



Long Acting Hormonal Contraceptives:

Contraceptive Implants

Evidence Based Clinical

Practice Guidelines

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FOREWORD

Achieving a high quality public health system that is accessible to all communities has been a priority for our country's leadership. A key element in reaching the Ministry of Health's vision, as stated in the Strategic Plan – A healthy community functioning within a high quality, integrated health system that is fair and operates with the highest standards in the region – requires ensuring that all clinicians are well-trained and utilize a standard set of reference materials for treatment of clients.

The Long Acting Hormonal Contraceptives; Contraceptive Implants Evidence Based Clinical Practice Guidelines is a continuation of the Evidence Based Clinical Guidelines series that was developed by the Ministry of Health and is intended for public health care professionals in Jordan. It is part of the National Reproductive Health Action Plan II efforts to decrease the total fertility rate and to increase the modern contraceptives prevalence rate in the Kingdom with an emphasis on long term family planning methods. This publication is the result of a thorough review of internationally recognized reference protocols, manuals, guidelines, and other materials and aims to enhance the skills of our health care professionals in providing high quality reproductive health and family planning services.

As guardians of our nation's health, it is of utmost importance that we ensure access to the best health care for the mothers, children and all family members of our current and future generations. The information contained in this series should be considered a standard reference and be disseminated to all relevant health professionals so they may benefit from the knowledge and skills that will result from their use.

All those who worked so diligently to produce this series, both Ministry of Health personnel and their technical assistance counterparts, deserve praise and appreciation.

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ACRONYMS

BMD	Bone Mineral Density
BMI	Body Mass Index
BRCA 1	Breast Cancer 1 (Tumor Suppressor Gene)
COC	Combined Oral contraceptives
CPR	Contraceptive Prevalence Rate
DMPA	Depot Medroxyprogesterone Acetate
DVT/PE	Deep Venous Thrombosis/Pulmonary Embolism
EVA	Ethylene-Vinyl-Acetate
FSH	Follicle Stimulating Hormone
GPP	Good Practice Point
HAART	Highly Active Anti-Retroviral Therapy
HCG	Human Chorionic Gonadotropin
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HLD	High Level Disinfection
IDDM	Insulin Dependent Diabetes Mellitus
IUD	Intrauterine Device
IUS	Intrauterine System
LAHC	Long Acting Hormonal Contraceptive
LAHC:CI	Long Acting Hormonal Contraceptive: Contraceptive Implant
LH	Luteinizing Hormone
MEC	Medical Eligibility Criteria
MOH	Ministry of Health
N/A	Not Applicable
NET-EN	Norethisterone Enanthate
NIDDM	Non-Insulin Dependent Diabetes Mellitus
OJT	On-the-job Training
PE	Pulmonary Embolism
PID	Pelvic Inflammatory Disease
POC	Progestin-Only Contraceptives
RCOG	Royal College of Obstetrics and Gynecology
SPC	Summary of Product Characteristics
STIs	Sexually Transmitted Infections
TFR	Total Fertility Rate
UK	United Kingdom
VTE	Venous Thromboembolism
WHO	World Health Organization

INTRODUCTION

Jordan is facing a real challenge in controlling its population growth. Figures showing stagnation in the total fertility rates (TFR) over the last decade has raised concerns about the trends of population growth in the future. Jordan's high TFR of 3.8 is a result of a leveling off of contraceptive prevalence at 59% combined with high discontinuation rates. More than two in five contraceptive users in Jordan (45%) stopped using a method within 12 months of starting use. Sixteen percent of users stopped using to switch to another method while 8% stopped using due to method failure, that is to say; they became pregnant while using the method.¹ The most widely used method in Jordan is the intra uterine device (IUD); hence Jordan is essentially a one method country with 22.6% of women using the IUD. On the other hand less than one percent of women are using contraceptive implants.¹

Long-acting contraception is vital to fulfilling the MOH's mission to help protect and improve its citizens' health and to help achieve national development goals. Experience globally confirms that without widespread availability and use of long-acting methods of contraception, a country cannot cost-effectively meet its lowered fertility goals. In turn, inability to reduce high fertility contributes directly and substantially to poor health, poverty, low levels of education, and high under -and unemployment- that is, to low national productivity, economic growth, and socioeconomic development.

Contraceptive implants, are especially very promising as they are easy to use, readily reversible and have gained acceptance among practitioners and clients alike, and may be the key towards achieving the goals of the Jordanian people.

This clinical practice guideline and training module was developed to focus on contraceptive implants; however, other long acting hormonal contraceptives are mentioned, mainly for comparison.

This publication was intended to be evidence based, so as to allow both the trainees and trainers to appreciate the importance of evidence based recommendations, and to give confidence in the information disseminated throughout this training module. Evidence base levels and grades of recommendations used are explained through tables 1 and 2 below.

Table 1: Levels of evidence

I a	Evidence obtained from meta-analysis of randomized trials
I b	Evidence obtained from at least one randomized controlled trial
II a	Evidence obtained from at least one well-designed controlled study, without randomization
II b	Evidence obtained from at least one other type of well-designed quasi-experimental study

III	Evidence obtained from well-designed non-experimental descriptive studies, correlation studies and case studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Table 2: Grades of recommendation

A	Evidence based on randomized controlled trials
B	Evidence based on other robust experimental or observational studies
C	Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
GPP	Good Practice Point where no evidence exists, but where best practice is based on the clinical experience of the multidisciplinary group developing the guidelines, e.g. Faculty of Sexual and Reproductive Health Care, or Faculty of Family planning and reproductive health care.

Evidence was identified using electronic search engines including, MEDLINE, EMBASE, PubMed, the Cochrane Library, and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms and text words.

Existing international guidelines were also searched and the reference lists of these guidelines were used to identify relevant publications. Guidelines from international clinical institutions were used in the development of the current guideline, these included guidelines from The Faculty of Family Planning and Reproductive Health Care; The Royal College of Obstetricians and Gynecologists (RCOG); The World Health Organization; The British Association for Sexual Health and HIV; The Royal College of Nursing; National Collaborating Centre for Women’s and Children’s Health; and Association of Reproductive Health Professionals. The Product Information data and the contraceptive implant insertion and removal training materials were developed in accordance with materials obtained from Organon pharmaceuticals.

The recommendations in this training module were graded using a scheme similar to that adopted by the RCOG and other guideline development organizations.

It is hoped that this training module will serve as a model for evidence based practice guidelines tailored for the needs and facilities of the Jordanian health care system.

CHAPTER 1: COUNSELING AND INFORMED CHOICE

1.1 BACKGROUND INFORMATION

Counseling and informed choice are the key to a woman's ability to freely select a method that she can use effectively. Free and informed choice means that the client chooses a method voluntarily without coercion or pressure. It is based on a clear understanding of the benefits and limitations of the methods that are available.

1.2 OBJECTIVES

1. Counsel clients who are interested in using long acting hormonal contraceptives (LAHC).
 2. Counsel clients who are interested in using contraceptive implants as a contraceptive.
 3. Explain, in simple language, how contraceptive implants prevent pregnancy.
 4. List the indications and precautions for using contraceptive implants.
 5. Provide post-insertion counseling to clients.
 6. Discuss how to combat rumors regarding sub-dermal implants.
- The goals of family planning counseling are to:
 - Help the woman understand the factors that can lead to an unwanted pregnancy.
 - Help her and her husband decide if she wants to use a contraceptive method.
 - Help her and her husband choose an appropriate method.
 - Prepare her and her husband to use the method effectively.
 - Recommendations for informed choice:
 - Women requiring contraception should be given information about and offered a choice of all methods, including long-acting hormonal contraception (LAHC) methods. (Grade GPP)
N.B: Within this module LAHCs are hormonal contraceptives that require usage less than once every cycle or month; they include:
 - Injectable hormonal contraceptives*;
 - The levonorgestrel intrauterine system (IUS);
 - The single rod contraceptive implant.
 - Women should be provided with the method of contraception that is most acceptable to them provided it is not contraindicated. (Grade GPP)
 - Contraceptive service providers should be aware that:
 - All currently available LAHC methods (the IUS, injectable contraceptives and implants) are more cost effective than the combined oral contraceptive pill even at 1 year of use. (Grade C)
 - IUDs, the IUS and implants are more cost effective than the injectable contraceptives. (Grade C)
 - Increasing the uptake of LAHC methods will reduce the number of unintended pregnancies. (Grade C)
 - Strategies to support informed choice

* Injectables are considered in this module as long acting methods according to the above mentioned definition; however, WHO/Department of reproductive health and Research, Johns Hopkins Bloomberg School of Public Health/Centre for Communication programs/INFO project (CCP) within their book Family Planning: A Global Handbook for providers. Baltimore, MD and Geneva: CCP and WHO 2007. Consider the injectables as short acting methods.

- Provide information on the various methods.
- Conduct in private, comfortable settings that foster trust.
- Focus on client's needs.
- Adhere to client's rights and social equality; exhibit respect and mutual understanding.
- Family planning information
 - Women considering LAHC methods should receive detailed information — both verbal and written — that will enable them to choose a method and use it effectively. This information should take into consideration their individual needs and should include: (Grade GPP).
 - Contraceptive efficacy.
 - Duration of use.
 - Risks and possible side effects.
 - Non-contraceptive benefits.
 - The procedure for initiation and removal/discontinuation.
 - When to seek help while using the method.
 - Counseling about contraception should be sensitive to cultural differences and religious beliefs. (Grade GPP)
 - Lack of understanding (possibly due to unclear instructions) may lead to misuse of a contraceptive method and to unwanted pregnancy.
 - Too much technical information, however, can be as harmful as too little because it may overwhelm the woman and make it more difficult for her to make a decision.
 - The information that the woman receives should be tailored to her needs. For example, a woman who has refused repeatedly the oral contraceptive pills because she thinks that they cause cancer has a different need for information than a woman who used the pills incorrectly.

1.3 THE PROCESS OF COUNSELING AND INFORMED CHOICE

Good family planning counseling focuses on the individual woman's needs and situation, and good counselors listen to the woman's questions and concerns. Counseling must be based on trust and respect between the client and the counselor.

- Family planning counseling should help a client:
 - Consider her reproductive goals.
 - Make free, informed choices about family planning.
 - Understand how to use effectively or stop using her chosen method.
- The key to good counseling is a good counselor who:
 - Understands and respects the client's rights.
 - Earns the clients trust.
 - Understands the benefits and limitations of all contraceptive methods.
 - Understands the cultural and personal factors that affect a woman's (or a couple's) decision to use family planning and a particular method.
 - Encourages the client to ask questions, and uses open ended questions.
 - Uses a nonjudgmental approach which shows the client respect and kindness.
 - Presents information in an unbiased, client-sensitive manner.
 - Actively listens to the client's concerns.
 - Recognizes when s/he cannot sufficiently help a client and refers the client to someone who can understand the effect of nonverbal communication.

