Tests of a forgotten barrier

The cervical cap, a barrier method of contraception almost forgotten since the 1950s when oral contraceptives hit the market, is undergoing extensive testing at roughly 60 clinics and hospitals around the country. Several different types of caps are under development, but two manufactured by Lambert's Ltd. of England, the Vimule and the Cavity Rim Cap (CRC), have already been widely tested in the United States (SN: 8/11/79, p. 102; 12/22 & 29/79, p. 431). Both are made of rubber, filled with spermicide before use, and held by suction on the cervix, the neck of the womb. In one preliminary study at Women's Hospital, Los Angeles County Medical Center, the Vimule was found to cause side effects ranging from slight irritation or abrasion to lacerations of the cervix in 12 of 20 women. Reporting these results in the November 1982 CONTRACEPTION, Gerald S. Bernstein and colleagues suggest that this was due to the construction of the Vimule, which has a slightly flared edge. The Cavity Rim Cap with its rounded edge caused no such effects in women studied by the researchers.

According to Henry Gabelnick of the National Institute for Child Health and Human Development in Bethesda, Md., the Vimule was dropped from studies supported by the Institute. Current studies are comparing the effectiveness of the CRC with the diaphragm, he says. Not all women can be fitted with the caps because of the limited range of sizes. For those who can use it, there are some advantages over the diaphragm: "There is normally no need to add spermicide after the first application," says Gabelnick. It uses less spermicide, and it can be left in place longer, although researchers haven't determined how much longer. Some women reportedly find it more comfortable than the diaphragm.

Although a number of studies on several versions of the cap are nearing completion, Gabelnick estimates that FDA approval is two or more years away.

Slow-release contraceptive systems

Contraceptive implants that slowly release levonorgestrel, a progestogen, or progesterone-like molecule, are now being tested or developed at several labs around the country. Although progestogens similar to levonorgestrel have been used in oral contraceptives in combination with estrogens for many years, "the trend for the future is toward lower doses with lower estrogen contents," says Dale Robertson of the Population Council's Center for Biomedical Research in New York City. The hope is that a levonorgestrel-only system would avoid side effects such as high blood pressure and increased risk of heart disease and stroke associated with estrogen. Levonorgestrel is the metabolically active form of Norgestrel. Both drugs are manufactured in the United States by Wyeth Laboratories in Philadelphia, Pa.

Progestogens including levonorgestrel act on the female reproductive system by inhibiting ovulation and thickening the walls of the uterus in the same way that the vigorously debated injectable contraceptive Depo-Provera does (SN: 2/19/83, p. 122). But Henry Gabelnick of the National Institute for Child Health and Human Development says that comparing the two "would be like comparing a Model T with a Ford Thunderbird." Levonorgestrel is much more potent, and so it requires a smaller dose. This, according to Gabelnick, is desirable for slow-release delivery systems, which need to be as small as possible for implantation within the body. An example is an arm implant called Norplant under study by the Population Council. The implant consists of narrow tubes that slowly release the drug over a period of five years. The National Institutes of Health are sponsoring studies on another method of slow release through injectable microcapsules filled with levonorgestrel, while the World Health Organization is sponsoring studies investigating a levonorgestrel-impregnated vaginal ring fitted to the cervix.

Important brain proteins synthesized

Some of the most important medical discoveries of the 1970s were the endorphins and enkephalins — human brain proteins that exert a spate of intellectual, emotional and behavioral effects (SN: 11/25/78, p. 374). Now the protein from which all the endorphins and enkephalins derive — beta-lipotropin — has been synthesized. So has one of the endorphins, beta-endorphin, which, injected as a drug, can counter depression.

Human beta-lipotropin has been made by James Blake and Choh Hao Li of the University of California in San Francisco by combining conventional chemical synthesis techniques with a new coupling method. They report their achievement in the March PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES (No. 6). Human beta-endorphin, in contrast, has been made with recombinant DNA methods by researchers at the University of California in San Francisco, headed by John D. Baxter. Actually Baxter and his team achieved their synthesis in 1980, Baxter told SCIENCE NEWS, but they have not published it in a scientific journal.

In an interview, Blake explained that the amount of beta-lipotropin made is much smaller than that which could be made with recombinant DNA. But even if it were made in large, economical batches by recombinant DNA, he said, "I don't know that there would be any real market for it. There isn't that much clinical use for human beta-lipotropin." Baxter, in contrast, foresees commercial potential for beta-endorphin made by recombinant DNA because of its antidepression effects and because the natural material now used in depression trials is terribly expensive — $3,000 an injection. Yet when he and his colleagues tried to find a drug company to apply their patented technique for making beta-endorphin, nobody "picked up the ball." "This surprised me," he said.

Protein predictor of Down's syndrome

At present, the best indicator of who's at risk of having a child with Down's syndrome, which is characterized by mental retardation, mongoloid features and a stocky build, is advanced age at the time of siring or conceiving (SN: 12/1/79, p. 381). However, there may be another predictor as well — the presence of a particular protein in the bloodstream — ongoing research by Julius Kerkay and colleagues at Cleveland State University suggests.

Since the late 1960s, but particularly in recent months, Kerkay and his co-workers have amassed evidence that not just women but men with this protein are at heightened risk of having a Down's syndrome child. Specifically, they have studied 80 mothers of Down's syndrome children and have found the protein in all but two of them. They have also identified the protein in the bloodstream of three fathers with Down's syndrome children. In fact, two of these men had two Down's syndrome children each, and each of the men was also married to a woman with the protein.

A question Kerkay and his team still have to answer, though, is whether the protein always indicates heightened risk of having a Down's syndrome child. Another question concerns the chemical nature of the protein. They are in the process of purifying it. A third question is what the protein's normal function is. Kerkay speculates that it might be made by a person in defense against an infection and inadvertently alter his or her genetic makeup. This alteration in turn could increase the chances of siring or conceiving a child with an extra chromosome number 21 or a translocation of a piece of chromosome 21 onto another chromosome — known causes of Down's syndrome.

In hopes that the protein will indeed turn out to be a reliable predictor of the risk of having a Down's syndrome child, Kerkay and his team are also attempting to develop a quick, inexpensive test for it. This test, Kerkay told SCIENCE NEWS, could then be used "to identify high-risk people."