

Ethics of contraceptive research: some issues

Contraceptive research has been driven by the need of the provider, not the user, comments the
Forum for Women's Health

What's so different about research on contraceptives? They're just like other drugs or devices. Aren't they?

Contraceptives are not just 'drugs'. They do not treat a state of 'illness'. They are taken by people who may otherwise be healthy — though the user's state of health is a major consideration both in research and otherwise.

Contraceptives are used because most people, especially women, need them badly enough to interfere with their normal bodily processes — a need which would force many people to accept whatever is available.

Contraceptives are used over a long period of time on a continuous basis. Any interference with the body's normal functioning will occur for an extended period — something to be remembered when determining the safety and harmlessness of a method.

Contraceptives obviously affect the reproductive cycle, and could possibly affect the next generation.

Most important, contraceptives satisfy a social, not medical need.

Contraceptive research should be seen in the context of the growing "technologising" of health care, the medicalising of disease diagnosis and treatment, an increasingly market-governed process, controlled by the pharmaceutical industry.

Contraceptive research gets justification from the population control lobby. This lobby directs the research, its language dominates in both the popular press and research settings, and it justifies the introduction of potentially risky methods.

The other, more sophisticated justification for introducing potentially risky contraceptives is that they reduce maternal mortality by preventing pregnancy itself.

However, 'population control' actually means control of certain populations. By now we know it to be racist and anti-poor. Its implementation is also associated with anti-woman attitudes. Women are considered responsible for reproduction, as they are for exercising control over this process. Contraceptive research follows the same line of thinking, even if it is at the cost of women's health.

Contraceptives have a long history of violating basic tenets of research. Some examples follow:

The 'Pill'

Oral contraceptives were introduced in the market in the 1960s, heavily promoted by governments and pharmaceutical companies, and used extensively by hundreds of thousands of women all over the world. Over the next decades, various problems came to light. Agitations by women's and health organisations forced refinements in the form of lower doses and combination pills. Ironically, manufacturers used this to argue that 'post-marketing surveillance', involving so many women (with their informed consent?) had made the pill much safer. They did not admit that the drug had not been properly researched in the first place.

Today, the oral contraceptive is the most researched and refined contraceptive on the market — though this research followed its introduction, instead of preceding it. As a result, it has now acquired the status of a 'gold standard': the risk factors identified over the years are measured against those of other contraceptives.

However, these research findings are not used correctly in India. It has been proposed for official over-the-counter sale, despite the potential dangers. It is part of the government's social marketing programme, by which neighbourhood women go door to door and convince other women to buy the contraceptive. The marketers are given incentives based on the quantity sold. To the buyers, the pill is presented as a cheap contraceptive, available at their doorstep.

Reports suggest that the practice violates all the recommendations emanating from research. Women are not told of its side effects, the contraindications based on user age and health conditions, and of the need for getting medical advice before starting use. They are not told clearly that the pill is not to be used as the first contraceptive method. Even more serious, the providers do not shoulder any responsibility for any complications resulting from the method, because it is 'chosen' by the consumer.

Injectables

For oral contraceptives to work, they must be taken regularly. A search was made for a 'user-independent' drug and drug-delivery method which would maintain a steady concentration of the necessary hormones at the required levels, and for a length of time. This led to the development of injectable contraceptives.

Injectable contraceptives did not get US FDA approval for almost 20 years, mainly because of evidence, in the WHO's multi-centre trials, of a carcinogenic effect. The problem was bypassed when the WHO changed its directives for contraceptive research, holding that evidence from animal studies was not fully indicative of a contraceptive's side effects. These

trials, conducted mainly in the third world, eventually concluded that injectables were relatively safe, but the details of the clinical trial's results were not made public.

For this reason, women's groups filed a petition asking for a ban pending the release of clinical trial results. Though this petition is in the court, injectables have been introduced in the Indian market for 'post-market surveillance'.

