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Expert Group Meeting on the Production and Distribution of Contraceptives in the Developing Countries (Sponsored by UNIDO) in conjunction with INFFA)

New York, NY - 14 November 1971

CHEMICAL CONTRACEPTION ✓

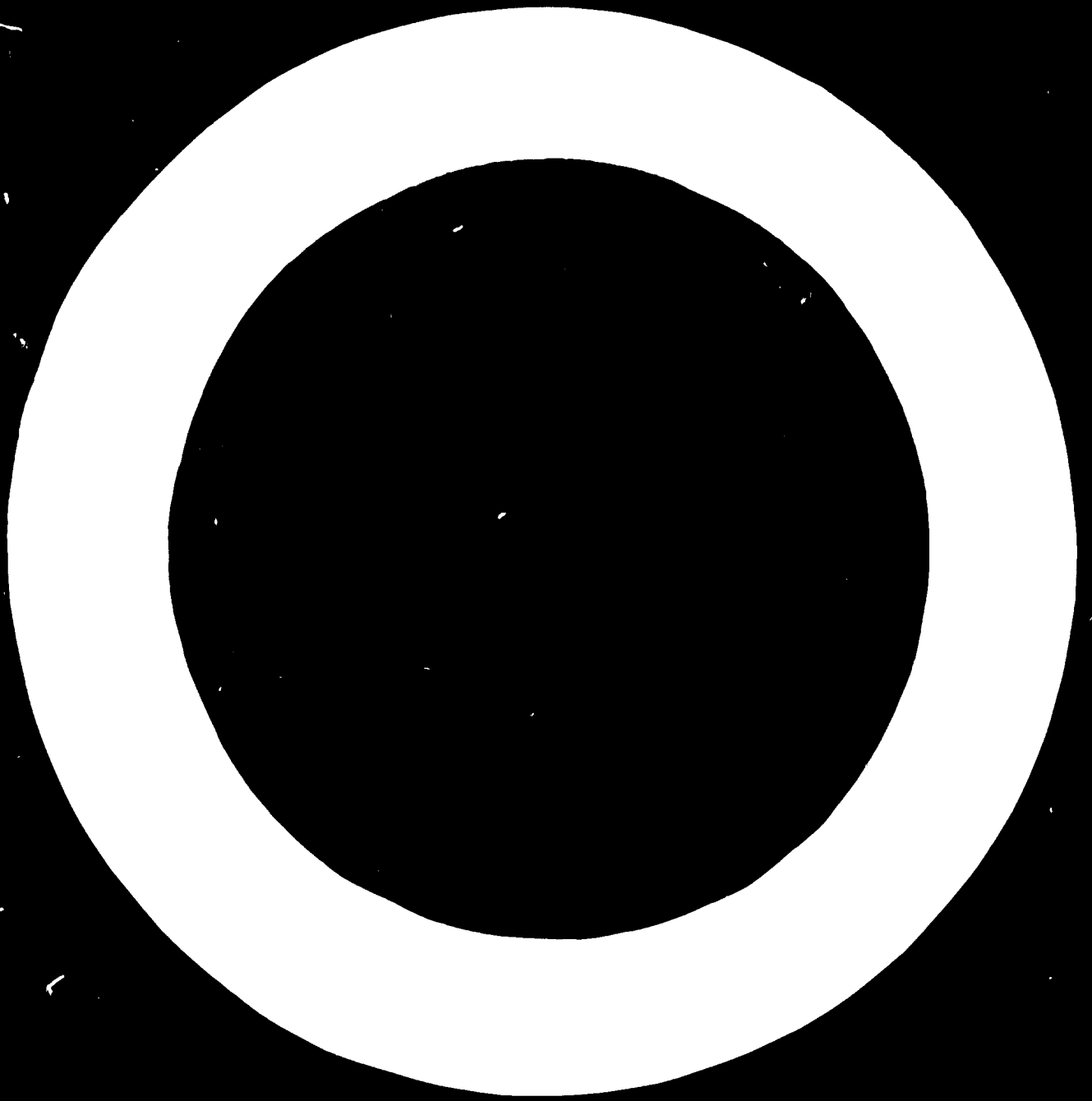
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It is generally acknowledged by those involved in contraception that any exhaustive search of the literature will produce Pearl rates for use effectiveness for traditional contraceptives which will vary from 3 to 25 failures per one hundred women years. This broad spectrum of reported results include the condom, the diaphragm with spermicide, and spermicidal agents used directly.

