

Negotiating safety and acceptability of new contraceptive technologies

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Dit artikel beschrijft hoe een mondiaal netwerk van "women's health advocates", waarvan de auteur deel uitmaakte, een adviseursrol voor zichzelf in de ontwikkeling van nieuwe contraceptieve technologieën wist te verkrijgen. Het artikel analyseert de wijzen waarop het netwerk kwesties van rechten en veiligheid inkaderde en hoe het netwerk wees op de mogelijkheid van misbruik van twee nieuwe langwerkende contraceptieve technologieën, Norplant en de anti-vruchtbaarheidsvaccinaties. De auteur kijkt terug op haar wisselende rollen in deze controversies. Aanvankelijk, in de Norplant-controversie, was haar voornaamste doel de gezaghebbende medisch-demografische arena die in de ontwikkeling van de technologie was betrokken, te confronteren met de ervaringen van vrouwen, die vanwege machtsverschillen tussen gezondheidswerkers en patiënten moeilijk toegang tot gezondheidszorg hadden. Bias en blinde vlekken in de mainstream wetenschappen werden bekritiseerd. In de anti-vruchtbaarheids controversie, begon ze in te zien dat beide partijen heteroog waren en waren betrokken in een verscheidenheid aan gezichtspunten en belangen. Dit besef leidde tot een nieuwe vorm van betrokkenheid, die van constructieve samenwerking waarin de auteur zocht naar manieren waarop in het proces van ontwikkeling van nieuwe technologie de werkelijke gebruikers van de technologieën nauwer betrokken konden worden in het vaststellen van de parameters van de technologie, het introductie draaiboek.

[script, reproductieve technologie, antropologie van het lichaam, advocacy]

Introduction

While many patient movements advocate for the introduction of new technologies, this paper describes how a global network of women's health advocates, in which I participated, contested and negotiated an advisory role for itself in the development of new contraceptive technologies. As a medical anthropologist my aim in the movement has been to give voices to users of contraceptive technologies, and to find ways for these users to influence the process of contraceptive development and testing. This role changes over time, a process that I reflect on in the conclusion.

Contraceptive technologies, like any technology, are inscribed during their development with cultural values and ideas about their future use. The new long-acting

contraceptives, which we contested, were developed out of a frustration with *user-failure* among contraceptive pill users. The contraceptive pill, which entered the market in the 1960s was designed as an instrument which would liberate sexually active women from the risk of pregnancy. However, it soon became clear that non-compliance with the pill's daily regime is high. Women forget to take the pill, use it only when they have sex, or use it in large quantities as an alleged abortifacient. Moreover, many stop using it altogether because of perceived adverse effects such as weight gain and headaches (Hardon 1997a). Concerned with rapid population growth, planners saw the need to develop more 'effective' forms of contraception (Hardon 1992). In developing long-acting implants and vaccines, researchers aimed to improve compliance and contribute to a reduction of fertility rates. Rather than delegating use of the contraceptive to women, they assigned healthcare professionals the role of administrator of the long-acting methods. It was this medicalization that the women's health advocacy movement opposed.

Adopting the view that technological innovation requires a renegotiation of gender relations and the articulation and performance of gender identities, Dutch and Norwegian researchers have introduced the concept of gender scripts (Berg & Lie 1993; Oudshoorn et al. 2002). The controversies surrounding the longer-acting hormonal methods can be conceptualised as contestations concerning such gender scripts. In the women's health advocacy movement, we specifically challenged the power granted to family planning providers. We also questioned the claims of scientists concerning the safety of the artifacts. We did not trust that biomedical researchers would adequately address possible adverse effects of the technologies for women's health, fearing that they would give precedence to effectiveness, at the expense of safety.

This paper describes how we contested the gender scripts of Norplant and anti-fertility vaccines, and how these contestations affected the process of technology development and introduction. Interestingly, the women's health movement was internally divided. One strand, concerned about the disempowering scripts of the technologies, aimed to stop the introduction of Norplant and halt research on anti-fertility vaccines; other alliances with whom I identified, were more inclined to enter into a dialogue with scientists, aiming to change the scripts of the technologies towards more empowering ones. Before describing in more detail the controversies surrounding long-acting provider-dependent contraceptives let me describe in some detail the origins of the women's health movement and its characteristics, to help explain its influence on technology development.

The women's health movement: origins and characteristics

The women's health advocacy movement is a broad movement with a variety of roots. The movement includes radical feminist groups calling for abortion rights, women's health organisations opposing medicalisation of women's reproductive functions, community-based health groups, feminist researchers and journalists. Women's health advocates would generally agree that they share a goal of empowering women to con-

trol their own fertility and sexuality with maximum choice and minimum health problems. They also have a common skepticism towards medical claims about the safety of the contraceptive technologies.

In the industrialised world, the movement finds its origins in second wave feminist movements,¹ which in the late 60s and early 70s rallied around the right to contraception and abortion and to express a growing concern about patriarchal control in medicine. Free contraception and abortion on demand were seen to be keystones of women's liberation (Berer 1997). An important global event on this theme was the first International Conference on Women and Health held in 1977 in Rome. At this meeting a broad range of women's health issues, including breastfeeding, maternal mortality and environmental health hazards were discussed. This meeting and subsequent ones were the beginnings of international networking around women's health concerns. They allowed for activist women to meet and exchange experiences and views, inspire each others' national campaigns, and create the basis for common global initiatives (Ravindran 1997).

In 1980 the *International Contraception, Abortion, and Sterilization Campaign: Women Decide!* (ICASC) was launched (Berer 1997). The members of ICASC in 1980 included feminist groups and networks in Europe, Latin America and the Caribbean, Africa, North America, India, Australia and New Zealand (ICASC 1980). ICASC became a platform for international solidarity and networking. It called for support of national-level campaigns demanding free access to contraceptive services (in Peru), and against unethical abortion trials (in Brazil). It also disseminated information on campaigns against reproductive technologies that are hazardous to women's health.

ICASC organised the fourth International Women and Health Meeting in Amsterdam in 1984; this changed the tone of international women's health activism. This meeting had as its slogan 'Population Control – No Women Decide!' It was there that the language for reproductive rights became international. The meeting challenged the rationale on which population programs aimed at reducing fertility in developing countries were based – namely, that limiting family size as a societal responsibility has precedence over individual well-being and individual right (Hartmann 1995; Garcia-Moreno & Claro 1994). Many of the Third World women attending the meeting said that a network whose name included the word abortion was too controversial for them to join. It was agreed that ICASC would change its name to the Women's Global Network on Reproductive Rights (WGNRR).²

By framing their concerns in relation to reproductive rights, the women's health advocates had found an oppositional collective identity and a powerful counterdiscourse to that of 'population control' – as defined by the World Population Plan of Action (WPPA) and adopted at the 1974 Conference on Population and Development in Bucharest, and the subsequent 1984 International Conference on Population held in Mexico City. The WPPA defined high fertility rates as a main cause of underdevelopment, and family planning directed towards married women in the South as an effective solution (Boland et al. 1994), setting targets for fertility decline. The women's health advocates argued that targets for fertility decline violated women's reproductive rights.