Post-marketing surveillance is now replacing phase III and phase IV trials, particularly for contraceptives. Depo-Provera has also been introduced in this manner, despite a petition pending in court. The protocol of post marketing surveillance requires the provision of a quarterly monitoring report. However, state drug controllers have not been issued directives asking for such reports.

Norplant

Various centres for research in human reproduction around the country are conducting what is being called the Phase III trials for Norplant[®]. This has a history.

An earlier, two-rod version of Norplant (Norplant-2) had already undergone Phase III testing in India. However, the manufacturers were forced to stop producing the silastic material for the rods because of fears of its carcinogenic effect on workers who would be exposed to large quantities of the material. Rather than spend on research to confirm or dismiss this fear, the company stopped production, and attention turned to the six-rod Norplant[®] made of a different material. In 1992, the ICMR announced phase IV trials of Norplant[®]. They argued that the progestin released by the two implants was identical, which meant the results of phase III trials of Norplant-2 could be applied to the six-capsule Norplant[®].

Widespread protests from women's groups followed. They held that Norplant[®] was a different device — the drug delivery system was different — and had to undergo safety tests before

pre-programme introductory trials. As a result of this pressure, a phase III trial for Norplant[®] was designed. The trial depended on the 'cafeteria' approach to select volunteers. Women approaching health services for contraceptive advice were asked to choose after being informed of the various methods available.

We feel there are problems with this method: when Norplant[®] is yet to be evaluated for safety and acceptability, how can it be offered as a choice with other tested and accepted methods?

Anti fertility vaccines

The most recent of fertility-controlling technologies is the anti-fertility vaccine (AFV), which works by inducing auto-immunity of some kind. Serious concerns have been voiced about its possible impact on the spread of HIV and other infectious diseases. It is also well known that women are more prone to developing autoimmune diseases. Yet researchers doing AFV research argue there is no scientific evidence to indicate whether an AFV, per se, would increase or reduce the risk of HIV infection, except that it is a non-barrier method.

Proponents of the AFV believe that it can ride on the popularity of immunisation programmes. Their concern is to reduce births, but they do not discuss its potential for abuse, a serious issue given the history of coercion in the family planning programme. Given people's vulnerability, and lack of access to information, it is entirely possible that an AFV could be administered without their knowledge, even under the guise of a disease control vaccine. This is not far-fetched when Indian women are sterilised or have IUDs inserted into them without their knowledge and permission. This fact, and the potential danger of AFVs, has led women's groups to call for a halt on all research in this area.

Sterilisation

It is only recently that the long-term, physiological side effects of

sterilisation are being discussed. With attention focussed on targets and camps.

Though even the WHO called for toxicological studies on animals before testing quinacrine insertion as a sterilisation method, it is being used by private practitioners in India. The government of Karnataka has given permission to introduce quinacrine in its programme. Thousands of women have been exposed to this mutagenic drug of doubtful efficacy. Why? Because as a chemical method, quinacrine does not elicit, in women, the fears associated with surgical interventions. In effect, women's fears are being used to introduce chemical methods unproven for both safety and efficacy. Various individuals, and women's groups, have raised legal challenges to the entry of quinacrine.

Contraceptive research must be reoriented

Contraceptive research is directed at control over women's fertility. It is based on a reductionist view of the human body. However, our physiologies are complex, consisting of various interdependent systems. Tampering with one affects all the others. Women's hormonal systems have been tampered with extensively through population control programmes over the last 35 years.

Any reorientation of contraceptive research must involve a stop to research on methods such as AFVs. This may be seen as anti-progress, anti-development, and interfering with the noble pursuit of acquiring scientific knowledge. However, women have suffered the consequences of this unchecked 'development' and 'noble pursuit' for too long. It is time to redefine what is meant by progress, and aim for knowledge that would help us as users of such technologies.

References

Detailed references for this paper can be obtained from the Forum for Women's Health