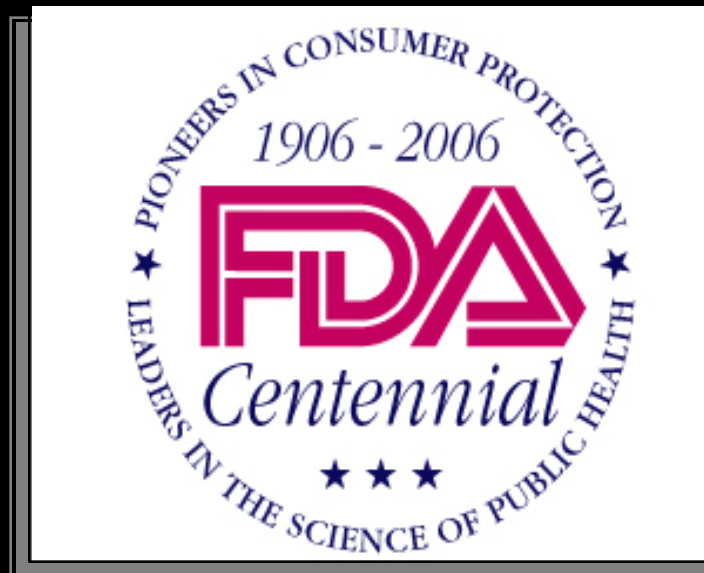


Bringing Science to Consumers: Designing Appropriate Health Education Materials



Alison Lemon, MHS
Food and Drug Administration
Office of Women's Health



- **Oldest consumer protection agency in the U.S.**
- **Ensures that regulated products are safe and effective.**