In the second half of the 1980s, the global women's health movement gained momentum. Issues of concern relating to contraception were the adverse effects of the Dalkon Shield (which led to litigation against its manufacturer, and a successful claim for compensation), the distribution of the hormonal injectable, Depo Provera, in family planning programs in the South, at a time the technology was still not approved for distribution in the United States, and the safety of the new long-acting hormonal implant Norplant (Hardon 1992).

The DES scare had led to worries about the possible long-term effects of these hormonal methods. Women's health advocates preferred methods that could be used by women and men without the interference of health professionals, and had no systemic effects, i.e. condoms and diaphragms. An important argument was that contraceptives are taken by healthy women: this alters the risk-benefit assessment as compared to medicines taken by sick people with an aim of restoring health. Thus both the anti-medicalisation and the anti-population control roots of the movement framed the issues raised about new contraceptive technologies.

By 1994, the women's health movement had become a strong global movement with several transnational advocacy networks. The WGNRR had doubled from 800 members and newsletter subscribers in 1988 to 1,655 in 1992. Its membership spanned 113 countries, more than half from the South. The Latin American and Caribbean Women's Health Network, created in 1984 by approximately 30 groups and individuals, had a contact list of more than 2,000 individuals and groups in Southern countries by 1992. And about 150 organisations in Asia had women's health on their agendas. In Africa, the organised women's health movement was relatively slow to develop. (Garcia-Moreno & Claro 1994). Most countries worldwide were reported to have at least some individuals and organisations that considered themselves women's health advocates.

In the Netherlands I was active in the Women and Pharmaceuticals Project of WEMOS, which we set up in 1983 prior to the 4th International Women and Health Meeting in Amsterdam. The project in 1990 split away from WEMOS as the Women's Health Action Foundation. I was involved in these women's health organizations first as a volunteer, then as a part-time research coordinator, and now as a board member.

The various transnational women's health networks mobilised their forces for the 1994 International Conference on Population and Development. One of the campaigns leading up to the Conference was the formulation and collection of signatories to the *Women's Declaration on Population Policies* which rephrased reproductive rights to give women primacy in decisions on fertility:

Women have the individual right and social responsibility to decide, whether, how, and when to have children and how many to have; no woman can be compelled to bear a child or be prevented from doing so against her will (Germain et al. 1994: 31).

At the 1994 Conference on Population and Development, the global population policy framework was radically changed. Population control was no longer center stage and fertility reduction targets were abandoned. Reproductive health was defined as:

a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are the rights of men and women to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for the regulation of fertility which are not against the law, and the right of access to appropriate health care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant. In line with the above definition of reproductive health, reproductive health care is defined as the constellation of methods, techniques and services that contribute to reproductive health and well-being by preventing and solving reproductive health problems. It also includes sexual health, the purpose of which is the enhancement of life and personal relations, and not merely counselling and care related to reproduction and sexually transmitted diseases, (ICPD *Programme of Action*, paragraph 7.2, United Nations 1994).

Despite solidarity in campaigning for reproductive rights of individual women of all ages, the global movement was increasingly divided on matters concerning access to fertility regulation methods and safety and acceptability of contraceptive technologies. Advocates called for greater choice of methods and individual rights to choose between them. Other more radically feminist groups held a basic distrust about the motives of their governments and opposed all forms of contraceptive technologies, such as Norplant and anti-fertility vaccines that could be used by states to achieve population control targets. Against this background, let us now turn to the Norplant and anti-fertility vaccine case studies which focus (1) on the ways in which we as women's health advocates contested the technologies; (2) describe how the scientists responded; and (3) show how the Norplant and anti-fertility vaccine scripts changed. To describe the controversies, I have studied the campaign materials and other texts from women's health advocacy groups including the correspondence with research institutions. Where I have participated in meetings as an advocate, I mention this in the text, and I elucidate my position within the movement on key issues such as the call to ban Norplant.³ Throughout the controversies I held a position at the University of Amsterdam as medical anthropologist. I have remained involved in health-related activism, always balancing the roles of activist and the reflexivity involved in research. In the conclusion of this paper I reflect on the balancing act.

Norplant contestations

Norplant is a hormonal contraceptive, consisting of five levonorgestrel-releasing rods. After surgical insertion in a woman's upper arm, it works for a period of five years. Women's health groups in Bangladesh, Thailand and Brazil became aware of this new technology when the New York-based Population Council (with funding from the US

government and private foundations) began a global program of multi-center clinical and acceptability trials, involving 44 developing and developed countries in the early 1980s (Correa 1994). At the national level, the women's health groups were initially concerned with unethical trial conduct. At the 1984 International Women's Health Meeting in Amsterdam, women's health advocates working for UBINIG in Bangladesh, for example, reported how women were recruited to participate in the trials by means of unethical advertisements, such as the one reprinted here (published in *Holiday Weekly* 1981):

A new birth control method

NORPLANT

A wonderful innovation of modern science

- * This method is for women
- * Norplant can be implanted under the skin of the arm
- * It will ensure sterility for 5 years
- * When removed, a woman can have a child again

Get more information from:

Bangladesh Fertility Research Programme
3/7, Asad Avenue (1st Floor) Mohammadpur, Dhaka

Family planning workers in Bangladesh reportedly said that Norplant would bring women happiness and they discredited other methods (Akhter 1995) Mobilised by UBINIG a petition was sent to the Ministry of Health signed by 150 concerned health workers. The trial was postponed. In Brazil, also, as a result of irregularities in trial conduct and protests from women's health advocates the trials were stopped. There was specific concern about failures in informed consent procedures (Correa 1994).

From national concern to global campaign

In 1989, women's health activists from Bangladesh, Brazil, India, Indonesia, Thailand, Denmark, Finland and The Netherlands met to discuss new contraceptive technologies, at a seminar sponsored by the Women and Pharmaceutical Project (Mintzes et al. 1993), for which I worked at the time as a part-time researcher. Irregularities in the introduction of Norplant were the main concern at the meeting. For the Women and Pharmaceuticals project I had reviewed the clinical evidence on Norplant. I wrote about conflicting views and safety and acceptability of Norplant. I saw as a basic failure of studies conducted on Norplant that they did not consider people's own ideas about reproductive physiology. I was concerned that so little had been written about the

consequences of the menstrual disturbances associated with Norplant in day to day life. I cited anthropological research that suggests that the consequences can be far-reaching. Menstruation is an important event in any woman's life. Delay or absence of menstruation is considered unhealthy in many societies; irregular menstruation is unclean and bad for one's health. In addition I pointed to the need to consider how the technology affects the user-provider relationship, commenting that the trials testing Norplant did not look into this issue. Especially the reported removal problems in my view had to be viewed within a framework of power-relations and diverging interest (Hardon 1993). Participants at the meeting from Indonesia, Bangladesh and Brazil shared these concerns. We decided to do field studies to learn more about the way in which Norplant was being introduced in different countries and to interview Norplant users about their experiences with the new method.