- The counseling session: REDI vs. GATHER framework:
 - REDI and GATHER are both counseling frameworks. Counselors started using GATHER almost two decades ago when need for counseling was directed to family planning.
 - With the continuous expansion of issues related to counseling, especially reproductive health issues, the frame work was modified to become REDI in order to provide flexibility to the counselor and client to identify needs and work towards fulfilling them.
 - Following are both frameworks giving the providers the flexibility to decide on the suitable one for each individual woman.
 - The GATHER system is one method used to organize the elements of the counseling process. This acronym is designed to help counselors remember important points in effective counseling. GATHER (see Table 3) is one approach for counseling. In practice, counseling should be tailored to the individual circumstances and may follow a different sequence or technique.

Table 3: Comparing REDI and GATHER

G	GREET	R	RAPPORT-BUILDING
A	ASK/ASSESS	E	EXPLORATION
T	TELL	D	DECISION MAKING
H	HELP	I	IMPLEMENTING THE DECISION
E	EXPLAIN		
R	REFER		

- The REDI system is used to identify client’s reproductive health needs. This is more flexible in terms of counseling sessions in which the client’s need is identified and the chosen method of family planning is fulfilled with all GATHER steps.

Table 4: The REDI technique

The REDI Technique	
R Rapport Building	<ul style="list-style-type: none"> ▪ Welcome the client. ▪ Make introductions. ▪ Assure confidentiality. ▪ Help the client to relax and feel comfortable.
E Explore	<ul style="list-style-type: none"> ▪ Explore the client’s needs, risks, sexual life, social context, circumstances and fertility plans. ▪ Assess the client’s knowledge/experience and give information, as needed. ▪ Assist the client to perceive or determine her reproductive health/family planning risks including pregnancy risk. ▪ Ask about her reproductive goals, including if she wants to become pregnant soon.
D Decision Making	<ul style="list-style-type: none"> ▪ Identify what decisions the client needs to make. ▪ Identify the client’s options for each decision. ▪ Help the client to weigh the benefits, disadvantages, and consequences of each decision (will there be any problems or issues regarding using this method not only for the client but for her husband as well).

The REDI Technique	
I	<ul style="list-style-type: none"> ▪ Encourage the client to make her own decision.
Implementing the decision	<ul style="list-style-type: none"> ▪ Make a concrete and specific plan for carrying out the decision. ▪ Identify skills that will be needed by the client (using condom, negotiation skills, etc.). ▪ Let the client practice skills, as needed, with your help. ▪ Make a plan for follow-up. ▪ Refer client to another service provider if needed.

1.4 CONTRACEPTIVE PRESCRIBING

- A medical history - including relevant family, menstrual, contraceptive and sexual history - should be taken as part of the routine assessment of medical eligibility for individual contraceptive methods. (Grade GPP)
- Healthcare professionals helping women to make contraceptive choices should be familiar with nationally agreed guidance on medical eligibility and recommendations for contraceptive use. (Grade GPP)
- When considering choice of LAHC methods for specific groups of women and women with medical conditions, healthcare professionals should be aware of and discuss with each woman any issues that might affect her choice. (Grade GPP)
- Healthcare professionals should exclude pregnancy by taking the menstrual and sexual history before initiating any contraceptive methods. (Grade GPP)
- Healthcare professionals should supply an interim method of contraception at the first appointment if required. (Grade GPP)
- Women who have a current venous thromboembolism (VTE) and need hormonal contraception while having treatment for the VTE should be referred to a specialist in contraceptive care. (Grade GPP)

1.5 CONTRACEPTION AND SEXUALLY TRANSMITTED INFECTION

- Healthcare professionals providing contraceptive advice should promote safer sex. (Grade GPP).
- Healthcare professionals providing contraceptive advice should be able to assess risk for sexually transmitted infections (STI) and advise testing when appropriate. (Grade GPP)
- Healthcare professionals should be able to provide information about local services for STIs screening, investigation and treatment. (Grade GPP)

1.6 CONTRACEPTION FOR SPECIAL GROUPS

- Women with learning and/or physical disabilities should be supported in making their own decisions about contraception. (Grade GPP)
- Contraception should be seen in terms of the needs of the individual rather than in terms of relieving the anxieties of relatives. (Grade GPP)
- When a woman with a learning disability is unable to understand and take responsibility for decisions about contraception, health care providers and other involved parties should meet to address issues around the woman's contraceptive need and to establish a care plan. (Grade GPP)

1.7 TRAINING OF HEALTH PROFESSIONALS IN CONTRACEPTIVE CARE

Healthcare professionals advising women about contraceptive choices should be competent to:

- Help women to consider and compare the risks and benefits of all methods relevant to their individual needs.
- Manage common side effects and problems. (Grade GPP)

Contraceptive service providers who do not provide LAHC in their practice or service should have an agreed mechanism in place for referring women for LAHC. (Grade GPP)

- Healthcare professionals providing intrauterine or sub-dermal contraceptives should receive training to develop and maintain the relevant skills to provide these methods. (Grade GPP)
 - The IUS should only be fitted by trained personnel with continuing experience of inserting at least one IUS a month. (Grade GPP)
 - Contraceptive implants should be inserted and removed only by healthcare professionals trained in the procedure. (Grade GPP)

CHAPTER 2: SPECIFIC COUNSELING FOR LONG ACTING HORMONAL CONTRACEPTIVES

2.1 PROGESTOGEN-ONLY SUBDERMAL IMPLANTS (CONTRACEPTIVE IMPLANTS)

Decision Making: Women should be given the following information:

- Contraceptive Efficacy
 - Contraceptive implants acts by preventing ovulation. (Grade GPP)
 - The pregnancy rate associated with the use of contraceptive implants is very low (less than 1 in 1000 over 3 years). (Grade C)
 - Contraceptive implant has marketing authorization for use for 3 years. (Grade GPP)
 - There is no evidence of a delay in the return of fertility following removal of contraceptive implants. (Grade C)
- Effects on Periods
 - Bleeding patterns are likely to change while using contraceptive implants. (Grade C)
 - 20% of women will have no bleeding, while almost 50% of women will have infrequent, frequent or prolonged bleeding. (Grade C)
 - Bleeding patterns are likely to remain irregular over time. (Grade C)
 - Dysmenorrhea may be reduced during the use of contraceptive implants. (Grade C)
- Risks and Possible Side Effects
 - Up to 43% of women stop using contraceptive implants within 3 years; 33% of women stop because of irregular bleeding and less than 10% of women stop for other reasons including hormonal (non-bleeding) problems. (Grade C)
 - There is no casual association between use of a contraceptive implants and changes in weight, mood, libido or headaches. (Grade C)
 - Acne may improve, occur or worsen during the use of contraceptive implants. (Grade C)
- Healthcare Professionals Should be Aware That
 - There is no evidence that the effectiveness or adverse effects of implants vary with the age of the user. (Grade C)
 - Women over 70 kg can use contraceptive implants as an effective method of contraception. (Grade GPP)
 - Contraceptive implants can safely be used by women who are breastfeeding. (Grade C)
 - Contraceptive implants use is not contraindicated in women with diabetes. (Grade GPP)
 - There is no evidence that implant use increases the risk of STI or HIV acquisition. (Grade GPP)
 - Contraceptive implants are a safe and effective method of contraception for women with STI, including HIV/AIDS (safer sex using condoms should be encouraged in this group) (Grade GPP)
 - All progestogen-only methods, including contraceptive implants, may be used by women who have migraine with or without aura. (Grade GPP)
 - Contraceptive implants are medically safe for women to use if estrogen is contraindicated. (Grade C)
 - There is no evidence of an effect of contraceptive implants use on bone mineral density. (Grade C)
 - Contraceptive implants are not recommended as a contraceptive method for women taking liver enzyme-inducing drugs. (Grade GPP)

- Practical Details of Fitting Implants:
 - Provided that it is reasonably certain that the woman is not pregnant, contraceptive implants may be inserted: (Grade GPP)***
 - At any time (but if the woman is amenorrheic or it has been more than 5 days since menstrual bleeding started, additional barrier contraception should be used for first 7 days after insertion).
 - Immediately after abortion in any trimester
 - At any time postpartum (after 28 days for non-breastfeeding women and after 6 weeks for breastfeeding women).
- Advice for Women at Time of Fitting
 - Women should be informed that contraceptive implants insertion and removal both cause some discomfort and bruising but that technical problems are unusual (less than 1 in 100). (Grade C)
- Follow-up and Managing Problems:
 - No routine follow-up is needed after implant insertion. However, a woman should be strongly encouraged to return at any time to discuss problems, if she wants to change her method of contraception, or if it is time to have the implant removed. (Grade GPP)
 - Irregular bleeding associated with implant use can be treated with mefenamic acid, ethinylestradiol or 17- Beta estradiol. (Grade B)
 - There is no evidence of a teratogenic effect of contraceptive implants use but, if a woman becomes pregnant and continues with the pregnancy, the implant should be removed. (Grade GPP)
 - If an implant cannot be palpated (due to deep insertion, failed insertion or migration) it should be localized by ultrasound investigation before being removed. Deeply inserted implants often need to be removed by an expert. (Grade GPP)

2.2 PROGESTOGEN-ONLY INJECTABLE CONTRACEPTIVES

Decision Making: Women should be given the following information:

- Contraceptive Efficacy
 - Progestogen-only injectable contraceptives act primarily by preventing ovulation. (Grade C)
 - The pregnancy rate associated with injectable contraceptives, when given at the recommended intervals, is very low (fewer than 4 in 1000 over 2 years) and the pregnancy rate with depot medroxyprogesterone acetate (DMPA) is lower than that with norethisterone enanthate (NET-EN). (Grade C)
 - DMPA should be repeated every 12 weeks and NET-EN every 8 weeks (Grade C).
 - There could be a delay of up to 1 year in the return of fertility after stopping the use of injectable contraceptives. (Grade C)
 - If a woman stops using injectable contraceptives but does not wish to conceive, she should start using a different contraceptive method immediately even if amenorrhea persists. (Grade GPP)
- Effects on Periods
 - Amenorrhea is likely during use of injectable contraceptives; this is more likely with DMPA than NET-EN, is more likely as time goes by, and is not harmful. (Grade C)
 - Up to 50% of women stop using DMPA by 1 year; the most common reason for discontinuation is an altered bleeding pattern, including persistent bleeding. (Grade C)

