INJECTABLE CONTRACEPTIVES TECHNICAL OVERVIEW

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Overview

- What are injectable contraceptives?
- Mechanism of action
- Types/differences
- Side effect profile
- Medical Eligibility Criteria
- Effectiveness
- Service delivery requirements



Pathfinder International



Injectable Contraceptives: at a glance



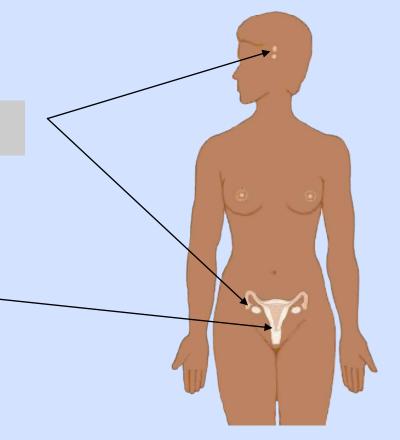
- Hormone-containing injection that is administered into a muscle (usually buttock or upper arm) or just under the skin
- Not visible; discreet
- Short-term contraceptive method
- Quick and easy to use
- 99.7% effectiveness with perfect use; 94% effectiveness with typical use



How do they work?

Prevents ovulation

Thickens cervical mucus



Almost all women can use injectable contraception



Types of Injectable Contraceptives

Brand Name	Depo- Provera	Sayana Press	Noristerat	Cyclofem	Mesigyna/ Norigynon
Generic Name	DMPA-IM	DMPA-SC	NET-EN		
Duration	3 months	3 months	2 months*	1 month	1 month
Reinjection Window	Between 2 weeks before and 4 weeks after 3-month mark	Between 2 weeks before and 4 weeks after 3-month mark	Between 2 weeks before and 2 weeks after 2-month mark	Between 1 week before and 1 week after 1-month mark	Between 1 week before and 1 week after 1-month mark
Formulation	Medroxy- progesterone acetate (MPA),150 mg	MPA, 104 mg	Norethisterone Enanthate	Combined MPA and estradiol cypionate	Combined NET- EN and estradiol valerate
Administration	Intramuscular	Subcutaneous	Intramuscular	Intramuscular	Intramuscular
Manufacturer	Pfizer	Pfizer	Bayer	Concept Foundation	Bayer
Unit cost	\$0.88	\$0.85 (for FP2020 countries)	\$1.15		\$0.85
Shelf life	5 years	3 years	5 years	5 years	5 years



How are DMPA-IM and DMPA-SC different?

Feature	DMPA-IM	DMPA-SC (Sayana Press)	
Mg/dose	150 mg	104 mg	
Package	Vial and syringe	Prefilled Uniject injection system	
Type of injection	Intramuscular (deep into the muscle); 3.8 cm needle	Subcutaneous (in the fatty tissue under the skin); 2.5 cm needle	
Where to inject	Arm (deltoid muscle)HipButtocks	Anterior thigh (front of thigh)AbdomenBack of arm	
Skin irritation	Skin irritation at injection site is not likely	Skin may be a little irritated at injection site	



Advantages of Injectable Use



Highly effective

- Easy to use and private no one can tell woman is using it
- Safe for breastfeeding mothers

- Has beneficial, non-contraceptive effects:
 - Reduces the risk of endometrial and ovarian cancer.
 - Protection from uterine fibroids, ectopic pregnancy and symptomatic pelvic inflammatory disease (PID)
- Special advantages for some women include:
 - May reduce sickle cell crises in women with sickle cell anemia
 - Prevents seizures in epileptics and prevents iron deficiency anemia

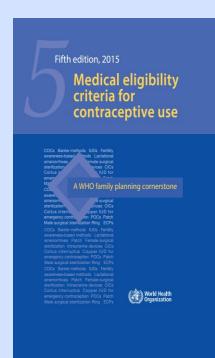


Potential Side Effects/Disadvantages

- Delay in return to fertility (average 10 months from last injection)
- May cause weight gain, headaches and nausea
- Issues and perceptions related to HIV, STIs and bone loss
- Changes in menstrual bleeding, including:
 - Light spotting or heavy bleeding
 - Amenorrhea after one year (although this is perceived as an advantage by some women)



Medical Eligibility Criteria



Category 1: No restriction on use

Category 2: Advantages generally outweigh theoretical or proven risks

Category 3: Theoretical or proven risks usually outweigh advantages

Category 4: Unacceptable health risk

Source: WHO RHR



Medical Eligibility Criteria for Use

Condition	Category					
	Implants	DMPA/ NET- EN/SP	POPs	Clarification		
High risk for HIV	1	2	1	Clarification (DMPA): There continues to be evidence of a possible increased risk of acquiring HIV among progestin-only injectable users. Uncertainty exists about whether this is due to methodological issues with the evidence or a real biological effect. In many settings, unintended pregnancies and/or pregnancy-related morbidity and mortality are common, and progestin-only injectables are among the few types of methods widely available. Women should not be denied the use of progestin-only injectables because of concerns about the possible increased risk. Women considering progestin-only injectables should be advised about these concerns, about the uncertainty over whether there is a causal relationship, and about how to minimize their risk of acquiring HIV.		