Collecting evidence on problems in practice

I coordinated the field studies which were conducted from 1989-1991 with support from the Dutch Agency for Development Cooperation. The findings of the studies were published in the book *Norplant: under her skin* (Mintzes et al. 1993). The collaborating action-researchers had found that women who suffered from menstrual bleeding in Finland and Indonesia were given estrogens or Vitamin K. We considered these inappropriate, arguing that these were *ad hoc* treatments using pharmaceuticals for purposes for which they had never been tested and a further medicalisation of healthy women following Norplant use.

The field studies also showed that in Indonesia, Thailand and Brazil women had difficulty in having Norplant removed. In some cases removal was refused by health workers. In other cases, the removal process itself was difficult, because of incorrect insertion and/or the breaking of rods during removal. Based on these field studies, the Women's Health Action Foundation (WHAF), which had emerged out of the Women and Pharmaceutical project, defined conditions that would need to be met for the method to be used safely. These included:

- 1 The recognition of women's reproductive rights in the provision of Norplant, specifically the need to provide women with a choice of methods, and informed consent when choosing for Norplant insertion;
- 2 The need to avoid medicalisation of side effects;
- 3 The need to consider the effects of menstrual disturbances on women's day-to-day lives;
- 4 The need for sterile administration;
- 5 The need for access to safe removal services;
- 6 Adequate follow-up care, and;
- 7 Appropriate provision of information in the media.

We did not call for a ban on introducing the methods, but rather engaged in a dialogue with the World Health Organization (WHO) and the Population Council on the need for good quality of care in providing the methods. We chose to confront the potentially

disempowering script of the technology by formulating guidelines for its actual use. Our attention shifted from the hardware, to the software – the arrangements through which the technology is made available. Good quality care, in our view, could enable users to select the contraceptive technology which best fit their day-to-day lives.

Creating common ground: an opportunity for dialogue

Responding to the growing concern among women's health advocates on contraceptive technologies, the WHO's Human Reproduction Program (HRP) organised a meeting with women's health advocates – 'Women's Perspectives on the Selection and Introduction of New Fertility Regulation Technologies' (WHO 1991) which I attended as a women's health advocate. In his introduction, the (newly appointed) director of the programme, Mahmoud Fathalla said:

the primary purpose is for the scientists to hear what women's perspectives are, and to have an open and informal discussion (meeting notes A. Hardon).

The meeting was organised with the New York-based International Women's Health Coalition. To ensure a balance of perspectives, similar numbers of scientists and women's health advocates were invited to participate (approximately 14 each), and regional diversity was ensured. The meeting concluded, among other things, that basic concepts of safety, efficacy and acceptability needed to be re-examined. The women's health advocates pointed to bias in the way scientists reported on these issues, as Judy Norsigan (working with the Boston Women's Health Collective) said:

with the vaginal ring, the scientists involved in its development stress the advantage of it being user-controlled. With Norplant, they do not mention that it is *not* user-controlled". (meeting notes A. Hardon).

And Sonia Correa, a Brazilian activist noted:

when the scientists talk about the male pill, they discuss the hormonal system in great details, including the hypothalamus, pituitary glands, hormonal balances. When the scientists discuss the vaccines, I get the feeling that we don't have a hormonal system... (Sonia Correa, meeting notes A. Hardon).

The scientists at the meeting pointed to the need for good quality care

We get the feeling now and then that the methods got the blame whilst it is the services that should be the target of complaints" (Olav Meirik, involved in the trials on Norplant, [WHO, 1991]).

Any type of new technology that we introduce in any country of the world will fail if you don't have good service delivery and good counseling (Kirsten Hagenfeld, cited in WHO 1991).

The dialogues at the three-day meeting made the reproductive scientists rethink the conditions for the safe introduction of Norplant. Two of the many recommendations from the meeting were that the WHO's HRP should:

- Discuss and revise, incorporating women’s perspectives, the definitions of and relative weight assigned to safety, efficacy, affordability and acceptability in selecting and introducing fertility regulation methods, and;
- Develop guidelines with women’s health advocates to specify under which circumstances particular methods should be introduced and to clarify the criteria by which introductory trials determine whether a method is appropriate for widespread introduction (WHO 1991).

The meeting endorsed a role for women’s health advocates in defining the scripts of new contraceptive technologies, more specifically in the construction of efficacy, safety and acceptability claims, and in the formulation of what we could call ‘introduction scripts’, i.e. scripts which accompany the hardware, with an aim to specify under which circumstances they should be introduced.

This meeting marked the start of more intensive collaborations between the WHO and women’s health advocates. Thereafter, it became routine to invite women’s health advocates to technical meetings. A subsequent symposium on ‘Contraceptive Research and Development for the Year 2000 and Beyond’, attended by managers of programmes involving reproductive research and women’s health advocates recommended (Declaration 1993):

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, including definition of criteria for safety, determination of research priorities, design and implementation of research protocols, setting and monitoring of ethical standards, and decisions on whether to pursue a fertility regulation method from one stage to the next, especially decisions to move from clinical trials to introductory trials, and from introductory trials to introduction of a method into family planning programmes.

The women’s health advocates seemed to have established themselves as ‘obligatory passage points’ for contraceptive development.⁴ Why were researchers and family planners willing to grant them such credibility and opportunities for representation? The women’s health movement was growing rapidly, and its collective ‘reproductive rights’ identity was attractive to major donors of the World Health Organization and other agencies involved in contraceptive development. The movement had moreover shown that on the ground in developing countries, it had the power to stop clinical trials. Working with women’s health advocates had become a necessity for the researchers, not because of symbiotic aims, but because of their power to control funds and to block access to experimental settings.

Actions and reactions

The book, *Norplant: under her skin*, was reviewed positively in the press, but criticised heavily by the developers of Norplant, the Population Council. Karen Beattie, responsible for the Norplant introduction program, wrote that the analysis was skewed, and that its conclusions on the need to avoid medicalisation were “truly amazing” (letter K.

Beattie April 30 1993 to R. Petchesky). In an attempt to attack our credibility, we were said to lack understanding of clinical research and practice. An intensive correspondence followed in which we responded to each of her criticisms (Response A. Hardon to K. Beattie, June 30 1993).

