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Last Updated

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Consults and Referrals

Use the PHSKC Consult and Referral Form to document this activity and keep a copy in the chart. For consults with the Family Planning Medical Director, please refer to the Family Planning Medical Director Consultation Information. Provider referral lists are kept on the internal PHSKC clinical program intranet under the titles of gynecology and vasectomy referral lists. These lists are updated semi-annually by the Family Planning Program using PHSKC provider recommendations; reflecting historical referral patterns. A listing on the referral list does not imply an endorsement or that a PHSKC provider must use these lists, they are only a resource and represent only a partial list of the providers in the entire area. The lists are not appropriate for client use and it is recommended the PHSKC Consult and Referral Form be completed and a client should be given the option of 2 to 3 different referral provider options.

Referral Follow-up
When a client is referred for a consultation the chart should be assigned to a staff member to follow-up. Staff should verify the referral appointment was kept, that a record of the referral recommendations is returned to our department, and the provider is alerted of the results or if the client does not keep the appointment.

Primary Care Referrals
If the client does not have a primary care provider, then utilization of the PHSKC primary care clinic system should be considered. If a client has a condition which necessitates referral, it is possible to refer to the primary care clinic provider first and then that system can manage the referral process or perhaps become the end provider for the referral problem. An extensive document describing referral resources for the breast evaluation and referral into the PHSKC system is linked here (Primary Care Referral Information).

Harborview Women's Clinic Referrals
For referrals to Harborview Medical Center, the Information About Referral to Harborview Medical Center Patient Handout should be used. There is also a handout on Harborview Medical Center Payment Options available. If you are referring a client emergently, then call the Urgent Care Clinic, part of the Emergency Department, at 206-731-5867. They do not make appointments. If you are referring the client for a gynecology evaluation or women's clinic consult, then call 206-731-3367 to make an appointment. If the client needs a procedure like a tubal ligation schedule the procedure through the patient care coordinator, at 206-731-8597 and fax information to 206-731-8038. The staff must also leave the patient information including age, language, and preferably several phone number choices and times to contact the person. The patient care coordinator must arrange the appointment with the patient directly. Sometimes it works to have the health department clinic RN/MA call and help arrange it especially if interpretation is needed. Send paper copies of pertinent records and the referral with the patient as well so the patient knows why they are being referred and she can carry records to her appointment if FAXed materials are lost.

Education

Client Contraception Education All clients should be informed or educated about all contraceptive methods. A good flip book brochure on choosing a birth control method is available in English and Spanish through the Washington State DOH (can use the DOH Forms and Publications Request Order Form and request DOH Pub 930-101 4/02 and Fax to 360-664-2929) and other contraceptive education materials method and brochures can be ordered from the PHSKC warehouse using the FP Brochure Distribution Center Order Form. The DSHS STD Educational Materials Order Form can also be used to order STD materials (360-236-3460 if questions) or their website http://www.doh.wa.gov/chf/STD/publications.htm. The Office of Population Affairs Publications Clearinghouse Order Form is another source of free materials on birth control methods.

All clients sign on registration the Family Planning Consent Form. As appropriate PHSKC brochures and handouts on the specific contraceptive methods should be shared with clients and the chart note should document which materials were shared with the client. Any client receiving a contraceptive requiring a prescription and medication should be given the FDA approved patient package insert for the medication to read as part of the discussion on the risks and benefits of a method.

The risks of estrogen containing methods include the following warning signs and symptoms: severe abdominal pain; severe chest pain or shortness of breath; severe headaches; eye problems such as blurred vision, or loss of vision, and severe leg pain (calf or thigh). Women also need information regarding common hormonal side effects and these include: nausea; spotting between periods (breakthrough bleeding); depression; breast tenderness; headaches; changes in sex drive; worsening in acne; high blood pressure; darkening of the skin on the face.

All clients should be counseled about the need for barrier protection against sexually transmitted diseases, the mechanism of disease transmission, and how to evaluate their sexual practices and their contraceptive method as to the need for STD protection and for HIV/STD prevention including choices such as abstinence and mutually monogamous relationships.

All clients should be told of how to access local health care if emergent or after hours care when needed. Use the Education, Counseling, and Risk Reduction Form to document contraceptive education and counseling once a year (no sooner than a 10 month interval). Vaccine recommendations for adolescents and adults can be found at website: http://www.cdc.gov/nip/recs/adult-schedule.pdf

When using the FP/STD Female Visit Form providers will indicate education and counseling topics discussed with clients by checking boxes on the visit form. The descriptions of the content and points discussed for the topics are provided below.

1. Contraception: counseling about contraception as a global topic, specific method could be indicated, what method or methods discussed at the visit, contraceptive planning, and method brochure or contraceptive choices flipbook could be supplied to the client. Specific information about a method is taken from the specific guidelines for each method individualized for the specific client.

2. How to start and how to use a method includes working with the woman on what she wants, does she want a Sunday start, to start the day of the visit, or perhaps to start with her next menses. Often the package for the pills or the method will be brought into the room and the woman will be shown how to remove the pills from the package, how to place the method like the patch, how to dispose of the used ring; these are all examples of how explicit the instructions can be and they are from the method chapters of the guidelines.

3. Back up method for 1 or 2 weeks. We circle if 1 or 2 weeks recommended for back up. We assess risk and need for back up contraception, ask if partner will use condoms or withdrawal, abstinence promoted as most effective, we remind women that they should be prepared, and provide ECP if important to their back up method plan.

4. EC availability/use/side effects to provide the information about it being available, can get from a pharmacy or a clinic, may also include discussion about how to use ECP and the common side-effects as presented in the EC chapter.

5. Advance provision ECP means women can be prescribed the packages to use in the future if the condom breaks or other unprotected sex. Women are advised to return to get a replacement package when needed.

6. Refused Advance provision ECP prescription indicates the woman typically identified by the provider as at risk for needing the ECP, such as a condom user, was offered an advance prescription but did not want to actually get it from the clinic that day.

7. BCM specific consent form was used and the topic on the form discussed as specified with the patient.

8. Estrogen side effects and thrombosis danger signs presented and discussed to the client along with the package insert from the prescription to include: breast tenderness, nausea for typical estrogen side effects and hair loss, acne, weight changes for possible progestin side effects. The serious risk of a blood clot could present with symptoms of severe or new headaches or visual changes, chest pain, shortness of breath, abdominal pain, or leg pain along with a leg or foot swelling.

9. Preconception counseling is identifying a client is at risk for possible pregnancy, either because she wants to get pregnant or is at risk for pregnancy, this can involve sharing the handout on this topic, folic acid necessity, screening for risks as discussed in the guidelines.

10. ECRR teaching done and form completed at this visit. The details of how to conduct an education, counseling, and risk reduction intervention are addressed in a document on the PHSKC health educator webpage.

11. STD/HIV prevention include the promotion of abstinence or mutual monogamy as the only 100% method, the importance of both male and female condoms, how to use the male condom to prevent breakage (sufficient lubrication, space at the tip, use prior to contact, and removal before loss of erection), screening partners, risk factors, sexual practices, the information and specific content of these messages comes from the

PHSKC STD guidelines, and many of these discussion can include brochures available from DOH on these topics.

12. Substance use addressed as an issue, identified this could be a problem for the client, specific history collected and discussed, risks of progression to other use, impairment of judgment, and health risks.

13. Tobacco cessation counseling as specified in the clinical guidelines.

14. Dietary education provided regarding the importance of calcium for bone health, iron if anemia, and weight reduction if obesity. All of these have specific handouts on the guidelines website and can be used to direct the content of the information.

15. Family involvement/Relationship safety involve the asking about the these issues, collecting the information, reminding the client that family will find out and should be involved often in family planning decisions and support. Identification of domestic violence or safety concerns, use of the guideline information about this topic and can help provide a safety plan and the state card/800 number.

16. Cervical cytology/HPV education regarding the importance of cervical cancer screening individualized for the woman and in context of her testing results. HPV or human papilloma virus information can be shared using the patient handout and the information from both the cervical cancer screening and STD guidelines.

17. Breast cancer self-exam/ screening information shared with the client using the guidelines. How to perform a self breast exam is often demonstrated on the client during a clinical breast exam. Referral for mammogram screening if indicated can be part of the visit and done using the breast guidelines.

Coverage and Access

Medicaid
If a visit is greater than 50% family planning, the encounter should be recognized as a Program 28 visit on the Encounter Form and this form and the instructions for completion of the encounter form are available as a resource from PHSKC public folders.

Women whose medical care was paid by Medical Assistance during pregnancy are eligible for family planning services and supplies for an additional 10 months beyond the 60-day post pregnancy period. The family planning services extension covers the following:

- Family planning annual service package (includes pap smear, physical exam, family planning counseling, and contraceptive method).
- Non-prescription, over-the-counter products like male and female condoms, contraceptive cream, film, foam, gel, and suppositories
- Sterilization – vasectomy or tubal ligation
- STD services are only covered under the Family Planning Only program when related to a BCM, for example chlamydia infection treatment prior to IUD insertion.

If the client becomes pregnant and requests an abortion, the Family Planning Only coupon does not cover abortions. The client can be referred to the client services specialist or to the CSO to request eligibility determination for the full medical package.

Take Charge
Take Charge is a 5 year Medicaid program (7/2001 to 7/2006) for Washington State residents lacking health insurance family planning benefits whose family income is at or below 200% of the federal poverty level. The Take Charge website can be used to check for program updates http://fortress.wa.gov/dshs/maa/familyplan/TCfront.html. Take Charge cards and brochures can be ordered using the DSHS Publications Order Form or through the DSHS website at http://www.wa.gov/dshs/dshsforms/index.html. People currently covered by Medical Assistance are not eligible, as family planning is included in their health care package. A Washington State resident is determined by intent to remain in Washington. For example, a student from another state that intends to reside here permanently or for an indefinite period of time then becomes a resident. But if the student states “I am here for the school year only and will return to my home state” would not qualify.

Approved applicants may use their Take Charge coverage to get family planning services and birth control methods at an approved Take Charge family planning provider, local pharmacy, or surgical center. These services and methods include:

- An annual exam (no sooner than every 10 months)
- Family planning reproductive health education and risk reduction counseling
- All federal Food and Drug Administration approved birth control methods, devices, and supplies
- Non-prescription, over-the-counter products like male and female condoms, contraceptive cream, film, foam, gel, and suppositories

- Sterilization – vasectomy or tubal ligation (once sterilization is done, coverage ends at the end of that coverage year)

Consumer Hot Line for Insurance Company Questions/Concerns
If a client has insurance questions, these numbers may help. The State Office of Insurance Commissioner has set up a special, toll-free hot-line for consumers that are designed to assist consumers with questions, concerns, or disagreements with insurance companies.

The Consumer Hot Line – 1-800-562-6900 – is staffed from 7 a.m. to 7 p.m. Insurance experts for different kinds of policies, including health, life, homeowner and auto, can help with complaints or questions involving coverage.

The Consumer Hot Line can also assist the public with filing formal claims against insurance companies. For further information, contact the Consumer Hot Line at 1-800-562-6900, or call the Office of the Insurance Commissioner at 360-753-3613.

Reproductive Health Access Reporting
The Reproductive Health Access Report is to document instances in which women have difficulty accessing Family Planning Services due to the changing health care environment, particularly difficulties arising out of managed care in Washington State. This project can help accurately describe the issue and direct advocacy efforts to decrease barriers to reproductive health care.

You can help by submitting the Reproductive Health Access Form whenever a client tells you she experienced *any* trouble getting the services she wanted or needed. Please complete the form and send to Maria Wood; Clinical Services, Family Planning Program; 401 - 5th Ave, Suite# 1000, Seattle WA, 98104. We will keep a record of the event and if appropriate, forward to the state insurance commissioner's office and/or possibly contact the woman to try and resolve the problem.

Coverage Question
"I have signed up for First Steps and now want an abortion will this change my medical coverage?"

Answer
"It's okay to change your status! Your pregnancy medical coverage coupon can be used to pay for a termination or for pregnancy care and it does not matter what you said to them at the time you applied. Even if you said that you were planning to continue the pregnancy at the time you applied that's ok, it can still be used for either service. The staff at DSHS has worked with many pregnant women that have changed their plans after applying for coverage.

After your termination, you will need to notify them (DSHS) that you've had a "change of circumstance"; you will have full medical coverage for yourself while you are pregnant and for 60 days after the termination. If you need to go to the doctor or to the dentist now is a good time to do that since it will be paid for; your coupon will change to "family planning only" 60 days after your termination.

Family Planning coupon will be good for 10 more months of coverage; it pays for any birth control method you choose even ones that you can get at the drug store like condoms or spermicides.

If you have other questions you can call DSHS at 1-877-980-9131. You can ask questions and you don't have to identify yourself.

We understand that getting services like this can be difficult emotionally as well as time consuming. Please don't hesitate to contact us again if you have more questions or need help."

Hep B Vaccine in Family Planning Clinics

- Family Planning staff can administer Hep B injections regardless of the client's age.
- Consult the Immunization Manual Guidelines for more information on Hep B.
- Medicaid Fee-for-Service does cover Hep B so clients with this coverage will not be charged for Hep B.
- Family Planning Only and Take Charge DO NOT cover Hep B so clients will be charged on the sliding fee scale for the vaccine and the administration fee.
- Self-pay clients 19 years old and younger will receive state-supplied vaccine at no charge. However, there is $15 administration fee that will be charged when the Hep B code is entered in Signature. This fee slides depending on the client's pay status.
- Self-pay clients 20 years old and older (including those who have coverage that does not include Hep B) will receive purchased vaccine. These clients will be charged for the vaccine and the administration fee. The vaccine will slide to the cost of the vaccine, which is currently $24. The $15 admin fee can slide to zero depending on the client's pay status.
- As with all services at PHSKC, services will not be denied due to a client's inability to pay. When the client is charged for Hep B, the charge will be entered in their account.

Delayed Physical Examination for Hormonal Contraception

Background
The following guidelines developed by PPWW support the practice of allowing a woman to delay a pelvic exam during a contraceptive visit:

Improved access to hormonal contraception: Patients would be able to access hormonal contraception as needed, without the delay of a full annual exam. The patient would be able to experience the advantages that hormonal contraception provides, over the other less effective contraceptive methods.

Education: Women may be able to learn more in a relaxed session, without the pressure of having to undergo a pelvic exam. Patients may also gain more information about women's health if they perceive that the pelvic exam is not tied directly to birth control and their access to it.

In the more than 40 years since the approval of birth control pills, the standards for prudent medical practices regarding hormonal contraceptives have evolved. An article by Stewart et al. (published in *JAMA* in 2001; 285: 2232-2239) lists recommendations for prescribing hormonal contraceptives by these national and international organizations:

Organization	Pelvic/Physical Exam
US Food and Drug Administration	Physical exam may be deferred if requested by the woman and deemed appropriate by the clinician. (1994)
US Agency on International Development	Pelvic exam is not necessary for safe use of combined oral contraceptives. (1994)
Planned Parenthood Federation of America	Pelvic exam may be deferred for up to 3 months, with blood pressure and history taken, along with breast exam. (1996)
World Health Organization	Pelvic exam is not necessary for safe use of combined oral contraceptives. (1994)
International Planned Parenthood Federation	Physical exam is not routinely required; careful medical history is taken. (1995)
American College of Obstetricians and Gynecologists	Pelvic exam is not necessary prior to initiating oral contraceptives in teenagers. (1999)

The FDA OCP labeling states the following:

> "It is good medical practice for all women to have annual history and physical examination, including women using oral contraceptives. The physical examination, however, may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinician. The physical examination should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including cervical cytology, and relevant laboratory tests. In case of undiagnosed, persistent or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy. Women with a strong family history of breast cancer or who have breast nodules should be monitored with particular care."

