CONTRACEPTION

Aims

This guideline is not intended as a comprehensive textbook about contraceptives. It aims to summarise pivotal clinical issues, modern contraceptive product groups that are available and widely used in South Africa, and gives guidance on patient counselling and method selection.

Contraception is one of the most effective and cost-effective interventions to prevent maternal mortality and improve women's well-being and health. It should be freely available to all women and should logically be funded by all public and private health care providers and funders.

Definitions

Contraception is an important aspect of fertility and family planning. It allows individuals and couples to decide when to start a family, spacing of children, and the size of the family, resulting in numerous social and economic benefits and especially enables empowerment of women. In addition, there are many non-contraceptive medical benefits.

Modern contraceptives employ a product or procedure which interferes with reproduction resulting from sexual intercourse and include permanent methods (male and female sterilisation), mechanical methods (male and female condoms, diaphragm and cervical cap), medical or chemical methods (sponge, spermicides), intra-uterine methods (copper and progestogen containing) and systemic hormonal methods (progestogen-only methods and combined estrogen-progestogen methods).

Traditional methods do not fulfil the criteria above, and include fertility awareness methods, withdrawal, lactational amenorrhoea and abstinence. (1)

Long Acting Reversible Contraception (LARC's) typically require administration less that once per month and are less user dependant. This group includes injectables, intrauterine devices/systems and subdermal contraceptive implants. There is a growing trend towards LARCs as first line in view of high efficacy and good continuation rates.

Effectiveness

The Pearl Index (PI) is the most used method of measuring contraceptive efficacy and is the percentage of women with unintended pregnancy during the first year of use; it needs to be compared to the PI of using no method, which is 85%. For most methods *typical use* is less effective than *perfect use.* Spermicides and sponges are the least effective methods and should not be used on their own as typical use leads to pregnancy in 24+%, perfect use in 10-20%. The difference between typical and perfect use is larger for methods that are more user dependant like fertility awareness methods and withdrawal (24% vs ~4%), female condoms (21% vs 5%), male condoms (18% vs. 2%), and diaphragm (12% vs.6%). Another factor that determines effectiveness is the continuation rate, which ranges from 40 to 57% for these methods at one year.(2)

Combined and progestin oral, transdermal (patch) and vaginal (ring) contraceptives have similar reported PI of 9% for typical use, 0.3% for perfect use and reported continuation rates of 67%. The PI of most of the LARCs are almost the same for typical and perfect use, and are reported to range from 0.05% for Implanon®, 0.2% for Mirena® and Depo-Provera (which has typical use PI of 6%) to 0.6% for Copper containing IUCDs. Male and female sterilisation has effectiveness of 0.15% and 0.5% respectively.(2) While all classes should be available, methods which do not depend on perfect use or motivation and which have high continuation rates should be prioritised.(3)

Interestingly, the reported Pearl index of newer products appears to be increasing, called "creeping pearl index". This trend is most likely caused by more frequent pregnancy testing, more sensitive pregnancy tests, and less compliant study populations. (4)

Clinical assessment and eligibility

Due to potentially serious side-effects, patients need to be screened for eligibility. The World Health Organisation (WHO) Medical Eligibility Criteria (MEC) publications use evidence regarding the safety of contraceptives in specific medical conditions and patient characteristics to categorise the safety of methods per condition. Summarised versions of the 5th edition (2015), the WHO MEC wheel and the WHO application for smartphones are also available. Four safety categories are specified for use with clinical judgement and when clinical judgement is not available.(5)

Modern contraceptive methods

Contraceptive classes are briefly discussed, more or less in order of long term efficacy with typical use, starting with the LARCs, which are the most desirable group of contraceptives.(6).

Permanent contraception

Permanent contraception involves either tubal ligation (TL) in women or vasectomy in men. Neither female, nor male sterilisation is an emergency procedure or reliably reversible. It must be well thought through and well-motivated, as numerous alternative highly effective forms of reversible contraception are available. SASOG has developed patient information and *pro forma* consent for female sterilisation to ensure careful counselling and to limit medico-legal risk.

Tubal ligation at the time of caesarean section or immediately postpartum (mini-laparotomy) is convenient and has a very low morbidity; as an interval procedure it is done via laparoscopy. Failure rates are low, provided the patient is not pregnant at the time, an effective method is used and both tubes are visualised and interrupted. Histology confirmation is a good option when the method allows. Informed consent should preferably be done during the antenatal period, as informed consent in the emergency setting is not ideal.