What FDA Regulates

Foods



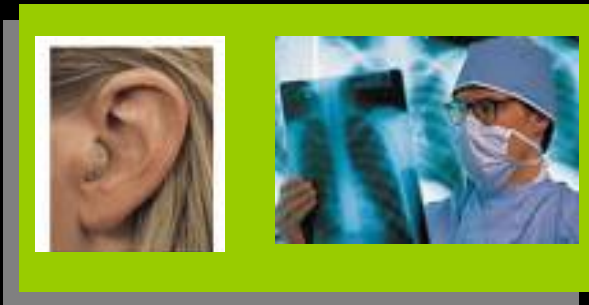
Biologics



Human Drugs



Medical Devices and Radiological Health



Cosmetics



Animal Drugs, Feed, and Testing

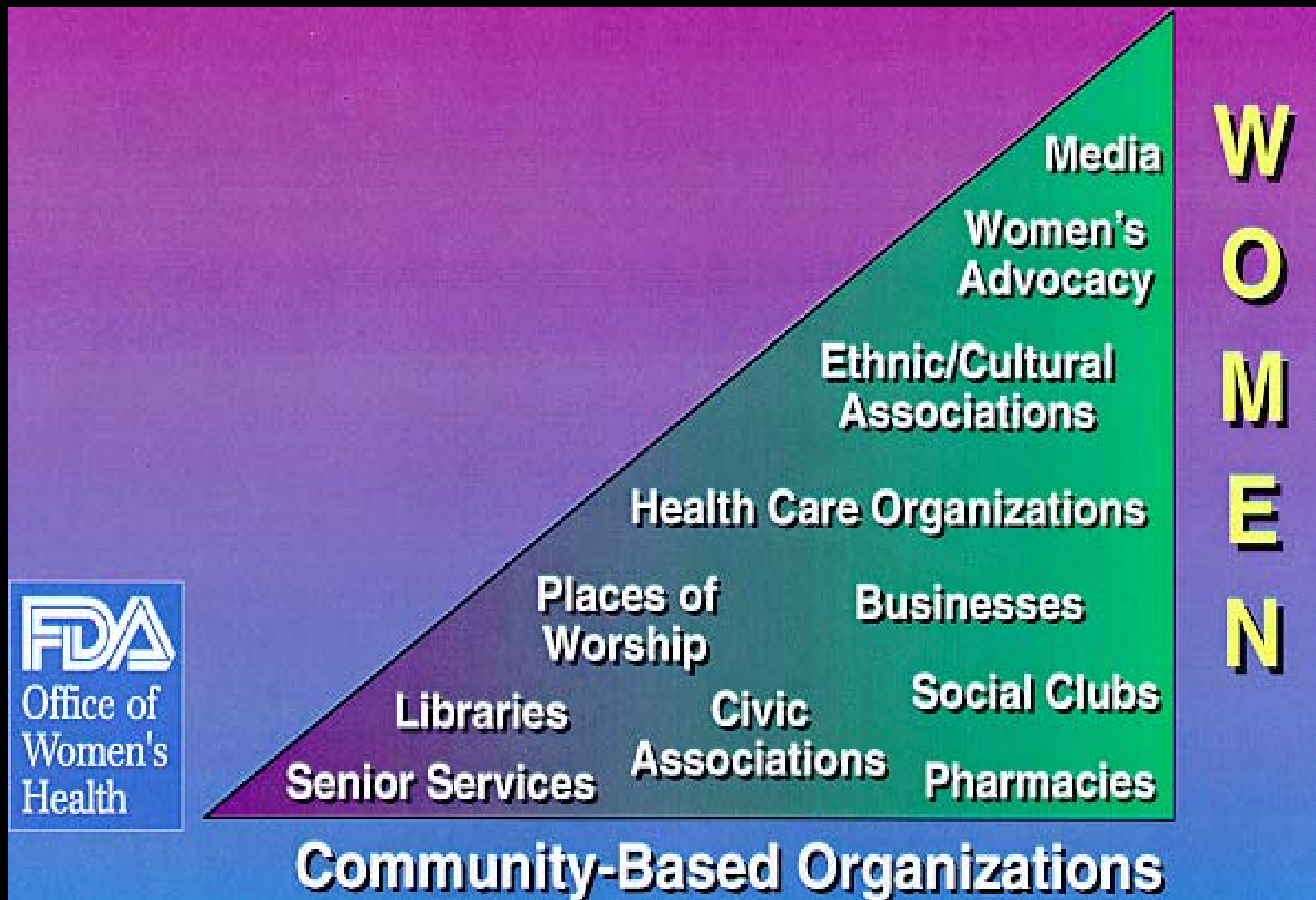


OWH Mission Statement

FDA's Office of Women's Health

- Protects and advance the health of women through policy, science and outreach**
- Advocates for the inclusion of women in clinical trails as well as sex/gender and subpopulation analyses**

Outreach Strategy



Take Time To Care

Umbrella Theme For Campaigns

- **Diabetes**
- **Pink Ribbon Sunday (Mammography)**
- **Menopause and Hormones**
- **Health Fraud**

Quality Materials Development

(2 year process)

- **HHS Requirements – advance approval of concepts**
- **Staff Expertise**
- **Drafts Approved by Centers**
- **Human Subject Protection = IRB, RIHSC**
- **Formal Focus Testing in English and Spanish (locally and in field)**
- **Evaluations require OMB clearance**

Publication Distribution

- Distributed over 3.5 million publications in 2006
- Received GSA Consumer Choice Award from FCIC
 - FDA/OWH most requested source of health information in HHS 7 consecutive years
- FDA Public Affairs Specialists
- National Organizations
- 75 conferences every year

Fact Sheets

- Allergies
- Antibiotic Resistance
- Asthma & Hay Fever
- Botox
- Buying Contacts Online
- Cell Phones
- Clinical Trials
- Contact Lens Care
- Cosmetics
- Depression
- Diabetes
- Diabetes Recipes
- Dietary Supplements
- Fibroids
- The Flu
- Food Safety at Home
- Food Safety for Seniors
- Food Safety/Take-Out
- Generic Drugs
- Whole Body CT Imaging
- Hair Dye /Straighteners
- Heart Disease
- High Blood Pressure
- Incontinence
- Infertility
- Lasik Surgery
- Liposuction
- Listeria
- Lung Cancer
- Mammograms
- Menopause
- My Medicines
- Osteoporosis
- OTC Drugs
- Pap Tests
- Sleep Disorders
- Stroke
- Sunscreens
- Tattoos
- Using Medicines Wisely
- West Nile Virus



Women and HIV

- Most women get HIV from having sex with men and not using a condom.
- African American and Latina women have a greater risk of getting HIV.

