987), and what kind of representations were not? Answering these questions requires a detailed account of who was entitled to bring representations to the fore, what these representations looked like, and where they originated. Another striking feature of immunocontraceptives is that, according to the researchers involved, they could be developed for both men and women. But representations of male users have faded, and most current research involves the development of methods to be used by women. Why? To explain this phenomenon requires an analysis of the material and political contexts in which the contraceptive developers took their decisions. These questions are addressed in this thesis.

Although the script approach has the potential to address the questions I just raised, Akrich does not take these issues into account. To be sure, Akrich (1995) has indeed observed that not all representations of users are of equal force, and that different ways of generating representations of users correspond to different circumstances; but she has not stipulated how the specificities of particular circumstances produce and reproduce certain representations. She has enlisted various strategies for achieving the alignment of divergent representations, but does little to explain what makes them succeed or fail. She concludes with the recommendation that
To strengthen the design process by incorporating a multiplicity of user representations, the main challenge is to coordinate the application of the various methods and reconcile their results (Akrich 1995, 182).

This conclusion leaves open the question of who is to do this coordination, what situates the reconciliation work, and what differences might be involved. In the contested field of contraceptive technology development, these are capital issues.

4.2 Who is allowed to represent users?

The other extension to the script approach that I propose responds to the wish to make explicit the representations of users inscribed in a developing technology before it is put into use. Madeleine Akrich (1992) has developed the concept of script by studying technologies after they were already in use. In such a situation we can follow Akrich’s methodological recommendation to trace the negotiations between the innovators and potential users, and

(...) to go back and forth continually between the designer and the user, between the designer’s projected user and the real user, between the world inscribed in the object and the world described by its displacement (Akrich 1992, 209).

As noted before, in earlier studies it was especially in situations of divergence between the projected users and the real users that the representations of users inscribed in the script became apparent. Does this mean that we have to wait until technologies go awry in their use before we can discern a script for users? That would seriously foil the practicality of the concept, but fortunately this is not the case. Akrich (1995) has also brought to the fore her view of the importance of users in the debate on Constructive Technology Assessment. CTA aims to develop instruments for managing technological change in its interaction with society. Akrich’s advice to people engaged in forecasting is that they should try to obtain an overview of the array of already existing user representations in order to assess their coherency. She also points to the role of CTA "to find ways of ensuring that certain user representations - which would otherwise not be considered by the innovators and entrepreneurs - are taken into account" (1995, 183). But how can this be done? How can we learn about the prevailing representations of users before they are inscribed in the script, and before the script is performed? In this book I seek to demonstrate that evolving scripts can indeed be made explicit in earlier stages by contrasting the representations of users of the involved scientists with those of other actors concerned in technology development. In
anti-fertility vaccine development, the international women’s health movement provided me with a suitable contrast-point. Since the late 1980s, members of women’s health groups have become actively involved with anti-fertility vaccines. Women’s health advocates are a diverse group of individuals, organizations, and informal groups all over the world who share the common goal of empowering women to control their own fertility and sexuality with maximum choice and minimum health problems, by providing information and alternative services, and by campaigning for a woman’s right to make informed choices about her fertility, for improved services, and for appropriate technologies (WHO/HRP/ITT 1991, 6, Hardon 1992). By sharing "commitments to certain activities and sharing resources of many kinds to achieve their goals" they compose a social world (Clarke 1990, 190). Of course, the experiences and perspectives of both the reproductive scientists and the international women’s health advocates vary widely. No monolithic women’s health advocates’ perspective exists nor does that of reproductive scientists as a whole. At the same time, however, the situated knowledges (Haraway 1991) of the women’s health advocates and the reproductive scientists are sufficiently different to render comparison fruitful.

The women’s health advocates do not claim to be able to speak in the name of users, nor are they expected to do so by the contraceptive developers; yet they do claim to be entitled to a voice in contraceptive development. In chapter three I explain how women’s health advocates acquired this political position in contraceptive development, and how their status remains contested. Their contribution has been justified on the basis of a mixture of normative and instrumental arguments, claiming e.g. that listening to different voices was good in itself, and that it would help to better identify the needs of users. The relation of this social movement to contraceptive development is comparable to the involvement of the AIDS movement in the United States in the development of new treatments, as analyzed by the American sociologist Steven Epstein (1995). In his study, AIDS activists ceased to be "real users" in their own eyes and in those of the biomedical researchers, as soon as they acquired the language of the experts and gained access to the relevant institutions. At the same time, they gained recognition as political representatives of people with HIV/AIDS. Members of women’s health groups have also gained credibility to voice their perspectives on contraceptive users in their encounters with reproductive scientists. This contact makes such social movements particularly interesting for elucidating scripts in the making. Instead of studying the negotiations between the innovators and the potential users, 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 would look like.
Actor-network theorists such as Bruno Latour (1987) do not distinguish between the political and the semiotic meaning of a given representation. This is helpful to illuminate the ever political sense of signs, things, and people speaking and acting on behalf of signs, things, and people. While recognizing the potential politics of any of these relations, I want to be more careful by not assuming beforehand that these relations involve the same types of politics and the same kinds of representations.\(^6\) One crucial difference between representations of users in a semiotic sense, and political representatives of users, is that the latter are endowed with human agency. Unlike the illustrations and descriptions of users in the texts of contraceptive developers and women’s health advocates, or a biochemical substance in a tube that might cause temporal infertility, the members of the women’s health movement can literally talk back to the scientists. Moreover, these human agents are endowed with intentionality and the ability to make choices, and they are fully accountable for their role as political actors. It is on this basis that they engage in negotiations with the contraceptive developers, and thus I can compare their notions about potential users with those of the contraceptive developers.