- Risks and Possible Side Effects
 - DMPA use may be associated with an increase of up to 2-3 kg in weight over 1 year. (Grade C)
 - DMPA use is not associated with acne, depression or headaches. (Grade C)
 - DMPA use is associated with a small loss of bone mineral density, which is largely recovered when DMPA is discontinued. (Grade B)
 - There is no evidence that DMPA use increases the risk of fracture. (Grade B)
- Specific Groups, Medical Conditions and Contraindications:

Because of the possible effect on bone mineral density, care should be taken in recommending DMPA to:

 - Adolescents, but it may be given if other methods are not suitable or acceptable. (Grade GPP)
 - Women older than 40 years, but in general the benefits outweigh the risks and it may be given if other methods are not suitable or acceptable. (Grade GPP)
- Healthcare Professionals Should be Aware That:
 - Women with a body mass index over 30 can safely use DMPA and NET-EN. (Grade GPP)
 - Women who are breastfeeding can consider using injectable contraceptives. (Grade C)
 - All progestogen only-methods, including injectable contraceptives, may be used by women who have migraine with or without aura. (Grade GPP)
 - DMPA is medically safe for women to use if estrogen is contraindicated. (Grade GPP)
 - Injectable contraceptives are not contraindicated in women with diabetes. (Grade GPP)
 - DMPA use may be associated with a reduction in the frequency of seizures in women with epilepsy. (Grade GPP)
 - There is no evidence that DMPA use increases the risk of STI or HIV acquisition.
 - DMPA is a safe and effective method of contraception for women with STIs, including HIV/AIDS (safer sex using condoms should be encouraged in this group. (Grade GPP)
 - Women taking liver enzyme-inducing medication may use DMPA and the dose interval does not need to be reduced. (Grade GPP)
- Practical Details of Giving Injectable Contraceptives
 - Injectable contraceptives should be given by deep intramuscular injection into the gluteal or deltoid muscle or the lateral thigh. (Grade GPP)
 - Provided that it is reasonably certain that the woman is not pregnant, the use of injectable contraceptives may be started. (Grade GPP)
 - Up to and including the fifth day of the menstrual cycle without the need for additional contraceptive protection.
 - At any other time in the menstrual cycle, but additional barrier contraception should be used for the first 7 days after the injection.
 - Immediately after first- or second-trimester abortion, or at any time thereafter.
 - At any time postpartum (at any time after delivery for non-breastfeeding women and after 6 weeks for breastfeeding women).
- Follow-up and Managing Problems
 - Women attending up to 2 weeks late for repeat injection of DMPA may be given the injection without the need for additional contraceptives. (Grade GPP)

- A pattern of persistent bleeding associated with DMPA use can be treated with mefenamic acid or ethinylestradiol or 17- Beta estradiol. (Grade C)
- Women who wish to continue DMPA use beyond 2 years should have their individual clinical situations reviewed; the balance between the benefits and potential risks discussed, and is supported in their choice of whether or not to continue. (Grade GPP)
- Healthcare professionals should be aware that if pregnancy occurs during DMPA use there is no evidence of congenital malformation to the fetus. (Grade GPP)

2.3 INTRAUTERINE SYSTEM

Decision making: Women should be given the following information:

- Contraceptive Efficacy
 - The intrauterine system (IUS) may act predominantly by preventing implantation and sometimes by preventing fertilization. (Grade GPP)
 - The pregnancy rate associated with the use of the IUS is very low (fewer than 10 in 1000 over 5 years). (Grade C)
 - The licensed duration of use for IUS is five years for contraception. (Grade GPP)
 - There is no evidence of a delay in the return of fertility following removal or expulsion of the IUS. (Grade C)
- Effects on Periods
 - Irregular bleeding and spotting are common during the first 6 months following IUS insertion. (Grade C)
 - Oligomenorrhea or amenorrhea is likely by the end of the first year of IUS use. (Grade C)
- Risks and Possible Side Effects
 - Up to 60% of women stop using the IUS within 5 years. The most common reasons are unacceptable vaginal bleeding and pain; a less common reason is hormonal (non-bleeding) problems. (Grade C)
 - There is no evidence that IUS use causes weight gain. (Grade C)
 - Any changes in mood and libido are similar whether using the IUS or IUDs, and the changes are small. (Grade C)
 - There may be an increased likelihood of developing acne as a result of absorption of progestogen, but few women discontinue IUS use for this reason. (Grade C)
 - The risk of uterine perforation at the time of IUS insertion is very low (less than 1 in 1000). (Grade C)
 - The risk of developing pelvic inflammatory disease following IUS insertion is very low (less than 1 in 100) in women who are at low risk of STIs. (Grade C)
 - The IUS may be expelled, but this occurs in less than 1 in 20 women in 5 years. (Grade C)
 - The risk of ectopic pregnancy when using the IUS is lower than when using no contraception. (Grade GPP)
 - The overall risk of ectopic pregnancy when using the IUS is very low, at about 1 in 1000 in 5 years. (Grade C)
 - If a woman becomes pregnant with the IUS in situ the risk of ectopic pregnancy is about 1 in 20, and she should seek advice to exclude ectopic pregnancy. (Grade GPP)

- Other Issues to Consider Before Fitting an IUS
 - Women who are aged 45 years or older at the time of IUS insertion and who are amenorrhic may retain the device until they no longer require contraception. (Grade GPP)
 - Contraceptive care providers should be aware that the risk of perforation is related to the skill of the healthcare professional inserting the IUS. (Grade GPP)
 - Testing for the following infections should be undertaken before IUS insertion: (Grade GPP)
 - *Chlamydia trachomatis* in women at risk of STIs.
 - *Neisseria gonorrhoeae* in women from areas where the disease is prevalent and who are at risk of STIs.
 - If testing for STIs is not possible, or has not been completed, prophylactic antibiotics should be given before IUS insertion in women at increased risks of STIs. (Grade GPP)
 - Women with identified risks associated with uterine or systemic infection should have investigations, and appropriate prophylaxis or treatment before insertion of the IUS. (Grade GPP)
- Specific Groups, Medical Conditions and Contraindications
 - The IUS may be used by adolescents, but STI risk should be considered where appropriate. (Grade GPP)
- Healthcare Professionals Should be Aware that
 - IUS use is not contraindicated in nulliparous women of any age. (Grade GPP)
 - Women of all ages may use the IUS. (Grade GPP)
 - The IUS can safely be used by women who are breastfeeding.
 - There is no evidence that the effectiveness of the IUS is reduced when taking any other medication. (Grade GPP)
 - IUS use is not contraindicated in women with diabetes. (Grade GPP)
 - IUS is a safe and effective method of contraception for women who are HIV-positive or have AIDS (safer sex using condoms should be encouraged in this group). (Grade GPP)
 - All progestogen-only methods, including the IUS, may be used by women who have migraine with or without aura. (Grade GPP)
 - Women with a history of venous thromboembolism may use the IUS. (Grade GPP)
 - IUS is medically safe for women to use if estrogen is contraindicated. (Grade GPP)
- Practical Details of Fitting IUS:

Provided that it is reasonably certain that the woman is not pregnant, the IUS may be inserted: (Grade GPP)

 - At any time during the menstrual cycle (but if the woman is amenorrhic or it has been more than 5 days since menstrual bleeding started, additional barrier contraception should be used for the first 7 days after insertion).
 - Immediately after first - or second- trimester abortion, or at any time thereafter.
 - From 4 weeks postpartum, irrespective of the mode of delivery.
 - Emergency drugs including anti-epileptic medication should be available at the time of IUS insertion in a woman with epilepsy because there may be an increased risk of a seizure at the time of cervical dilation. (Grade GPP)

- Advice for Women at Time of Fitting
 - Women should be informed:*
 - About symptoms of uterine perforation or infection that would warrant an early review of IUS use. (Grade GPP)
 - That insertion of an IUS may cause pain and discomfort for a few hours and light bleeding for a few days, and they should be informed about appropriate pain relief. (Grade GPP)
 - About how to check for the presence of IUS threads, and encouraged to do this regularly with the aim of recognizing expulsion. (Grade GPP)
- Follow-up and Managing Problems
 - A follow-up visit should be recommended after the first menses, or 3-6 weeks after insertion, to exclude infection, perforation or expulsion. Thereafter, a woman should be strongly encouraged to return at any time to discuss problems, if she wants to change her method of contraception, or if it is time to have the IUS removed. (Grade GPP)
 - The presence of Actinomyces-like organisms on a cervical smear in a woman with a current IUS requires an assessment to exclude pelvic infection. Routine removal is not indicated in women without signs of pelvic infection. (Grade GPP)
 - Women with an intrauterine pregnancy with an IUS in situ should be advised to have the IUS removed before 12 completed weeks of gestation whether or not they intend to continue the pregnancy. (Grade GPP)

CHAPTER 3: CONTRACEPTIVE IMPLANTS CLINICAL PROFILE

3.1 BACKGROUND

Contraceptive implant is a single-rod, long acting, reversible hormonal contraceptive implant, that is preloaded in a sterile disposable applicator, to facilitate easy and rapid sub-dermal insertion under the skin of a woman's upper arm.

3.2 OBJECTIVES

1. Explain mechanisms of action of contraceptive implants.
2. Identify the indications and precautions for using contraceptive implants.
3. Screen clients who request contraceptive implants and determine whether further medical evaluation is necessary.
4. Define correct follow-up management procedures for clients with contraceptive implants.
5. Outline correct management of side effects and other health problems associated or related to contraceptive implants use.
6. Explain indications for removal of contraceptive implants.
7. Define the proper steps for contraceptive implants insertion using the contraceptive implants insertion and removal checklists.
8. Define the proper steps for contraceptive implants removal using the contraceptive implants insertion and removal checklists.
9. Demonstrate competency in insertion and removal of contraceptive implants in arm models using the contraceptive implants insertion and removal checklists.

3.3 CHARACTERISTICS

▪ **Structure and pharmacology:**

The ethylene-vinyl-acetate (EVA) rod is 4 cm long and 2 mm in diameter and contains 68 milligrams of crystalline etonogestrel (3-Keto-desogestrel), the active metabolite of the third generation progestagen “desogestrel” that has been used in combined oral contraceptives, which is released over a three year period. (Figure 1).²

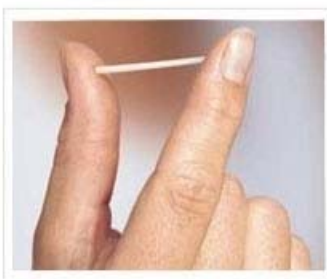


Figure 1: Contraceptive implant

A daily release rate of 30 micrograms of etonogestrel inhibits ovulation completely in most women. The daily release rates over time are shown in Table 5.