What is HIV?

HIV stands for Human Immunodeficiency Virus. HIV is the virus that causes AIDS.

HIV is a virus that attacks your immune system. The immune system has "T cells" that help protect your body from disease. A person with HIV does not have as many "T cells" as a healthy person. HIV makes it hard for your body to fight off sickness.

A person with HIV is called HIV positive (HIV+).

How do you get HIV?

You can get HIV by:

- Having sex with a person who is HIV+ and not using a condom
- Sharing needles or syringes ("drug works") with someone who has HIV
- Getting blood from a person who has HIV

You can't get HIV by:

- Being in the same room with

someone who has HIV

- Sharing a knife or fork, sheets, toilet seats, or phones with someone who has HIV
- Kissing a person with HIV
- Shaking hands with someone with HIV
- Getting bitten by a mosquito or other bug

What are the signs?

- You cannot tell who has HIV just by looking at them. Most people do not show any outward signs when they first get HIV.
- A person can spread HIV even if he or she does not look sick.
- **An HIV test is the only way to know for sure if you or someone else has HIV.**

It may take a few weeks or months for the HIV to show up on a test. This is called the "window period". This means that a person who was just infected may not test positive, even though they have the virus. During the "window period" a person can pass the virus to others.

Always protect yourself from HIV.



OVER

2007

- **New design & layout**
- **Updated contents**
- **Color groupings**

Heart Disease in Women



A lot of people think that women do not get heart disease. More women die from heart disease than from anything else. Any woman can get heart disease.

When you think about heart disease, you probably think about chest pain. Women might not have chest pain. If they do, they might call it an achy, tight or "heavy" feeling instead of pain. The pain might even be in the back between the shoulder blades, instead of the chest.

Women might think these signs are no big deal because they don't "sound" like a heart attack. Don't ignore these signs. Go to your doctor or clinic right away.

What are the signs of heart disease in women?

The most important sign is feeling really tired—even after enough sleep. Other signs of heart disease in women are:

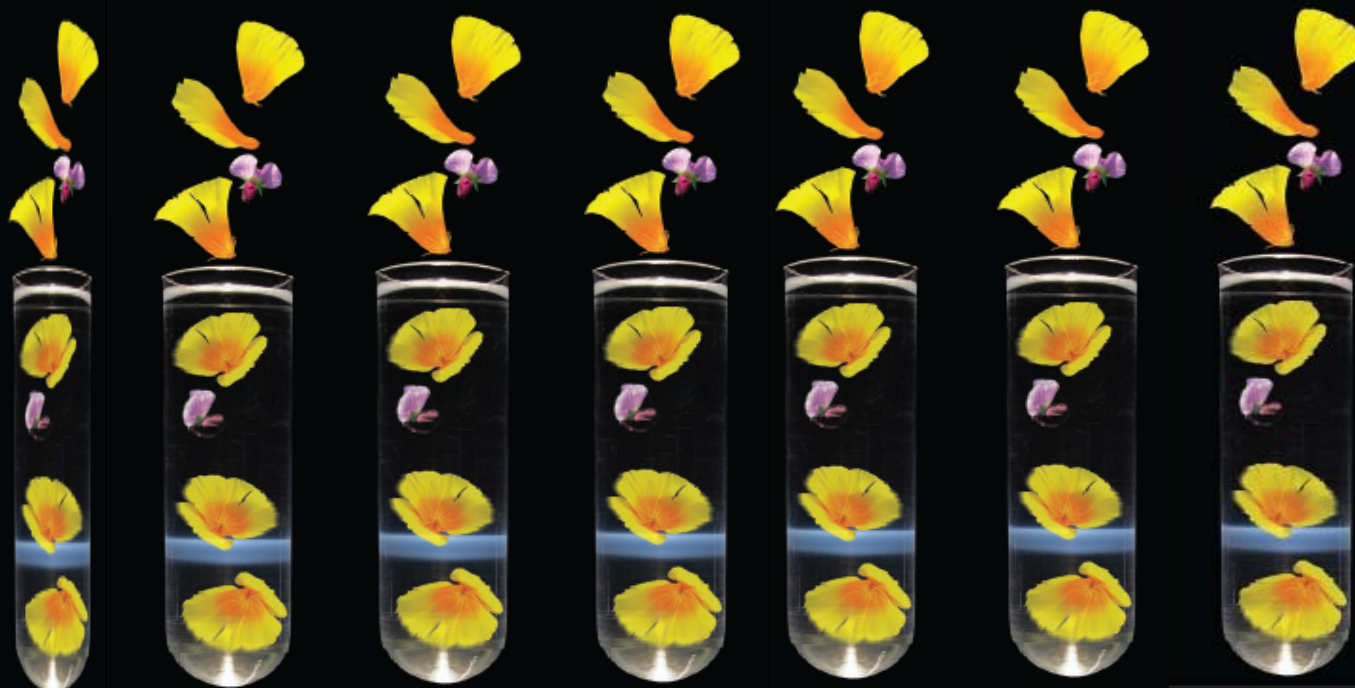
- Trouble breathing
- Trouble sleeping
- Feeling sick to the stomach
- Feeling scared or nervous
- New or worse headaches
- An ache in the chest
- Feeling "heavy" or "tight" in the chest