Rationale
There are several reasons for a delayed pelvic examination. Primarily it allows flexibility and a client-centered approach to the provision of contraceptive services. Clients may have had an examination at another clinic and the need for immediate examination with our program may not be feasible, deemed needed, or even paid for by insurance. The client may be menstruating and it is preferable to delay the pelvic examination until she is more comfortable and until the pap test and other necessary tests can be obtained. Some clients are afraid of pelvic examinations and a delay may be indicated to give more time for education and reassurance. Other women may come to the clinic before the initiation of sexual activity and delaying a pelvic examination through an intact hymenal ring is frequently desirable, since there are no risks of STD or cervical cancer. As well some clients may be unable to wait in the clinic that day for an examination or a clinician may not be immediately available. A client may request a delayed examination for any reason.

Nineteen percent of women getting contraception chose a delayed pelvic visit at Planned Parenthood of Western Washington (PPWW) from 7/01 to 3/02 and a survey of 207 of these women yielded this information:

- 16 percent stated that they had never had a pelvic exam.
- 56 percent indicated that they had had a pelvic exam within the last year.
- 8 percent stated that they had avoided hormonal birth control because of the pelvic exam requirement.
- 91 percent stated their intention to have a pelvic exam within the next year – 33 percent of these with a private provider.

Policy
To provide hormonal contraceptives with an optional pelvic exam when:

- Extensive education takes place, covering STIs, birth control, and the importance of the pelvic exam.
- STI and pregnancy urine testing should still be offered.
- Personal and family history is reviewed by a provider and the vital signs are taken.
- The exam has been done elsewhere during the past year, with records obtained or documented.
- An exam within six months is strongly encouraged.
- The clinician exercises medical judgment.
- The clinician updates the patient's care annually.
- After six months without an exam, an extension is permitted, with a disclaimer or waiver by signing the Specific Birth Control Method Informed Consent Form.

Procedure
- Women requesting a delayed pelvic examination prior starting hormonal contraceptives must register, sign the same consents for care, and complete the **Family Planning Medical History Form** which is reviewed by a medical provider.
- Counsel the client about the benefits of a physical examination and testing for STD and cancer.
- Include the danger signs, risks, and benefits of the contraceptive method chosen.
- Review the FDA package insert and educational handout materials with the client.
- A prescribing provider reviews the entire history and records weight and blood pressure.

- Strongly consider HCG testing if irregular or delayed menses, especially in teens.
- Consider urine CT screening if under age 25.
- If there are no special risk factors, the practitioner may prescribe three cycles of pills or a DMPA injection using the Contraceptive guidelines.
- Hormonal contraception users should be strongly encouraged to undergo examination especially if their menses is irregular, even if virginal, and the American College of OBGYN recommends all women (even virgins) be examined by age 21 or after 3 years of sexual activity when younger than 21 to detect treatable precancerous conditions. In addition there is evidence that long term users of the OCP may have increased risks of cervical cancer.
- At remote sites or when no clinician is available on-site, the prescription may be given over the phone by a clinician to the clinic RN who does the counseling and testing of the client.
- The clinician must countersign the verbal order in the chart when next at the clinic site.
- Dispensing cannot be done without a prescription and prescriptions can only be written or given verbally by licensed providers with prescribing authority.
- When the client returns, complete the examination, and exam documentation then prescribe the continuing contraceptive method for the year or as indicated by the guidelines.
- If client presents after three months and again wants the delayed pelvic option, this may be given with careful documentation of counseling regarding the benefits of an exam. Document in the chart, the client understands that she may have a pre-cancer of the cervix or a STD that could cause infertility, and is refusing screening.
- After six months the client cannot get further hormonal prescriptions without signing the **Specific Birth Control Method Informed Consent Form**, documenting her formal refusal of examination. The refusal of exam must be documented every year the client continues to receive hormonal contraceptives by both progress notes and the signed consent form.

Documentation of Family Planning Visits

History Documentation

The PHSKC Department Policy and Procedures manual chapter titled "Medical Record Documentation Policy" are to be followed by PHSKC clinics. PHSKC retains records for 10 years after the last visit for adults and for up to 21 years after the last visit for a minor. What follows in this chapter are specific items to the Family Planning Program.

Health History: Clients complete a Female or Medical History Form or Male FP/STD visit form at the initial exam or first visit to the clinic and with every annual exam. It is reviewed as appropriate, dated, and signed by the practitioner managing the visit. Each item checked by the client on the history form should have comments or notes written beside or in the progress notes. If a Spanish version of the history form is used to assist in data collection, the information must be transcribed on to the correct English form or the Spanish with English translation version of the form can be used. The program requires an English medical history as documentation for billing and to share with other English speaking providers.

Use the Female Contraceptive/STD Visit Form for new or annual visits to document exam services. The male exam is part of the Male Family Planning/STD Visit Form, and should be used for all male visits. For female visits, the Female Contraceptive Visit Form should be used to document the exam and treatment in the context of a contraceptive visit. For clients under age 18 it is important to address and document discussion regarding parental / family involvement. Minors can give consent for contraceptive and STD healthcare, however, if there are questions, consult the Ability of Minors to Consent to Health Care Summary of Legal Requirements. A plain progress note is appropriate for other visits. The Family Planning Flow Sheet should be kept current with each visit to allow a quick summary of vital statistics like blood pressure, weight, pap results, and birth control method history.

Standard medical terminology and abbreviations are to be used when documenting Family Planning patient visits. The approved PHSKC Charting Abbreviations List is available for reference.

Use forms or other appropriate documentation for each specific contraceptive method as indicated in the Family Planning Practice Guidelines. When using the forms if an entire section of the form is to be left blank, then a single line should be struck across the section. The provider billing for the visit is responsible for signing the entire visit note or form and by signing the provider signifies their agreement with any other documentation done by others on the form, such as vital signs or medications used collected by an RN, MA, or health educator as designated by the provider.

All clients seen by the Family Planning program should sign the Family Planning Consent Form at their initial visit. This form has a second side to address hormonal methods which only females would sign. Clients need to sign this consent form at their initial visit and if there is ever a change

in their status as a returning client, such as two years since their last visit, which will revert them to a new patient again, then they will need to resign the consent form for family planning. All procedures require consent forms specific for the treatment to be signed. If the client requires a Birth Control Method Specific Informed Consent Form, then it should be re-signed at each annual visit, as that is the time of the annual prescription for the specific method.

Pregnancy Screening: Use the Pregnancy Detection section of the guidelines to complete the Pregnancy Screening Form for visits involving pregnancy testing to document counseling, exam results, follow-up plan, and/or verification of pregnancy for insurance purposes.

ROS Review

A review of systems for a level 4 or 5 visit needs to include 10 body systems. The Female Contraceptive Visit Form allows the documentation of the ROS using a list of ROS to prompt the provider to address the appropriate systems if appropriate. A circle around the system on the form indicates this specific system was addressed in the history and symptoms were absent unless indicated otherwise by notes. Systems are listed below and include the following subsets of specific symptoms queried for their absence or presence.

- Constitutional: night sweats, fatigue or weakness, weight gain or loss, fevers or chills
- Integumentary/skin: hair loss, skin rash or growth, bleeding or bruising
- Gastrointestinal: stomach pain, constipation, vomiting, nausea, diarrhea, heartburn, black stools
- Genitourinary: pain with sex, painful periods, heavy period bleeding, vaginal odor or discharge, bladder pain, incontinence, frequency, blood in urine, urgency
- Breast: pain, discharge, lumps
- Neurological: psychiatric, numbness, shaking, depression/anxiety
- Cardiovascular: chest pain or palpitations
- Respiratory: shortness of breath, cough, coughing up blood
- Ears/Mouth/Nose/Throat: hearing loss, ear pain or ringing or buzzing, problems with teeth or gums
- Eyes: double vision, eye pain, wear glasses or contacts
- Musculoskeletal: arm or leg swelling, joint pain or joint swelling or stiffness

Exam Findings Documentation

When using the Family Planning approved forms in the exam section the option of checking a box labeled normal is provided. The box indicating a normal finding on the exam must correlate with the following descriptions and variations or abnormal findings need to be documented with text.

Female Exam Forms

General Exam

- Thyroid, normal: symmetric, smooth, non-enlarged, no nodularity
- Breasts, normal: symmetric, smooth, no discreet masses or lumps, no adenopathy or nipple discharge
- Heart, normal: regular rate and rhythm, no murmurs appreciated
- Lungs, normal: clear to auscultation without wheezes or rales
- Abdomen, normal: non-tender, no masses, no hepatosplenomegaly
- Skin, normal: no suspicious nevi, lesions, or rashes seen; extremities without

abnormalities

Pelvic Exam

- Lymph nodes, normal: no groin adenopathy or enlargement appreciated
- Vulva/vagina, normal: adult female maturation, no lesions, no suspicious nevi, normal BUS (bulbo-urethreal-skene glands) and no urethral caruncle or prolapsed epithelium, estrogenized, vaginal rugae, pink & moist
- Discharge, normal: discharge clear, white, or scant without odor or purulence
- Cervix, normal: no lesions or mucopus, ectopy appropriate for age and parity, non-tender
- Uterus, normal: symmetric, smooth, firm, mobile, non-tender & non-enlarged
- Adnexae, normal: non-tender, no masses palpated
- Rectal, normal: spincter intact, no masses felt, stool if checked negative for blood

Chart Stickers

Do Not Destroy Sticker: The purpose of the Unique Retention Sticker is to mark the medical record of clients getting an implant or device inserted by our clinic, like the IUD or Implant, so these records will not be destroyed. The chart may be purged and taken to storage but it cannot be destroyed for 15 years after the date of insertion of the device even if the device is removed. The Pharmacy Implant & Intrauterine System Log sheets are also to be stored for 15 years in the event of a product alert or recall. Product liability suits may be filed up to 15 years after product usage, which may require finding old records to find out if the client got an implant, which is being recalled, for example.

1. Label the charts of:
   - IUD users when PHSKC has performed the insertion.
   - Contraceptive implant user when PHSKC has performed the insertion.
   - Patients with colposcopy and CIN II/III biopsy result performed by PHSKC. We need to have this information kept until the patient is 65 years or older after which time the possibility of cervical cancer is very low.
2. Mark charts by folding sticker over the edge of the chart so it can be seen while on the medical record shelf so opposite the number side of chart. The " Unique Retention Sticker" should show on the outside of the chart while the information is hidden on the inside of the chart.
3. Put the date of the IUD or implant insertion, or biopsy date as indicated. If the sticker is used for other charts to avoid purging write the reason and date after other.
4. Example of sticker available from the warehouse.

Unique Retention	**IUD**: ☐ T380A ☐ LngIUS Date_____ **Implant**: ☐ Implanon ☐ Other Date_____ **Other**: _____

Allergy Sticker: The Allergy Sticker should be affixed to the problem list and the outside of any chart of a patient with a declared allergy. At every healthcare visit, patients should be queried regarding allergies and any new allergy should be recorded on the problem list. Print the stickers on a sheet of labels (Avery Yellow Fluorescent Labels 5972, 1" x 2 5/8").

Allergy Alert

_____

Urine Dip Results Sticker: This sticker can be affixed to the progress notes to document the in clinic lab result of the urine dip analysis. Here is an example of the sticker:

BLOOD	BILIRUBIN	UROBILINOGEN	KETONES	GLUCOSE	PROTEIN	NITRITE	LEUKOCYTES	pH	SPEC. GRAVITY
Neg Tr -50	Neg +	Normal 1	Neg Sml Mod	Normal 50 100	Neg Tr 30	Neg Pos	Neg Tr	5 6 7	1.000 1.005 1.010 1.015

Print the stickers on a sheet of labels (Avery Shipping Label 5163, 2" x 4") which should be white.

Telephone Triage Documentation

Registered Nurses do the *assessment and planning* for triage calls, using the nursing process.

The triage nurse is identified at each site, including when regular staff is gone. Triage decisions are based on assessment, pertinent medical history, patient response to symptoms and generally result in following disposition:

- Emergency.....911 or send to ER
- Urgent-see ASAP/same day .....Call back <1 hour
- Non-urgent-see within 1-3 days .....Call back <4 hours
- Safe to treat at home-give home care info. .....Call back <4 hours

All calls where health care advice is given are documented on the appropriate form Triage Form. The original copy is placed chronologically in the medical record in the program notes with tape on the top and bottom of form so cannot be lost. The NCR copy is retained chronologically in a confidential file for 3 months and then shredded. This NCR copy may be used for several activities: follow-up log, to demonstrate legal compliance, QA activities, and Utilization Review.

Whenever possible, the Medical Record is consulted before assessment and planning of chief complaint is completed (with the caller) and documented on Telephone Triage form or directly into medical record.

Documentation for telephone triage is complete, concise, signed and dated (including time call came in and time call is returned) and follows documentation guidelines for essential elements.

RN's assess Triage slips at minimum 1X/hour. Acute symptoms/illness calls are returned when noted ASAP. Non-urgent calls for health care information are returned within four hours. Examples: general home-care questions, calls for pharmacy refills, lab tests, routine follow-up calls.

Situations which require follow-up by nurse or provider are documented as such and calls are returned within time frame stated.

Triage calls will be monitored by PHSS regularly for skill, customer service, and timeliness.

Average talk time of a telephone call to assess and make recommendation (triage) is six minutes. (Benchmark)

Examination of Family Planning Clients

Physical Exam

A physical exam involves a systematic evaluation of the body incorporating the techniques of inspection, palpation, percussion, and auscultation. Several excellent books have been published which describe examination assessment techniques and screening procedures in depth. Clinicians conducting health exams should rely on such texts as reference guides if needed.

The physical exam should be brief, yet complete, with an emphasis on those areas suggested by history. Professional judgement should be used in determining if part of the exam should be omitted or postponed if situations necessitate (i.e. lack of privacy, client refuses). For a visit for a specific problem, the exam should be directed at the systems related to that problem.

The following is a general outline for the physical exam. This outline lists the specific systems or areas which should be examined and the types of observations which are important to each area. It is not intended to be all-inclusive.

General Physical: Provide on initial and Family Planning annual exams.

- Height - provided on initial visit, repeat at age 18 and 24.
- Weight
- Blood pressure, (Pulse for IUD insertion and temperature if infection check)
- Inspect oropharynx and tongue (only if oral symptoms or tobacco user)
- Visualize and palpate thyroid
- Lung auscultation (Only if pulmonary symptoms present or age<21)
- Heart auscultation (Only on initial exam or if cardiac symptoms or age<21)
- Palpation of abdomen to feel for masses and enlarged or tender liver
- Breast examination and palpation for nipple discharge, masses or abnormality and assess axillary and supraclavicular lymph nodes.
- Entire body skin inspection for suspicious nevi, skin lesions, or rashes.

Genital Exam: Provide on initial, annual, and infection check exams. If STD evaluation, refer also to PHSKC STD Clinical Guidelines.

Female:
Use Female Medical Exam Form.

- External genital skin, labial structures, urethra, glands, inspect and palpate
- Speculum exam of vaginal mucosa and ectocervix
- Consult STD guidelines (http://www.metrokc.gov/health/apu/std/std-clinicalguidelines.doc). for specimen collection instructions. The order for specimen collection should be as follows:
  1. Vaginal secretions: pH, saline wet mount, KOH sniff test, and microscopic evaluation for fungal elements (KOH or Gram stain).

2. Endocervical secretions for culture or other approved test for N. gonorrhoeae (or urethra if cervix is absent) and test for C. trachomatis (or urethra if cervix is absent).
3. Cervical cytology (consult Cervical Cancer Screening section of the Guidelines). Always use both the spatula and cytobrush. If mucopurulent endocervical discharge is present, it is preferable to defer cytology test until cervicitis has resolved.