The debate with the Population Council continued when the agency published their booklet, *Introducing Norplant in Developing Countries* (Population Council 1993). The WHAF contested the Population Council's claims on the low risk of ectopic pregnancy (low because the risk of pregnancy is low). We suggested that the ectopic pregnancy risk should be related to that of other contraceptives, not as compared to that when *not* using contraceptives. The WHAF also contested the claims on safety for breastfed babies of six weeks and older. The Population Council claimed that studies had shown no significant effects on the growth or health of infants whose mothers used levonorgestrel implants. WHAF stated that long-term effects or infant exposure to hormones were not known. WHAF also commented on the way the booklet dealt with the issue of long-term effects. The booklet suggested that the issue was covered by initiating a five-year post-marketing surveillance study. The answer to the question raised in the booklet "are long-term effects known?" should have simply been no, not yet, WHAF suggested. Finally, the booklet failed to mention that bleeding irregularities are common. The Population Council booklet stated that intermenstrual bleeding is "not considered menstruation" and should not inhibit or interfere with a women's daily routine in cultures where menstruation may prohibit certain activities. WHAF opposed such 'redefinition' of women's experience that bleeding equals menstruation (WHAF letter to S. Waldman, Population Council, March 28, 1994).

Ban Norplant

While as WHAF activists we were negotiating with the WHO and the Population Council on the conditions for safe use of, and the safety claims for Norplant (re-scribing the technology), other women's health activists were developing a different strategy. The problems with Norplant were discussed at the International Conference on People's Perspectives on Population, held in Bangladesh in December 1993 (a meeting organised by UBINIG and the Third World Network), attended by women from 34 countries. The symposium concluded in the *Declaration of People's Perspectives on Population*:

Increasingly technologies are invented that are controlled by the providers, that is, the physicians, the drug companies, the state. Formerly, contraceptives, like the diaphragm, were more under the control of women. Whether in relation to curbing or enhancing fertility, these provider-controlled technologies effectively undermine women's control over their lives while burdening them with full responsibility for fertility and absolving men of their responsibility. Therefore, long-acting contraceptives such as Norplant are not an advance in contraceptive technology, but an advance in control. They are purposeful instruments inspired by eugenicists whose programs of population control were

designed explicitly to curtail the number of black, indigenous, disabled and poor white peoples (Akhter 1995: 105).

Norplant alliance lobbied for their views in the process leading up to the 1994 International Conference on Population and Development (ICPD). UBINIG was one of the accredited NGOs and as such participated in the preparatory committee meetings held in New York. Farida Akter reported how she became concerned about differences in views on Norplant

In the third and last preparatory meeting of ICPD, we were quite concerned about the active promotion of some contraceptives such as Norplant as women's choice. The international feminist groups mostly led by Northern women and the elites of the South were vocal about women's reproductive rights, which included the right to choose Norplant. This was quite alarming as they were giving a misleading picture about women's needs and choice specially those for women in Third World countries (Akhter 1995: 106).

In response, UBINIG and FINNRAGE, along with other groups distributed the leaflet *No to Norplant* to the delegates of the preparatory conference in New York. It stated:

Norplant is a provider-controlled and an inherently coercive method... We urge governments, the UN bodies and women's groups all over the world to call for the withdrawal of Norplant from the family planning programmes from all the countries and to provide safe and user-controlled methods of fertility regulation in concert with broad-based health care programs. (Akhter 1995: 108).

Biomedical scientists respond: post-marketing studies

In the meantime, biomedical researchers had responded to the contestations by conducting more post-marketing studies on Norplant in which adverse effects, including menstrual disturbances, were systematically recorded. In fact, there is probably no other medical technology which has been subjected to such comprehensive post-marketing research. In 2001 the results of a five-year, post-marketing survey of 16,000 women in eight developing countries was published. It found that Norplant was as safe and effective as IUDs and sterilisation. No major adverse effects were reported. However, menstrual disturbances were found to be by far the most common reason for discontinuation of the method (which involved minor surgical intervention). In the editorial of a special issue of *Contraception* on implantable contraceptives, Olav Meirik (2002) concluded:

Norplant has at times been controversial in developed countries, and women's health advocates have questioned the clinical management and safety of Norplant in developing countries. The characteristics of Norplant that primarily provoked the controversies are related to the provider dependency of the method, including the surgery for placement and removal, and bleeding disturbances induced by the method. Disruption of menstrual bleeding patterns is an adverse effect of all progestogen-only contraceptives. Apart from being a considerable nuisance, unpredictable and prolonged vaginal bleeding affects women's daily lives and restricts their community and religious activities in some cul-

tures. Comprehensive information and good counseling about bleeding disturbances are, therefore, imperative for implant provision. Moreover, if bleeding disturbances are unacceptable to women, they must have easy access to implant removal (Meirik 2002: 1).

Registered in many countries, withdrawn in some, and rarely used

By 2001, Norplant had been registered as a safe and effective contraceptive method in 60 countries, but was not used widely. Its successor, Norplant II (called Jadelle) had been registered in several European countries. The pharmaceutical company Organon developed a one-rod implant, Implanon, which was approved for three years of use in the European Union, Canada and Indonesia. The Jadelle and Implanon implants have fewer rods and are therefore more easily inserted and removed. Categorized with injectables, these methods account for around 4% of global contraceptive users; 39% is accounted for by female sterilisation, and 26% of contraceptive users use the IUD, 11% the pill. It is estimated that only around 10 million women worldwide use implants (Bongaarts & Johansson 2000).

Low rates of Norplant use are probably the main reason that manufacturers have withdrawn Norplant in two countries: the United Kingdom and the US. In both countries it had sparked mass legal action from women who claimed to suffer side effects, ranging from non-stop bleeding, to hair loss, to suicidal depression. In the UK the method also ran into trouble because general practitioners wanted an extra payment for inserting the rods, which the Department of Health refused (Boseley 1999; Wyeth 2002). In the UK Hoechst withdrew the method in 1999 because the controversy had destroyed its reputation, insisting that the reasons were commercial: not enough women were switching to the method. It denounced the 'unholy alliance of bureaucrats, lawyers and media it held responsible for Norplant's demise (Boseley 1999). In the US, after being confronted with legal action in 1997-1999 (resolved through settlement), Wyeth ran into problems again in 2000 when laboratory testing showed that specific lots of the product might not release enough hormone to deliver effective, ongoing, protection against pregnancy. They advised the women concerned to use backup contraception. In July 2002 it announced that due to "limitations in product component supplies" the Norplant system would not be reintroduced in the US (Wyeth 2002). Wyeth offered to pay for removal services, and was reportedly planning to introduce the two-rod Jadelle implants instead (American Health Consultants 2002).