Source: WHO Guidance Statement on Hormonal contraceptive eligibility for women at high risk of HIV, 2017 http://apps.who.int/iris/bitstream/10665/254662/1/WHO-RHR-17.04-eng.pdf?ua=1



Ongoing Research

- Evidence for Contraceptive
 Options and HIV Outcomes
 (ECHO) trial comparing HIV
 acquisition risk among users
 of DMPA-IM, Jadelle Implant,
 and Copper T IUD
- More information: <u>http://echo-consortium.com/</u>

Gates Open Research

Gates Open Research 2017, 1:17 Last updated: 15 JAN 2018



STUDY PROTOCOL

Rationale and design of a multi-center, open-label, randomised clinical trial comparing HIV incidence and contraceptive benefits in women using three commonly-used contraceptive methods (the ECHO study) [version 1; referees: 2 approved]

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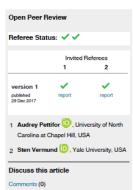
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Abstrac

Background: In vitro, animal, biological and observational clinical studies suggest that some hormonal methods, particularly depot medioxyprogesterone acetate – DMPA, may increase women's risk of HIV acquisition. DMPA is the most common contraceptive used in many countries worst affected by the HIV epidemic. To provide robust evidence for contraceptive decision-making among women, clinicians and planners, we are conducting the Evidence for Contraceptive Options and HIV Outcomes (ECHO) study in four countries with high HIV incidence and DMPA use: Kenya, South Africa, Swaziland, and Zambia (Clinical Trials gov identifier NCT02550067).

Study design: We randomized HIV negative, sexually active women 16-35 years old requesting effective contraception and agreeing to participate to either DMPA, the copper T 380A intrauterine device or levonorgestrel implant. Participants attend a contraception support visit after 1 month and quarterly visits thereafter for 12 to 18 months. Participants receive a standard HIV prevention package and contraceptive side-effect management at each visit. The primary outcome is HIV seroconversion. Secondary outcomes include pregnancy, serious adverse events and method discontinuation. The sample size of 7800 women provides 80% power to detect a 50% difference in HIV risk





Effectiveness of contraceptive methods in typical use

"Not all contraceptives are the same"

Method	# of unintended pregnancies among 1,000 women in first year of typical use			
Implant	0.5			
Vasectomy	1.5			
Female sterilization	5			
IUD (Cu-T / LNG-IUS)	8/2			
Injectable (Depo-Provera)	60			
Pill	90			
SDM	120			
Male condom	180			
Female condom	210			
Withdrawal	220			
No method	850			

Source: modified from *The RESPOND Project, adapted from Trussell* J. Contraceptive failure in the United States. *Contraception* 2011; 83:397–404.



Service Delivery Considerations

- About 32-40 million women use DMPA and about 3 million women use other injectables
 - Injectables are the most commonly used methods in many countries (e.g., Kenya) and account for about half of the method mix in Ethiopia, Haiti, Madagascar, Malawi, Rwanda and South Africa
- Monthly injectables are used mostly in Latin America
- At least one injectable is available in all service delivery sites in most LMICs through fixed services, community health workers, in pharmacies and drug shops and through social marketing



Service Delivery Requirements

Providers must counsel clients about advantages

and side effects, especially the effects on menstrual bleeding and return of fertility

MESSAGES TO CLIENTS USING CONTRACEPTION

Changes to Menses are NORMAL



Many women have misconceptions about changes to menses (periods) that occur with use of hormonal contraception or the cooper IUD. Use this simple tool to help that may occur. In addition, in each counseling session your clients understand that changes to their menses when they use a hormonal contraceptive method or the cooper IUD are NORMAL Provide your clients with evidence-based the NORMAL acronym to address these points with them

method-specific changes

reassure your clients about these changes and discuss the potential benefits of reduced bleeding and amenorrhea. Use

NORMAL — Changes to your menses are NORMAL when you use a contraceptive method. With hormonal methods, menses could become heavier or lighter, occur more frequently or when you don't expect, it, or you could have no menses at all. Changes to your menses may also be different over time! With the copper IUD, menses could become longer and heavier, but remain regular; spotting could also occur during the first few months after IUD insertion.

OPPORTUNITIES — Lighter or no menses can provide OPPORTUNITIES that may benefit your health and personal life.

RETURN — Once you stop using a method, your menses will RETURN to your usual pattern, and your chances of getting pregnant will RETURN to normal.²

METHODS — Different contraceptive METHODS can lead to different bleeding changes. Let your provider know what types of bleeding changes you would find acceptable.

ABSENCE OF MENSES — If you are using a hormonal method, absence of mense does not mean that you are pregnant. If you have another symptom of pregnancy or if you missed your menses while using the copper IUD, talk to your health care provider or use a pregnancy test.³

LIMIT — If changes to your menses LIMIT your daily activities, there are simple treatments available. Talk to your provider.⁴

senses both before and after a client selects a If applicable, inform your client that when using table contraception (e.g., DMPA), return to tility will likely be delayed after disc thad. For other methods, return to

of pregnancy. Absence of measure during the first eth after initiation of the implant or progestin-

eatment for bleeding associated with the coppe ILID includes a 5-day course of transxamic acid or