- Bimanual exam to palpate vaginal walls, cervix, uterus, and adnexa
- Rectovaginal exam after age 50 for stool giauac or if adnexal mass or pain concerns
- If a virgin, not sexually active, with no STD or menstrual complaints or symptoms, then the pelvic exam may be delayed until the age of 21 using the Delayed Pelvic Guidelines. After the age of 21, for hormonal prescriptions, patient is strongly advised to have a pelvic exam. However, the client may choose to sign a Birth Control Specific Informed Consent Form to refuse.
- For the chart carefully document counseling regarding the benefits of an exam and the reasons for exam refusal. Cervical cancer screening should be initiated by 3 years after sexual coitarche or by age 21.
- Adolescents still benefit from breast exam to detect masses, anomalies, and development.
- The Feminine Hygiene Menstrual Product **or** Female Anatomy handouts can be offered to patients, and if appropriate, the Bacterial Vaginosis**,** Trichomonas**, or** Yeast Patient Handouts.

Male
Refer to PHSKC STD clinical practice guidelines (http://www.metrokc.gov/health/apu/std/std-clinicalguidelines.doc). Use Male Medical Exam Form. Use the Male Anatomy and Testicular Exam handouts as needed.

Specimens
All specimens sent should be logged on the Lab Test Tracking Log so that tracking can be done to ensure timely results and follow-up

Reportable Diseases: If a reportable disease is discovered during a Family Planning patient visit, the health care provider must report the case to the appropriate Public Health Department within the allotted time. Please refer to the Reportable Disease List for more information or view the Washington State DOH website at (http://www.doh.wa.gov/notify/).

Scheduling Clients

Exam priorities are listed below. This list is only to help guide scheduling and to give examples of appropriate Program 28 visits.

1. OCP and injection refills for established patients not due for annual exam.

2. Annual exams for renewal of their birth control method.

3. New exams to begin contraception.

4. Post abortion or post partum clients with contraception needs.

5. OCP and injection refills for new patients that will need to get records but not an exam.

6. Emergency Contraception prescription and possible contraception start/exam.

7. Pregnancy detection testing, exam, and possible contraception if terminating.

8. Implant, IUD, or sterilization (male or female) consults.

9. Contraceptive method questions.

10. Women asking for pap testing alone. Ask if contraception method needed, if not, consider referral to the Breast and Cervical Health Program or other community site.

11. STD concerns, vaginal discharge, recent exposure to partner with an STD.

12. HIV testing.

13. Abdominal, pelvic, urinary, or breast complaints. If it is a new client and that is the primary reason for the visit request, then the RN should screen the call, however, it is likely the person will be referred elsewhere because we are a categorical family planning STD program. Unless these complaints relate to contraception or STD services, coming to our clinic is inappropriate and not in the patient's best interest as we do not have the resources (for example, ultrasound).

14. The encounter form cannot be coded to Program 28 unless the visit documentation has proof that contraceptive or STD management services were provided. For example, a visit that was only for a urinary tract infection in a married, monogamous woman with a history of sterilization would have little reason to code under Program 28. For that matter, even her pap smear would not fit this criteria.

IMPLANT INSERTION OR REMOVAL SET-UP & PREPARATION

All removal and insertion procedures need the following supplies:
Large gauze sponges, 4x4s, 5 –10 #
2 sterile drapes
Blue pad (or some absorbent pad) for exam table
Set of sterile gloves
Betadine solution or other antiseptic, Hibiclens, if iodine allergy reported
1% lidocaine with epinephrine vial
An 18 G needle to draw up the lidocaine into the 5 to mL syringe
A 25G 1 ½ inch needle for infiltration into the dermis
Steri-strips and a pressure dressing (gauze wrap and tape) should be available if needed
Working gooseneck or standing lamp

Supplies needed for implant removals:
Implant system removal instruments, pre-packaged and sterilized to include:

- 2 curved hemostats
- 1 straight hemostat
- Norgrasper, modified vasectomy clamp
- #11 or #15 scalpel blade
- For Implanon ™removal fewer instruments may be needed but until there has been enough procedures it is prudent to be prepared.

For insertions:
Implant system package obtained from the pharmacy, patient visit sticker applied to Pharmacy Implant and Intrauterine System Log and record lot number, expiration, and insertion date on log and procedure form

When putting patient into the room, make sure:

1. Pregnancy test is performed and documented on FP Flow Chart **before** procedure if indicated.
2. Query about any UPIC in the past two weeks and document on form.
3. Weight, BP and LMP documented on procedure form and FP Flow Chart.
4. Document absence of allergy to latex, betadine, and lidocaine, or tape.
5. Lot number and expiration date of the implant kit written on the form prevents the insertion of implant kits that are expired.
6. All supplies laid out on the counter and Mayo stand covered with paper drape.
7. Implant consent form and procedure form labeled with visit stickers.
8. Verify patient has a copy of the manufacturer brochure in the appropriate language and has had the chance to review it.
9. Make sure emergency supplies and protocols are available if an allergic reaction or vaso-vagal episode occurs

Pharmacy

Pharmacy Guidelines for Program 28

1. Dispensing at the site can only be paid for by Program 28 if the medication, dose, and packaging (# of pills per bottle) is on the current approved PHSKC Family Planning Program Formulary.
2. Providers can write prescriptions for these medications instead of dispensing if compensation requires a pharmacist to dispense the medication for payment; such is the case with some insurance prescription policies.
3. A provider can always offer clients prescriptions for medications or amounts that are not on our formulary and the client can then purchase the medication at a local pharmacy.
4. Sites will maintain their family planning program pharmaceutical supplies using the family planning program order forms once a month and stocking the amounts determined as reasonable for the specific site for a one month supply of each medication. In case of a drug recall consult the Pharmaceutical Recall Policy.

Maintenance of the Dispensary at Non-Pharmacy Sites

1. Stocking:
   Only items on the approved Family Planning Program Formulary List are to be stocked at non-pharmacy/dispensary sites. No other items will be included without approval from the Family Planning Medical Director or the Chief of Pharmacy**.** Pharmacy Medication Stickers for the approved medications are supplied by the pharmacy as needed and when updates occur. Family Planning staff should determine the amount to stock at each site. We recommend that you review your stock on a weekly basis and compare it with the amount needed for a one-month supply. Pharmacy staff will work with you to determine the schedule for ordering at your site. It is important to be aware of medication expiration dates and to return any stock to the pharmacy expiring soon. Be careful to keep the stock with the designated stickers to avoid dispensing a product with a sticker that does not have the corresponding Lot # or Expiration Date. Each dispensary site should have a designated clinic staff person (can be MA or RN usually) as a pharmacy contact person to work with the pharmacy on stocking, ordering, and supplies.

2. Ordering:
   Submit all orders for Family Planning pharmaceuticals for the non-pharmacy/dispensary sites on the Clinic Stock Order Form, which are kept on the PHSKC intranet site.

3. Dispensing:
   The medication labels have 4 stickers to facilitate dispensing. Please adhere the large patient prescription sticker with the patient's name and provider name to the medication, the next sticker should go at the bottom of the encounter form as it has the encounter number and NDC number (and fits at the bottom of the page), the next and the thinnest sticker is for the medication sheet in the patient chart, and finally the last sticker on is fixed on the medication dispensing log in the pharmacy (even though it may overlap slightly on the prior sticker) as this sticker has the expiration date, Lot #, and all other important information

needed to record for in the event of a product recall. If you have a Spanish speaking client, an additional Spanish label for medication instructions, in Spanish is available, if this label covers the English label completely then it is very important to write the lot # on the Spanish label. It may be easier to place the Spanish instructions on a separate sheet of paper and give that to the client. Log all medication dispensed for Family Planning clients at non-pharmacy/dispensary sites on the Family Planning Medication Dispensing Log. The log sheets can be shredded after 24 months. The medication and prescription information should then be recorded on the Medication List in the chart with allergies clearly flagged using the Allergy Sticker.

4. We can only dispense and administer medications obtained and stored by our system. If a client presents with a medication such as a contraceptive injection we cannot administer this medication as we do not know how it was stored or in some cases it is not even a FDA approved drug.

Dispensing Documentation

The state board of pharmacy requires pharmacy records to be kept for 2 years. It is important to track medications dispensed and the manufacturer in case of a Class I drug recall where patients need to be notified. For all medications even if only a sample, it is necessary to know which manufacturer and lot number was dispensed to which patient. The logbook allows for that check without having to pull all the charts. Alternately, an electronic report can be run on a specific pre-pack dispensed to each patient at a pharmacy site and the charts can be pulled to check that the sticker with the identifying information was noted.

Prescription Laws

1. Verbal prescriptions to the pharmacy – It is legal for a practitioner with prescriptive authority to verbally give a prescription order to a pharmacist, with the exception of Schedule II narcotics. Designated agents of a prescribing practitioner may also give verbal prescription orders to a pharmacist after having received the order, either written or orally (see prescribing through a third party).

2. Prescribing through a third party – A practitioner with prescriptive authority can designate a person who may phone in prescriptions to a pharmacy. This person can be a nurse or even a receptionist in the clinic. This person cannot, however, authorize medication refills or medications without express permission, either written or oral, of the prescribing practitioner. If a verbal order is taken, written documentation in the patient's chart needs to reflect the full name of the prescribing practitioner and the exact prescription as dictated. The chart entry should be co-signed by the practitioner within 30 days with a separate entry on the day of the co-signing stating the verbal order, for example "Consulted on June 13, 2001 regarding need for refill of oral contraceptive pills. Gave prescription for Orthocyclen 3 packages as documented in the June 13, 2001 note." Written prescriptions may be completed by a third party but must be signed by a practitioner with prescribing authority.

Prescription and Dispensing Chart Documentation

The prescription can be documented on a prescription pad and given to the client for an outside pharmacy. Alternately, the prescription can be documented by adhering the medication sticker (includes medication name, dose, lot number, and expiration date) to the Medication List in the chart. If a free sample is dispensed the same documentation must be done in the dispensing

log and patient chart. The provider must sign with a legal signature (initial of first name, last name, and title), date, and supply the dosing schedule. Most of our medications come with a sticker, which supplies most of this information, and the sticker should be placed on the medication sheet. In the progress notes or on the visit form, a statement can be made, "see med sheet," for the prescriptions prescribed and dispensed for that visit. If prescribing a year of injections or OCPs, the medication sheet or the Female Family Planning / STD visit form can reflect the 13 pill packages or every 12-week dosing for 1 year. Alternately, the entire prescription can be written into the progress note. The Drug Reactions Handout is available for patients to help warn of side effects or problems when prescribing multiple medications. To prescribe more than a 28 day supply for outside pharmacies or DSHS of OCP, write the prescription for #84 pills with 3 refills.

Reporting Problems to the FDA

Any problems like allergic responses, site or product problems, or unusual reactions or problems detected while using the medications used by Family Planning patients should be reported to the Family Planning Medical Director and to the FDA. You may call the FDA at 1-800-FDA-1088 or fill out the form online at http://www.fda.gov/medwatch/report/hcp.htm. A copy of this form is to be given to the Site Supervisor to forward to the Downtown Pharmacy and Chief of Pharmacy.

Sexual Assault and Domestic Violence

39% of American women have experienced domestic violence or sexual assault at some point in their lifetimes (Collins, et al., 1999). Survivors of abuse have more chronic physical and mental health problems and suffer from more injuries than women who have never experienced abuse (Hendricks-Matthews, 1993). From the immediate threat to physical safety posed by domestic violence, to the long-term health consequences caused by sexual assault, violence against women represents a major public health concern. Providers may not know that their patients have experienced abuse because they do not routinely ask about current or past abuse. Research shows that patients want their providers to ask these questions, and that they believe their providers can help with these problems. Fortunately, Title X-supported clinics inquire about domestic violence at a much higher rate than do other clinics. More than 80% of clinicians at Title X clinics report that either verbal or written screening occurs routinely at their clinics, as opposed to less than 40% of a general sample of clinicians (Friedman, 1992; CDC, 2004) Provider knowledge of current or past sexual assault and domestic violence are imperative to the proper diagnosis, treatment and clinical management of patients.

Health Consequences of Sexual Assault and Domestic Violence

It is important to remember that individual responses to domestic violence and sexual assault will vary. More severe symptoms for childhood sexual assault survivors are associated with abuse onset at an early age, abuse by a parent, extended or frequent abuse, or use of force. Symptoms may be less severe or persistent if victims felt support from important persons in their life or if they posses certain inherent resiliency factors. General sequelae associated with sexual assault and domestic violence are listed below (Hendricks-Matthews, 1993).

Emotional
- Anxiety and panic attacks
- Lowered self-esteem
- Fear and phobias
- Anger

Cognitive
- Hallucinations
- Flashbacks and intrusive memories
- Dissociation

Interpersonal
- Sexual dysfunction
- Revictimization proneness

Somatic
- Insomnia
- Nightmares
- Nausea, gagging or vomiting
- Chronic pelvic pain
- Stomach pain
- Eating disorders
- Chronic illnesses that defy medical diagnosis

Behavioral
- Substance abuse
- Impaired social function
- Personality disorders
- Aggressive and antisocial behaviors
- Suicidal tendencies

Effects of Sexual Assault and Domestic Violence on Reproductive Health and Pregnancy

Childhood sexual assault can have long-term consequences for women's reproductive health. Gynecological problems such as chronic pelvic pain, dyspareunia, vaginismus and non-specific vaginitis are commonly reported. Sexual interest and sexual functioning may also be impacted, ranging from a lack of interest in sex or an inability to achieve orgasm, to sexual activity with multiple partners and involvement in prostitution. Childhood sexual assault is also significantly associated with adolescent pregnancy and increased STD rates, including HIV (ACOG, 2000). Domestic violence places women at risk of unintended pregnancy and STD exposure, as their partners may control their access to birth control and reproductive health information. Furthermore pregnant women are at a higher risk of domestic violence than women who are not pregnant (Straus and Gelles, 1990). Young pregnant women are at an even higher risk (Hedin and Janson, 2000; Parker et al, 1994)

How to Ask About Sexual Assault and Domestic Violence

- Never ask about DV or SA in front of others **-** If you can't ask her alone, don't ask
- Ask *all* women
- Normalize questions; find a way to ask that feels comfortable for you

- Begin with a **framing statement** explaining that you ask everyone. Many women who have experienced abuse may believe that you can "see it on them." The framing statement reassures them that this is not true. One example might be:

  "Domestic violence and sexual assault are major health issues for women. Because so many women have experienced abuse, I ask all my patients these questions."

- Ask questions that are **behavior-specific**. For instance:

  "Have you ever been forced into sexual acts as an adult or a child?"

  "Has your partner ever pushed, hit, kicked, or physically hurt you? Has he/she ever forced you to engage in sexual activities?"

  "Has your partner ever put you down, said hurtful things, or threatened you?"

Instead of:

"Have you ever been sexually assaulted or raped?"

"Has your partner ever abused you?"

If a client discloses abuse to you, document it in the chart and offer referrals. Offer all clients the option to call the Domestic Violence Hotline, at 1(800) 562-6025, or the Sexual Assault Resource Line, at 1(888) 99VOICE (1-888-998-6423). An advocate from these agencies can offer counseling, safety planning, and resources. The hotlines are also available for professional consultation. Further information is listed below about documenting, making a CPS call, and working with clients in currently abusive relationships.

Documenting Sexual Assault, Domestic Violence and Child Abuse

- Document any domestic violence, sexual assault or child abuse in the progress notes of the chart.
- Document information of general clinical importance in the general progress notes for the visit, such as recent sexual assault, or history of sexual assault which is affecting current health.
- If extensive notes are needed, such as CPS calls, or documentation of an incident, document this on a separate sheet from any other notes, with a reference to the note containing the abuse information in the general progress note. As with other sensitive information, this allows confidentiality to be maintained. When medical history is requested from another clinic, these more extensive notes should be excluded. Similarly, if abuse information must be shared with another agency, medical history should be excluded. Providers' best judgment must be used in weighing clinical importance against confidentiality of the client when sharing chart information.
- When documenting calls made to CPS or law enforcement, including the name of the intake worker, what was reported, and any follow-up calls made.