Generally, use failure has been primarily attributed to the fact that most of these methods are coital dependent. Most use effectiveness data seem to group these methods in a range of 6 to 15 failures/OHWY. With the advent of the IUD with pregnancy rates of 3 and the oral contraceptive at less than 0.5 pregnancies per one hundred woman years, more emphasis was placed on these more "reliable" newer methods by the proponents of contraception. Yet both of these newer methods generally require medical intervention for insertion of the IUD or prescribing for the pill. Actually, however, in practice in developing countries, oral contraceptives as with other prescription medicines are sold over the counter by the pharmacist without benefit of prescription. It should be noted that drop-out rates with these methods in the developing countries may be as high as 40% after one year.

With the need to reach more couples through the commercial networks, more attention has recently been given to the traditional contraceptives. In particular, emphasis has been put on condom distribution in such programs as Nirodh in India. This is appropriate as the condom has been the one traditional method which probably has as many users as the pill around the world. Another factor for this recent emphasis on the condom is that in many cultures, sexual activity is originated by the male. In cultures and socio-economic groupings where the woman recognizes that the risk of pregnancy is

hers, she will use the pill rather than depend on her partner for contraceptive protection.

Vaginal spermicidal preparation have had limited appeal compared to other methods, either to the family planning programs or to women served through the commercial channels. They do have one distinct value which merits consideration and further attention. They are the only female oriented contraceptive method which can be distributed through the commercial distribution system without medical intervention and with almost no side effects. Further, women in certain cultures have been oriented to blocking the vagina in some manner to prevent pregnancy and in these countries, some vaginal spermicidal method would be a useful adjunct to availability of the condom in the neighborhood shop.

The vaginal spermicidal preparation has another virtue that it may in most instances be produced and packaged locally in a developing country as the technology is quite simple. The vaginal contraceptive preparations are aerosol foam, foaming tablets and foaming liquids and suppositories, jellies and creams.

Manufacturing and packaging techniques depend more on the vehicle than the spermicide. Any country in which various jellies, creams and ointments are presently produced by the local pharmaceutical industry can produce contraceptive jellies and creams since the batching and mixing operations are identical as is the packaging into tubes, which may be manual or semi-automatic. The vehicle for the spermicide in jellies and suppositories is generally polyethylene glycol and other water soluble polymers or lipids, such as gum tragacanth. Creams use oil and water emulsions such as stearic acid for better spreading. Both jellies and creams use glycerine

as a part of the vehicle. These preparations require an applicator or inserter to provide the proper dosage and to permit the positioning of the contraceptive high in the vagina, near the cervix. The applicator may be produced by the local plastic industry. The consumer must purchase a tube with twelve to twenty applications which may be somewhat costly to women with little disposable income. Frequently, jellies and creams are used in conjunction with the diaphragm.

The vaginal aerosol foaming preparations require, in addition to the usual pharmaceutical batching equipment rather sophisticated equipment to pressurize the container with fluorocarbons after introducing the spermicidal agent and the vehicle into the can. For optimal economy this would require high-speed equipment and therefore, high consumer demand. Consideration must be given to producing a plastic inserter or applicator, as well. Before local manufacture should be considered, demand creation should occur using imported products. It is useful to note that purchase of vaginal foam is a high investment for many consumers with limited income although varying sizes of cans with 20 to 100 applications per can are possible. The unit cost per application goes down with the larger size can while the consumers initial investment goes up. A further problem of aerosol foam is that the bulk nature of the cans make handling for the retailer difficult and create additional transport problems.