Vasectomy is done by surgically interrupting the vas deferens and is not immediately effective. After a number of ejaculations, three months after the procedure, a post vasectomy semen analysis with documented azoospermia will confirm effectiveness. Until such time another form of contraception must be used. Patients must be advised to use another form of contraception until azoospermia is proven. Effective re-anastomosis does not guarantee restoration of fertility due to the induction of antibodies.

Intra-uterine contraceptive devices

Both copper-containing and medicated devices are classified as LARCs and have excellent efficacy and continuation rates, but require a skilled healthcare provider to insert them.

Levonorgestrel medicated intrauterine systems (IUS) are available in two products in SA, namely Mirena® and Kyleena®, both highly effective as contraception, but only Mirena® is also indicated and very effective as treatment for heavy menstrual bleeding in view of the larger total (52mg vs 19.5mg) and daily dose (20µg vs. 12µg) levonorgestrel dose. Kyleena® has fewer hormonal side effects (mostly due to the androgenic effects of the levonorgestrel), but also lower rates of amenorrhoea and more infrequent bleeding. It has a slightly thinner applicator (3.8mm vs. 4.4mm) and smaller frame size, making it very suitable for nulliparous women.

Copper intrauterine contraceptive devices (IUCD) have been available for many years, have excellent safety, cost effectiveness, efficacy and continuation data and are registered for 5 or 10 years, dependent on the amount of copper it contains. In SA it is the most underutilised method. The most important limitations to use are an increase in menstrual volume and pain in some women and also an undeserved bad reputation based on fears of infection, infertility and ectopic pregnancy. The best available evidence has shown that there is no increased risk of pelvic infection or infertility when using the IUCD, and ectopic pregnancy is not increased. Infection related to insertion (usually in the presence of cervicitis) can occur within the first 3 weeks following insertion (7) and is very uncommon with meticulous insertion technique.

Progestogen-only methods

Progestogen intrauterine systems can also be classified under progestogen-only methods, but the mechanism of action is local rather than systemic. See above.

Sub-dermal progestogen implants are highly effective LARC's and were actively introduced in 2014 in South Africa initially as the etonogestrel implant, called Implanon®, a 4cm rod placed in the left upper inner arm by a trained health care provider. It has been replaced by Nexplanon® (pre-loaded thus easier to insert, and radio-opaque for easier location), which is bio-equivalent, still active for 3 years and contains 68mg of hormone. Heavy menstrual flow occurs in some women and there is ongoing concern of efficacy with concomitant use of efavirenz and rifampicin. Other methods include the levonorgestrel (LNG) implant consisting of 2 rods, effective for 5 years and seen in some immigrants.

Injectable progestogens include the widely used 3-monthly or 12-weekly depot medroxyprogesterone acetate (DMPA) and the 2-monthly or 8-weekly norethisterone enanthate (NET-EN) and newer subcutaneous depo injections. Both are considered as LARCs, but the effectiveness is lower than the methods discussed above, mostly due to compliance. Concerns include undesired bleeding patterns, slow return to fertility, weight gain, headache and some effect on bone density. Progestogen dominance may assist to reduce endometriosis and endometrial overgrowth and these methods can be used in women with estrogen contra-indications. A subcutaneous contraceptive injectable containing 104 mg of DMPA is undergoing registration in SA. It is also used 12-weekly, has the same effectiveness and side effect profile as the DMPA IM, but has the benefit of being self-administered.

Progesterone only pills are very short-acting and dependent on compliance. It should be taken with a maximum of three hours fluctuation every day. The quoted Pearl index is however similar to combination hormonal contraceptives. Side effects are very low, and the method is very useful when estrogen is contra-indicated, during breast feeding, peri-pubertal and peri-menopausal women.

Combined hormonal methods

There are various delivery mechanisms for combined hormonal contraceptives, which all work in similarly, usually by delivering a combination of estrogen and progestogen for 21 to 24 days, followed by 3 to 7 days without. These methods can also be used continuously especially in women with pre-menstrual progestogen withdrawal headaches, and some women have amenorrhoea in this way. Variation in side effect profile is mostly related to the type of progestogen and dosage of both hormones. While venous thromboembolism is the largest concern with combined methods, it is far more common in pregnancy and postpartum than with any contraceptive.(8) The WHO MEC must be used to ensure safe use before prescribing.(5)

Combined oral contraceptives are divided into monophasic, biphasic, triphasic and quadriphasic preparations depending on the changes in hormone dosage over the cycle. The estrogenic component can be high, low or ultra-low dose. The progestogenic component is categorized according to the parent compound (testosterone; spironolactone; 19-nortestosterone) and when it was developed i.e. 1st generation; 2nd generation; 3rd generation and 4th generation.