In the Netherlands controversies occurred around Implanon, introduced by Organon. The company had in the late 1990s sought advice from WHAF on how to introduce the new contraceptive. We stressed appropriate information to users, and good training of doctors in insertion and removal. This didn't prevent problems from occurring. Fourteen women in the Netherlands became pregnant while using the implants, apparently because the implants weren't properly injected. The problem turned out to be caused by a suboptimal design of the inserting tool. The women affected won a court case against their GPs, who subsequently tried to refer the claims to Organon. The Dutch association of general practitioners now warns their members of difficul-

ties in inserting and removing it. Only around 4000 women start using the method per year (Brandt 2004).

Anti-fertility vaccine contestations

With Norplant, we raised concerns about the introduction of the method in family planning programs and about misleading claims on safety. When we became aware of the technology it was already on the market in many countries. Our field studies allowed women's health advocates to present researchers with actual problems experienced with the technology. The contestations led to a rescribing of the technology, with adjusted safety claims and accompanying introduction scripts, which enabled a cautious process of introduction.

The anti-fertility vaccine contestations are different, because unlike Norplant, the anti-fertility vaccines were contested when they were still in the process of being tested in clinical trials, i.e. the scripts were still under construction and more open to adaptation. The contestations led to the halt of trials on a risky prototype, and the construction of new prototypes with more empowering scripts.

The origins

The idea of regulating fertility by immunological means has its origins in the turn of the century when the relatively new science of reproductive immunology showed that conception and embryo implantation can be interrupted by immunological manipulation (Jones 1982; Barzellatto 1991).

In the late 1970s, the International Committee for Contraception Research of the Population Council initiated human, clinical pharmacological studies with an anti-hCG vaccine in Sweden, Finland, Chile, and Brazil (Nash et al. 1980). Following these early experiments, two Phase I clinical trials (small-scale safety trials on volunteers) were conducted in the 1980s: anti-hCG vaccines were tested under the auspices of the Population Council in India and Scandinavia with a total of 88 surgically sterilised women (Talwar et al. 1990). A WHO-sponsored trial testing the safety of an anti-hCG vaccine was conducted in Australia with 30 surgically sterilised women (Jones et al. 1988).

In their published reports on these studies, the researchers refer to their work as part of an important solution to the global population crisis. Two researchers from the New Delhi National Institute of Immunology (NII), for example, wrote:

Most conservative estimates predict human global population to cross six billion by the end of the 20th century.... It poses a major challenge for developing countries and demands mobilization of additional resources...to maintain the complex relationship between growing population and environment. To overcome this problem it is pertinent to evolve new safe and effective contraceptive agents. Vaccines for immunocontraception are an interesting proposition as it will be cost-effective, and most developing countries have infrastructure for the appropriate delivery (Gupta & Koothan 1990).

For the anti-fertility vaccines to be acceptable, according to the WHO biennial report on human reproduction, they should:

...have long-lasting protective effect after a single course of immunization; they would not cause menstrual-cycle disturbances and other hormone-dependent side-effects; they would be easy to administer by a well-accepted procedure; and they could be manufactured at low unit cost (WHO 1990).

Different assessments on acceptable risks to users

While the researchers agreed on the attractiveness of a longer-acting injectable immuno-contraceptive to users, they differed in their assessments of acceptable risks. Two distinct prototypes of anti-hCG vaccine were emerging, one which I have characterised elsewhere as maximising efficacy, the other as maximising safety (Hardon 1997). WHO's HRP chose to maximise safety by selecting the small section (peptide) of the beta sub-unit as an antigen with possible drawbacks in terms of efficacy. Talwar and his colleagues at the NII in India, did not select an antigen that is unique for hCG; instead they used the whole beta-hCG sub-unit which is in some ways similar to the LH hormone which regulates the menstrual cycle, and thus was likely to cause women to have menstrual disturbances. By choosing the whole beta-hCG sub-unit as antigen, they disregarded the 1978 guidelines of the WHO Task Force on immunological methods which advised against selecting antigens which carry a risk of 'cross-reactivity' (WHO 1978). The Indian researchers argued for "a moderate degree" of cross-reaction with LH, as long as women menstruate normally, in order to enhance effectiveness of the vaccine (Talwar et al. 1988).

Mitchison, who chaired the WHO Steering Committee of the Task Force on Vaccines for Fertility Regulation of which Talwar was also a member, commented on this issue in a review article:

With regard to the relative merits of the two types of vaccine described above, it is still too early to reach a conclusion. Quite possibly, both vaccines will find their place in the armamentarium of contraceptive agents. The cross-reactions elicited by the intact beta chain vaccine are worrying, but that concern diminishes as the number of women who have been vaccinated without adverse consequences increases (Mitchison 1990: 726).

Initial questions from a women's health perspective

We raised initial questions from a women's health perspective about the safety and acceptability of anti-fertility vaccines at the 1989 WHO symposium on the safety and efficacy of vaccines for fertility regulation, which I attended with Judith Richter as consumer representatives on behalf of Health Action International (an international network of consumer, health and development organisations). We were the only advocates invited to this meeting.

The aim of the symposium was to review aspects of present and past work on the development of anti-fertility vaccines, particularly relevant to the testing of their safety

and efficacy (Ada & Griffin 1991). At this meeting, we were first confronted with the controversy among the researchers on the relative safety features of the two anti-hCG vaccine prototypes that were emerging. Not willing to confront the Indian researchers in plenary, the researchers involved in the safer beta-hCG *peptide* vaccine urged us to raise questions on this issue.

In a report on the symposium published in the WGNRR newsletter, I summarised our concerns with both anti-hCG vaccine prototypes (Hardon 1989). These included concerns about the intrinsic qualities of the vaccine such as:

- the difficulty of ‘switching off’ the immune response (the temporary irreversibility is a problem for women who experience side effects, such as menstrual disturbance or auto-immune reactions);
- the unknown consequences if a woman is pregnant when given the vaccine;
- the risks of cross-reactivity and allergic reactions to the immuno-carrier.

In addition, there were concerns about operational issues to be considered, especially in settings where healthcare services are inadequate. These included:

- the need for a test to determine whether a woman still has a protective level;
- the need for additional protection during the immunological lag period (the period after the injection and before the immune response has developed to an effective level);
- the vaccine’s potential for abuse if distributed in coercive population programs (women could be injected with the anti-fertility vaccine without their consent).

In the same report, I suggested that the clinical trials conducted with the whole beta sub-unit were inappropriate because of the potential health risks related to cross-reactivity. Griffin responded in the form of a letter to the editor, with assurances that the development of the vaccine would be stopped if serious adverse effects occurred, or if the vaccine was found to have teratogenic effects (causing deformities in the unborn child). With respect to the trials using the whole beta sub-unit, he commented that the trials conducted did not reveal the occurrence of menstrual disturbances due to the cross-reactivity (Griffin 1990).

