CERVICAL CAPS: Old and Yet Too New

Prescriptions for birth control pills have decreased following reports of dangerous side-effects. Many women are returning to the barrier methods—to the diaphragm and to an older, less familiar device.

BY MARY-SHERMAN WILLIS

Few women (or their doctors) who consider themselves well versed in the armamentaria of contraception seem to be familiar with the cervical cap, although their grandmothers probably were. The cap is a thimble-shaped device that fits over the neck of the uterus and functions as a barrier to sperm. It was once considered as safe and effective as the diaphragm, and in most cases more convenient. Yet it fell from favor after the 1930s, only recently to reappear. Despite the long history of its use, more than 1,000 years, the U.S. Food and Drug Administration is still questioning whether it should be classified as a contraceptive. A new version of the device may now trigger safety studies and resolve the issue.

In general, the cervical cap "caps" the cervix, the neck of the uterus, which protrudes into the vagina. It remains in place by suction and requires little or no spermicidal jelly because there should be no gaps around its edge. (The diaphragm, currently a more popular barrier contraceptive method, is held in place by spring tension against the vaginal wall. With the additional seal of contraceptive jelly, it blocks the entire lower portion of the vagina.)

During its lengthy history the cap has been fashioned of material ranging from molded opium to cast aluminum. In the 18th century (by his own account) Casanova presented a prospective lover with half a squeezed lemon to use as a cervical cap, noting that the remaining citric acid served as a spermicide. By the 19th century caps were made of gold, platinum, silver or ivory, but eventually cheaper rubber and plastic caps replaced them.

During the 1920s, cervical caps outsold diaphragms 4 to 1 in Germany. They were then manufactured by several companies for European use. But today Lamberts (Dalston) Ltd. in London has a virtual monopoly on the product, which the British call a pessary. Lamberts makes twelve sizes and charges about $5 per cap.

Only one company has made caps for the U.S. market, and they stopped production 15 years ago, when "there was not much demand for them," according to Art Christensen of Holland-Rantos Co., of Piscataway, N.J. Cervical caps have never been approved by the Food and Drug Administration.

On April 8, the FDA issued a proposed ruling that does not classify the cervical cap as a contraceptive, according to Lillian L. Yin, executive secretary to the six-member FDA Obstetrical and Gynecological Devices Panel. Only one company — Milex Products Inc., a medical supply company in Chicago—registered with the FDA. However, the Milex cap is intended not for contraception, but rather for holding sperm near the cervix during artificial insemination. The cap as a contraceptive, therefore, will probably be classified as a device that may not be marketed until the potential manufacturer provides data to support its efficacy and safety.

Most U.S. women who use cervical caps today depend on the British manufacturer. As many as 10,000 to 15,000 U.S. women are getting caps from 60 to 70 distribution points across the United States, estimates Barbara Seaman, author of *Women and the Crisis in Sex Hormones* (Rawson Assocs., 1977), a book credited with popularizing the cervical cap. Neither government nor industry has an accurate count of the number of U.S. women using the caps. Gabriel Bialy, chief of the contraceptive branch of the National Institutes of Health, says, "I don't believe the figures are obtainable. It's never been properly investigated and it should be looked into."

Current FDA uncertainty about the cap, and the need to instruct patients in its use, are making private physicians leery of the device, many proponents believe. But the cap has found a warm welcome at some women's health clinics, and among some midwives and family practitioners — where patients are encouraged to help themselves by becoming educated about their bodies.

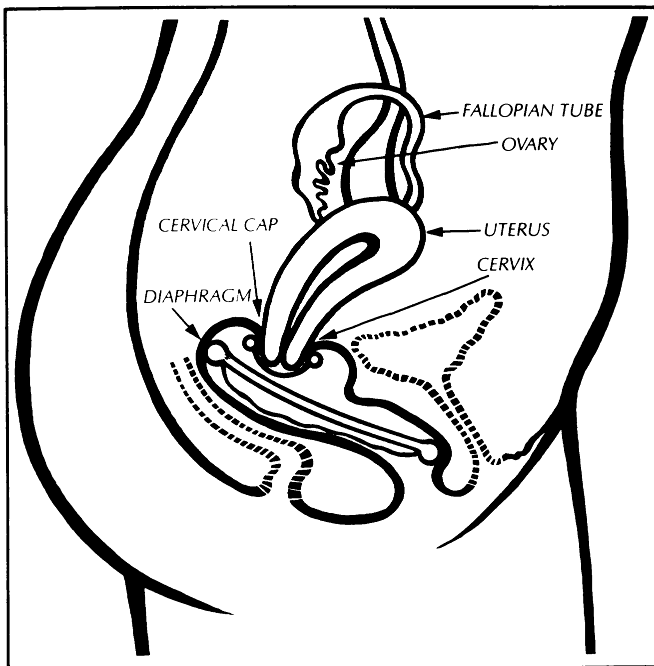
Distribution of the cap in the United States started again in New Hampshire several years ago, and spread throughout New England, across to Iowa, and on to Oregon and California. (Distributors are markedly absent from the southern states.)

A big problem, proponents find, is that the literature on the cap is outdated, to say the least. The last quantitative study of the cap appeared in October 1953 in the AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY.

Faced with this dearth of information, most health clinic practitioners taught themselves how to use the cap, and are conducting their own studies to test the results. Sarah Berndt, head of the cervical cap team at the New Hampshire Feminist Health Center, says the center has fitted almost 500 women since June 1978. Six women said cap failure was responsible for their pregnancies. The results of the center's survey should be out next year.