- A burning feeling in the chest
- Pain in the back, between the shoulders
- Pain or tightness in the chest that spreads to the jaw, neck, shoulders, ear, or the inside of the arms
- Pain in the belly, above the belly button

There is good news: You can take steps to keep your heart healthy.

Lower your risk of heart disease

- Find out if heart disease runs in your family.
- Visit your doctor or clinic often. Find out if you are at risk.
- Don't smoke. Stay away from other people who are smoking.
- Get your blood pressure checked often. You might need medicine to keep it at the right level.
- Control your diabetes.
- Get your cholesterol checked often.
- Stay active. Walking every day can lower your chances of a heart attack.
- Eat right and keep a healthy weight.
- Eat less salt.
- If you take birth control pills, don't smoke.



OVER

2007

2007

2007

2007

2007

2007

2007

Colesterol

¿Sabía usted que...?

- Las mujeres mayores de 20 años de edad deben hacerse controlar su nivel de colesterol.
- Las mujeres mayores de 55 años de edad suelen tener niveles de colesterol más elevados que los hombres.
- El colesterol elevado puede aumentar sus probabilidades de tener una enfermedad cardíaca.

¿Qué es el colesterol?

- El colesterol es un material similar a la grasa presente en la sangre. El cuerpo produce su propio colesterol. Cuando usted ingiere alimentos que tienen un alto contenido de grasa o colesterol, es posible que su colesterolemia (cantidad de colesterol en la sangre) aumente.
- El colesterol puede acumularse en el interior de los vasos sanguíneos del corazón. Si se acumula demasiado colesterol, la sangre no puede fluir al corazón, y esto podría causar un infarto.

Colesterol bueno y colesterol malo

No todo el colesterol presente en la sangre hace daño a la salud. Hay tres tipos de colesterol: la lipoproteína de alta densidad (HDL, por sus siglas en inglés), la lipoproteína de baja densidad (LDL, por sus siglas en inglés) y los triglicéridos.

El buen colesterol

- Se le conoce en inglés como HDL (lipoproteínas de alta densidad).
- Previene que las arterias se tapen.
- Protege contra la enfermedad del corazón (cardiopatía).
- Una concentración adecuada en la sangre es de 60mg/dL o más.

El mal colesterol

- Se le conoce en inglés como LDL (lipoproteínas de baja densidad).
- Causa que se acumule y obstruyan las arterias.
- Causa la enfermedad del corazón (cardiopatía).
- Una concentración adecuada en la sangre es menos de 100 mg/dL.

Los triglicéridos

- Son otra forma de grasa (lípidos) en la sangre.
- Pueden aumentarle el riesgo de sufrir una enfermedad del corazón (cardiopatía).
- Una concentración cerca del límite elevado (150-199 mg/dL) o un caso de concentración elevada (200 mg/dL o más) puede requerir tratamiento.