Action and reactions

The above concerns about safety and the anti-fertility vaccine’s potential for abuse have caused many women’s health advocates to vehemently oppose this technology and to question the rationale for its development. During workshops and meetings held in the early 1990s, they commented on the supply-defined contraceptive development process, calling for a reorientation towards user needs (Richter 1992). Faye Schrater, a feminist immunologist, wrote a review article in which she supported the concern of women’s health advocates about “allergy, autoimmunity, irreversibility and teratology” and possible abuse and direct or indirect coercion by the state (Faye Schrater 1992: 47).

In line with the increased commitment to involve women’s health advocates in the development of new contraceptive technologies, as asserted in the 1991 meeting

(WHO 1991), in August 1992 WHO organised a meeting for researchers and women's health advocates to discuss the issues at stake concerning anti-fertility vaccines. In a background paper for this meeting, the manager of the Task Force on Vaccines for Fertility Regulation, provided information on the state of the art as a basis for discussion. Central to Griffin's paper was the assurance that technical solutions could be found for the concerns about the intrinsic characteristics of the vaccines. More animal studies and clinical trials were needed to clarify the exact mechanism of action, to develop methods to reverse the effects and to assess long-term safety. He asserted that sufficient information was available to indicate that it would be feasible to develop anti-fertility vaccines that were free of overt pharmacological activity and the metabolic, endocrine and physical disturbances that often accompany other methods of birth control; and could confer mid- to long-term (three months to one to two years) but not permanent protection following a single administration. The user, he suggested, would be able to select the preparation offering the length of duration desired (Faye Schrater 1992).

This notion of reproductive choice was new. Whereas prior to our actions, the scientists claimed to develop a longer-acting injectable contraceptive with limited potential for so-called 'user failure', Griffin now proposed that users should be able to choose the length of efficacy they wanted. The non-permanent nature of the vaccine's effect, and the possibility of reversing the effect on demand, in his view, would alleviate the consequences of abuse, should it occur.

Women's health activists call for a stop

In June 1993, 19 women's health advocates from 12 countries met in Bielefeld, Germany, hosted by the German organisation BUKO Pharmakampagne (a non-governmental organisation involved in Third World health and development issues) to discuss their views on the anti-fertility vaccine. I was invited but could not attend. The meeting had an open and closed section. Griffin was invited to the open session and asked to present the scientific data on the anti-fertility vaccines. He was questioned at length about its safety and efficacy. In the closed section of the workshop the women's health advocates drafted the *Call for a Stop on Research* (Yanco et al. 1996).

In November 1993, the WGNRR launched the global *Call for a Stop of Research on Anti-Fertility Vaccines* which was sent to research institutes and funders signed by 232 organisations from 18 countries:

We, the undersigned, call for an immediate halt to the development of immunological contraceptives because of concerns about health risks, potential for abuse, unethical research, and the assumptions underlying this direction of contraceptive research.

...Immunological contraceptives will not give women greater control over their fertility, but rather less. Immunological contraceptives have a higher abuse potential than any existing method.

...Immunological contraceptives present no advantage for women over existing contraceptives.

...They interfere with complex immunological and reproductive processes. There are many potential risks: induction of autoimmune diseases and allergies, exacerbation of infectious disease and immune disturbances, and a high risk of fetal exposure to ongoing immune reactions.

....the concept of antifertility 'vaccines' was conceived in a "demographic-driven, science-led" framework (WGNR 1993).

By May 1996, this call had been endorsed by 472 groups from 41 countries. Brazil (around 120 signatories), India (95 signatories) and Germany (around 60 signatories) account for more than half of the responses. (Yanco et al. 1996).

Representatives of research institutions react

In the first half of 1994, the research institutions, such as the WHO's HRP, the Population Council and the Contraceptive Research and Development Programme (CONRAD) sent reactions to the WGNRR, the campaign's global secretariat. In these reactions, they refer to the routine procedures in the development of contraceptives. They stated that safety and efficacy were being assessed in clinical trials and that the outcomes of these trials would resolve the issues. They also emphasised that their institutions supported reproductive rights principles, implying that the research was not demographically driven, and that the methods could have benefits to users.⁵ Dr. Benagiano, director of the WHO's HRP, for example, stated:

I agree completely with the aim of WGNRR...the right of women to decide whether, when and how to have children....It is however my contention that this aim also includes the right of women to choose what method of family planning to use, including, if they wish so, an antifertility vaccine.

and:

We feel that a fully developed and tested family planning method ...will be an attractive option for those women who wish to postpone their first pregnancy, to space births at an interval that has positive health benefits for the mother and her children... (Benagiano 1994).

Interestingly, these responses suggest that family planning providers were no longer the configured users of the technology, but women, who had the freedom to choose between contraceptive options.

In an attempt to contribute to the dissemination of non-specialist information on anti-fertility vaccines, and in response to the *Call For a Stop*, the May 1994 issue of *Reproductive Health Matters* contained an article in which the researchers involved in the development of the safer beta-hCG *peptide* vaccine reviewed the current status of anti-fertility vaccines (Griffin et al. 1994). In this review they repeated their concerns about the safety of the anti-hCG vaccine based on the whole beta-hCG sub-unit developed by the NII and Population Council, stating that

the theoretical consequences of this LH cross-reactivity are interference with ovulation and disruptions to the menstrual cycle and the risk of pathology in the pituitary gland in which LH is produced' (Griffin et al. 1994: 110).

While acknowledging the theoretical risks, which we had raised, they also quoted the findings of the NII clinical trials, which suggested no evidence of such adverse effects. They argued that antibodies to sperm and other reproductive tissues occur *naturally*, in otherwise healthy individuals, leading to infertility. Therefore vaccine-induced antibodies are not intrinsically hazardous. Concerning the problem of abuse, they pointed to the need for improved quality of care and education. This rescribing of the technology as natural and apparently safe, widened the divergence in views within the women's health advocacy movement, as reflected in responses to the article in the next issue of *Reproductive Health*. S. Shervington, Director of the Women of Colour Reproductive Health Forum in New Orleans, suggested that each woman would have to decide for herself if the contraceptive's side effects were worth the risk. (Shervington 1994). Macklin, a professor of bioethics, argued: "*Those who would restrict women's options are being paternalistic in their attempt to curtail the freedom to choose*" (Macklin 1994: 112). And, Faye Schrater distinguished between the two types of anti-hCG vaccines in development. She considered that the long-term risks of the prototype developed by NII and the Population Council were unacceptable. She supported further development of the safer alternative developed by WHO (Fay Schrater 1994). None of these respondents supported the campaign to stop the development of all anti-hCG vaccines.

Clinical trials continue

As the controversy over the anti-fertility vaccines intensified in the early 1990s, the scientists continued to plan and conduct phase-two trials to test the efficacy of new vaccines. Reporting on early results of his phase two trials in 1993, the Indian scientist Talwar and his colleagues were the first to prove efficacy of an anti-fertility vaccine. Only one pregnancy occurred when 88 women used the anti-hCG vaccine as their only method of contraception for approximately 1,000 months (Talwar et al. 1993). The problem confronting the researchers was the variation in immune response. Around 20% of the women were 'poor responders' (producing insufficient amounts of antibodies).