The Emma Goldman Clinic in Iowa City has a year-long study underway with 90 women. The clinic has dispensed about 300 caps in the past two years, and Nancy Kassel of the clinic's cervical cap team says she knows of 4 pregnancies among those cap users. In Berkeley, Calif., at the Berkeley Women's Health Collective, 150 caps have been inserted during the past six months, and two pregnancies occurred, says Beth Dean. And in Brookline, Mass., James P. Koch, Harvard research

Continued on page 442



The cavity rim cap covers the cervix; the diaphragm fills the lower vagina.

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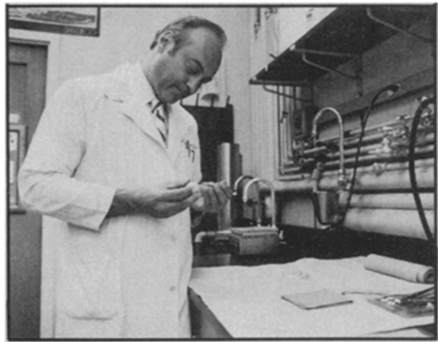
... Cervical caps

associate at the Boston Hospital for Women, is funding his own study of more than 400 patients. Results are due to be released soon.

When asked if NIH was supporting any research on the cervical cap, Bialy said, "Not at this point, but we definitely plan to do something within the next fiscal year." However, he adds, "I don't think we're going to get a flood of proposals. The average obstetrical gynecologist is not familiar with this device."

Probably the most important obstacle to the cap's success is educating a woman to use it. Belita Cowan of the Washington-based National Women's Health Network, which distributes an information package on the cap, says that any cap program "has to include patient education and follow-up. I don't want to see the government fund a study ignoring the other half of the efficacy question."

Several questions must be raised in the studies besides the cap's efficacy — questions that may eventually determine how the cap will be classified by the FDA. One issue is the length of time the cap should be worn. Users appreciate the long periods a cap can remain inserted, up to the entire intermenstrual period according to the 1953 report. Koch, however, advises his patients to leave a cap in position no more than a week, and preferably only three days, because the spermicide, which he says must be used with the caps, loses its potency. Most clinics agree.



M. Shields

University of Chicago dentist Robert A. Goepp examines his custom-made caps.

Yin, who says the cap may well be the best form of contraception for young women, still worries that "if the thing is left in so many days, year after year," cervical erosion and cancer may develop. "How are we going to answer that?" she asks. And Lamberts, says its director, Peter P. Watkins, is not at all in favor of leaving the cap in place for more than a day. "It should be used rather like a normal diaphragm," he says. Some researchers have, however, found favorable developments during women's long-term cap use; the covered cervix looks healthier than an uncovered one, perhaps because it is protected from harmful bacteria, one study says.

Whether or not to use spermicidal jelly is another controversial issue. The ideally fitting cap should need no jelly, but the cervix changes size depending on the time of the month, on the position of the body or on age. So almost everyone agrees that some jelly is necessary, although in smaller amounts than with a diaphragm because the cap is smaller and because, in the airless environment inside the inserted cap, jelly might have a longer life. Yet the jelly might interfere with the cap's suction. Andersen says that the original Holland-Rantos cap was not meant to be used with jelly. Seaman believes that for economic reasons the cap will not be manufactured if jelly is not required; the jelly is a much better profit-maker than the cap alone, she says.

The time and jelly issues might be resolved if a perfect fit could be guaranteed. A perfectly fitting cap would constitute a foolproof barrier, cause no irritation and require no spermicides. Dentist Robert A. Goepp met that challenge with a process for perfect fit. In addition, Goepp's caps are equipped with a "barrier maze" one-way valve, so menstrual fluid can pass through and the caps can be left in place indefinitely. Goepp, director of the University of Chicago's Zoller Dental Clinic, says he "acted like a dentist acts. Every dentist knows that things have to fit exactly, and I suspected that cervixes vary from person to person." Working with Ewe Freese, chairman of Obstetrics and Gynecology at the Chicago Medical School, he designed a procedure for making a model of a cervix. He presses against the cervix a tray filled with the material dentists use for making impressions of patients' teeth. From the resulting mold, a vacuum casting machine produces a custom-fitted cervical cap in about 20 minutes. The barrier maze cannot clog up, Goepp says, although he would not tell how it works because the university is patenting the design.

The Chicago cap has been tested on 48 women, some who have worn it longer than a year without ill effect. Goepp explains that there is little chance for "foreign body irritation" from such a cap because it rests on a layer of cervical mucus that flows continually under it. The next step is to test it for efficacy, a task too large and expensive for the Chicago team to undertake, he says, although without such a test, the FDA will not approve this cap.

Yet Goepp's device may still get on the U.S. market before the conventional cap does, despite the lengthy and expensive testing required. H.T. Milgrom of Milex explains one reason why: "Since the cervical cap is an old art, there's no way of acquiring a patent. Why spend the money to clear it for the FDA and then have everyone and his brother get in on the market? Some government agency should do the work to clear it for the FDA. If not, the item will never appear on the market." But Goepp's patentable device may be worth the testing expense. □

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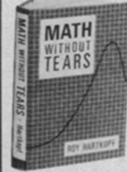

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