Providing Clinical Services to Sexual Assault Survivors

Gynecological and obstetric procedures may be traumatic, triggering memories of past abuse. These include procedures such as vaginal, rectal and breast examinations, being connected to intravenous lines and lab monitors, and the experience of giving birth. Survivors may react to these events with anxiety or panic attacks or may dissociate completely. When working with a survivor of sexual assault, it is important to thoroughly explain procedures in advance, ask permission to touch her, and affirm her ability to stop the exam at any time. Other techniques to help ease her fear and prevent dissociation include: maintaining eye contact, allowing her to control the pace of the examination, talking her through the examination, and allowing her to have support people present.

Working with Clients in Currently Abusive Relationships

When working with clients who are currently in abusive relationships, it is important to discuss strategies to increase their safety and the safety of their children. Although it is tempting to advise the client to leave the relationship, this may not be the safest option at the moment. She will leave when she is ready and able to do so. However, we can help develop strategies to minimize harm to the client and the client's children. Ask the client:

- Where is her partner now? Returning when?
- Does she feel safe to go home today?
- Does she feel comfortable calling 911 in an emergency?
- What concerns does she have for her children's safety?
- What is the plan if future violence occurs?
- If one thing could be done to support you, what would it be?

If she does not feel safe to go home today, discuss her options. If her partner is in the lobby, she may want to call 911 from the clinic. Help her facilitate this process. If she is at the clinic alone, she may have someone she can stay with, or may be able to go to a shelter. Offer to let her call the Domestic Violence or the Sexual Assault Resource Line from the clinic phone. An advocate may be able to provider her with more thorough safety planning and discuss her options with her.

If it is safe for her to take written materials with her, offer the Domestic Violence Safety Plan Pocket Guide. These cards can be ordered from DSHS (publication # 22-276X) online at: https://fortress.wa.gov/prt/printwa/wsprt/default.asp

Making a CPS Report

Public Health employees are mandated to report suspected abuse or neglect of children under the age of 18 to Children's Protective Services, at 1(800) 562-5624. This includes, but is not limited to:

- Disclosure from a child or parent that a child is being abused or neglected by an adult
- Suspicious or unexplained injuries
- Disclosure of domestic violence that lead you to suspect that children in the house may be being abused (note: domestic violence does NOT always indicate child abuse)
- Disclosure of a significant age difference between an adolescent client and her/his partner (click here for guidelines – links to "reporting guidelines" section within this document)

It is important to let your client make the CPS call herself if she is willing and able (adults AND adolescents). For more information on crimes that require a CPS report, see "Abuse and Neglect Reporting for Children and Vulnerable Adults" (http://publichealth/policy/famplan/mandated-reporting.ppt)

Information that will need to be included in a CPS report, if possible, includes:

- Name, address, and date of birth of the child
- Name and address of the child's parents, stepparents, guardians, or other persons having custody of the child
- Any injuries or description of neglect or sexual abuse
- Any evidence of previous injuries, including their nature and extent

Emergent Rape

If a client presents with a rape that has occurred within the last 96 hours, and would like a rape exam, refer to Harborview at (206) 521-1800, or other local hospital. Not all clients will be interested in receiving a rape exam – it is important that the client make this decision totally on her own. The purpose of a rape exam is to gather forensic evidence for prosecution of a criminal case.

If the client would like to speak with someone immediately about her assault, allow her to use a phone to call the Sexual Assault Resource Line, at 1 (888) 998-6423. A trained counselor can help her discuss her options and can address her immediate trauma. Be helpful and supportive with the client, and make sure to maintain her confidentiality. Your help and support at this time will contribute to her healing from this trauma.

If the client is not interested in receiving a rape exam at a facility where forensic evidence can be collected, she should be offered emergency contraception and STD testing and treatment. She should be spared from an appreciable wait in the waiting area. Consideration might be given to completing registration data in the examination room. Maximum emotional support should be provided and all efforts should be made to minimize additional emotional trauma. It is our function to be non-judgmental and to provide care that is emotionally and medically appropriate.

Offer emergency contraception if it has been less than or 120 hours from assault. Also offer STD prophylaxis and treat as for positive GC and CT. Consider hepatitis B immunization, referral for HBIG, and possible HIV prophylaxis medication if high risk assault (anal, multiple assailants, or assailants known to use IV drugs or from endemic areas).

Adolescents

Adolescents may present with recent rape, current or past childhood sexual assault, or sexual exploitation or coercion. It can be confusing to know how to best help an adolescent, and what information must be reported to CPS. Adolescents may react to sexual assault in a number of ways. They may be very distraught, or may seem completely unfazed. They may withdraw from all sexual activity, or may engage in sexual activity with multiple partners. It is important to remember that all of these reactions are normal, and all clients who have experienced sexual assault should be offered resources to help in their healing process.

Some adolescent clients seeking reproductive health care may be have partners who are significantly older. They may be uncomfortable and feel pressured in these relationships, or may be very happy. Regardless of their feelings for their partner, in Washington State it is illegal for adolescents under the age of 16 to be involved with partners who are significantly older. Specific age differences are listed on the following page under "Reporting Guidelines."

Providers must notify CPS if clients are victims of child abuse or neglect, including the sexual crimes detailed in the "Reporting Guidelines" section of this document. Again, it is important to let adolescent clients know that a CPS call will be made, and to allow them to make the call if they are willing. These crimes must be reported to CPS even if the adolescent states that the sexual contact was consensual. Washington State does not recognize the ability of a minor to consent under these circumstances.

If an adolescent has been abused or assaulted by a peer of the same age, you are also mandated to report this to CPS. Let the adolescent know that what has happened to her is not acceptable, and that she has every right to call the police on her own behalf if she chooses. Of course, she should also be referred to appropriate services, and should be allowed to call the domestic violence or sexual assault resource lines.

Reporting Guidelines

In addition to reporting any suspected child abuse or neglect, there are several laws outlining specific age differences which constitute criminal sexual abuse.

Child Molestation is sexual contact with a person who is much younger than the offender; Rape of a Child is intercourse with a person who is much younger than the offender. There are three degrees, depending on the ages of the victim and the offender. Child Molestation and Rape of a Child are both felony crimes. *RCW 9A.44.073; RCW 9A.44.076; RCW 9A.44.079; RCW 9A.44.083; RCW 9A.44.086; RCW 9A.44.089*

- First Degree – victim is less than 12; offender is at least 24 months older than the victim for rape, or 36 months older for child molestation
- Second Degree – victim is 12 or 13; offender is at least 36 months older than the victim
- Third Degree – victim is 14 or 15; offender is at least 48 months older than the victim

Furthermore, Sexual Misconduct with a Minor is intercourse or sexual contact with a person who is 16 or 17 by a perpetrator *who is in a significant relationship* to the minor (for example, a coach, teacher, nurse, boss, counselor), and *who abuses a supervisory position* within that relationship in order to engage in such behavior. Sexual Misconduct with a Minor in the first degree is a felony; second degree is a gross misdemeanor.

- First Degree – intercourse; offender is at least 60 months older than the victim
- Second Degree – sexual contact; offender is at least 60 months older than the victim

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Transfer Clients

Between Health Department Clinics

Ideally when a client transfers to a different clinic within the health department there will be time to obtain the medical records before the visit. In this case, care is continued at the new site as appropriate. Ascertain if the client plans to return to the former site, in which case the records should be returned to that site.

Clients who appear at a site different from their usual site within the health department can usually be managed by contacting the other site within the health department. When that site is closed so records can not be obtained, the client should be handled as appropriate for the current medical problem. If the client needs a refill of contraceptives, usually only three cycles can be given until the clinician can assure that the client does not have an outstanding medical problem, such as an abnormal pap test or an untreated infection.

Satellite sites which have staff only part-time may make a list of clients needing medical follow-up and send a copy to the primary clinic in that district, in case the client contacts the primary clinic when the satellite clinic is closed. Include client number and nature of the outstanding problem. If records indicate the annual has been done and the client has no problems, then contraceptives to complete the year can be provided at the primary clinic.

Transfer Clients from HMC-STD Clinics for Ongoing Contraception

Clients seen in the STD program may be started on oral contraceptives and are ordinarily given 3 cycles of pills with a referral to one of the Family Planning/STD Clinics. They will have had only a brief history and exam taken. The Pap test may not have been done if she had an infection. To get ongoing contraceptive care they need to:

1. Complete paper work including the medical history forms, consents, and all required registration materials.
2. Perform the remaining parts of the physical examination including weight, height, blood pressure, hematocrit, thyroid, and breast examination.
3. Can call the cytology lab for a verbal report. If the pap results were abnormal, contact the HMC/STD program and obtain a copy of the report.
4. Arrange for any other follow-up that may be indicated. Review use of the contraceptive method and any problems. If appropriate, prescribe sufficient medication if needed to complete one year.

Transfer Clients (Outside Health Department for Contraception)
Ordinarily transfer clients are considered new clients and need a complete examination and history taken. Transfer clients may request waiver of the complete examination for circumstances such as having recent complete examination elsewhere, being post-partum, moving, no longer able to afford private care, unable to pay insurance co-pay, or underinsurance or non-coverage of contraception.

Transfer clients continuing oral contraceptives, who are not getting the complete exam on the first visit, may be prescribed one to three cycles of pills pending receipt of records. This is the Delayed Pelvic option which can be reviewed by consulting that section of the guidelines. Similarly, transfer clients continuing injection contraception may be given one injection pending receipt of their records. The transfer client must still register, sign any required consent and history forms. A practitioner reviews the history, and weight and blood pressure are taken. A provider evaluation and medical history review occurs with documentation. Then the prescription for pills or injection is given.

Once records are received, transfer clients requesting pill or DMPA refills must:

- Have results of their physical examination reviewed by the practitioner and any required physical completed as necessary;
- Have results of laboratory tests reviewed by the practitioner. If the Pap test was not normal, a copy of the laboratory report should be obtained and reviewed;
- Have contraceptives ordered in the chart by the practitioner;
- A transfer client is charged for the time needed to review and document her medical history and examination, as needed, to provide contraceptive care. If a pelvic is necessary, an initial exam should be done.
- If client then refuses examination, consult the Delayed Pelvic Exam section of the guidelines.
- Clients who choose to have annual examinations outside our system, to continue obtaining pharmaceutical supplies, should be strongly counseled to consider having at least every other gynecologic annual exam with our program to enhance the provision of her contraceptive care.

Cervical Cap

Background

The cervical cap is one of the oldest forms of female controlled contraception. The original device was a half a lemon then there were metal and then latex cups that fit over the cervix. The FDA approved the latex Prentif cervical cap years ago, it must be fitted by an exam, it comes in 4 sizes, and requires a spermicide for efficacy. As of 2005 the company decided to no longer sell the Prentif cap in the United States. There is now a silicone cap, the FemCap, which comes in 3 sizes determined by reproductive history (22mm=nulligravid, 26mm=nullipara, 30mm=parous). The spermicide is placed in the cup portion of the cap facing the cervical os and in an external groove of the cap. The typical user failure rate is 20-40% in nulliparous compared to parous women in the first year of use (perfect user rates are 9-26% respectively). These rates are higher than the diaphragm rates of 6-20% for perfect-typical failure rates.

Contraindications and Precautions

- When placement is prohibited by variations of anatomy limiting fit or conditions that hamper reaching into the vagina, such as thick abdominal fat, short fingers, or a deep vagina;
- Psychological obstacles such as a client's reluctance in touching her own genitals, unless her partner wishes to insert device. The partner must come in to clinic to learn proper insertion;
- An inability to learn the proper method of insertion;
- Recurrent urinary tract infections. Advise women to drink ample fluids;
- History of toxic shock or vaginal Staphylococcus;
- Allergy to rubber (latex) for Prentif cap use;
- Allergy to spermicide. Advise women to try a change of spermicide and if problems persist, to change contraceptive method;
- Intractable yeast infections or bacterial vaginosis;
- Cervicitis or unresolved PID;
- Delivery within last six weeks;
- PAROUS WOMEN especially if vaginal delivery, have a much higher failure rate due to the change in cervical size and poor fit of the cervical cap. Nulliparous women have a first year perfect use failure rate of about 9% while parous women have a failure rate of 26%. The diaphragm failure rate is not increased with parity as long as the size of the device is fitted properly.

Benefits

- Little interference with sex;
- Better sensation than diaphragm;
- More comfortable than diaphragm;
- Some protection from STD.

Prescription of Cap
This method is not available on site. Clients requesting a cervical cap may be given appropriate education and then referred to purchase the FemCap directly from the website or the prescription can then be sent to the Downtown PHSKC Pharmacy and they will then order the cap for the client. Each cap costs approximately 60 dollars.

Initial Clinic Visit
The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The minimum required physical examination is performed and recorded, and if needed, additional examination done as indicated by the history. Minimum laboratory tests are obtained and reviewed. Where disease is diagnosed or suspected on the basis of any of the above, referral will be made either to the clinic physician or other care provider as appropriate. Inform the client about emergency contraception and for many clients it is appropriate to prescribe and dispense a package of EC for use if method failure such as non-use or slippage. It is even reasonable to consider recommending the client use a male condom with ECP in the first few months of learning how to use the cervical cap.

Subsequent Clinic Visits
The woman should return if she has problems or as needed for supplies. A cytology test and exam should be done yearly.

Possible Side Effects
- **Increased vaginal discharge complaints:** Examine for yeast, bacterial vaginosis, etc. If problems persists, the client may need to change to a non-barrier method.
- Pain or injury in either partner from contact with the FemCap device.

Patient Method Education
- Use the device prior to genital contact.
- Have annual fitting checks especially if weight changes or pregnancy.
- Replace the device if latex is brittle, cracked, or every 2 years if FemCap device.
- Place a teaspoon of spermicidal jelly in the center of cap facing the cervical os and in the external groove of the FemCap prior to use.
- May apply the device up to 6 hours or just prior to intercourse.
- Leave the device in place for a minimum of 6 hours after intercourse and a maximum of 48 hours.
- Wash the device in mild soap and water, store in a cool dry place without powders.
- Oil-based lubricants and medications will damage the latex Prentif and deteriorate the cap. The FemCap should also be replaced every two years but is not latex.

Condoms - Female

Description
The female condom, which goes by the brand name Reality, is made of a vinyl tube with 2 rings. One ring fits outside the vulva and the other ring helps to hold the vinyl tube in the vagina. The failure rate with the first year of use is 5 to 25% and although it has been shown to decrease trichomonas reinfection, it is not as effective as the male condom in preventing STDs or pregnancy. Breakage is very rare but slippage with semen exposure is more common at 7–21%.

Contraindications and Precautions
- Inability to learn correct insertion technique;
- Anatomical abnormalities that interfere with proper placement or retention such as pelvic relaxation, vaginal septum, large vagina, etc;
- Allergy to the vinyl device or the silicon lubricant;
- Is less effective than male condoms with a failure rate 5-25% during the first year.
- There was more semen exposure with the female condom with a large disparity between penis and vaginal size and with very active intercourse *(Am J Epidemiology 2003: 157: 282-302).*

Benefits
- Contraceptive protection;
- Some protection against STDs;
- Available without prescription;
- Women can initiate method.

Possible Side Effects
- **Allergy to vinyl** may occur in either partner: Allergy is uncommon. Change contraceptive method;
- **Displacement**: condom may be pushed inside the vagina or pushed aside by the penis. If this occurs client should consider emergency postcoital contraception (EC);
- **Discomfor**t due to the external ring, there is only one size so this cannot be helped;
- **Noise or discomfort**: use more lubricant.