Medicine Charts

- HIV &AIDS
- Depression
- Smoking
- Menopause
- High Cholesterol
- High Blood Pressure
- Birth Control

Why Medicine Charts?

- Response to the public
- Direct to consumer advertising
- Balanced, simplified information
- Based on the label

The Process

- Original draft based on the label
- Reviewed by appropriate centers
- Back and forth process
- Sign off by center directors
- Focus groups

Depression

Medicines To Help You

Do you feel depressed? Do not feel ashamed. Women are more likely than men to feel depressed. About 1 woman in 5 has depression in the U.S.

There is hope.

Depression can be treated with medicine or counseling. Sometimes both are used. Talk to your doctor to find out what will work best for you.

Use this guide to help you talk to your doctor or pharmacist about medicines called **antidepressants** (an-tee-de-press-ants) that can help to treat depression. Ask your doctor to tell you about all of the risks of taking the different medicines. This guide only talks about some of the risks.

Signs of Depression

Everyone feels sad at times. People with depression feel sad most days. These feelings can get in the way of everyday life.

If you are depressed, you may:

- Feel sad
- Feel tired all the time
- Sleep too little or all the time
- Cry a lot
- Lose interest in eating
- Eat too much
- Have trouble paying attention
- Feel nervous or cranky
- Think about death or try to kill yourself
- Notice that things that used to make you happy, do not make you happy anymore

Talk to your doctor about your feelings if you have noticed these signs for at least 2 weeks. Only your doctor or counselor can tell you if you have depression.

Depression and Pregnancy

Some women become depressed when they are pregnant or after they give birth. Other women notice that their depression gets worse during pregnancy.

“The Baby Blues”

Having a baby can be a joyful time. However, some women cry a lot and feel sad right after they have a baby. This is called “the baby blues”. This feeling usually goes away after about two weeks.

If you still feel sad after two weeks, go to your doctor or clinic. You may be depressed. This type of depression is called postpartum depression because it starts after a woman has a baby. A woman can have this kind of depression up to one year after she has a baby.

No one knows the exact cause of depression during or after pregnancy. It may have something to do with:

- Stress
- Hormones – After a woman has a baby, her hormone levels drop quickly.
- Having depression before you get pregnant.
- Lack of support from family and friends.
- Young age – The younger you are when you have your baby the more likely you are to become depressed.

FDA Office of Women's Health – www.fda.gov/womens

Medicines To Help You



Depression

Use this guide to help you talk to your doctor, pharmacist, or nurse about your medicines for depression. The guide lists all of the FDA-approved products now available to treat this condition. You will also find some general information to help you use your medicines wisely.



Selective Serotonin Reuptake Inhibitors (SSRIs)

Brand Name	Generic Name	Warnings
Celexa	Citalopram	<p>Do not take with certain other medicines:</p> <ul style="list-style-type: none"> • Monoamine Oxidase Inhibitors (MAOIs) • Thioridazine • Orap <p>Women should talk to their doctors about the risks of taking Paroxetine during pregnancy.</p>
Lexapro	Escitalopram	
Paxil	Paroxetine	
Pexeva	Paroxetine	
Prozac	Fluoxetine	
Zoloft	Sertraline	
		<p>Common Side Effects</p> <p>Nausea Tremor (Shaking) Nervousness Problems Sleeping Sexual Problems</p>
		<p>Less Common but Serious Side Effects</p> <p>Seizures Abnormal Bleeding Withdrawal Symptoms</p>
		<p>Mothers who take these drugs late in pregnancy may have babies with feeding problems and irritability.</p>

For up-to-date information about the risks and side effects for each drug
Check <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

Monoamine Oxidase Inhibitors (MAOIs)