In early 1994, the WHO initiated phase two clinical trials on its theoretically safer anti-hCG prototype in Sweden. Of 25 volunteers selected to participate in the trial, the first seven to receive the vaccine all experienced totally unexpected side effects which included pain at the injection site, fever, and in two cases, sterile abscess formation. The trials were stopped by mid-1995 (WHO 1995a).

Following this experience, the Task Force on Vaccines for Fertility Regulation of WHO shifted its attention to 'advanced prototypes' and 'optimised vaccines'. The aim was to develop a totally synthetic anti-hCG vaccine containing bioengineered immunogens, and a controlled-release system designed to provide immunity of a predictable and controlled duration. An *orally* active formulation of this 'optimised' version

of the anti-hCG vaccine was also being investigated (WHO 1995b). In aiming to develop an oral vaccine, the researchers showed that they took the critique of women's health activists on provider-controlled methods seriously.

Negotiating with funders

In mid-1995, the activists involved in the *No-To-Anti-Fertility Vaccines Research Campaign* met again, in Canada, where they also aimed to negotiate with representatives of the International Development Research Centre (IDRC). IDRC had supported the development of the anti-fertility vaccine at the NII in India, and held the patent on the anti-hCG vaccine developed in India. The agency defended its support of NII by referring to the claims of Talwar and his colleagues that 'Phase II clinical trials showed that the vaccine could prevent pregnancy and continued to confirm the absence of adverse effects (IDRC 1995). Given this defensive reaction to the campaign, I was surprised to hear in an interview I held with Dr. Talwar in India during a site visit there in 1996 (he had then retired as director on the NII) that IDRC had decided to stop funding the development of anti-fertility vaccines by the NII in New Delhi. He stated "Our research has been stopped by the women dictating...because they were so persistent I got a low priority".⁶ In January 1997, a letter from the president of IDRC confirmed that funding had stopped, but said this was only because NII officials were not intending to request further funding.⁷

Nature Medicine (Jayaraman 1997) reported in May 1997 that India was indeed downgrading research on contraceptive vaccines. The Department of Biotechnology is said to have decided to halve the project's annual grant and to downgrade the vaccines from one of 16 high-priority 'missions' to a regular 'research mode'. The new director of the NII, Dr. Basu is quoted saying: "We cannot allow this vaccine to enter phase III trials until its long-term safety is established" (Viswanath and Kirbat 1997).

WHO reflects on research priorities

In 1995 and 1996, reflection on research priorities was also taking place at the WHO. In a discussion paper, the HRP put forward criteria for the programme's future research and development policy practice. It stated:

The views, needs and preferences for fertility regulating methods as expressed by men and women, past, current or potential users, should guide the selection of new methods for development (WHO 1995c: 13).

In line with these ideas, the HRP organised a meeting in November 1995 on Women's and Men's Perspectives on Fertility Regulation Methods and Services which I attended. At this meeting, researchers presented the results of studies on the acceptability of contraceptive technologies. It became clear that individual preferences and perspectives varied widely, and were sensitive to the methodology used (WHO 1997). The Program also set up a Gender Advisory Panel (GAP) consisting of scientists, women's health advocates, and health professionals working in reproductive health. The GAP

was asked in its first meeting in 1996 to advise the HRP on the future of its research in the field of contraception. Having reviewed the work on fertility regulating vaccines, the GAP agreed that, "This method could fill a need for future generations, provided that some of the unanswered questions... were satisfactorily answered by continued research"(GAP/WHO 1996: 13). The GAP specifically recommended that the Programme conduct follow-up studies with those women who had already participated in clinical trials of the anti-hCG vaccine, and that social science research be done to elucidate different population groups' responses to a potential vaccine, including questions about possible fears, social consequences, service problems, mode of delivery, and mode of action. Women's health advocates in the GAP were granted the power to co-define the scripts of the technologies under development. Rather than representing the interests and needs of future users of the technologies, they proposed methods by which researchers could give voice to actual users of experimental technologies in the context of clinical trials.

Women's health advocates present themselves as users

The increased concern at WHO about the needs of users led to new campaign activities. In early 1996, the women's health advocates involved in the *No-To-Anti-Fertility Vaccines Research Campaign* launched an international postcard action, following an informal telephone conversation with Griffin, in which he reportedly said that the HRP would consider ending research on the anti-hCG vaccine if "potential users would not want the method".⁸ In this postcard action, women were called upon to sign postcards addressed to Griffin, stating:

I do not support the development of immunological contraceptives. Women and men alike need contraceptives that enable them to exercise greater control over their own fertility, without sacrificing their integrity, their health, or their wellbeing. In addition, the potential for abuse is simply too great with immunological contraceptives, which could easily become tools for population control (Yanco et al. 1996).

In this campaign, women positioned themselves as users, and claimed a right to stop research on vaccines.

In conclusion

This article has focused on the way the women's health movement in which I participated contested new contraceptive technologies. One of the most remarkable consequences was the emergence of a strong commitment among scientists to engage women's health advocates in the development and introduction of new contraceptive technologies. How did we achieve such influence? The scientists found their methods and findings challenged and came to realise they could not ignore the movement. Early on in the Norplant controversy, groups in Bangladesh and Brazil, concerned about the unethical conduct of trials, stopped the introduction of Norplant by mobilising support

against the trials. Through the global network such cases became known all over the world, and at national level women's health advocates were alerted to possible unethical trials.

We could not only stop the trials; we could also oppose the funding of such programmes. This was a concern for publicly-funded UN institutions such as the WHO. The WHO is governed by an assembly in which developing country governments are represented, and its programs are funded by additional funding from the governments of The Netherlands, Finland, US and Canada, countries in which the global women's health advocacy movement was especially active.

But how could the movement have had such an impact when it was also internally divided? I have shown how women's health groups, which were more concerned about the population control objectives of nation states and which had relatively little trust in the capacity of states to change their programs, vehemently opposed the introduction of Norplant on the grounds that it could be abused. Active in this *No-to-Norplant* campaign were women's health groups from Bangladesh and Brazil, where the technology had been resisted in the first place. They were supported by women from Germany, a country which had bitter experience with policies based on eugenics. Women's health groups, for which I worked, were engaged in a dialogue with scientists on the conditions of safe use and on bias in assessments of safety and efficacy. We used data from field studies to provide evidence on the problems that could occur. While very concerned about the split in the movement in the midst of the converties, looking back and reflecting on the events, it became clear to me that the split did not weaken impact, but, in fact, enhanced success. The threat of a Norplant ban, made it attractive for the scientists to engage less radical women's health groups like the WHAF, in designing the initial trials and setting condition for safe use. The effect of both strands of global activism has been a slower and more cautious introduction of the technology in developing countries.