Dispensing
This method may be available on site, but due to cost, only three should be dispensed at a time. Many women may decide not to use them or switch to the more effective male condom.
- Female condoms are available without a prescription over the counter. Medicaid will cover the cost if the client is given a prescription to fill at outside pharmacies.
- If the woman brings a condom, then clinic examination and demonstration may facilitate learning to place the condom. The woman observes her cervix with a mirror and palpates her cervix while in the clinic. Review instructions for placement and removal of the condom.
- EC should be supplied as a back-up. This is especially important given the high failure rate.

Condoms - Male

Benefits

- Good contraceptive protection if used consistently.
- Good protection against STD. Protection is best with latex or vinyl condoms as natural skin condoms have pores large enough for viral particles.
- Lower incidence of abnormal Pap smears.
- Treat premature ejaculation
- Decrease antisperm antibodies
- Available without prescription at low cost.

Contraindications and Precautions

- Inability to maintain an erection when a condom is used
- Allergy to rubber (latex). There are vinyl condoms but they can have a 10% breakage rate for some men and in a randomized trial had more failures (Obstet Gynecol 2003; 101:539-47). Therefore, these condoms should be used only with latex allergies or individuals accepting a higher failure rate.
- Oil based lubricants and medications can cause rapid deterioration of latex condoms and subsequent failure. Avoid oils, grease, ointments, hand lotion, petroleum jelly, rubbing alcohol, and medications containing these substances. Vinyl condoms like the female condom are not latex and can be used with oil-based lubricants.
- Reduced sensitivity for either partner. Use of water-soluble lubricant or spermicide inside tip of condom and in vagina may help enhance sensitivity. Vinyl condoms (Avanti) have been reported to be preferred with greater sensation, however, the breakage and slippage hence failure rates are higher.
    - Interruption of foreplay to apply. Partner may help apply the condom.
    - Can not use with female vinyl condom because this can cause the male latex condom to break. Male vinyl and skin condoms have not been studied when used with female condom.

Possible Side Effects (May occur in either partner)

- **Allergy to spermicide or lubricant:** Try condoms without spermicide or lubricant. If symptoms improve try lubricated condoms without nonoxynol-9.
- **Allergy to latex:** Allergy to latex is common. Use non-latex condoms like vinyl or natural skin condoms or change contraceptive method.
- **Breakage:** May be due to incorrect application trapping air or without a space to collect semen. Frequently occurs from improper storage or use of oil based substances which cause deterioration. Care must be taken with sharp objects or fingernails. Review proper use. Suggest a stronger condom if appropriate. Studies with vinyl condoms found that they were more likely to “pop” as they had less ability to stretch. Therefore, a larger size should be used if possible. In Europe there is a “baggy” condom with a vinyl bag and elasticized base.

Dispensing

- Offer condoms to all clients as an interim, supplemental or backup method of contraception.
- Offer condoms to **ALL** persons (male and female) for protection against STD unless they state they are in a mutually monogamous relationship.
- All clients with a STD should be given condoms both for protection during treatment and to prevent future infection.
- Provide handouts on the use and application of condoms whenever they are dispensed.
- Placing condoms in a basket on the counter or in high, but obviously visible, containers in both women's and men's rest rooms is encouraged.
- Make condoms available without necessity for examination or filling out clinic forms. However, if an encounter form is generated, list the condoms as a contraceptive method so the program can get credit for the dispensing of the condoms, but do not bill as a pharmacy item for the condoms because they were not dispensed as a pharmacy item.
- The male vinyl condom and the female condom are specific items and should be dispensed from the pharmacy, billed for separately using the encounter form, and not left in baskets as they require additional counseling and cost.
- Inform the client about emergency postcoital contraception (EC). For most clients it may be appropriate to give EC prescriptions prophylactically and this should be encouraged.
- Using a condom is much safer than unprotected sex.
- Water based lubricants used with condoms can decrease the risk of the condom breaking.

Patient Method Education

- Condoms alone are 88% effective with typical use and 98% with perfect use. Almost all condom failures are due to non-use, breakage, or slippage, therefore the use of EC in these cases could increase efficacy of the method. It is strongly recommended that women using condoms for contraception be educated about EC and be provided a prescription of EC to use in the future if needed. (see Emergency Contraception chapter in Guidelines)
- If a woman insists she wants to use spermicidal foam in addition to the condom, she should insert the contraceptive foam 15 minutes prior to intercourse to allow dispersal of the chemical. The foam is there to help kill sperm if the condom breaks or slips off.
- (See Spermicide section of the guidelines.) Spermicidal chemicals, usually nonoxynol-9, or N9, when used in repeated or high doses can cause vaginal irritation and breaks in the vaginal epithelial barrier. This has been shown to increase the risk of transmission of blood borne diseases like HIV or Hepatitis. A single low dose use of $\leq$150 mg of N9 is probably safe, but the need to use N9 foam with a condom has never been proven to be more effective than a condom alone.
- The amount of N9 in a N9 impregnated condom is tiny and it is probably not sufficient to kill all the sperm in the ejaculate. This type of condom does not have a long shelf life and it has been associated with releasing the latex proteins and therefore could increase the risk of latex allergy. Therefore, these condoms are not recommended for vaginal or rectal use. The rectal mucosa is especially vulnerable to the N9 chemical damage and N9 should never be used in the rectum.
- Apply condom prior to genital contact.
- If lubricant is used, it can be put on the glans of the penis prior to putting on the condom – it can improve penile sensation and pleasure.

- Pinch the tip of the condom so that an inch of deflated condom is at the top of the glans making room for the ejaculate.
- After ejaculation, withdraw the penis prior to becoming flaccid and hold the base of the penis to keep the condom from slipping off and leaving ejaculate near vagina or vulva.
- Dispose of the condom properly.
- Use a new condom with each act of intercourse.
- Withdrawal or coitus interruptus can also be practiced if condoms are not available. It involves male ejaculation outside the vagina. If a man has urinated prior to intercourse this can reduce the number of viable sperm in the urethra and ejaculation is external, away from the entire genital area, there can be some reduction in exposure (better than nothing). However, the pre ejaculate fluids can still contain infectious agents and this method is inferior to traditional barrier methods.

Diaphragm

History and Examination

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The minimum required physical examination is performed and recorded, and if needed, additional examination done as indicated by the history. Minimum laboratory tests are obtained and reviewed. Fit the diaphragm and have the client practice insertion with the provider rechecking placement prior to dispensing the method as there are a few clients that may not be able to place and remove the device. Inform the client about emergency postcoital contraception. For most clients it may be appropriate to give an EC prescription to take if a method failure occurs such as non-use or a hole found in the latex device.

Subsequent Clinic Visits

- Women newly fitted with a diaphragm should be scheduled for a return visit after several uses, about two to four weeks after the initial visit. Examine the client after she inserts the diaphragm to determine competency and to recheck for proper fitting. Some providers may choose to have the client return wearing the diaphragm for more than 6 hours to check for slippage and comfort;
- All women should receive an annual minimum required physical examination;
- Women should be refitted after every pregnancy, pelvic surgery, or weight change of over 10 to 15 pounds.

Contraindications and Precautions

- When fitting is prohibited by variations of anatomy such as pelvic relaxation (rectocele, cystocele) which would prevent pocketing the front rim of the diaphragm beneath the symphysis pubis, an anatomically short anterior wall, vaginal septum, or conditions which hamper self-reach into the vagina, notably thick abdominal fat, short fingers, or a deep vagina;
- Gynecological obstacles such as a client's reluctance in touching her own genitals, unless the partner wishes to insert the device. The partner must come in to the clinic to learn proper insertion;
- An inability to learn the proper method of insertion;
- Recurrent urinary tract infections. Advise ample fluids and voiding before and after intercourse. Also check the diaphragm, as it may be too tight and pressing too tight behind the urethrea. Another option is to switch to a flat spring device as they are less rigid and cause less pressure, however they are more difficult to place correctly and should only be fitted in experienced diaphragm users;
- History of toxic shock or vaginal Staphylococcus;
- Allergy to rubber (latex);
- Allergy to spermicide;
- A study has shown a 22% failure if the diaphragm is used <u>without</u> spermicide and a 12% failure if spermicide is used. Therefore, efficacy depends on spermicide use;
- Intractable yeast infections or bacterial vaginosis.

Benefits

- Some protection from STD (especially bacterial);
- Holds blood during menses;
- Little interference with sex (may insert hours before);
- Some users report increased pleasure as there is more lubrication and even the diaphragm ridge may increase friction of the glans of the penis;
- Low incidence of side effects;
- Lower incidence of abnormal Pap smears.

Fitting of the Diaphragm

- The proper size is gauged from the pelvic examination and confirmed by insertion and inspection. The woman is asked to bear down (as though having a bowel movement) while the diaphragm is in place, to evaluate the fit. The largest size that fits properly should be used;
- The coil or flat spring is best for a normal vagina. The arcing spring is best for poor vaginal support, moderate prolapse, or marked anteflexion or retroversion;
- Educate the woman, by means of a chart, instruction sheet, and self-examination, to recognize her cervix and pubic symphysis by palpation, both with and without the diaphragm in place;
- Check placement after insertion of the diaphragm. Have client remove the diaphragm. Review and educate until the clinician feels satisfied that the client has mastered the technique and is capable of determining that the cervix is covered by the diaphragm;
- The proper size diaphragm or a prescription is dispensed along with a supply of jelly or cream appropriate for the woman's sexual activity and she is told to return for more supplies as needed;
- Warn women using the diaphragm that oil-based lubricants and medications will damage the rubber and hasten deterioration of the diaphragm. Advise only contraceptive creams or gels or water-based lubricants with the diaphragm. See the condom section above for a more complete list of substances.
- Cleaning fitting rings. First, wash with mild soap and water to remove cellular debris then soak either in a 1:10 dilution of bleach for 30 minutes or 70% ethyl or isopropyl alcohol for 15 minutes. Rinse thoroughly with water and allow to air dry. Keep rings in a clean dry place between use.

Possible Side Effects

- **Allergy to latex or spermicide:** Most diaphragms are made from natural rubber latex and some individuals may have an immediate allergic reaction, including hives, swelling and even difficulty breathing. If a severe reaction then do not prescribe. It is possible to order a silicone diaphragm, in particular the Milex Wide-Seal (800-621-1278 or 773-736-5500; http://www.milexproducts.com/products/other/diaphrams.htm). Advise women to try a change of spermicide, use cortisone cream on vulva for a few days, and if the problems persist, change spermicide or contraceptive method. The client may try to use a different type of jelly, but since they are all detergent variants and most with N9, the woman may continue to experience what is usually not a true allergy but an inflammatory reaction to the detergent. Unfortunately the failure rate is increased without spermicide use. The client can also try removing device at 6 hours, the soonest possible, and rinsing well with water.

- **Increased vaginal infections:** Both yeast and bacterial vaginosis may be increased. Diagnose and manage infections as appropriate. If problems persist or recur frequently consider changing to a non-barrier method.
- **Increased urinary tract infection:** Advise women to drink fluids, before and after coitus voiding, and toilet paper wiping from front to back of perineum. If the client experiences frequent UTIs, consider changing to a non-barrier method.

Patient Method Education

The woman should be given written materials and counseled about correct use of the method to include:

- Diaphragm size and fit check with weight change or pregnancy and preferably with each annual exam unless long term user;
- Stretching and examining the device monthly and replacing if latex is cracked or brittle;
- Place a tablespoon of spermicidal jelly, NOT FOAM, into the center of the device so the jelly contacts the cervical os;
- Insert up to 6 hours prior to intercourse;
- Leave in place a minimum of 6 hours after intercourse and no more than 24 hours;
- Apply additional spermicidal jelly into the vagina in front of the device with repeated acts of intercourse;
- Rinse the device after use and store with no powders somewhere clean and dry.

Depo Medroxyprogesterone Acetate (Depo-Provera) or DMPA

Overview

Depo provera is a microcrystalline suspension of medroxyprogesterone acetate (DMPA), a first generation progestin. It has been available around the world as a contraceptive for 30 years. It is slowly released and reaches therapeutic levels (average 3.5 ng/mL) in 3-7 days. It is very effective with a failure rate of 3 pregnancies in 1000 women using DMPA in the first year when given every 12 weeks. DMPA blocks ovulation unless the serum levels drop below 0.1 ng/ml, thickens cervical mucus, and atrophies the endometrium. Serum levels can persist up to 9 months. Because DMPA induces ovarian suppression there is often only a very low level of natural estradiol production (levels less than 30 pg/mL are common) and therefore it is similar to the levels of estrogen experienced by women during lactation and menopause.

Absolute Contraindications

For women with any of the following, DMPA ***should not*** be injected:

- **Allergy** to Lunelle or Depo provera in the past. There are chemicals in the injection preparation (preservatives/vehicle) which can trigger allergic reactions including anaphlaxis (very rare) and dermatologic (rash, itch).
- **Known pregnancy**, although there is no evidence of teratogenesis in women who inadvertently receive DMPA early in pregnancy they may delay entry into prenatal care because they do not recognize the pregnancy.
- Known or suspected **breast or uterine cancer**.
- **Use of aminoglutethimide (Cytadren):** This drug used rarely to treat adrenal tumors or Cushing's disease interrupts the synthesis of cortisol, aldosterone, and estrogen by inhibiting cholesterol conversion. The drug induces metabolism of the DMPA, which may reduce the bioavailability of the DMPA, hence decrease effectiveness.
- Any condition that could worsen with **increased cerebral fluid** in the **brain** like a meningioma, brain tumor, or pseudotumor cerebri.
- **Osteoporosis**, **osteopenia, or condition known to induce bone loss** such as chronic oral steroid use, prior stress fracture, hereditary bone or collagen or malabsorption disorders. These women should not get long-term DMPA without consultation and management with primary care including imaging to assess bone density.

Relative Contraindications

Women with the following ***may be given*** DMPA if an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Plans for pregnancy within one year:** Client must understand that they may have amenorrhea, irregular menses, and may be unable to get pregnant for 12-18 months after the last shot was given. No infertility workup is indicated until 18 months from the last DMPA injection. If the woman is age 33 or older and plans a pregnancy soon, she needs to sign the Birth Control Method Specific Informed Consent Form to document she was warned the use of DMPA may greatly decrease her fertility.
- **Inability to tolerate irregular, frequent bleeding:** Client must be aware that irregular bleeding is common and expected during the first 6 to 12 months of DMPA usage.
- **Inability to tolerate amenorrhea:** Client must be aware that amenorrhea is to be expected

after using DMPA for 12 months in 50% of women and 80% by 2 years of use.