Table 5: Daily release rates of etonogestrel in relation to duration from application.³

Duration of Application	Peak Serum Levels
Week 5-6	60-70 mcg/day
After 1 year	35-45 mcg/day
After 2 years	30-40 mcg/day
After 3 years	25-30 mcg/day

Within 24 hours after insertion, serum levels rapidly increase to concentrations that inhibit ovulation. After removal of the implant, serum levels of etonogestrel decline within one week to undetectable levels, indicating a potential for rapid return to fertility after removal. Serum levels are shown in Table 6.

Table 6: Peak serum levels of etonogestrel in relation to duration from application.³

Duration of Application	Peak Serum Levels
After insertion for few weeks	781–894 pg/ml
After 1 year	192–261 pg/ml
After 2 years	154–194 pg/ml
After 3 years	156–177 pg/ml

▪ **Mode of action:**

○ Inhibition of ovulation:

Contraceptive implant prevents pregnancy mainly by inhibition of ovulation due to suppression of gonadotrophins (Luteinizing hormone (LH) and Follicle Stimulating hormone (FSH)) secretion. In studies where the occurrence of ovulation was monitored, no ovulations were detected at all in the first two years post-insertion.⁴

○ Effect on cervical mucus:

Etonogestrel increases the viscosity of the cervical mucus that contributes to its contraceptive effectiveness by inhibiting sperm penetration.²

A decrease in endometrial thickening is also observed during the use of contraceptive implants.⁴

Women should be informed that the primary mode of action of Contraceptive Implants is prevention of ovulation. (Grade B)

▪ **Efficacy:**

Contraceptive implant is a highly effective contraceptive. No pregnancies were observed among users. The failure rate for contraceptive implants is 0.05%. This means that only 1 in 2,000 women using contraceptive implants will become pregnant over the course of one year of use.

Unlike other birth control methods, there is no differential for perfect use versus typical use, as no user action is required after insertion. Most cases of reported failure were due to incorrect insertion or accidental insertion during pregnancy.

The high contraceptive effectiveness is labeled as being maintained for three years after insertion.⁵

In comparison, surgical sterilization has a failure rate of 0.2%. While these statistics suggest that contraceptive implants is four times more effective in preventing pregnancy than surgical sterilization; it is important to remember that sterilization is permanent, whereas contraceptive implants must be replaced every three years to continue to be effective. On the

other hand, contraceptive implants is completely reversible, while sterilization is usually permanent and cannot be reversed.⁵

Women can be advised that the duration of use for the progestogen-only implant is 3 years (Grade C).

The contraceptive effect is related to the plasma levels of etonogestrel, which is inversely related to body weight and decrease with time after insertion.

There have been concerns that efficacy of progestogen-only implants may be reduced in women with a body mass index (BMI) >30 kg/m². However, a meta-analysis of clinical trials reported no pregnancies at 1 year among implant users weighing ≥70 kg (n = 78). United Kingdom (UK) Medical Eligibility Criteria (MEC) recommends that women with a BMI >30 kg/m² can use a progestogen-only implant without restriction.^{6,7}

Women should be advised that the pregnancy rate associated with use of Contraceptive Implants is very low (<1 in 1000 over 3 years) (Grade B)

Women with a BMI > 30 kg/m² can use a progestin only implant without restriction and without a reduction in contraceptive efficacy for the duration of the licensed use (Grade C)

▪ **Return to fertility:**

After removal of contraceptive implants, return to fertility is achieved very rapidly. If protection against pregnancy is needed for more than three years, another contraceptive implant can be inserted immediately after removal.^{7,8}

Women should be informed that there is no evidence of a delay in return of fertility following removal of Contraceptive Implants (Grade B)

▪ **Indications:**

Contraceptive implant may be used to postpone the first pregnancy, to space pregnancy or to provide long-term contraception when the desired family size is reached. As with all other progestagen only contraceptives, contraceptive implants is particularly suitable for women in whom estrogen intake is contraindicated.

3.4 CONTRAINDICATIONS

The World Health Organization (WHO) has formulated evidence based MEC for starting contraceptive implants, also, the UK MEC for contraceptive use provides evidence-based recommendations to allow couples to select the most appropriate method of contraception. For most women, contraceptive implant is a safe option.^{9,10}

There are few circumstances where WHO MEC and UK MEC recommendations suggest that the theoretical or proven risks usually outweigh the advantages of using the method (WHO MEC/UK MEC 3) or that use of the method represents an unacceptable health risk (WHO UK MEC 4) (Table 7). The only WHO/UK MEC Category 4 is current breast cancer.^{9,10}

Table 7: UK MEC for progestogen-only implant use⁹

UK MEC Level	Conditions
<p>UK MEC 1 (A condition for which there is <i>no restriction</i> for the use of the contraceptive method)</p>	<ul style="list-style-type: none"> • Age: menarche to >45 years • Parity: nulliparous and parous • Breastfeeding[*] • Postpartum • Post-abortion immediately first- and second-trimester, and post-septic • Past ectopic pregnancy • History of pelvic surgery • Smoking • Obesity • Hypertension^{**} • History of high blood pressure during pregnancy • Family history of VTE in a first-degree relative aged <45 years or ≥45years • Major surgery without prolonged immobilization • Minor surgery without immobilization • Immobility (unrelated to surgery) (e.g. wheelchair use, debilitating illness) • Varicose veins • Superficial thrombophlebitis • Valvular and congenital heart disease uncomplicated and complicated by pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis • Non-migrainous headaches mild or severe • Epilepsy and not using liver enzyme-inducer • Depressive disorders • Endometriosis • Benign ovarian tumor • Severe dysmenorrhoea • Gestational trophoblastic neoplasia: when HCG is normal • Cervical ectropion • Cervical intraepithelial neoplasia

^{*} The WHO continued to recommend that women who are breastfeeding should generally not use progestin-only contraceptives (category 3) until six weeks postpartum. The systematic review of the evidence found no adverse effects of these methods on breastfeeding patterns and, while the evidence is more limited, no adverse effects on infant growth, development, or health when women using progestin-only methods started breastfeeding before six weeks postpartum.¹⁰

^{**} WHO MEC list history of hypertension where blood pressure can't be evaluated; or hypertension where systolic >160 or diastolic >100 as Category 2.¹⁰

UK MEC Level	Conditions
<p>UK MEC 2 (A condition for which the advantages of using the method generally outweigh the theoretical or proven risks)</p>	<ul style="list-style-type: none"> • Benign Endometrial or ovarian cancer • breast disease or a family history of breast cancer • Uterine fibroids with or without distortion of the uterine cavity • PID current; or past history of, with or without subsequent pregnancy • STI current, vaginitis or increased risk of STI • Risk of HIV/AIDS, or current HIV not using anti-retroviral therapy • Schistosomiasis, pelvic and non-pelvic tuberculosis, malaria • Diabetes, current or history of gestational disease • Thyroid disorders • History of cholestasis pregnancy related • Viral hepatitis carrier • Inflammatory bowel disease • Anemias, thalassaemia, sickle cell disease, iron deficiency • Raynaud's disease primary and secondary without lupus anticoagulant • Non-liver enzyme-inducing antibiotics (some anti-retrovirals UK MEC 2 (A condition for which the advantages of using the method generally outweigh the theoretical or proven risks • Multiple risk factors for arterial cardiovascular disease • Hypertension vascular disease • Past history of Deep Venous Thrombosis/Pulmonary Embolism (DVT/PE) • Major surgery with prolonged immobilization • Known thrombogenic mutations • Current and history of ischemic heart disease (initiation) • Stroke (initiation) • Known hyperlipidemias • Migraine headaches without aura in women any age; with aura at any age (initiation); past history of migraine with aura at any age • Vaginal bleeding unsuspected irregular, heavy or prolonged • Cervical cancer • Breast disease undiagnosed mass; carriers of known gene mutations associated with breast cancer (e.g. BRCA1) • HIV/AIDS current HIV using antiretroviral therapy; or current AIDS and using Highly Active Anti-Retroviral Therapy (HAART) • History of cholestasis past COC-related • Gallbladder disease symptomatic treated by

UK MEC Level	Conditions
	cholecystectomy, medically treated or current; asymptomatic <ul style="list-style-type: none"> • Raynaud’s disease secondary with lupus anticoagulant and thus a tendency to thrombosis • Highly active anti-retroviral therapy (HAART) Cirrhosis mild compensated disease • Diabetes Non-Insulin Dependent Diabetes Mellitus (NIDDM) and IDDM, non-vascular disease; with retinopathy/ neuropathy; or other vascular disease or diabetes of >20 years duration
UK MEC 3 (A condition where the theoretical or proven risks usually outweigh the advantages of using the method) <i>NB. The provision of a method to a woman with a condition given a UKMEC Category 3 requires expert clinical judgment and/or referral to a specialist contraceptive provider since use of the method is not usually recommended unless other methods are not available or not acceptable.</i>	<ul style="list-style-type: none"> • Current VTE on anticoagulants* • Current/arising ischemic heart disease (continuation) • Stroke (continuation) • Migraine headaches with aura at any age (continuation) • Unexplained vaginal bleeding suspicious for serious condition • Gestational trophoblastic neoplasia when HCG is abnormal • Breast disease past history of breast cancer and no evidence of recurrence for 5 years • Viral hepatitis active disease • Cirrhosis severe decompensated disease • Liver tumors benign and malignant • Drugs which induce liver enzymes (e.g. rifampicin, rifabutin, St John’s Wort, griseofulvin), and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)
UK MEC 4 (A condition which represents an <i>unacceptable health risk</i> if the contraceptive method is used)	<ul style="list-style-type: none"> • Breast disease: Current breast cancer
<p>Initiation = Starting a method of contraception by a woman with a specific medical condition.</p> <p>Continuation = Continuation with a method already being used by a woman who develops a new medical condition.</p>	

* WHO MEC list this condition as Category 2.¹⁰

3.5 SIDE EFFECTS

- **Menstrual irregularities are the most commonly encountered side effects:** ^{11, 12}
 - Amenorrhea is more frequently encountered than with Norplant users, in one study, the reported cumulative rate of amenorrhea at 3 years was 14%.
 - Infrequent bleeding/spotting episodes, less than three attacks of bleeding in 90 days (26.1%).
 - Frequent bleeding/spotting episodes, more than five attacks of bleeding in 90 days, is less common than with Norplant users (6%).
 - Prolonged bleeding/spotting episodes, more than 14 consecutive bleeding days in 90 days is more common than among Norplant users (11.8%).
 - Compared to Norplant, the bleeding pattern during contraceptive implants use is characterized by less bleeding, but also by a more variable pattern. There is a slight overall increase in hemoglobin concentration during contraceptive implants use.^{11,12}
 - Bleeding changes were more prominent in the first 3 months following insertion. The majority of women discontinuing contraceptive implants during the first year of use do so because of bleeding problems.