Akrich’s analyses (1992, 1995) have concentrated on the designers who inscribe their representations of users into technologies. She does not explore the role of user representations of other social groups in the design of technologies.\(^7\) This is a pity, both for theoretical and for political reasons: theoretically, because Akrich’s emphasis on the ways in which images of future users mediate in technological development offers a promising means to gain insight into the creation of successful and unsuccessful artifacts, and to study the politics embedded in a given script. Social movements concerned about technological developments also construct representations of future users of these technologies, and perhaps these representations can also be integrated into technological designs. The political relevance of including women’s health advocates in the analysis lies further in the normative project of formulating ways to steer technology development with the participation of all the various actors involved.

There is another group of actors with a seemingly ambiguous status vis-à-vis the process of representing future users: clinical trial participants. In clinical research, the safety and efficacy of the potential method is tested in humans. The participants in the clinical tests are the first embodied agents who are actually injected with an anti-fertility vaccine. The clinical testing of immunocontraceptives provides me with another opportunity to study an evolving script before the method is introduced. Clinical trial participants "represent" users in two ways: in a statistical sense and as embodied agents. In this latter role, they can act as co-producers: just like real users, they possess agency. These ‘test-users’ may adopt, modify, or reject the technology,
or assign meanings to it that no one has anticipated. In addition, the results produced in clinical trials are meant to be generalizable for future users, but the carefully selected participants by definition differ from these future users. The effects of this inherent dilemma in testing on the configuration of future users has been described by Woolgar (1991). Woolgar has examined usability trials with a new type of microcomputer, meant to assess the responses of potential users. Company employees typically thought of real users as "others", as "outsiders", and as unknowable entities. People participating in the trials were, by the mere fact that they were trial subjects, no real users. This same dilemma is the subject of ongoing discussions among clinical researchers, biostatisticians, social scientists, and policy makers (Hansen and Launso 1989, Sherman, Temple and Merkatz 1995, Meinert 1995, Heise, McGrory and Wood 1999). In these debates, the issue becomes how the researchers in anti-fertility vaccines development constructed the clinical trial participants so as to represent the future users. How did their configuration work affect the development of the script of the contraceptive? Also, given the potential agency of the test-users, it is interesting to see what we can learn from their encounters with the foreseen users inscribed in the anti-fertility vaccines. Clinical testing thus provides yet another occasion in which evolving scripts may be distinguished early on.

5. The scope of this study

My approach also has its limitations. I have not been able to study actual end-users of anti-fertility vaccines, persons who potentially will be injected with preparations designed to regulate their fertility. No opportunity existed to examine what the technology might have meant to them, or how they might have incorporated it into their lives, or not. As I have explained, awaiting the introduction of a new contraceptive technology is not always the best option if we want to influence the course of its development. If representations of users are inscribed in a technology from the beginning, there are good reasons for users and their political representatives to try to have a say in technology development over its entire life cycle. This requires additional analytical tools. My analysis of these inscription processes with their constraints and possibilities, and the extensions to the script approach that I propose, might be helpful in meeting this need. If anti-fertility vaccines development had already reached the stage of implementation, I would have had the opportunity to study real end-users, e.g. by attending consultations at family planning clinics or by interviewing them about their use of the method. This would have been very interesting, and certainly may be a subject for further investigation. Examination of the unfolding of the script of
anti-fertility vaccines in the context of actual use would have enabled me to compare these dynamics with the processes of inscription. Examples of research that do include an analysis of both the inscription of representations of users by the designers, and the subsequent domestication of the technology by real users are provided by Akrich (1992, 1995) and by Rommes, Van Oost and Oudshoorn (1999). My study focuses instead on the making of the script, the processes of inscription. In order to gain insight into the mutual construction of the technology and its users at this stage, I proposed to use additional contrast points, and to examine the room for manoeuvre of different actors to construct and integrate their particular notions of future users.