Brand Name	Generic Name	Warnings
Emsam (Skin Patch)	Selegiline	<ul style="list-style-type: none"> • Do not take MAOIs if you are also taking other medicines for depression or central nervous system stimulants or depressants. • Do not eat certain foods like cheese, wine, protein foods that have been aged, or any food containing tyramine. • Do not take cold pills or decongestants.
Marplan	Isocarboxzaid	
Nardil	Phenelzine	
		<p>Common Side Effects</p> <p>Nausea Dizziness Restlessness Problems Sleeping Drowsiness</p>
		<p>Less Common but Serious Side Effects</p> <p>Headache Stroke Fainting Heart Palpitations Blood Pressure Changes</p>

For up-to-date information about the risks and side effects for each drug
Check <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

2003 OWH Birth Control Chart

Birth Control Guide

The Food and Drug Administration has approved a number of birth control methods. The choice of birth control depends on factors such as a person's health, frequency of sexual activity, number of sexual partners, and desire to have children in the future. Failure rates, based on statistical estimates, are another key factor. The most effective way to avoid both pregnancy and sexually transmitted disease is to practice total abstinence (refrain from sexual contact).

Failure rates in this chart are based on information from clinical trials submitted to the FDA during product reviews. This number represents the percentage of women who become pregnant during the first year of use of a birth control method. For methods that the FDA does not review, such as periodic abstinence, numbers are estimated from published literature. For comparison, about 85 out of 100 sexually active women who wish to become pregnant would be expected to become pregnant in a year.

Serious medical risks from contraceptives, such as stroke related to oral contraceptives, are relatively rare. This chart is a summary of important information, including risks, about drugs and devices approved by the FDA for contraception and sterilization. It is not intended to be used alone, and a health professional should be consulted regarding any contraceptive choice. Review product labeling carefully for more information on use of these products.

Type of Contraceptive	FDA Approval Date	Description	Failure Rate (number of pregnancies expected per 100 women per year)	Some Risks	Protection from Sexually Transmitted Diseases (STDs)	Convenience	Availability
Male Condom Latex/ Polyurethane	Latex: Use started before premarket approval was required Polyurethane: cleared in 1989; available starting 1995	A sheath placed over the erect penis blocking the passage of sperm.	11 (a, b)	Irritation and allergic reactions (less likely with polyurethane)	Except for abstinence, latex condoms are the best protection against STDs, including gonorrhea and AIDS.	Applied immediately before intercourse; used only once and discarded. Polyurethane condoms are available for those with latex sensitivity.	Nonprescription
Female Condom	1993	A lubricated polyurethane sheath shaped similarly to the male condom. The closed end has a flexible ring that is inserted into the vagina.	21	Irritation and allergic reactions	May give some STD protection; not as effective as latex condom.	Applied immediately before intercourse; used only once and discarded.	Nonprescription
Diaphragm with Spermicide	Use started before premarket approval was required.	A dome-shaped rubber disk with a flexible rim that covers the cervix so that sperm cannot reach the uterus. A spermicide is applied to the diaphragm before insertion.	17 (b, d, e)	Irritation and allergic reactions, urinary tract infection. (c) Risk of Toxic Shock Syndrome, a rare but serious infection, when kept in place longer than recommended.	None	Inserted before intercourse and left in place at least six hours after; can be left in place for 24 hours, with additional spermicide for repeated intercourse.	Prescription

Medicines To Help You



Birth Control Guide

This guide gives the basic facts about the different kinds of FDA-approved medicines and devices for birth control. Ask your doctor to tell you about all of the risks and benefits of using these products.