Women should be informed about the likely bleeding patterns that may occur with a progestogen-only implant (Grade C).

Women should be advised that 20% of users will have no bleeding, while almost 50% will have infrequent, frequent or prolonged bleeding and that bleeding patterns are likely to remain irregular (Grade C)

- **Subjective symptoms such as:**
 - Headache, nausea, breast pain, and mood changes.
 - Weight gain: Retrospective studies have reported that some women experience weight gain while using progestogen-only implants. Cumulative weight gain up to three years' use ranged from 2.8% to 12.7%. Weight fluctuation in women of reproductive age is common; there is no evidence to support a causal association between progestogen-only implants and weight change.
 - Acne and chloasma.
 - Local pain and infection at the site of contraceptive implants insertion are rarely encountered.
 - Ectopic pregnancies very rarely occur as contraceptive implants consistently inhibit ovulation. However, the possibility should be considered wherever a differential diagnosis is being established for cases of amenorrhea and acute abdominal pain.¹³
 - Other adverse effects on bone mass; lipid and carbohydrate metabolism, blood pressure or liver functions are rarely encountered.^{11,14,15}

Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and weight change, mood change or loss of libido (Grade C)

Women should be advised that acne may improve, occur or worsen during the use of progestogen-only implant (Grade C).

Women should be advised that the overall risk of ectopic pregnancy is reduced when using progestogen-only implants when compared to using no contraception (Grade B).

▪ **Major health concerns:**

- Venous thromboembolism (VTE):

VTE is uncommon in women of reproductive age, with an incidence usually quoted as approximately 5 per 100,000 woman-years. A recent review which combined findings from more than 30 studies suggested that the incidence of VTE in the general population of women of reproductive age is higher than the generally quoted figure (i.e. around 50 per 100,000 woman-years). This estimate remains controversial but may mean that the additional risk attributable to contraceptive use is smaller than previously thought.¹⁶

Few studies have been large enough to evaluate the risk of VTE with progestogen-only contraception. A WHO collaborative study collected data from Africa, Asia, Europe and Latin America to evaluate the risks with use of oral and injectable progestogen-only contraception. Although limited by small numbers and inherent bias, the data suggest that there is little or no increase in risk of VTE associated with use of these progestogen-only methods. No specific data on VTE risk with progestogen-only implants were found.^{16,17}

Women should be informed that evidence suggests there is little or no increase in risk of venous thromboembolism associated with use of a progestogen-only implant (Grade C).

- Breast cancer:

The Collaborative Group on Hormonal Factors in Breast Cancer undertook a re-analysis of 54 studies to investigate the relationship between breast cancer and hormonal contraceptives. Progestogen-only methods were used by just over 2% of the women studied.¹⁸

Progestogen-only implants are not specifically highlighted. There are insufficient data to make an evidence-based recommendation concerning the effect of progestogen-only implants on breast cancer risk. Nevertheless, as for other progestogen-only methods, any attributable risk (if any) is likely to be very small.¹⁸

- Bone mineral density (BMD):

Most concerns regarding BMD relate to long-term use of progestogen-only injectable contraception. An open prospective study found no change in BMD at the lumbar spine, femoral neck or distal radius in women (aged 18 to 40 years) who had used either a progestogen-only implant or an IUD for two years.^{15, 19}

BMD was significantly lower in the mid-shaft of the ulna, but not in the distal radius, after 18 months of progestogen-only implant use in women aged 19 to 43 years. Although a statistically significant reduction was seen, a clinically significant mean decrease in BMD of one standard deviation was not reached.¹⁹

Women should be informed that there is no evidence of a clinically significant effect on bone mineral density with use of a progestogen-only implant (Grade B).

- Drug interactions:

The Summary of Product Characteristics (SPC) for the progestogen-only implant recommends additional contraceptive protection while using a liver enzyme-inducing drug and for 28 days after its cessation. The efficacy of progestogen-only implants is *not reduced* with non-liver enzyme-inducing antibiotics.²⁰

Women using liver enzyme-inducing drugs short term (<3 weeks) may choose to continue with a progestogen-only implant. Additional contraceptive protection, such as condoms, should be used and until 4 weeks after the liver enzyme-inducing drug has been stopped. Information should be given on the use of alternative contraception if liver enzyme inducing drugs are to be used long term. (GPP)

3.6 ACCEPTABILITY

The following factors can affect the acceptability of contraceptive implants:²¹

- The nature of initiation and discontinuation particularly being a minor surgical procedure.
- The desired contraceptive duration.
- The encountered side effects affect particularly the degree to which women tolerate disturbance of the menstrual bleeding pattern, hence the importance of counselling.²¹

3.7 INSERTION OF CONTRACEPTIVE IMPLANTS

- Timing of insertion:⁶
 - Anytime the woman is reasonably sure she is not pregnant.
 - Contraceptive implants can be inserted on day 1-5 of the menstrual cycle, no back method should be used.
 - It can be inserted immediately or within one week after first or second trimester abortion.
 - Women who are postpartum (following vaginal or operative delivery, breastfeeding or bottle-feeding) may choose to use a progestogen-only implant without restriction. A cohort study²² compared changes in breast milk volume and composition in women who elected to use a progestogen implant or a copper-bearing IUD at 6 weeks postpartum, there were no significant differences between the groups. Follow-up at 3 years in the same cohort²³ of women revealed no differences in infant development and no treatment-related side effects.^{22,23} A progestogen-only implant may be inserted before Day 21 postpartum if this is more convenient for the woman. This early insertion may cause bleeding and is outside the terms of the product license.

A progestogen-only implant can be inserted immediately following surgical abortion or medical abortion or miscarriage; no additional contraception is required. If inserted >5 days after abortion or miscarriage then condoms or abstinence should be advised for 7 days (Grade C).

Progestogen-only implants can safely be used by women who are breastfeeding (Grade C).

Women can have a progestogen-only implant inserted up to and including day 21 postpartum with immediate contraceptive protection. If inserted after day 21 then condoms or abstinence should be advised for 7 days for non-breastfeeding women (Grade C).

- Who is illegible to perform insertion?
Insertion should be performed by health professionals who are appropriately trained, and maintain competence by attending regular updates.^{24, 25}
- Steps of insertion:^{3, 24}
 - Insertion should be performed under strict aseptic and antiseptic precautions following appropriate infection prevention procedures including disposal of used material.
 - The capsule should be inserted at the inner side of the upper arm 6-8 cm above the elbow in the groove between the biceps and the triceps.
 - It is important that the contraceptive implants capsule be inserted correctly, directly under the skin so as to ensure easy uncomplicated removal.
 - The woman should lie on her back with the non-dominant arm turned outwards and the elbow flexed.
 - Be sure that all equipments needed for insertion are ready.
 - Wash your hands and wear a pair of sterile gloves.
 - Clean the insertion site with a disinfectant, such as povidone iodine, beginning at the incision site and moving outward in a circular manner, and then allow drying.
 - Put a specially designed sterile towel to isolate the insertion site.
 - Anesthetize the insertion site with an anaesthetic spray or by injecting 2 ml of 1% lidocaine under the skin along the insertion channel. Some physicians buffer the lidocaine with 7.5% or 8.4% sodium bicarbonate solution to reduce the burning sensation associated with the acidic anesthetic preparation.^{26, 27}
 - As an assistant opens the sealed envelope, you remove the sterile disposable applicator carrying the contraceptive implants.
 - Keep the needle and the implant sterile and change them if contamination occurs. Always hold the applicator with the needle pointing up until insertion to prevent the contraceptive implants implant from dropping out of the needle. Be sure that the implant is inside the metal cannula and if it protrudes out, return it inside by tapping against the plastic part of the cannula.
 - Stretch the skin at the insertion site (the medial side of the upper arm at the sulcus between the biceps and the triceps muscle, 6-8 cm above the elbow). (*Illustration “a”*)²
 - Remove the plastic cover and introduce the needle in an upward direction (bevel up) under the skin at an angle of 20 degrees as superficially as possible while lifting the skin with the tip of the needle. Insert the needle to its full length. (*Illustration “b”*)²
 - Break the seal of the applicator by pressing on the obturator support.
 - Rotate the obturator 90 degrees in relation to the cannula and fix it firmly against the arm with your right hand. (*Illustration “c”*)²
 - With your left hand, slowly pull the cannula out of the arm with the obturator immobilized in its place. By doing this, the implant will be left in the upper arm under the skin. (This procedure is the opposite of giving an injection where you push the plunger while the syringe is fixed). (*Illustration “d”*)²

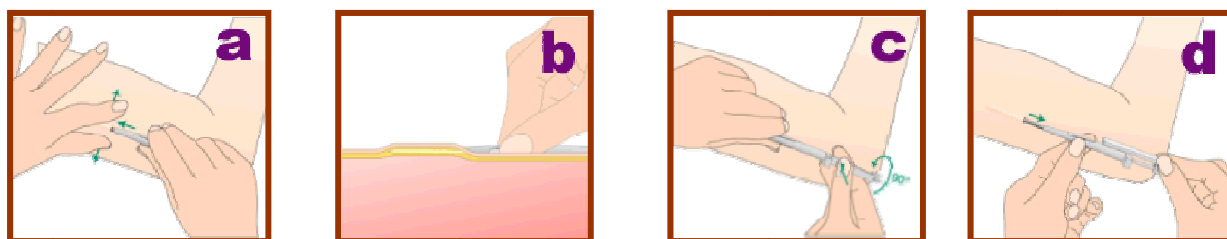


Figure 2: Illustrations of contraceptive implants insertion steps

- Rotate the obturator 90 degrees in relation to the cannula and fix it firmly against the arm with your right hand. (*Illustration “c”*)²
- With your left hand, slowly pull the cannula out of the arm with the obturator immobilized in its place. By doing this, the implant will be left in the upper arm under the skin. (This procedure is the opposite of giving an injection where you push the plunger while the syringe is fixed). (*Illustration “d”*)²
- Palpate the skin to check that the implant has been inserted.
- Apply sterile gauze and a pressure bandage to reduce the risk of bruising.
- Instruct the woman to remove the bandage next day when she can wash.