The vaginal foaming liquid is comprised of several surface active ingredients, all of which have spermicidal activity. The liquid has an 85% water content and is introduced into the vagina using a small 2 inch diameter by 1/4" thick sponge to which it is applied. The sponge is meant to provide a mechanical block to sperm, as well. The formulation and packaging of the liquid into small bottles is most simple and the plastic sponge may be produced locally.

Vaginal foaming tablets use tartaric acid and soda bicarbonate to create the carbon dioxide for distributing the spermicide in the vagina. Corn starch is used as a filler. Great care must be given to limiting humidity during batching, tableting and packaging. Although the simplest manual or semi-automatic tableting machine that can produce aspirin can produce foaming tablets, the stringent requirements for low humidity may require an air-conditioned production facility or production may have to be limited to those times during the year when the humidity is suitably low.

The packaging material for foaming tablets is most critical as they require a well-sealed aluminum foil/polyethylene pouch for each individual tablet to prevent vapor transmission. Foaming tablets have been packed in glass vials of twelve but once opened, the absorption of moisture may produce a non-foaming tablet which is almost rock hard. Recent advances in packaging however may permit inclusion of a deliquescent substance in the vial cap to absorb moisture. Individual foil wrapped tablets have the advantage of being offered singly by the retailer which will enable low cost unit purchase by the consumer.

We have discussed the vehicle or media for each of the spermicidal preparations. The vehicle dictates the mode of packaging and the ease of distribution through the commercial or family planning network. The vehicle may also dictate the acceptability of the preparation to the woman and her partner. The jellies and creams are rather bulky and liquefy under body heat and may run out of the vagina which many women find messy. The foaming liquid requires a sponge to block the cervix and it is difficult to control the dosage to apply the sponge. Aerosol foam, jellies and creams require use of separate applicator.

Let us now consider the spermicides which are used in these preparations. The most commonly used is nonyl phenoxy polyethoxy ethanol (Noxynol 9) or similar polyethoxy derivatives. These are surface active agents with high spermicidal activity (10mg will kill the sperm in a normal ejaculate). The Noxynol 9 has little potential for irritation and no significant histological changes have been observed when it is used.

Other spermicidal agents used individually or in combination are methoxy-polyoxy ethylene glycol 550, ricinoleic acid, benzethonium chloride, sodium lauryl sulfate or related compounds. Many of these compounds are surface active ingredients as well. Phenyl mercuric acetate presently used in a jelly and in a foaming tablet is a very potent spermicide but some concerns have been expressed regarding effects of the mercuric compound in long term use in the body.

Spermicidal effectiveness for vaginal contraceptives is measured by the I.P.P.F. agreed test which tests the time for a unit dosage to kill an ejaculate. Safety is checked by the Margaret Sanger Research Bureau test which involves application to the vagina for 21 days and checking for irritati

Another method of evaluating the effectiveness of vaginal spermicidal contraceptives is to examine the vagina and cervix within 5 hours post coitus for motile sperm, in a method developed by Sims-Huhner. Tagging of the vaginal contraceptive with a fluorescent dye or gentian violet will permit evaluation of dispersal in the vagina.

A water soluble plastic film about 5cm square, impregnated with spermicide is to be introduced commercially in the near future in Western Europe and East Asia. This vaginal contraceptive is to be offered as an improvement to a precursor now widely distributed in Hungary. The newer

product uses Noxyol 9 rather than CPB in a different formulation within the film. One possible advantage for this product is that it delivers the appropriate dosage of spermicide as the jellies and creams without their vehicle bulk and without the need for a special inserter. It also has potential for simple transportation and handling. Consumer acceptance has yet to be measured and in some countries, direct digital manipulation by the woman of the vagina, as with the foaming tablets and liquid may be culturally unacceptable. Local manufacture in the developing countries may be limited as the film must be cast on a heated drum or belt using special equipment.

One of the vaginal contraceptive spermicidal preparations discussed may be a useful adjunct to distributing condoms through the commercial channels as in the Nirodh program.





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