- **Known HDL cholesterol <40 and family history of CAD** (1st degree male relative with MI or stroke before age 55 or female relative before age 65.). Obtain lipid panel prior to first or second injection, if results are normal, the clinician may continue to prescribe DMPA. Repeat the lipids in one year to make sure lipids continue to be normal. If abnormal (specifically HDL <40 or LDL >180) then advise no DMPA unless she signs the Birth Control Method Specific Informed Consent Form, as DMPA use may worsen her lipid profile and could lead to coronary artery disease.
- Women with **seeking more than 2 consecutive years of DMPA use** (see Bone Health Guidelines). We know women experience a low estrogen state with DMPA use and this can decrease their bone density. The bone loss is reversible just like during lactation and it is common for bone density to decrease by 6 to 7% similar to menopause. It is unknown if prolonged use of DMPA in the adolescent years will impact peak bone density acquisition. A small cohort study followed former DMPA users into their menopause years and found these women had already lost their estrogen sensitive bone component and they did not experience additional bone loss at menopause and these women using HRT responded with an increase in bone density (Cundy T. et al. Menopausal bone loss in long term DMPA users. Am J Obstet. Gynecology 2002; 186: 978-83). The 2001 WHO Medical Eligibility Criteria for Contraceptives recommends caution in prescribing DMPA for **women aged <18 or >45** because of these concerns. At the time of initiating use of DMPA for these clients, the Birth Control Method Specific Informed Consent Form is to be signed to document the woman is aware of the low estrogen and bone effects while using DMPA and still chooses DMPA over other methods. In addition all PHSKC clients getting their 8th or more continuous DMPA injection should also sign this informed consent form annually. The Bone Health/Calcium/ Osteoporosis Handout can also be given although it is unlikely calcium or exercise can completely reverse the effects of long-term hypo-estrogenism.
- **Undiagnosed abnormal vaginal bleeding**.
- **Severe depression** but if stable and on medication, she could try a trial of oral Provera (medroxy progesterone acetate) 30 mg (likely more than a contraceptive dose and 10 mg may be enough but unstudied, so prudent to use more than 10mg a day), every day for 30 days. If mood or depression is not worsened, the client could consider DMPA.
- **Women 50 or older** should usually not be prescribed DMPA unless bone density, lipid testing, menopause screening, and mammogram monitoring are addressed by their primary provider. These services currently are outside the scope of the family planning practice and would need to be coordinated and performed by the woman's primary provider. Because of the concerns regarding bone density it is usually not in the woman's best interest to continue DMPA after 50 although if this is the only method she can use, for example has thrombotic risk factors for the OC, then it is reasonable to provide the DMPA rather than risk a pregnancy providing documentation of the counseling and decision making is performed.

Benefits

- Highly effective
- Easy compliance
- Long-acting - only one injection every twelve weeks
- Decreased PMS, ovulatory pain, menstrual flow, cramps, and anemia
- Decreased PID due to thickened cervical mucus and atrophic endometrium
- Treats endometriosis
- Decreased endometrial and ovarian cancer
- No adverse effects on nursing and many promote breast milk production

- No interference with epilepsy medication serum levels, and because progesterone raises the seizure threshold, DMPA can actually decrease the number of seizures
- Proven to decrease painful crises in sickle-cell anemia patients

When to Administer
When beginning DMPA, it is best to administer the first dose within five days of the onset of menses or less than 7 days from abortion so the woman will be fully protected from the time of the injection. DMPA is not rapidly absorbed and will not act as an emergency contraceptive to blcok ovulation emergently.

Women not at risk for pregnancy may have an injection at any time of the month. For other women, the first injection should be during the first 5 days of the menstrual cycle and if not, the shot can be given that day only if a negative UCG test is documented and the same day start/restart protocol used which means the patient agrees to use a back-up method for 7 days, understands the possible risk of false negative HCG test if she has had unprotected sex in last 2 weeks, gets ECP if needed, and agrees to return for a four week follow-up pregnancy test or if no bleeding.

Women who have had unprotected sex, and if it has been less than 120 hours, may desire an ECP prescription. Advise additional caution if multiple acts of unprotected intercourse since her risk of an early pregnancy is increased and consider waiting till menses for DMPA administration. If the DMPA was administered and the woman is subsequently found to be pregnant and undergoes an abortion, the DMPA should be re-administered sooner (8 weeks or sooner) rather than the prescribed 12 week interval because it is not known if the pregnant metabolic state could hasten the metabolism of the DMPA.

Anyone worried about a possible pregnancy may choose to wait for menses to start their DMPA. Clients should use backup contraception for 7 days following the first injection if not given within 5 days of onset of menses, or if greater than 2 weeks from a delivery. Ovulation may have occurred and the DMPA is not an EC and it takes 7 days for the DMPA progestin effect on the cervical mucus to be established. Back-up contraception is only needed for 7 days from injection because although women can still ovulate within 3-4 days after injection, by 7 days the serum levels of DMPA will be adequate to both block ovulation and to change the cervical mucus to a barrier to sperm, *(Fertility and Sterility 1998; 70: 817-20)*.

Postpartum, DMPA can be given the day after delivery at many institutions, however irregular bleeding may be less if it is begun 4-6 weeks postpartum. There is no reason to withhold DMPA if contraception is needed since ovulation can occur by 3 weeks postpartum in non-lactating women.

History and Examination
The standard medical history should include history of depression, obesity, vaginal bleeding, or breast concerns. The physical examination is performed and recorded to include weight, blood pressure, cervical, breast, and pelvic examination. If the delayed pelvic option is used, the pelvic must be done prior to the second injection or after 6 months of use or else they must sign the Birth Control Method Specific Informed Consent Form (see Delayed Pelvic section of the guidelines). The client should be educated about the risks and benefits of DMPA and alternate contraceptive methods. Complete the Female Family Planning / STD Visit Form for each following visit until the annual examination, which can be no sooner than 10 months from

the last annual exam. Clients should be assessed for their risk for low bone density if they have decided to use DMPA beyond 2 years of use. Risk factors for low bone density are discussed in the Bone Health Guidelines.

Lab Tests
Pregnancy testing should be documented for most DMPA starts or restarts and often prior to the second injection if the first injection was a same day start/restart, and is mandated if there has been no vaginal bleeding since the initial shot. In long-term DMPA users with amenorrhea there is no need to repeatedly test for pregnancy unless there are missed shots or concerns. Remember even after years of DMPA use being more than a week late for a shot can still result in pregnancy. A hematocrit or hemoglobin may also be indicated if the client has been experiencing heavy bleeding.

Injection Technique
Give the client a copy of the patient product package insert to read BEFORE the injection and discuss the rare possibility of allergic reactions and advise her to wait in the clinic for 15-20 minutes following her injections if she chooses although this is not required by the package labeling. The risk of reaction is very small and it can happen even in prior or long-term users. In the early studies with DMPA used by 4200 women over 1 to 6 years, only 1.1% of women reported a rash, 0.4% reported allergic reactions (not otherwise specified), and 0.9% reported hives (Package insert). Providers administering DMPA need to follow the PHSKC clinic policies for allergic reaction and anaphylaxis including insuring there is epinephrine on site. It is recommended to inject the epinephrine into the DMPA injection site as well to slow the drug absorption. In cases of documented allergic reaction she should probably be sent to a hospital for additional observation in case there is a delayed reoccurrence or worsening of symptoms as she may need steroids or antihistamine treatment as well. As of 2004 a generic version of DMPA became available and it has the identical ingredients and amounts of these vehicles or preservatives (polyethylene glycol, polysorbate, sodium chloride, methylparaben, and propylparaben) as the brand product. However any manufacturing lot can vary and even the supplier can change so the potential for something that triggers an allergy is always possible with an injection.

The prescription can be indicated by DMPA checked on the chart note to read: “DMPA 150 mg IM injection every 12 weeks for one year” and this is duplicated on the medication list in the chart. The solution should be kept at room temperature and any heating of the solution is not recommended as it could change the solubility. The injection is prepared using a vial or prefilled syringe and a safety needle if possible. If the solution is drawn up from a vial then it should be injected within 5-10 minutes after filling the syringe to prevent any precipitation. **Shake the solution** well prior to drawing out of the vial and if a pre-filled syringe; shake just before injecting with a 21 to 23-gauge needle into the deltoid muscle or gluteus muscle. Both deltoid and gluteus sites are equally efficacious, but if any known failures, site or medication problems occur, please report to the FDA at 1-800-FDA-1088 or fill out the form online at http://www.fda.gov/medwatch/report/hcp.htm. For gluteal injection use a 1.5” needle. For deltoid injection use the non-dominant arm. If the client’s weight is less than 60 Kg (142#), use a 5/8” or even ½” needle to achieve muscle penetration of 5mm. If weight is between 60 and 90 Kg (142# to 198#), a 1” needle should suffice, and if greater than 90 Kg (198#), a 1.5” needle may be required to ensure intramuscular administration. If patient is obese, greater than 70 kg and not tall, then they will need deltoid injections to maximize contact with muscle tissue rather than adipose tissue. **DO NOT MASSAGE THE INJECTION SITE**. There is no need to rotate

the site, as every-three-month injections will not scar. Document the dose, date, and lot number in chart by placing the medication sticker on the medication log sheet and document the site of injection on the exam form. Record the date of the next planned injection using the DMPA Perpetual Calendar and if possible, the whole year or four planned shots, on the reverse side of the Menstrual Diary Card for the client's use.

Follow-up Visits

Twelve weeks after the first injection (can be 2 weeks early or 1 week late), no sooner that 65 days for Medicaid payment, and no more than 91 days between injections, the client should return for another injection. A DMPA Reminder Postcard can be mailed or the Menstrual Diary Card used. Document and evaluate any side effects at revisits. Weight and BP should be done at the time of the second injection and yearly thereafter. Check the weight at subsequent visits on all women who complain of weight change or who had significant change at the prior visit. Do a pregnancy test before the second injection, if she was a same day start/restart or if she has not had any bleeding since the first injection. The client can use the Menstrual Diary Card to document abnormal bleeding pattern.

If a woman is over one week late, making it more than a 13 week interval, she may receive an injection that day only if the sensitive pregnancy test (25 mIU) is negative, and the same day start/restart guidelines are used meaning she agrees to back-up contraception for 7 days gets ECP if indicated, understands the small possibility of a false negative pregnancy test if unprotected intercourse in prior 2 weeks, and agrees to return in four weeks for a pregnancy test especially if no bleeding.

At the 8th consecutive injection, the client is to sign the Birth Control Method Specific Informed Consent Form documenting the counseling regarding prolonged DMPA use and hypoestrogenic effects and possible risks. The Bone Health/Calcium/Osteoporosis Handout could be given to the client as well. At annual revisits this consent form is to be resigned to document ongoing counseling was done regarding the hypoestrogenic effects of the method and she continues to choose DMPA over other contraceptive methods. The company making DMPA November 2004 added a black box labeling warning to the DMPA package insert instructing providers to not prescribe DMPA after 2 years unless no other contraceptive method is acceptable. While it is very unlikely that a woman in her mid-20's to her late 30's is at any more risk with DMPA use than from lactation (which is not a risk factor for later hip fracture). In women under age 18 or older than 45 who have been using DMPA without interruption over 2 years with risk factors for low bone density (see Bone Health Guidelines) encouragement to switch her method to one with estrogen should be done and if she does not, then advising her about the availability of bone density measurement may be appropriate to assist in the counseling and risk assessment for continuation of the method.

It is prudent to recommend smoking cessation, minimize alcohol, caffeine, and carbonated beverage intake, adequate calcium intake of 1000 to 1500 mg of elemental calcium (see Bone Health/Calcium/Osteoporosis Handout), and weight bearing exercise for all women, especially teens, including those using DMPA. Studies show that women with long term DMPA use have 6% less bone density than other women. After stopping DMPA, the bone density increases. DMPA produces a relative hypo-estrogen state and thin Caucasian smokers who are already at risk for osteoporosis may be counseled that DMPA may not the best choice for them. However, in some populations, like New Zealand, some women have used DMPA for as long as 20 years and there is not an epidemic of bone fractures. Lactation is a hypo-estrogen state and

pregnancy is also a time of bone loss, yet women do not get irreversible osteoporosis from these events. Extended use, especially in adolescence, of DMPA may be different however and if peak bone density is not attained this could have serious consequences later in life. It is known that if a woman enters the menopausal years with osteopenia or low bone density then her risk later in life can be double that of a woman with normal bone density for hip fracture and hip fracture can be a major cause of death (see Bone Health Guidelines).

Possible Side-Effects

Heavy or Prolonged Bleeding: About 30% of women will have prolonged (more than 7 days/month) bleeding and 10% of women will have very prolonged (more than 15 days/month) bleeding after the first injection.

- Obtain a history of the amount (pads/day) and duration of bleeding.
- Encourage use of Menstrual Calendar Reminder Card to document bleeding pattern.
- Reassure client that irregular bleeding is expected with DMPA and only 50% of women have amenorrhea after 1 year (4 shots) and 80% by 2 years (8 shots).
- Measure hemoglobin and give iron as indicated.
- Do a pelvic examination and make sure normal cytology and no evidence of infection.
- Test for pregnancy as appropriate. Remember the method does fail sometimes.
- Assure women that bleeding decreases after repeated injections of DMPA and most women have amenorrhea with time.
- Verify the woman has no chlamydial or other genital infection because without treatment her bleeding will not stop.

Early Excessive Bleeding in first 6 months of use can be managed with**:**

- Consider giving the second DMPA injection early (no sooner than 65 days) to accelerate uterine endometrial lining atrophy. Although, this is unlikely to work if the woman has been using contraceptive hormones (progestin) for greater than 3 months prior to DMPA use because the endometrium is probably already atrophied from progestin use.
- Ibuprofen 400 to 800 mg three times daily or Naprosyn 500mg twice a day for 5 days can also decrease bleeding volume and recurrence.
- One or two cycles of oral contraceptive pills with more estrogen and a low dose of a weak progestin like norethindrone (a pill like modicon) may be prescribed to try to regulate bleeding. Although there can be spotting due to uterine lining atrophy, estrogen use in randomized trials did not decrease the bleeding more than placebo. NSAIDs did help the bleeding.
- If bleeding continues then refer for possible pelvic ultrasound and endometrial biopsy as fibroids, tumor, or endometritis are possible.

Amenorrhea: Amenorrhea is expected on DMPA. After twelve months 50% of women have amenorrhea and 80% by two years of use. Test for pregnancy if there is a question of pregnancy.

Inflammation of Injection Site: Examine the site for swelling, redness or infection. Advise warm compresses, elevation, and rest the area as appropriate. For significant cellulitis, antibiotics targeting strep or staph skin flora pathogens may be prescribed for 3 to 5 days but if no improvement in 48 hours she should be referred (consult the Family Planning Medical Director) as she may need additional antibiotics and/or surgical treatment.

Weight Gain: A small but steady weight gain of about 2 to 4 pounds a year is common on DMPA but not inevitable. The cause may be from an increased appetite and sedation from the use of this 21 carbon progestin, which is very similar to natural progesterone. Another progestin, megace, similar to provera is actually used to induce weight gain in AIDS and cancer patients. Many women can use DMPA without weight gain and in a trial comparing the IUD to DMPA in Thailand there was not difference. Share the Getting Fit handout with the client.

Headache: Evaluate stress and other factors, which may cause headaches. Advise ibuprofen, aspirin or acetaminophen, relaxation techniques, or other measures to control headaches. If headaches are severe or persistent, referral to primary care or to a neurologist is appropriate and consider discontinuation of DMPA.

Vaginal dryness or vulvar atrophy complaints: Topical estrogen cream can be used daily for 4 to 6 weeks (0.625mg conjugated estrogens/dose). If the client needs estrogen replacement for symptoms for more than six weeks, then it is too expensive to do both injections and daily estrogen and she should change to COC pills or Lunelle. Interestingly, one study has actually found a decrease in yeast infections in long time DMPA users due to loss of estrogen and glycogen.

Discontinuation of DMPA Injections

Fertility can resume promptly in some women 13 weeks from the last injection and if pregnancy prevention is desired clients should be advised they will need contraception immediately and if starting a different hormonal method at more than 12 weeks from the last injection then 7 days of backup is prudent since changing dose and formulation. Clients should understand that menses might be absent or irregular for over 9 to 18 months after the last injection but that ovulation could happen prior to menses. If pregnancy is not desired, alternate contraception should be started within 12 weeks of the last injection. Infertility evaluations are not usually indicated until 18 months from last DMPA injection. Amenorrhea evaluation should be begun if still no menses 12 months from last injection. At age 50 most women will not be using DMPA for contraceptive purposes and DMPA should be discontinued since the effect of DMPA on breast cancer in older women is unknown and bone density is a known concern.