3.8 REMOVAL OF CONTRACEPTIVE IMPLANTS^{3,24}

- Service providers should follow strict infection prevention, aseptic and antiseptic precautions during the procedure.
- Steps of insertion:
 - Woman should lie on her back with the arm in which contraceptive implants had been inserted turned outwards and the elbow flexed.
 - Ensure that the necessary instruments and equipment needed for removal are ready.
 - Wash your hands and wear a pair of sterile gloves.
 - Clean the area with a suitable antiseptic e.g. Povidone iodine; beginning at the incision site and moving outward in a circular manner, then allow drying.
 - Locate the implant (*Illustration “a”*)² and anesthetize the proposed site of the incision (just below the distal end of the implant with 0.5-1 ml of 1% lidocaine).
 - Apply the anesthetic under the implant so as the skin will not swell causing difficulty in locating the implant. (*Illustration “b”*)²
 - Touch the proposed site for incision by the tip of the scalpel to ensure that the anesthesia has worked.
 - Make a longitudinal incision 2mm long at the distal end of the implant. (*Illustration “c”*)²
 - Push the implant gently towards the incision until its tip becomes visible.
 - Grasp the implant with a mosquito forceps and pull it out (*Illustration “d”*)²
 - If the contraceptive implants implant is encapsulated and its tip will not appear, incise the tissue on its tip with a scalpel and then grasp the tip of the implant and pull it. (*Illustration “e”*)²
 - If the tip of the contraceptive implants is not visible, gently insert a forceps into the incision and grasp the implant. With a second forceps or a scalpel, dissect the tissues around the implant, grasp its tip and pull it. (*Illustration “f”*)²

- Close the incision with steri-strips or a band-aid. Apply sterile gauze and a pressure bandage to reduce the risk of bruising.
- Instruct the woman to remove the pressure bandage next day and to uncover the wound after 2 days when she can wash.
- Keep under observation for 5 minutes before discharging home to exclude any adverse reactions.

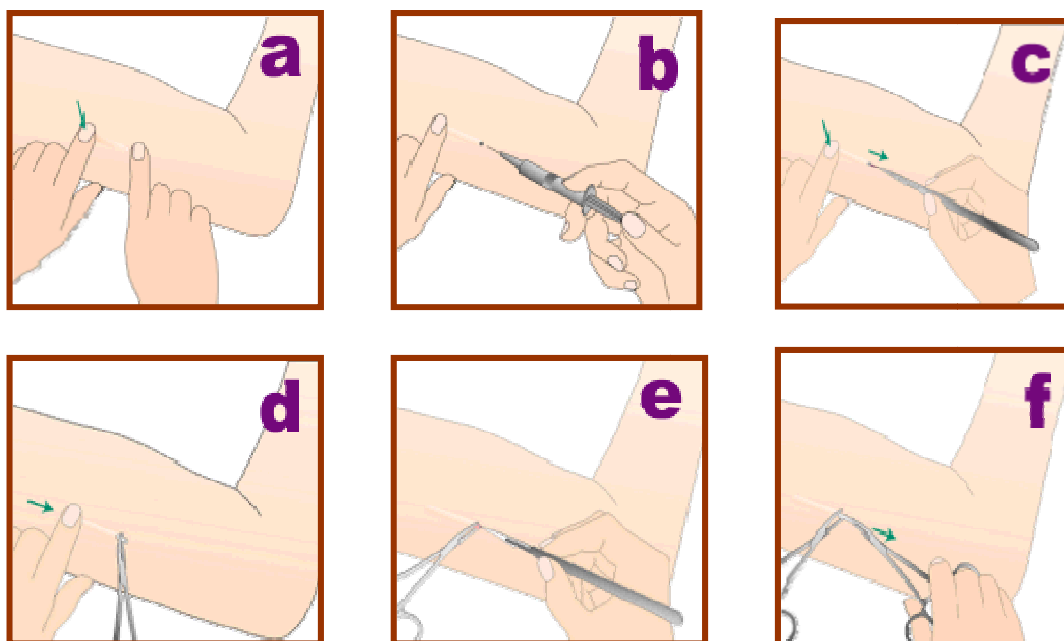


Figure 3: Illustrations of contraceptive implants removal steps

- Key counseling topics for contraceptive implants users: ²⁴
 - Safety and efficacy.
 - How contraceptive implants works.
 - Initiation and discontinuation involves minor surgical procedures.
 - Advantages and disadvantages.
 - Possible side effects with emphasis on menstrual irregularities.
 - Protection for three years after which the implant should be removed.
 - Provider can discontinue contraceptive implants use at woman's request by removing the implant at any time.
 - Contraceptive implants does not protect from STIs including HIV.
- Equipment needed for insertion: ^{3,24}
 - Contraceptive implants set.
 - 10% Iodine solution.
 - Sterile gloves.
 - 1% Lidocaine solution or a surface spray anesthetic and a sterile syringe and needle.
 - Band-aid or steri-strips
 - Sterile gauze.
 - Bandage

- Adrenaline and atropine.
- Sodium bicarbonate solution 7.5% or 8.4%.
- Equipment needed for removal/replacement: ^{3,24}
 - 10% Iodine solution.
 - Sterile gloves
 - 1% Lidocaine solution and a sterile syringe and needle
 - Sodium bicarbonate solution 7.5% or 8.4%.
 - 2 mosquito forceps
 - Scalpel
 - Band-aid or steri-strips
 - Sterile gauze
 - Bandage

CHAPTER 4: INFECTION PREVENTION

4.1 BACKGROUND

With contraceptive implants insertion or removal, as with any invasive procedure, there is risk to patients, providers and other staff from contact with blood and other body fluids that may carry blood-borne diseases such as hepatitis B and HIV/AIDS.

To minimize this risk, universal precautions must be observed at all times in providing reproductive health care services, handling equipment and disposing of waste. The risk of transmitting infection is reduced through using protective barriers (including hand washing and appropriate processing of reusable instruments), using the no-touch technique for performing insertions and removals of contraceptive implants, and disposing of contaminated waste properly.

4.2 OBJECTIVES

At the end of this chapter participants will be able to:

1. Identify the importance of infection prevention during contraceptive implants insertion/removal.
2. Identify the importance, indications and procedures of hand washing.
3. Identify the importance, indications and procedures of using gloves.
4. Identify the importance and solutions used for antisepsis.
5. Adopt non touch technique during contraceptive implants insertion/removal.
6. Identify the importance and procedures of waste and sharps disposal.

4.3 DEFINITIONS

- **Microorganisms:** Microorganisms are animals or plants of microscopic size and they are the causative agents of infection. They include bacteria, viruses, fungi and parasites. For infection prevention purposes, bacteria can be further divided into three categories: vegetative (bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides), mycobacteria (bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria) and endospores (which are relatively resistant to disinfectant and sterilant activity and drying conditions). Endospores are the most difficult to kill.
- **Asepsis and Aseptic Techniques:** These techniques are used to prevent contact with microorganisms; they are general terms used in health care settings to describe the combination of efforts made to prevent entry of microorganisms into any area of the body where they are likely to cause infection. The goal of asepsis is to reduce to a safe level, or eliminate, the number of microorganisms on both animate (living) surfaces (skin and mucous membrane) and inanimate objects (surgical instruments and other items).
- **Antisepsis:** Process of reducing the number of microorganisms on skin, mucous membranes or other body tissue by applying an antimicrobial (antiseptic) agent.
- **Antiseptics:** Substances that are used for preventing action and/or arresting growth of microorganisms.
- **Decontamination:** The use of physical or chemical means to remove, inactivate, or destroy blood-borne pathogens on a surface or item to the point where they are no longer capable of

- transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
- **Cleaning:** Cleaning is the process that physically removes all visible blood, body fluids and any other foreign material such as dust or dirt from skin and inanimate objects. Cleaning consists of washing with soap and detergent with water.
- **Disinfection:** Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).
- **High-Level Disinfection (HLD):** The process that eliminates all microorganisms except some bacterial endospores on inanimate objects. Examples are boiling, steaming or use of chemical disinfectants.
- **Sterilization:** The process that eliminates all microorganisms, including bacterial endospores, from inanimate objects. Examples, high pressure steam (autoclave), dry heat (oven), chemical sterilants or radiation.

4.4 PROTECTIVE BARRIERS

Protective barriers are physical, mechanical or chemical processes which help prevent the spread of infectious microorganisms from client to client, clinic staff to client, or vice versa.

Protective barriers include:

1. Hand washing.
2. Wearing gloves (both hands) and surgical attire.
3. Using antiseptic solutions for preparing the skin prior to surgery or a procedure such as contraceptive implants insertion or removal.
4. Processing equipment, instrument and other items.
5. Using drapes during surgical procedures.
6. Managing clinical waste.

Following is detailed information regarding some of the above mentioned barriers:

- **Hand washing:**
Hand-washing may be the single most important procedure in preventing infection. To encourage hand washing, program managers should make every effort to provide a continuous supply of fresh water and soap.
 - **Indications:**
 - Before and after examining a client especially when touching mucous membrane.
 - Before putting on sterile or high-level disinfected (HLD) gloves.
 - After removing gloves, as they may have invisible holes or tears.
 - After handling contaminated objects, such as used (soiled) instruments.
 - When accidentally touching blood or other fluids (e.g., when collecting laboratory specimens).
 - **Items required:**
 - Soap
 - Clean running water
 - Basin to collect water
 - Clean, dry towel

Note:

- A. When it is difficult to wash hands frequently, use an alcohol handrub. The solution can be prepared by adding 2 ml of glycerine, propylene glycol or sorbitol to 100 ml of 60%-90% alcohol. Use 3-5 ml of this solution for each application and continue rubbing the solution over the hands for about 2 minutes, using a total of 6-10 ml per scrub.**
- B. Microorganisms grow and multiply in moisture and in standing water. Therefore, avoid basins containing standing water, even with the addition of an antiseptic agent such as Dettol® or Savlon®, because microorganisms may survive and multiply in these solutions.**

- Types:
 - For non-surgical procedures (e.g. examination of a client, pelvic examination insertion/removal of IUD): Wash hands with plain soap for about 15-30 seconds; then rinse in a stream of water and dry hands with a clean towel.
 - For surgical procedures (e.g., uterine evacuation, laparoscopy, Mini-laparotomy, vasectomy, insertion and removal of contraceptive implants):
 - Remove all items of jewelry, including wristwatch.
 - Wash hands with an antiseptic for 3 to 5 minutes.
 - Scrub hand with a soft brush or sponge. Begin at the fingertips; wash between all fingers and move toward the elbow.
 - Repeat for the second hand.
 - Rinse each arm separately, fingertips first, holding hands above the level of the elbows to prevent water from running down from the elbow to the hands.
 - Dry hands with a sterile towel.
 - After hand-washing has been completed, hold hands above the level of the waist.

