Diaphragms

Section: 22. Medicines for reproductive health and perinatal care > 22.1. Contraceptives > 22.1.4. Barrier methods

ATC codes: Pending

Indication	Contact with health services for contraceptive management ICD11 code: QA21.Z
Medicine type	Device
List type	Core
Formulations	-
EML status history	First added in 1987 (TRS 770) Changed in 2003 (TRS 920)
Sex	All
Age	Adolescents and adults
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Diaphragms

Summary of evidence and Expert Committee recommendations

The Committee considered an application submitted by the Department of Reproductive Health and Research, WHO, to delete nonoxynol as a condom-additive vaginal spermaticide and virucide. In addition, a safety analysis was received from the WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden, along with a copy of the USFDA proposed rule on the labelling of over-the-counter vaginal contraceptive drug products containing nonoxynol-9. In the application, reference was made to a large multi-country study sponsored by WHO, the former Global Programme on AIDS (GPA) and the Joint United Nations Programme on HIV/AIDS (UNAIDS), results of which indicated that, contrary to expectation, there is a higher incidence of HIV infection in women using nonoxynol-9 than in women using a placebo gel. Prompted by this finding, the Department of Reproductive Health and Research, WHO, in partnership with the CONRAD Program, convened a technical consultation in October 2001 to review the implications of the new data on the use of nonoxynol-9 as a spermicide. All available evidence regarding the use of nonoxynol-9 as a contraceptive, its effectiveness in preventing infection with gonorrhoea or Chlamydia trachomatis, and its effectiveness in preventing HIV infection was summarized in the report of the consultation (1). The main conclusions reached are as follows: — although nonoxynol-9 has been shown to increase the risk of HIV infection when used frequently by women at high risk of infection, it remains a contraceptive option for women at low risk; — nonoxynol-9 offers no protection against STIs such as gonorrhoea or chlamydia; — there is no evidence that condoms lubricated with nonoxynol-9 are any more effective in preventing pregnancy or infection than condoms lubricated with silicone, and such condoms should no longer be promoted; however, it is better to use a nonoxynol-9 lubricated condom than no condom at all; — nonoxynol-9 should not be used rectally. In 2002, and subsequent to the consultation, the final results of the WHO/GPA/UNAIDS-sponsored study (the COL-1492 study) were published in the Lancet (2); a systematic review of the use of nonoxynol-9 for STI and HIV prevention was also published (3). In light of the presented evidence, the Department of Reproductive Health and Research proposed that the specific mention of condoms lubricated with

nonoxynol should be removed from the Model List, but that condoms themselves should be retained. The role of condoms in the prevention of pregnancy and HIV transmission is well proven; condoms are also the mainstay of HIV and STI prevention programmes. A silicone-oil lubricant is recommended in the joint WHO-UNAIDS publication The Male Latex Condom (4). The Committee, on the basis of the evidence before it, recommended to maintain condoms on the Model List but to delete the mention of nonoxynol in view of the increased risk of transmitting HIV infection. As there is insufficient evidence to suggest an alternative spermicide to nonoxynol, the Committee recommended that the reference to spermicides be deleted as well. The Committee acknowledged the continued need to offer diaphragms as part of the contraceptive mix in family planning, despite their moderate contraceptive effect, and thus recommended that they too should be maintained on the Model List. With regard to the use of nonoxynol with a diaphragm, the Committee noted that most observational studies are conducted with spermicide and that one randomized study reported a statistically non-significant additional beneficial effect of the spermicide in preventing pregnancy (5). The Committee therefore recommended the removal of the reference to spermicides, including nonoxynol, in the entry for diaphragms, in view of the lack of evidence of any additional benefit of spermicides and the strong suggestion of the potential of nonoxynol to increase the risk of transmission of HIV infection.

1. WHO/CONRAD Technical Consultation on nonoxynol-9. Summary report. Geneva, 9–10 October 2001. Geneva, World Health Organization, 2002 (http://www.who.int/reproductive-health/rtis/honoxynol9.html,accessed 8 October 2003). 2. van Damme L et al. Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-transmission among female sex workers. Lancet, 2002, 360:971–977. 3. Wilkinson D et al. Nonoxynol-9 spermicide for prevention of vaginally acquired HIV and other sexually transmitted infections: systematic review and meta-analysis of randomized controlled trials including more than 5000 women. Lancet Infectious Diseases, 2002, 2:613–617. 4. The male latex condom. Geneva, Joint United Nations Programme on HIV/AIDS, 1998 (WHO/RHT/FPP/98-15). 5. Bounds W et al. The diaphragm with and without spermicide. A randomized, comparative efficacy trial. Journal of Reproductive Medicine, 1995, 40:764–774.