Pregnancy with DMPA Injection

DMPA has never been shown to cause birth defects but the original androgenic, high dose OCPs did cause some genito-urinary anomalies hence the DMPA labeling. Many women have been pregnant at the time of injection or had the method fail and become pregnant while using DMPA and there have been no long term effects identified in these children, except one study where women using DMPA during the pregnancy had smaller infants, but this could be due to late diagnosis of pregnancy, unwanted pregnancy, or late prenatal care. Termination of pregnancy is not needed if DMPA exposure occurs. However, recommend her obstetrical provider be notified of her DMPA use in pregnancy and if problems develop, FDA reporting is advised.

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GENERAL INFORMATION (all methods):

EC = Emergency Contraception (all methods—oral formulations)
ECP = Emergency Contraceptive Pills (all pill forms -- progestin-only and combined)
COC = Contraceptive Oral Contraceptives (refers to pills containing both estrogen and progestin)
Plan B = Progestin-Only Pill

Overview

Emergency contraception is the use of a drug or an intrauterine device, IUD, to prevent pregnancy shortly after unprotected intercourse. Depending on current policy issues and/or provider availability and skill, options include the IUD, levonorgestrel, the Yuptze regimen, mifepristone, danazol and some combination regimens. Clinics at Public Health Seattle King County (PHSKC) use only the IUD and pill regimens.

It is estimated that emergency contraception in the United States alone could prevent 1.7 million unintended pregnancies and 0.8 million abortions each year which amounts to almost half of all unintended pregnancies[1, 2]. It is less effective than many accurately used and highly effective forms of birth control.

Sometimes ECP's are referred to as "the morning after pill" or the "after-sex pill," terms that should be avoided to prevent confusion about their purpose or timing.

Proper education of the public, policy makers, health care providers and advancement in consumer access to EC, are important public health preventive measures against unintended pregnancy. There is significant room for improvement in access to EC and understanding of its use. Despite moderate increases in the availability of EC over the past 5 years, use remains low. In a 2003 national survey, representative of women ages 18-49, only 6% of women were aware of emergency contraception, a modest increase from 2% in 2000[3]. Except for a few Western European countries and China, emergency contraception is largely under-utilized worldwide.

Comparing regimens

Both the levonorgestrel and mifepristone methods seem to be more efficacious and better tolerated than the classical Yuzpe regimen. Further evaluation of the effectiveness of first-line methods such as levonorgestrel, mifepristone, and the IUD are needed to determine optimum effectiveness related to time of unprotected intercourse[4].

Indications for EC

- Contraception was not used when intercourse took place
- A male or female condom broke, slipped or leaked
- A woman's diaphragm or cervical cap was not applied correctly or was dislodged during intercourse, found to be torn, was not properly inserted or was not left in the vagina for the suggested time period.
- Missed combined oral contraceptive pills. The WHO general guidelines recommend EC with two or more missed pills; however clinical judgment will determine the final recommendation[5]. While ovulation is unlikely if few pills have been missed, treatment is indicated if the woman wishes to avoid pregnancy.
- Progestin-only pill (minipill) taken more than 8-12 hours late.

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- More than two weeks late for Progestogen-only injectable contraceptive (depo medroxyprogesterone).
- Late starting a pill, ring or patch cycle
- Coitus interruptus: Failure to withdraw in time (ejaculation in vagina or on external genitalia)
- Expulsion of IUD
- Lapsed use of any method
- Rape/sexual assault
- Dispense when starting or changing to a new birth control method

When EC won't work

Failure could result under the following circumstances:

- An already established implantation
- An excessive lapse of time between unprotected intercourse and ECP ingestion
- Client failure to take the total dosage
- Emesis within two hours of ingesting the pills. A pharmacokinetic study suggests it takes three hours to obtain therapeutic progestin serum levels to block ovulation[6].
- Ongoing sexual intercourse without contraception or ECP

ECPs and Pregnancy: ECPs are not teratogenic

While both Plan B and OCPs used as emergency contraception are contraindicated for a woman with a known or suspected pregnancy, there is no known harm to the woman, her pregnancy, or her fetus[2].

ECPs and Breastfeeding

When prescribing EC to women who are breastfeeding, it is best to use high dose LNG ECP or Plan B®, both of which are considered safe over COCs.

ECPs and Lack of long-term protection post-administration

If sexual activity continues after ECP administration, ongoing contraception is needed to prevent pregnancy as the first dose will *not* protect against further acts of sexual intercourse.

Contraindications

The only absolute medical contraindications for both types of ECPs are an established pregnancy and hypersensitivity to the product[2].

Cautions

ECP as a form of birth control

Provide information that EC as a form of birth control is less effective than a consistently used birth control method. A typical woman using ECPs would have at best an 80% efficacy rate, while use of a regular hormonal method would give her an efficacy rate in the high 90's. However, there are no medical contraindications to repeated use, and this remains a safe option available to all women per their discretion. See section below on starting a birth control method at time of EC visit.

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Repeated use

Repeated use of emergency contraceptive pills (ECP), either progestin-only or combined oral contraceptives is assumed to be safe by most evidence-based resources[2].

Use in women with medical complications

According to the World Health Organization (WHO), recurrent use – while not defined – *may* be harmful for women with those conditions classified as 2, 3 or 4 for combined oral contraceptives (COC), combined injectable contraceptives (CIC), or progestogen-only contraceptives (POC).[4, 7]

Clinical judgment in regard to the above scenario is crucial when considering repeated use of ECP for women with co-existing medical conditions. While WHO suggests that ECP may theoretically be harmful, WHO also provides a list of medical conditions that together with unintended pregnancy, significantly increase a woman's risk status and presents a more serious risk than Plan B hypothetically would. While repetitive use or use of EC as a regular contraceptive is not recommended, it is not contraindicated and may be protective in most cases.

Progestin-Only EC:
Plan B®

- The most commonly used form of emergency contraception.

Background

As a result of the FDA's August 24, 2006 decision to allow Duramed (a division of Barr Pharmaceuticals) to make Plan B® available without a prescription, on Nov. 1, 2006, Duramed released new over the counter (OTC) Packaging for Plan B®. See FDA Plan B® Information Page for more information: http://www.fda.gov/cder/drug/infopage/planB/default.htm

Mechanism of action

- The mechanism of action is dependent upon the time ECP is taken in the menstrual cycle.
- High dose levonorgestrel ECP has been shown to block or delay ovulation. During the first portion of the cycle, the pre-ovulatory phase, follicular development and egg maturation are disrupted and may cause anovulation or delayed ovulation.
- Post-fertilization, ECP probably does not work.[8]. Reliable evidence does not indicate that endometrial damage or luteal dysfunction occurs[8].

Plan B does not disrupt a Pregnancy

- The National Institutes of Health (NIH), the Food and Drug Administration (FDA), and The American College of Obstetricians and Gynecologists (ACOG), define the beginning of pregnancy as the time of implantation.
- Most of the time, use of Plan B® either partially or completely blocks the surge of luteinizing hormone (LH) which prevents ovulation or results in ova that are resistant to fertilization. Therefore, while theoretically possible, it is unlikely that it interrupts the implantation of a pregnancy[8].

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- Levonorgestrel is a progestational drug that is also used to assist implantation of a pregnancy. Thus, it is unlikely that Plan B® interferes with implantation; in fact, it may even be supportive[8].
- Therefore, it is unlikely that Plan B® interrupts or harms an established pregnancy[2].

Efficacy

- Currently Plan B® is the most effective ECP available in the United States
- Overall, Plan B® reduces the risk of pregnancy by 89%[9].
- It is effective up to 5 days after unprotected sex, but should be taken **as soon as possible.**
- It becomes *much* less effective each day.

PRESCRIBING Plan B® or Ovrette

Available Forms

Name of Drug	Drug Formulation per pill	Dosage (1.5 mg Levonorgestrel)
Plan B®	0.75 mg levonorgestrel	2 pills (Take the 2nd dose 12 hours after the first dose)
Ovrette	0.075 mg norgestrel	40 pills

Single dose:

- Single dose of Plan B® for emergency contraception simplifies the regimen for patients, does not increase side-effects, and should be offered[10].
- Provide the woman with both pills and a cup of water to take on site.

Advanced EC

- A recent systematic review evaluating the provision of advanced EC did not reveal lower rates of unintended pregnancy in the women receiving advanced doses. However, women in the advanced provision group were more apt to use EC and use it more quickly. There was no difference between the groups in terms of condom use, rates of unprotected intercourse or the rate of STIs[11]. Users of barrier or new hormonal methods could benefit from an advance ECP prescription.

- When giving ECP for future use, caution women to make sure the ECP package has not expired when the time comes for them to use it. Counsel the woman to call the clinic and schedule a follow-up appointment for a refill, a pregnancy test if needed, or an ongoing method of birth control.

Side effects

Five percent of women report vomiting with progestin-only ECP. Taking the pills with food may help nausea. Giving Plan B® as a single dose (two pills at one time) does *not* increase side effects[10].

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Antiemetics

Dimenhydrate, (Dramamine®) over the counter (or two 50mg tablets or 4-8 teaspoons liquid), diphenhydramine, (Benadryl®) (one or two 25 mg tablets) or prescription for promethazine, (Phenergen®) tablets (one 25 mg tablet or rectal suppository) may be taken with the ECP dose. In one study evaluating the pharmacokinetics of levonorgestrel, the mean Tmax was reached at a little over 2 hours[6]. It is likely that absorption occurs much sooner. If the client vomits within a half hour of taking her pills or if visible pill fragments are seen with emesis, it may be reasonable to consider repeating the dose.

Patient Education Points

- The earlier you take emergency contraception, the more effective it is.
- You may have spotting or breakthrough bleeding.
- The medication may cause your regular cycle to occur earlier or later than normal.
- If you are using a primary method of contraception, continue to use it normally.
- If your regular cycle does not occur within 3 weeks of ECP ingestion, call the clinic to set up an appointment for a pregnancy test
- The pills may cause nausea. It is OK to take them with food.
- Emergency contraception does not protect against sexually-transmitted infections or diseases.

Exam and Lab

Physical Exam

There is no required physical examination. If the patient is due for an exam or annual, take the opportunity to schedule.

Pregnancy test

Determining the possibility of pregnancy is not always straightforward. Embryo implantation does not occur until 6 to 7 days following conception or fertilization. It is at this time of implantation that HCG is made by the trophoblast. It may then take another day or two before there are detectable HCG levels in the urine. Therefore, the pregnancy test may not turn positive until nine to eleven days after fertilization.

Woman who menstruate regularly and who are not late for their menses do not need a pregnancy test. Pregnancy testing may be appropriate if the woman is late for her period, if unprotected intercourse occurred a week or more prior to the visit, or if the patient is uncertain of the details of her recent sexual activity or the pattern of her menses.

Negative pregnancy test at time of EC visit

If the woman has a negative pregnancy test, schedule a visit in three weeks for a repeat pregnancy test and contraception counseling. Pregnancy testing is especially important if she is late or has an irregular menstrual cycle. After using ECPs, 80% of women will experience their period within 2 days of its expected onset. Ninety-five percent of women will have menstruated within 7 days of the expected onset of their menses[10]. If the patient has not experienced menses by 3 weeks after taking EC she should be evaluated for pregnancy.

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Starting a birth control method at time of EC visit

If the client is seen in the clinic, provide a birth control method and schedule appropriate follow-up at that time. If not seen in the clinic, refer the patient to the nearest FP clinic to be seen as soon as possible.

Supply condoms or other contraception if sexual activity will continue, because ECP will not protect against pregnancy from future coitus. Strongly consider a second ECP package because many women seeking ECP may need another ECP prescription, especially if the woman has not chosen an effective ongoing contraceptive method.

The client may receive a contraceptive injection the day she is given EC or be given one package of pills to begin the day following ECP if the client does not want to wait for her menses to start the method. The same day start/restart guidelines must be used for the selected method.

Comment [L1]: Jeff, please insert hyperlink to same day/restart guidelines

Women wishing to begin an ongoing hormonal method at the time of EC should be counseled regarding the need to return for a repeat pregnancy test if she does not experience menses at the end of the first month of use. Women should also be counseled regarding the theoretical risks of exposure to hormonal methods in early pregnancy.

Back-up contraception

Emphasize the need for back-up contraception for 7 days when a same day start is initiated and a pregnancy test if she misses her next period.

Positive pregnancy test at time of Follow-up Visit

In the case of ECP failure and pregnancy detection at follow-up, provide pregnancy options counseling. According to the FDA labeling there is no increased risk of ectopic pregnancy or birth defects following the LNG or Plan B ECP in the FDA application[11].

Sexual Assault or Domestic Violence Incident

Refer the woman for counseling and explain reporting requirements for statutory rape. See Guidelines section for sexual assault and domestic violence, click here.
Inform the woman that any information that is legally required will be conveyed respectfully in order to protect her privacy as much as possible. Provide sexually transmitted infections (STI) services as needed. See Guidelines for screening for STI's.

Sexually Transmitted Infections

Provide STI services as needed. See Guidelines for screening for STI's. (Female, Male)

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COMBINED ORAL CONTRACEPTIVE PILLS OR "YUTZPE" METHOS

Background

If PlanB® or the IUD is not appropriate or available, the Yutzpe regimen should be offered[4]. Developed in the 1970's, the Yutzpe method is based on a modified regimen of combined oral contraceptive pills – oral contraceptive pills that contain an estrogen and a progestogen.

Mechanism of Action

Traditional combination oral contraceptives (semi-synthetic estrogen plus progestin) reduce fertility primarily by suppressing the mid-cycle LH surge, ovulation and the development of the corpus luteum[9].

Efficacy

The Yutzpe method is not as effective as the IUD or Plan B® regimens and prevents about 75% of unintended pregnancies[4].

Cautions/Considerations in COC ECP use

Thromboembolic disease

Progestin-only or IUD insertion are preferable in all women. However, there are no medical contraindications to ECP even if estrogen containing pills are used in women with known thromboembolic disease. The half-life of the estrogen is only eight hours and with consumption of only two doses of pills, it is unlikely that significant hemodynamic alterations will occur.

Breastfeeding and COC ECP

During breast feeding, long-term estrogen use may decrease a woman's milk supply. Since ECP use is of short duration, estrogen-containing pills can be used but, as always, the progestin-only ECP is preferred.

Prescribing

- **"Yuzpe" ECP Equivalent Dose Table**
- Two doses are administered 12-hours apart. Each dose contains 100 micrograms of the synthetic estrogen (ethinyl estradiol) and 0.5 mg of levonorgestrel.
- The first dose should be taken while the woman is in the clinic. The second dose should be taken in twelve hours. There is no evidence to support taking the entire combined OCP dose at one time.

Side Effects

Nausea and vomiting occur in 15 to 30% of women taking combined ECP with estrogen. Taking the pills with food may help nausea[10].

Antiemetics

Dramamine over the counter (or two 50mg tablets or 4-8 teaspoons liquid), diphenhydramine (one or two 25 mg tablets) or prescription for phenergen tablets (one 25 mg tablet or rectal suppository) may be taken with the first dose and repeated one hour prior to the second dose.

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In one study evaluating the pharmacokinetics of levonorgestrel, the mean Tmax was reached at a little over 2 hours.[6] It is likely that absorption occurs much sooner. If the client vomits within a half hour of taking her pills or if visible pill fragments are seen with emesis, it may be reasonable to consider repeating the dose.

Patient Education Points

- The earlier you take emergency contraception, the more effective it is.
- You may have spotting or breakthrough bleeding.
- It may cause your regular cycle to occur earlier or later than normal.
- If you are using a primary method of contraception, continue to use it normally.
- If your regular cycle does not occur within 3 weeks of ECP ingestion, call the clinic to set up an appointment for a pregnancy test
- The pills may cause nausea. It is OK to take them with food.
- Emergency contraception does not protect against sexually-transmitted infections or diseases.