Vaginal contraceptive ring is placed in the vagina for three weeks out of four, where it releases a continuous dose.

Contraceptive transdermal patch is also placed for three weeks and works similarly to the oral route; compliance may be improved.

Special clinical situations

Post-Partum contraception

This opportunity to discuss, plan and offer contraception must not be missed, and a method should be provided before discharge as ovulation can occur before the 6-week visit. *Sterilisation* must have been discussed during pregnancy to prevent hasty decisions.

IUCD's are very safe and effective in this context, provided a few rules are followed, and are certainly underutilised. It can be inserted at the time of caesarean section, immediately after delivery and up to 48 hours in the postpartum period. Patients should be counselled that the risk of perforation and expulsion is relatively high especially after later insertion. An IUCD is contra-indicated if there has been prolonged rupture of membranes; chorioamnionitis or postpartum haemorrhage. Women should be counselled that the device could be expelled without them realising and therefore it is important to confirm the device placement at the 6 week visit. They should seek medical assistance for any symptom suggesting infection, heavy bleeding or expulsion.

Breast-feeding patients should choose *progestogen-only pills* over combinations. Combined oral contraceptives can be started after three weeks in non-breast-feeding women without risks for venous thromboembolism.

Lactational amenorrhoea is effective, provided that breastfeeding is exclusive, the mother has amenorrhoea, and the baby is less than 6 months old.

Emergency Contraception

The *copper IUD* is the first choice emergency contraceptive as it is the most effective method, can be used up to 120 hours after unprotected sexual intercourse (UPSI) and provides ongoing contraception for five years or longer.

The *levonorgestrel single dose tablet* available as Escapelle® is 1.5mg tablet taken immediately up to 72 hours after unprotected sexual intercourse (UPSI). It has been used up to 96 hours, but contraceptive effectiveness decreases significantly. It will not prevent ovulation if taken after the onset of the LH surge. LNG may also be used in 2 divided doses i.e. 0.75mg 12 hourly for 24 hours.

The *selective progestogen receptor modulator* ulipristal acetate, Ella®, inhibits ovulation for 5 days at a dose of 30mg immediately and is effective up to 120 hours after UPSI because it still inhibits ovulation after onset of the LH surge. It is not effective after the LH peak, meaning that it is important to ascertain how close to ovulation the UPSI was.

The *Yuzpe method* consist of two tablets high dose combined oral contraceptives taken immediately but within 72 hours of UPSI, followed by another two after 12 hours. The method is no longer recommended due to the high dose of estrogen and the side effects of nausea and vomiting, but can be used in the absence of other available methods.

Menstruation may be delayed when using emergency contraception, but up to 75% of women taking UA will experience their period at the normal time.

Deep or Difficult Implant removals

Implants for removal that cannot be palpated may be removed under ultrasound guidance ideally using a high frequency linear probe 10 – 18 MHz; abdominal and vaginal probes have also been used successfully. (9).

Contraception in the perimenopause

During the peri-menopause the small remaining risk for pregnancy must be balanced with the risks, costs and inconvenience of the contraceptive hormone dosage in the older woman. Menopausal hormone therapy (MHT) does not protect against pregnancy. Older age, menopausal symptoms and longer period of amenorrhoea all lower the chances of remaining fertility.

After the age of 50 years, many women will have co-morbidities or risk factors that make combined oral contraceptives (cardiovascular risks) and injectables (bone density risks) undesirable. FSH-levels cannot be interpreted in women using these two methods, but can be done on a yearly basis after interrupting COC's for 8 days, to determine ovarian function.

Fertility after age 55 years is very uncommon, so most women can safely stop contraceptives or change to MHT. LNG IUS, progestogen only tablets and implants all allow the use of FSH levels to ascertain ovarian failure, but are all considered safe to continue also after menopause. LNG IUS has a longer effective lifespan of up to 10 years in women >45 years.(10)

Risk of HIV acquisition

Findings from observational trials suggested an elevated risk of HIV acquisition among women at high risk using progestogen-only injectable contraceptives.(8) The WHO subsequently conducted a randomised clinical multicentre study with sites in South Africa, eSwatini, Zambia and Kenya, called the ECHO trial, randomising women to either DMPA, Levonorgestrel implant or copper IUD. The study showed an equal risk of HIV acquisition of 4% across all methods without any significant difference in HIV acquisition.(11) Following this evidence, injectables are categorised as MEC category 1, and considered safe regarding HIV-acquisition.(12)

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Clinical Guideline

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It never replaces clinical judgement and individualised care.

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