- **Glove use:**
 - Examination gloves can be used for pelvic examination. Use new examination gloves for each procedure; these gloves cannot be reused because they are too thin to be processed.
 - Surgical gloves are used for contraceptive implants insertion/removal but they are not necessary if a no-touch technique is used. If surgical gloves are used, new gloves are best.
 - Utility gloves are used for housekeeping chores involving potential blood contact such as decontamination and instrument cleaning procedures. Utility gloves may be decontaminated and reused; however, cracked or torn gloves should be discarded.

Note:

Wearing gloves don't replace the need for hands washing

- **Antisepsis:**

Infection following minor surgical procedures such as contraceptive implants insertion or removal may be caused by microorganisms from the skin of the patient or from the hands of

the health care worker. Washing hands before and after each case, and washing the patient's arm area thoroughly with antiseptic solution prior to performing contraceptive implants insertion or removal is an important infection prevention measures. Many chemicals are known as safe skin antiseptics. The following antiseptic solutions are commonly available in different parts of the world:

- Chlorhexidine gluconate (4%) (e.g., Hibiclens®, Hibiscrub®, Hibitane®)
- Chlorhexidine gluconate and cetrimide, various concentrations (e.g. Savlon®)
- Iodophors, various concentrations (e.g., Betadine®)

Note:

A. Do not use alcohol or alcohol containing preparations. Alcohols burn; they also dry and irritate skin and mucous membranes, which in turn promotes the growth of microorganisms.

B. Antiseptics do not have the same killing power as the chemicals used for HLD. Thus, antiseptic solutions should never be used to high-level disinfect inanimate objects such as instruments

▪ **No-touch Technique:**

- In procedures such as contraceptive implants insertion and removal it is possible to introduce pathogens into the body, resulting in infections. To avoid that from occurring, clinicians should always use the no-touch technique during the entire procedure and only use instruments that are sterilized or high-level disinfected before use.
- Using the no-touch technique means that the parts of the instruments that enter the body (through the skin) should not get in contact with any contaminated surfaces before touching the skin.
- Specifically, the insertion trocar, the scalpel blade, and any gauze used during the process of insertion or removal should not touch the examination table, non-sterile areas of the instrument tray, gloves or clinicians hands before they are used.
- Clinicians should handle the instruments only by the area or end that does not come into contact with the patient.

▪ **Processing contraceptive implant insertion/removal equipment and other items:**

To minimize the risk of transmitting infection to both patients and staff from instruments and gloves following contraceptive implants insertion/removal, these items need to be decontaminated, cleaned and then either sterilized or high-level disinfected. Environmental surfaces such as the examination table should also be decontaminated and cleaned after each procedure.

When is sterilization absolutely essential? And when can HLD be an acceptable alternative?

Most authorities recommend that instruments and other items used for surgical procedures, such as contraceptive implants insertion/removal, should be sterile. Some guidelines are more flexible, however, and state that when sterilization equipment is not available, HLD can be used. In fact, the sole use of sterilization is not possible or practical in many service delivery sites in both developing and developed countries. Sterilization, when correctly performed, is clearly the safest and most

effective method for processing instruments; however, if it is neither available nor suitable, then HLD is the only acceptable alternative.

Note: For either the sterilization or HLD process to be effective, decontamination and thorough cleaning of instruments and other items must be done first.

- **Managing waste:**
 - Handling needles and syringes: take precautions to prevent injuries from used needles and sharp instruments, which pose a great risk of hepatitis B or HIV/AIDS transmission in health care settings. These injuries may occur during surgical procedures, when cleaning instruments, during disposal of needles, and when handling sharp instruments after procedures. While disposable syringes and needles are recommended for use in all patient care and surgical procedures, they do not solve the problem of needle stick injuries nor are they always available.
 - Safety tips when using disposable needles and syringes:
 - Use each needle and syringe only once.
 - Do not disassemble needles and syringes after use.
 - Do not recap, bend or break needles prior to disposal.
 - Dispose of needles and syringes in a puncture proof container.
 - Waste disposal:
 - After completing the contraceptive implants insertion/removal, and while still wearing gloves, dispose contaminated disposable objects (gauze, cotton and other waste items) in a properly marked, leak-proof container or plastic bag.
 - Dispose all sharp instruments (needles, scalpel blades, the trocar and syringes) separate puncture-proof container
 - Waste should be disposed by burning or burying.

APPENDICES

APPENDIX 1: Client Assessment Checklist for Contraceptive Implants Use

If **ALL** of these conditions are negative (**NO**), contraceptive implants can be inserted.
If **any** positive response (**YES**), the woman should be further evaluated before insertion of contraceptive implants.

	YES	NO
• First day of menses more than 5 days ago.	<input type="checkbox"/>	<input type="checkbox"/>
• Breast feeding and less than 6 weeks postpartum.	<input type="checkbox"/>	<input type="checkbox"/>
• Bleeding/spotting between periods or after intercourse.	<input type="checkbox"/>	<input type="checkbox"/>
• Past history or presence of breast mass.	<input type="checkbox"/>	<input type="checkbox"/>
• Past history or current thromboembolic diseases.	<input type="checkbox"/>	<input type="checkbox"/>
• Abnormal yellow skin (jaundice).	<input type="checkbox"/>	<input type="checkbox"/>
• Taking drugs for epilepsy or tuberculosis.	<input type="checkbox"/>	<input type="checkbox"/>
• Hypertension.	<input type="checkbox"/>	<input type="checkbox"/>
• Migraine (vascular headache).	<input type="checkbox"/>	<input type="checkbox"/>
• Depression.	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX 2: Contraceptive Implants Insertion Checklist for Physicians

Contraceptive Implants Insertion		Case Definition: Woman chooses contraceptive implant as her family planning method.			
General Information		Case Information		Assessment Information	
Date of Assessment:		Case #:		Assessment Method	
Governorate: _____		File #: _____		<input type="checkbox"/>	Direct Observation
Hospital/Health Center _____		Date of Insertion: _____		<input type="checkbox"/>	Medical Record Audit
Service Provider: _____				<input type="checkbox"/>	Provider Interview
Assessor:					

#	Skill Description	(% of Compliance)	Skill Compliance			(Complete section only if Skill Compliance is "NO") Cause for Non-Compliance
			YES	NO	N/A	
1.	Established effective client provider relationship					
1.1	The woman is greeted with respect					
1.2	Client's concerns is listened and responded					
1.3	Used supportive nonverbal communication (such as nodding and smiling)					
1.4	Privacy is ensured (such as draw curtains around the treatment area, door is closed)					
1.5	Ensured that patient was counseled for contraceptive Implant use and "Client Assessment Checklist" is reviewed					
1.6	The procedure to be performed is explained in details and in language the woman can understand, client is assured she will not feel pain during procedure, only needle insertion					
1.7	Client is asked about allergy to anesthetics					
1.8	Ensured that client had washed her arm with soap and water, rinsed it to remove all soap and dried it with a clean towel					
1.9	Client is helped to get on the insertion bed, covered with blanket and correctly positioned the non dominant arm					
2	Followed infection control precautions during Implant insertion procedure					
2.1	Washed his/her hands before procedure					
2.2	Put on gloves (both hands) with surgical attire					
2.3	Used antiseptic solutions for preparing the skin prior to Implant insertion, then allowed to dry					
2.4	Processed equipment, instruments and other items					
3	Insertion of Implant					
3.1	Insertion site on medial side of arm 6-8 cm above the elbow between biceps and triceps muscles is correctly chosen					
3.2	The insertion site is anesthetized with anaesthetic spray or injecting 2 ml Lidocaine solution buffered by 7.5% or 8.4% Sodium bicarbonate solution (if available)					
3.3	Assistant opened the sealed envelope and he/she removed the sterile disposable applicator					
3.4	Applicator was held with needle up to prevent					

#	Skill Description	(% of Compliance)	Skill Compliance			(Complete section only if Skill Compliance is "NO") Cause for Non-Compliance
			YES	NO	N/A	
	falling out of Implant capsule					
3.5	The needle of Implant was never touched					
3.6	Ensured that Implant is inside the needle					
3.7	Skin was stretched at insertion site before inserting the needle					
3.8	After removal plastic cover the needle was introduced with angle not more than 20 degrees up to its full length under the skin					
3.9	The seal of the applicator is broken					
3.10	The obturator is rotated 90 degree					
3.11	The obturator is fixated and cannula pulled out of the arm					
3.12	The skin is palpated to ensure that the Implant is in place					
4	Post Insertion Tasks					
4.1	Sterile gauze and pressure bandage is applied					
4.2	Client is instructed about care of the insertion site, removal of bandage ,washing and symptoms that necessitate reporting to clinic					
4.3	Waste materials is properly decontaminated and disposed according to guidelines					
	Average Total Percent Compliance					

APPENDIX 3: Contraceptive Implants Removal Checklist for Physicians

Contraceptive Implants Removal		Case Definition: Woman wants to remove her contraceptive implant as she wants to get pregnant.			
General Information		Case Information		Assessment Information	
Date of Assessment:		Case #:		Assessment Method	
Governorate: _____	File #: _____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Direct Observation		
Hospital/Health Center _____	Date of Insertion: _____		Medical Record Audit		
Service Provider: _____			Provider Interview		
Assessor:					

#	Skill Description	(% of Compliance)	Skill Compliance			(Complete section only if Skill Compliance is "NO") Cause for Non-Compliance
			YES	NO	N/A	
1.	Effective client provider relationship is established					
1.1	The woman is greeted with respect					
1.2	Client's concerns is listened and responded					
1.3	Used supportive nonverbal communication, (such as nodding and smiling)					
1.4	Privacy is ensured (Draw curtains around the treatment area, door is closed).					
1.5	Client is asked for reason of removal (if less than 3 years after insertion)					
1.6	The procedure to be performed is explained in details and in language the woman can understand, client is assured that she will not feel pain during procedure, only needle insertion					
1.7	Client is asked about allergy to anesthetics					
1.8	Ensured that client had washed her arm with soap and water, rinsed it to remove all soap and dried it with a clean towel					
1.9	Client is helped to get on the insertion bed, covered with blanket and clean dry cloth is placed under the arm					
1.10	Capsule is palpated to locate point of removal					
2	Infection control precautions is followed during implant removal procedure					
2.1	Physician's hands are washed before procedure					
2.2	Gloves (both hands) is put with surgical attire					
2.3	Removal site is prepared by swabbing with antiseptic beginning at the incision point and moving outward in a circular manner, then allowed to dry					
2.4	Processed equipment, instruments and other items					
3	Removal of contraceptive Implant					
3.1	The capsule is located and the area below the distal tip is anesthetized by injecting 0.5-1 ml of Lidocain solution buffered by					