The second case focused on women's health contestations concerning the anti-fertility vaccines. Here too there were divergences within the women's health movement on the goal of the campaign. In addition, there was disagreement between scientists on the safety of the vaccines. Strategically, it is interesting that the women's health advocates who called for an end to research on anti-fertility vaccines did not distinguish between the various prototypes being developed. By seeking an alliance with some reproductive scientists, they could have increased their credibility and impact in terms of their desire to redirect the contraceptive development process. They chose not to. Their main concern was the disempowering script of the provider-dependent technology, not the relative safety of the different prototypes under development. The *No To Anti-Fertility Vaccine Research Campaign* resulted in the relatively unsafe Indian prototype vaccine being disbanded. The Indian government deprioritised the project and funding by the Canadian government was discontinued.

In response to the *No To Anti-fertility Vaccine Research Campaign*, the researchers at WHO and the Population Council asserted new gender scripts. In contrast to the start when the configured users were family planning providers, scientists now asserted, in

response to the campaigns, that they intended to focus on the interests of women as end-users. They reframed their mission in terms of reproductive choice, and took up new research questions related to the reversibility of the vaccines' effect, and the possibility of developing an oral vaccine to prevent abuse. Moderate women's health advocates, with whom I identified, were willing to be involved in setting terms for further clinical trials on such safer, more empowering vaccine prototypes. We helped formulate studies on acceptability to future users in WHO's GAP. Some women's health advocates even agreed with the WHO researchers that a potential advantage of the peptide-based anti-hCG vaccine prototype was freedom from hormone-dependent adverse effects.

The controversies raise issues of representation (Van Kammen 1999). Both strands of women's health advocacy claim to be able to represent the interest of users. But their representations of users differ. The *No-to-Norplant* and *No To Research on Anti-Fertility Vaccines* groups see users as victims of a state-led medical establishment enabled power, which is inscribed in the technology. They put themselves forward as representatives of poor and oppressed women and demand the right to stop the development and introduction of the new technologies. Engaging in the more moderate strands of activism, I took as a point of departure that women's interests and needs differ from one setting to another, and that they are best met by making available to women a range of contraceptive options to allow for a free and informed choice. By engaging in the construction of safety and efficacy claims, and by outlining conditions for the introduction of the new technologies (in what we have called introduction scripts) we aimed to facilitate free, informed choice and safe use of the technologies.⁹

Participating in the controversies, my mode of engagement has changed over time. Initially, in the Norplant controversy, my aim was to confront the authoritative medical-demographic arena involved in the development of the technology with the lived experiences of women, whose access to health care is constrained by power-differentials between health workers and patients. Bias and blind spots in mainstream science were critiqued. This critique was multi-disciplinary it dealt both with the biomedical efficacies of the technologies as with their social uses and abuses. This position could be characterized as one of subaltern alignment.

Subsequently, still working in dual roles as medical anthropologist and women's health advocate in the antifertility vaccine case, I became interested in the way the scientists' discourse on safety and acceptability of the technology to future users changed in response to the claims made by the women's health advocates (Hardon 1997b). Increasingly, the researchers started promoting vaccines as an option for reproductive choice. These claims were made at a time when reproductive health and reproductive rights (as opposed to population control) had moved to the forefront of the policy agenda in light of the 1994 United Nations International Conference on Population and Development held in Cairo. This led me to reflect on the assumptions underlying both the positions of the women's health advocates and that of the scientists. I came to see that both parties were in fact heterogeneous, involving a variety of views and interests. Both women's health advocates and the reproductive scientist referred to projected user needs to support their positions. In the whole controversy actual users of the tech-

nologies were absent. This realization led to a new form of engagement, that of constructive collaboration, in which I sought for ways in which in the process of technology development actual users of technologies could be more closely involved in setting the parameters for the technology, the introduction scripts.

Users views and needs will, of course, differ across socio-cultural settings. In the Norplant case we could identify users, as the technology had already been introduced on the market. Anthropological enquiry allowed for an understanding of user experiences and views. For the antifertility vaccines, clinical trials were and still are the only setting in which women experience the technology. Elucidating user views in such an early stage of technology development is more challenging, but can be done. In our meetings with the scientists I suggested that social science studies could focus on why women-users decide to participate in the trial or not, taking into consideration the content and form of the information on the safety and efficacy of the technology offered to the potential user. What trade-offs do people make in these situations? Why do they choose to participate in the trial? By listening to users in clinical trials, they could thus be given an opportunity to actually influence the framework through which scientists are constructing facts about method safety and efficacy.

The cases presented in this article suggest that there is a need to create space for researchers, health movements, future users and other actors in various socio-cultural contexts to discuss what they see as valid research methods and appropriate requirements for and acceptable risks of new contraceptive technologies and other medical technologies. Ideally, such methods would allow for a negotiation between actors on the way in which facts about the efficacy, safety, and acceptability of new technologies are constructed. Participating in such negotiations as researchers requires reflection on our mode of engagement, and transparency concerning this role towards all other actors involved in the processes.

Notes

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- 1 The first feminist wave was the suffrage movement, which emerged in the 19th century.
- 2 Keck and Sikink (1998) in an intriguing analysis of global advocacy networks suggest that the women's movement more than other transnational advocacy movement, characterises itself as networks.
- 3 Methodologically, I have been inspired by the dialogical approach (Schrijvers 1991), which distances itself from the general academic value that researchers should not engage in action. Instead, it fosters exchange between researcher and researched and reflection on this exchange. The dialogical approach is especially suitable for research that takes an ongoing controversy as its subject.
- 4 Epstein (1995) describes a similar process, which occurred in the AIDS movement. However, the AIDS activists shared with researchers an interest in developing new technologies. The women's health advocates tended to oppose the development of new technologies.

- 5 H.L. Gabelnick (1994). Letter dated March 2, 1994, signed as the Director of the CONRAD Program for Contraceptive Research and Development; M. Catley-Carlson (1994). Letter dated June 28, 1994, signed as the President of the Population Council (with a request for wide distribution of the letter). All letters are directed to B. Stemerding, responding to the campaign.
- 6 I held the interview with Dr. Talwar in August 1996 at the NII.
- 7 K.A. Bezanson (1997) January 24, 1997 letter to Karen Seabrooke, International Campaign against Population Control and Abusive Hazardous Contraceptives.
- 8 B. Stemerding (1996). January 24. Letter to all people involved in the campaign. Amsterdam: WGNRR.
- 9 Clarke and Montini (1993), in an excellent arena analysis of the heterogeneous constructions of the abortion pill RU486, make a distinction between actors who treat the technology as a black box, and those, such as the more moderate women's health advocates in our case studies, who seek to open the box and point to instabilities in the technology.

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