Birth Control Guide



Methods	Number of pregnancies expected per 100 women	How to use it	Some Risks
Sterilization Surgery for Women	1	One-time procedure, nothing to do or remember	<ul style="list-style-type: none"> Pain Bleeding Infection or other complications after surgery Ectopic (tubal) pregnancy
Surgical Sterilization Implant for Women	1	One-time procedure, nothing to do or remember	<ul style="list-style-type: none"> Mild to moderate pain after insertion Ectopic (tubal) pregnancy
Sterilization Surgery for Men	1	One-time procedure, nothing to do or remember	<ul style="list-style-type: none"> Pain Bleeding Infection
Implantable Rod	1	One-time procedure, nothing to do or remember	<ul style="list-style-type: none"> Acne Weight gain Cysts of the ovaries Mood changes Depression Hair loss Headache Upset stomach Dizziness Sore breasts
IUD	1	One-time procedure, nothing to do or remember	<ul style="list-style-type: none"> Cramps Bleeding Pelvic inflammatory disease Infertility Tear or hole in the uterus Lower interest in sexual activity Changes in your periods
Shot/Injection	1	Need a shot every 3 months	<ul style="list-style-type: none"> Sore arm Bleeding between periods Weight gain Breast tenderness Headaches
Oral Contraceptives (Combine d Pill) "The Pill"	5	Must swallow a pill every day	<ul style="list-style-type: none"> Dizziness Nausea Changes in your cycle (period) Changes in mood Weight gain High blood pressure Blood clots Heart attack Stroke
Oral Contraceptives (Progestin-only) "The Pill"	5	Must swallow a pill every day	<ul style="list-style-type: none"> Irregular bleeding Weight gain Breast tenderness
Oral Contraceptives (Estrogen/Contraceptive Patch) "The Patch"	5	Must swallow a pill every day	<ul style="list-style-type: none"> Risks are similar to other oral contraceptives Bleeding Spotting between periods
Patch	5	Must wear a patch every day	<ul style="list-style-type: none"> Exposure to higher average levels of estrogen than most oral contraceptives
Vaginal Contraceptive Ring	5	Must leave ring in every day for 3 weeks	<ul style="list-style-type: none"> Vaginal discharge Swelling of the vagina Irritation Similar to oral contraceptives
Male Condom	11-16	Must use everytime you have sex, requires partner's cooperation. Except for abstinence, latex condoms are the best protection against HIV/AIDS and other STIs.	<ul style="list-style-type: none"> Allergic reactions
Diaphragm with Spermicide	15	Must use everytime you have sex	<ul style="list-style-type: none"> Irritation Allergic reactions Urinary tract infection Toxic shock
Sponge with Spermicide	16-32	Must use everytime you have sex	<ul style="list-style-type: none"> Irritation Allergic reactions Hard tamers moving Toxic shock
Cervical Cap with Spermicide	17-23	Must use everytime you have sex	<ul style="list-style-type: none"> Irritation Allergic reactions Abnormal Pap test Toxic shock
Female Condom	20	Must use everytime you have sex. May give some protection against STIs.	<ul style="list-style-type: none"> Irritation Allergic reactions
Spermicide	30	Must use everytime you have sex	<ul style="list-style-type: none"> Irritation Allergic reactions Urinary tract infection
Emergency Contraception – if your primary method of birth control fails			
Emergency Contraceptives "The Morning After Pill"	15	Must use within 72 hours of unprotected sex. It should not be used as a regular form of birth control.	<ul style="list-style-type: none"> Nausea Vomiting Abdominal pain Fatigue Headache

Most Effective
 Least Effective

Barrier Methods

Put up a block, or barrier, which keeps the sperm from reaching the egg

Male Condom (Latex or Polyurethane)



What is it?

- A thin film sheath placed over the erect penis to stop sperm from reaching the egg.

How do I use it?

- Put it on the erect penis right before sex.
- Use it only once and then throw it away.
- Pull out before the penis softens.
- Hold the condom against the base of the penis before you pull out.

How do I get it?

- You do not need a prescription.
- You can buy it over-the-counter.

Possibility of getting pregnant

(Number of pregnancies expected per 100 women who use this method for one year)

- Out of 100 women who use this method, 11-16 may get pregnant.
- The most important thing is that you use a condom every time you have sex.

Some Risks

- Irritation
- Allergic reactions (If you are allergic to latex, you can try condoms made of polyurethane.)

Does it protect me from sexually transmitted infections (STIs)?

- Except for abstinence, latex condoms are the best protection against HIV/AIDS and other STIs.
- Condoms are the only contraceptive product that may protect against most sexually transmitted infections (STIs).

Join Us!

www.fda.gov/womens

• w

Acknowledgements:

Marsha Henderson, MCRP

Kimberly Thomas, MPH

Susana Perry, MS

Deborah Kallgren, BS