#	Skill Description	(% of Compliance)	Skill Compliance			(Complete section only if Skill Compliance is "NO") Cause for Non-Compliance
			YES	NO	N/A	
	0.2 ml Sodium bicarbonate 7.5% or 8.4% solution (if available) under the implant					
3.2	Anesthetic effect is checked before making the incision					
3.3	A longitudinal incision 2 mm is done at the distal end of contraceptive Implant					
3.4	The contraceptive Implant is pushed down until the tip is became visible in the wound					
3.5	The contraceptive Implant is grasped with a mosquito forceps and pulled out					
3.6	The contraceptive Implant is showed to the client					
4	Post Removal Tasks					
4.1	Incision is closed with a band-air or steri-strips					
4.2	Sterile gauze and pressure bandage is applied					
4.3	Client was instructed about care of the site ,removal of bandage ,washing and symptoms which necessitates reporting to the clinic					
4.4	Client was observed for at least 5 minutes before sending home					
	Average Total Percent Compliance					

APPENDIX 4: Utilizing the Contraceptive Implants Insertion and Removal Checklists

General Rules:

- Health professionals who insert (and remove) progestogen-only implants should be appropriately trained, maintain competence and attend regular updates. (Grade C).
- Checklists do not include the steps involved in counselling clients or for infection prevention procedures; it is assumed that the trainee has already mastered these skills as a pre-requisite to attending this course.
- Checklists are intended to primarily be used during the early skill acquisition phases of learning, when trainees are practicing on models and for monitoring the physicians' performance during implementing the on-job-training by trainers.
- Trainees can use the Checklists to:
 - Follow the steps as the clinical trainer is demonstrating the insertion/removal procedures.
 - Repeat the steps during training on arm models to gain experience; all trainees are expected to perform all the steps correctly and in the exact sequence.
- As trainees progress through the course and gain experience, dependence on the detailed checklists decreases.
- Once skill is acquired, trainees can use the checklists to rate each other's performance.

These checklists can be used as a:

- Basis for discussion and preparation for evaluation.
- Training tool for the trainees during acquiring the skills in arm models.
- Guidance tool for the trainer/trainee during the course for mastering the skills in arm models.
- Evaluation tool for the trainer at the end of the course for certification/licensing before providing the service at the clinical site.
- Follow-up tool for regulatory/accreditation bodies at the clinical site as part of service evaluation.

APPENDIX 5: Management of Side Effects for the Use of Contraceptive Implant

Symptom	Assessment	Management
<p>Amenorrhea (absence of vaginal bleeding or spotting)</p>	<p>Exclude pregnancy by checking symptoms, perform a pelvic exam (speculum and bimanual) and a pregnancy test (if indicated and available).</p>	<p>Amenorrhea may occur in up to 18% of contraceptive implants implant users. However, amenorrhea for 6 weeks or more after a pattern of regular menses may signal pregnancy and should be evaluated.</p> <p>If negative pregnancy test, but enlarged uterus, counsel client to return in 2 to 4 weeks for repeat pelvic exam and pregnancy test.</p> <p>If ectopic pregnancy is suspected, refer for complete evaluation.</p> <p>If intrauterine pregnancy is confirmed, counsel and refer for appropriate care. Remove the rod and assure her that the small dose of hormone (etonogestrel) to which she was exposed will have no harmful effect on the fetus.</p> <p>There is no evidence of a teratogenic effect of a progestogen-only implant, but if a user becomes pregnant and continues with the pregnancy then the implant should be removed (Grade C).</p>
<p>Moderate bleeding: same as normal menses Bleeding/Spotting Prolonged spotting: more than 8 days</p>	<p>Perform a pelvic exam (speculum and bimanual) to:</p> <ul style="list-style-type: none"> • Exclude gynecologic causes as vaginitis, cervicitis, cervical polyps or uterine fibroids. • Exclude pregnancy (intrauterine or ectopic) or incomplete abortion if suspected, perform pregnancy test. 	<p>If abnormality of the genital tract is found, treat the problem if possible or refer for treatment. Do not advise to discontinue contraceptive implants. Advise client to return for additional counseling after management of problem.</p> <p>Women should be informed about the likely bleeding patterns that may occur with a progestogen-only implant. (Grade C).</p> <p>Women should be advised that 20% of users will have no bleeding, while almost 50% will have infrequent, frequent or prolonged bleeding and that bleeding patterns are likely to remain irregular (Grade C).</p> <p>If hemoglobin is less than 9 g/dl, hematocrit less than 27, give iron therapy (2-3 tablets of Ferrous gluconate or 2 tablets Ferrous sulfate daily for 1</p>

Symptom	Assessment	Management
		<p>to 2 months) and nutritional counseling, check for improvement within one to two weeks. If no improvement refer to further investigation.</p> <p>Women who experience problematic bleeding while using a progestogen-only implant and who have had gynecological pathology excluded may be offered mefenamic acid or ethinylestradiol or 17-Beta estradiol (alone or as an oral contraceptive) for treatment (Grade C).</p> <p>There is no evidence to support the use of vitamin E or aspirin, and limited evidence for non-steroidal anti-inflammatory drugs other than mefenamic acid.</p> <p>Research suggests that doxycycline and mifepristone may also be beneficial.</p> <p>Women who experience problematic bleeding while using a progestogen-only implant should have a sexual history taken to establish STI risk and/or be investigated for gynecological pathology if clinically indicated (Grade C).</p> <p>If a woman does not wish treatment or if treatment fails then the implant should be removed and other contraceptive methods discussed.</p>
Headache	<p>Ask if there has been a change in pattern or severity of headaches since beginning contraceptive implants implant.</p> <p>Perform physical examination, measure blood pressure.</p> <p>Examine as appropriate:</p> <ul style="list-style-type: none"> • Eyes (fundoscopic) • Neurologic system 	<p>If headaches are mild, treat with paracetamol and reassure.</p> <p>Reevaluate after 1 month if mild headaches persist.</p> <p>Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and headache (Grade C).</p> <p>Women of any age with a history of migraine (with or without aura) may use progestogen-only implants (Grade C).</p> <p>Women who develop new symptoms of migraine without aura while using progestogen-only implants may continue the method (Grade C).</p>

Symptom	Assessment	Management
		Women who develop new symptoms of migraine with aura while using progestogen-only implants should be advised to seek medical advice, as investigation may be appropriate. Continued use of progestogen-only implants may be considered (Grade C).
Breast Tenderness (mastalgia)	Exclude: Pregnancy Lumps or cysts Discharge or galactorrhea	Refer for evaluation if abnormality present. If no abnormality, reassure. No need to remove implant
Nausea/ dizziness/ nervousness	Exclude pregnancy	If pregnant, refer as above for Amenorrhea . If not pregnant, reassure that this is not a serious problem(s) and usually disappears with time.
Excess Hair Growth (Hirsutism), Acne, Dermatitis, or hair loss	Review history, pre- and post-insertion of contraceptive implants.	Pre-existing conditions such as increased facial or body hair might be worsened. Changes usually are not excessive, may improve over time, and do not require discontinuation of contraceptive implants unless client requests it after counseling. Women should be advised that acne may improve, occur or worsen during the use of a progestogen-only implant (Grade C).
Weight Gain or Loss (change in appetite)	Compare pre-insertion weight (if known) and current weight. Rule out pregnancy. Check that the client is eating and exercising properly.	Counsel client that normal fluctuations (increase or decrease of 2 kg) may occur over 5–7 years. Review diet if weight change is excessive. Women should be advised that there is no evidence of a causal association between use of a progestogen-only implant and weight change, mood change or loss of libido (Grade C).
Lower Abdominal/ Pelvic Pain (with or without symptoms of pregnancy)	<ul style="list-style-type: none"> • Take Careful History • Perform abdominal and pelvic (speculum and bimanual) examination. • Check vital signs: <ul style="list-style-type: none"> ▪ Pulse ▪ Blood Pressure ▪ Temperature • Exclude: <ul style="list-style-type: none"> ▪ Ovarian cysts ▪ Ectopic pregnancy ▪ PID ▪ Appendicitis 	Refer immediately if the client has any of the following: <ul style="list-style-type: none"> • Lower abdominal tenderness • Elevated resting pulse (more than 100 BPM) • Decreased blood pressure (less than 90/60) • Elevated oral temperature (38.3° C) • Suspected/confirmed pregnancy and acute anemia Follow up ovarian cyst by Ultrasonography.

Symptom	Assessment	Management
	<ul style="list-style-type: none"> • Do laboratory test <ul style="list-style-type: none"> ▪ Hb/Hct ▪ Pregnancy test 	
Capsule Expulsion	Check for partial or complete expulsion of capsule.	Refer to an implants provider. Remove partially expelled capsule. If an area of insertion is not infected (no pain, heat and redness) replace with new capsule. If area of insertion is infected, see “Infection” below.
Infection	Check area of insertion for infection (pain, heat and redness), pus or abscess.	<p>If infection (not abscess):</p> <ul style="list-style-type: none"> • Do not remove capsule, and instruct client not to attempt to remove the capsule. • Clean with (soap and water or antiseptic). • Give appropriate oral antibiotic for 7 days. • Ask client to return after 1 week. If no improvement, remove capsule and insert a new one in the other arm or help client choose another method. Continue to treat infection with 7 additional days of antibiotics. <p>If an abscess is formed remove the implant, drain, OR refer.</p>
Thromboembolic disorder (including blood clots in legs, lungs, or eyes)	Assess for active thromboembolic disease (severe leg pain, difficulty in breathing or seeing).	<p>If strong evidence of blood clotting disorder, refer for complete evaluation. Low-dose progestins do not increase the risk of blood clotting problems; therefore, discontinue only at client’s request.</p> <p>Women should be informed that evidence suggests there is little or no increase in risk of venous thromboembolism associated with use of a progestogen-only implant (Grade C).</p>
High Blood Pressure	Previously normal BP that becomes elevated.	Counsel client that increase in blood pressure does not require discontinuation. If mild or moderate hypertension, just observe and if severe hypertension refer for further treatment.
Jaundice	<p>Acute jaundice occurring after contraceptive implants insertion is not method-related.</p> <p>Exclude: Active liver disease (hepatitis) Gall bladder disease</p>	<p>Etonogestrel has little effect on liver function and does not increase the risk of gall bladder disease or liver tumors.</p> <p>If the woman has hepatitis contraceptive implants is unlikely to worsen liver disease and is safer than pregnancy.</p>

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