Where can representations of users be found? I examined the texts of scientists, policy-makers, and women’s health advocates. My analysis is based on more than 100 articles published in major scientific journals such as the American Journal of Reproductive Immunology, Fertility and Sterility, and Human Reproduction, which report on the identification and selection of candidate antigens, animal studies, and clinical work in anti-fertility vaccine development. These articles were identified by a Medline search for the period 1975 to 1995 using the key words "vaccine", "fertility", and "immunoccontraceptive", as well as the names of authors. In addition, I have read some of the key references in the early phases of anti-fertility vaccine development. I also analyzed policy documents from organizations and institutes that conduct contraceptive research (WHO, the Population Council, the Indian National Institute of Immunology, and the National Institutes of Health), and minutes of the meetings of steering committees that hold an intermediate position between science and policy. In particular, I analyzed the policy documents on the integration of users’ perspectives and the reports of encounters between scientists and women’s health advocates. I collected and analyzed many of the relevant documents accompanying the clinical research, such as protocols, information brochures, and consent forms. In addition, I interviewed the principal researchers involved from the United States and from India, policy makers at the WHO and the Population Council, and a number of international women’s health advocates.

6. Outline of the thesis

The chapters in this book follow the developmental trajectories of anti-fertility vaccines. Anti-fertility vaccine development started in the early 1970s, when the concept of immunological approaches to fertility regulation became articulated in an initial research programme. Chapter 1 is about this agenda-setting stage. In order to develop a research programme, agreement had to be reached about a doable research problem (Fujimura 1987). I
describe who was entitled to bring representations of future users to the fore, and examined what their content. The actors involved believed that these potential methods would suit everybody in any context. This outcome was not as politically neutral as it might appear at first sight. It reflected the impossibility of the contraceptive developers to deal with diversity and with contextualized representations of users. This representation of future users as everybody in any context cleared the way for the forces of habit. In chapter 2 I analyze the selection of biochemical substances that were considered suitable for the development of anti-fertility vaccines. In spite of the scientists’ claims that anti-fertility vaccines could be developed for either males or females, the representation of men as future users became less dominant than representations of female users. I argue that the remaking of women’s bodies as the site of contraception was enabled and constrained by specific material and political factors. Of central importance from a perspective on change, I explore the circumstances under which the contraceptive developers could diverge from the beaten track and develop an anti-fertility vaccine for men. In the following chapter, I examine how the main design characteristics of anti-fertility vaccines evolved. The contraceptive developers aimed to develop a long-acting, easy to administer injectable method. Members of women’s health groups were concerned about the potential for abuse of anti-fertility vaccines, and disputed the proposed product profile. I distinguish the mechanisms that define the limitations and possibilities for taking into account such alternative perspectives on the developing technology. Chapter 4 is about the testing of the safety and efficacy of the new method in clinical trials. I study under what conditions and with what consequences clinical trial participants were selected, and examine the ways in which they were to represent the future users of anti-fertility vaccines. I also analyze when agency is ascribed to clinical trial participants, and the extent to which the agency of clinical trial participants affects the testing. In the Conclusions, I summarize the highlights of my findings and suggest possible broader implications.
Notes by the Introduction

1. See for example the President’s message of the Population Council’s annual report with the telling title "Contraceptive development and introduction with user satisfaction in mind: twenty years of learning." (Population Council 1990), and the WHO/HRP discussion paper "Perspectives on fertility regulation: past and present work by the Special Programme and other agencies." (WHO/HRP 1995). See also Talwar (1994), Griffin, Jones and Stevens (1994), and Call for a Stop (1993).

2. See also Von Hippel (1988) for an identification of areas where the separation between developers and users is relatively unclear.

3. According to Mastroianni, Donaldson, and Kane (1990), thirteen large pharmaceutical firms became involved in contraceptive research and development in the 1960s. At present, only Ortho and Wyeth-Ayerst in the United States, and three large European companies, Schering AG, Organon and Roussel Uclaf, have substantial contraceptive research and development programmes. Syntex, Searle, Parke-Davis, Upjohn, Mead Johnson, Eli-Lily, and Merck, Sharpe & Dohme have all abandoned new contraceptive research. There are several reasons for the fact that there are so few large companies left to work on contraceptive innovation. The Program for Appropriate Technology in Health, an international nonprofit health research organization, carried out a survey among executives of fourteen drug companies. These businessmen believed that the market was well served by the current contraceptives. According to the report, industry has determined that it can spend fewer resources and achieve greater profit by modifying existing contraceptive products than by developing new contraceptives. Product modifications are often given the same patent protection as new products. Industry also worries about product liability, regulatory demands, and the high costs and long time needed to develop new contraceptives. In comparison to drugs taken for acute diseases, regulatory requirements are more stringent for compounds that are meant to be used by healthy persons for 15-25 years of their lives. U.S. executives believed that contraceptive vaccines pose special liability and regulatory challenges, since they are both a vaccine and a contraceptive, the two riskiest products for a pharmaceutical manufacturer in that country (PATH 1993, Service 1994).


6. A similar critique has been voiced by Amsterdamska (1990).

7. See also Oudshoorn (1998) about the role that representations of users by journalists play in technological innovation.

8. Statistically spoken, the selected participants in clinical trials embody the dilemma between the internal and the external validity of the testing.