Copper-Bearing Intrauterine Device as EC

Mechanism of Action

- The copper IUD works primarily by blocking fertilization and may prevent pregnancy after fertilization. The levonorgestrel-releasing IUD (Mirena) has not been studied for EC and is not recommended.

Efficacy

- Emergency insertion of a copper IUD is more effective than ECPs, and may reduce the risk of pregnancy by as much as 99%[2].

Contraindications

Contraindications and eligibility criteria are the same as for insertion at other times. For example, if a woman needs EC because of unprotected intercourse with a new sexual partner, sexual assault or rape, or when the risk of a sexually transmitted infection is present, an IUD is not appropriate. See IUD guidelines for references and complete list.

Prescribing

- The copper IUD may be inserted up to 5 days after unprotected intercourse.
- The copper IUD can be left in the uterus for up to 12 years after insertion for EC.
- Refer to the IUD guidelines and perform a pregnancy test before insertion for emergency contraceptive purposes.

Follow up and risk of Ectopic Gestation

A three week follow-up visit is important to rule out pregnancy. Any contraception that reduces the chance of pregnancy also reduces the risk of ectopic gestation; therefore, IUD's significantly reduce a woman's chance of an ectopic pregnancy overall. However, if a pregnancy occurs with an IUD in place, the ratio of ectopic to intrauterine pregnancy may be increased[12], [13].

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DISPENSING Plan B®

Over the Counter – Plan B®

As directed by the FDA, Barr marketed Plan B® as an OTC item for men and women ≥ 18 years old. The FDA also mandated that the product must be stored behind the counter and only sold at locations under the purview of a pharmacist. As a result, Barr developed a dual packaging with instructions to deliver the medication with or without a prescription. Pharmacists must be available to answer any questions or concerns.

It is only available at the pharmacy counter. It is not stocked on open shelves.

The FDA requires clients to show an ID to prove their age. According to the agreement between Barr and the FDA, any valid government-issued identification is sufficient for proof of age. Appropriate forms of ID are similar to those required for pseudoephedrine sales. The DEA has published this listing of acceptable IDs: http://www.deadiversion.usdoj.gov/meth/alternate_ID2.pdf.
Short list of acceptable IDs.

- If the individual is ≥18 years, Plan B® is available to males and females, over the counter (OTC).
- If < 18 years, Plan B® is only available to females and she will either need a prescription or may obtain via pharmacy access (see Pharmacy Access for women 17 and under without RX).

Access to EC within PHSKC:

The distribution of Plan B® depends on whether the clinic is a dispensing site or pharmacy site

Dispensing sites

- A provider visit is required for *all clients* male and female
- For all recipients, the labeling process will remain the same (label placed on product, encounter form, med log in chart, and in medication log book)
- Note age authorization component on male visit form for MA or NP to verify at each visit for men 18 and over
- Men who are not at least 18 cannot receive EC under any circumstances

Pharmacy sites (North, Columbia and Downtown)

- All **new** patients must see a provider to obtain EC, no matter their age. If a patient hasn't been seen within 3 years, s/he is considered a new patient and must be reestablished with a provider visit
- Those females ≤ 17 must see a provider every visit.
- Those patients, who are **established and 18 and older**, do not have to see a provider.
- Established patients *will* be referred to a provider, however, if

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- They purchase more than 3 Plan B® packs at one time from a pharmacy site or
- Purchase more than 10 packs in a month's time from a pharmacy site

- Please see pharmacy policy titled "Dispensing Emergency Contraception" for more details on PHSKC pharmacy practice and tracking system.
- Public Health Employees' Website - Homepage

Take Charge coverage of EC:

- Take Charge covers EC only for women. EC for men is not covered by Take Charge.

Men 17 and younger

Currently, Plan B® labeling indicates "Rx only for age 17 and younger." The FDA has not specified whether or not men 17 and younger may receive Plan B® for another person's use (a female partner). Neither the FDA, nor Barr pharmaceuticals explicitly prohibit Plan B® for males who are 17 and younger. However, the packaging does not indicate use for men 17 and younger, and the Washington State Board of Pharmacy currently prohibits writing an Rx for anyone other than the person for whom the Rx is intended. For this reason, *PHSKC is not dispensing or prescribing to men 17 and younger.*

Pharmacy Access for women 17 and under without Rx or Provider Visit

- Women 17 and under can obtain EC from some pharmacists without a prior clinic visit in Washington state. When a provider is not available or during after-clinic hours, pharmacy access is a potential window for treatment. Pharmacy access allows individually trained pharmacists to determine if it is medically appropriate to provide Plan B® without an advance prescription from the provider or clinic.

- Dispensing of Plan B® in this form is dependent on individual pharmacists and whether or not they choose to provide this service. Access will be determined by which pharmacist is working at the time the patient arrives at the pharmacy. This arrangement is pharmacist-specific, so clients should call ahead, as only a relatively small number of pharmacists have made arrangements to do this.

- Typically the FP CSO nurses and/or FP health educators maintain updated lists on which pharmacies are proponents of EC pharmacy access. Check with local staff for the most up-to-date regional EC pharmacy access list. Remember that while the pharmacy may be a proponent of EC access, the pharmacist on duty at the time has to be amenable.

Comment [N2]: Jeff, please ask Andrea Gerber for the list

Comment [mw3]: There is no current list, too hard to update. Instructions are sufficient without a link to a list.

Pharmacy Access and Resources

- Pharmacy access is available in AK, CA, HI, NH, NM, MA, ME, VT, and WA. For a listing of pharmacies that provide this service, visit www.EC-Help.org.
- 1-888-NOT-2-LATE is a phone resource to help women find clinics that provide ECP prescriptions or a local pharmacy that provides ECP.
- Finally, the Office of Population Research at Princeton University offers the latest available products and updates: http://ec.princeton.edu

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Pharmacist refusal

While a pharmacist is under the legal and professional obligation to deliver lawfully prescribed or mandated medications, there are incidents in which pharmacists continue to refuse to fill birth control prescriptions and/or dispense emergency contraception. Such refusals can create a serious barrier to services needed in pregnancy prevention and the protection of women's health. It is the duty of health care providers and patients alike to monitor pharmacist refusals, to stock Plan B for OTC access, or honor prescriptions for women under 18. For further guidance and a guide of the laws, regulations, and overview of state law, see The National Women's Law Center's January 2007 publication, "Don't Take 'No' for an Answer."
http://www.nwlc.org/pdf/DontTakeNo2007.pdf

Standing Orders

Provision of EC by standing order in CSO Program

PHSKC has an approved policy for standing orders (PHSKC Standing Order Policy) in place for ECP under the general standing order policy and under the direction of the Family Planning Medical Director (PHSKC FP ECP Standing Order). The FP CSO program uses standing orders and provides access to FP care via DSHS offices across the county. The ECP standing order protocol can only be used by trained PHN staff. This program is to be monitored periodically using the ECP Standing Order Program Chart Review Form. Clients will be assessed for eligibility according to ECP guidelines. Emergency contraception will not be provided to males, of any age, by standing order protocol.

Comment [F4]: Please insert

Standing Orders Forms and Charting:

Complete the client Consent for ECP by Standing Order and ECP Standing Order Chart Form. Precautions and contraindications should be noted on the chart form.

Comment [F5]: Wrong link

Standing Orders and Pregnancy Testing

A pregnancy test is indicated if the patient is unsure of the details of past and recent sexual activity, or if there is a possibility of a detectable pregnancy. A pregnancy test may be deferred if there is little or no possibility of pregnancy at the time of ECP administration. A pregnancy test may also be deferred if the patient is certain of the dates of last sexual activity and it would be too soon to detect bHCG in the urine. If a client is unable to leave a urine sample, the RN may administer ECP if they determine there is little possibility of pregnancy.

Standing Orders Follow-up

If a birth control method is desired, facilitate a clinic visit with a provider as soon as possible. Instruct that if she does not have a menstrual period in three weeks to schedule a clinic visit with a provider as she may be pregnant.

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References:

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8. Marions S, Hultenby K, Lindell I, Sun X, Stabi B, Danielsson GK. Emergency Contraception with Mifepristone and Levonorgestrel: Mechanism of Action. Obstetrics and Gynecology 2002; 100: 65-71.

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12. Furlong LA. Ectopic pregnancy risk when contraception fails. A review. J Reprod Med. 2002 Nov; 47(11):881-5.

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13. Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. "Is there and increased risk of ectopic pregnancy if using an intrauterine device for emergency contraception?" [Online] 12 July 2006. http://www.ffprhc.org.uk.offcampus.lib.washington.edu/admin/uploads/No1694.pdf

"Yuzpe" ECP Equivalent Dose Table

Comment [N6]: Jeff, please shade every other block as in L. Miller's original draft

In 1997, The FDA determined the safety and effectiveness of the following regimens.

Available Forms

Drug	Drug Formulation (each pill)	Dosage and Pill Description
Alesse	0.20mg ethinyl estradiol 0.10 mg levonorgestrel	5 pink pills
Aviane	0.20mg ethinyl estradiol 0.10 mg levonorgestrel	5 orange pills
Cryselle	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 white pills each dose
Enpresse	0.03 mg ethinyl estradiol 0.125 mg levonorgestrel	4 orange pills each dose
Ovral	0.05 mg ethinyl estradiol 0.25 mg norgestrel	2 white pills each dose
Ogesterel	0.05 mg ethinyl estradiol 0.25 mg levonorgestrel	2 white pills each dose
Lo-Ovral	0.03 mg ethinyl estradiol 0.30 mg norgestrel	4 white pills each dose
Lessina	0.20mg ethinyl estradiol 0.10 mg levonorgestrel	5 pink pills
Nordette	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 light-orange pills each dose
Levlen	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 light-orange pills each dose
Levlite	0.20mg ethinyl estradiol 0.10 mg levonorgestrel	5 pink pills
Levora	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 white pills each dose
Low-Ogestrel	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 pills each dose
Nordette	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 pills each dose
Portia	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 pills each dose
Seasonale	0.03 mg ethinyl estradiol 0.15 mg levonorgestrel	4 pills each dose
Triphasil	0.03 mg ethinyl estradiol	Yellow pills only 4 pills each

	0.125 mg levonorgestrel	dose
Tri-Levlen	0.03 mg ethinyl estradiol 0.125 mg levonorgestrel	Yellow pills only 4 pills each dose
Trivora	0.03 mg ethinyl estradiol 0.125 mg levonorgestrel	4 pills each dose

Examples of government-issued identification include but are not limited to:

United States passport (unexpired or expired).
Alien Registration Receipt Card or Permanent Resident Card, Form I-551.
An unexpired foreign passport that contains a temporary I-551 stamp.
An unexpired Employment Authorization Document issued by the Immigration and Naturalization Service which contains a photograph, Form I-766; Form I-688, Form I-688A, or Form I-688B.
In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, an unexpired foreign passport with an Arrival-Departure Record, Form I-94, bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, so long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form I-94.
A driver's license or identification card containing a photograph, issued by a state or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address.
School identification card with a photograph.
Voter's registration card.
U.S. military card or draft record.
Identification card issued by Federal, State, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address.
Military dependent's identification card.
Native American Travel Documents.
United States Coast Guard Merchant Mariner Card.
Driver's license issued by a Canadian government authority.

Fertility Awareness or Infertility Basal Body Temperature Charting

History and Examination

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. Special attention should be paid to length and regularity of cycles. Signs or symptoms of vaginal infection should be evaluated and appropriately treated. Inform the client about emergency postcoital contraception if using FAM for contraception. It is appropriate to give an EC prescription prophylactically. Use Fertility Awareness Chart is available to teach charting and taking of the daily temperature, cervical mucous quality, menses, coitus, and even cervical position.

Subsequent Clinic Visits

Women newly instructed should be scheduled for a return visit three menstrual cycles after the initial visit. The record of menses, basal temperature, cervical mucus observation, coitus frequency, and symptoms should be evaluated and reviewed with the client.

Precautions/Contraindications

- Irregular menses;
- Inability to keep careful records;
- High failure rate, more appropriate for birth spacing;
- 85% of women under age 35 have regular cycles.
- Women with cycle lengths less than 26 days or more than 32 days are not good candidates for this method as their ovulation cannot be easily predicted.
- Couples must be able to abstain for 12 days if using the cycle beads.

Benefits

- Acceptable to many religious groups;
- Very helpful for timing planned pregnancy or for infertility evaluation;
- Teaches about normal menstrual cycle;
- No artificial substances involved;
- Low side effects.

Instructing the Client

- Offer referral to classes for fertility awareness birth control;
- During pelvic examination, have the client hold a mirror so she may inspect her cervix. Obtain cervical mucus. Show her how to test the mucus by stretching it between two pap sticks or two slides. Show her how to test stickiness by rubbing between fingers. Have

her insert and remove the speculum until she has mastered the technique of locating her cervix, if desired;

- Review the method of obtaining basal body temperature and show the client a sample temperature chart. Encourage use of a digital thermometer;
- Review calendar method and give the client a new calendar to record her cycle. It is generally felt that the calendar method is not reliable until there is documentation of at least three regular cycles and that by combining cervical mucous and temperature, the method's efficacy is greatly increased.
- Schedule a return appointment to review charts. Remind the client to return sooner if problems occur or she develops signs of a vaginal infection.
- If using the Basal Body Temperature Chart to plan a pregnancy, then ascertain the presence of a biphasic graph. Refer to a gynecology clinic if there is evidence of no ovulation. Emphasize with the client that the egg only survives 12 to 24 hours and sperm three to five days so coitus must be frequent and timed appropriately for pregnancy to occur (see Infertility section in Gynecology chapter).
- The Cycle Beads can be obtained and stocked in the clinic or the kit is available at www.cyclebeads.com . This kit with instructions and a necklace of colored plastic beads can make it easier for women to use natural family planning. A black ring which can only move in one direction is moved each day to a bead and the color of the bead determines the risk of pregnancy. The red bead marks the first day of menstruation, the 6 brown beads before the ovulatory window and the 13 brown beads following ovulation signify when the risk of pregnancy is low ("sex during brown beads"), and the 12 white beads are the time when pregnancy is most likely to happen. If a woman's menses begins before or on the dark brown bead this tells her that her menstrual cycle was less than 26 days and she may not be the best candidate to use natural family planning.

Implant Contraceptives

Overview

Mechanism of action

Efficacy

Benefits

Absolute Contraindications

Organon lists two additional contraindications:

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When to Schedule the Insertion and the Need for Back up Contraception*

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Coding for Implanon

Follow-up Visits

Possible Side Effects

- Heavy or Prolonged Bleeding:
- Amenorrhea:
- Infection of Implant Site:
- Implant site scarring or hyperpigmentation:
- Expulsion:
- Headache:
- Progestin hormone side effects:
- Weight Gain:
- Ovarian Enlargement or Cysts:

Reporting Problems from the Implant Systems to the FDA

Discontinuation of the Implant

Removal Visit

Forms

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Implant Contraceptives

Overview

Implants are controlled release systems using a polymer to make a rod which is implanted into subcutaneous tissue. Synthetic progestin hormones are delivered directly to the circulation, bypassing the gastrointestinal and hepatic first pass effects. Because the implant use does not depend on the user, implant systems are highly effective, and have failure rates lower than sterilization. The only implant available for use in the US is Implanon®.

Mechanism of action

Progestin-only implants block ovulation and thicken cervical mucous.[1] Within 24 hours of insertion of an implant system, the circulating progestin levels are contraceptive but it takes 7 days before the cervical mucous becomes protective. Therefore, unless the system is placed within the first five days of the menstrual cycle, ovulation could still happen with the first cycle so a back-up method for the first 7 days is needed. There continues to be some ovarian follicular activity because without estrogen, as with the combination OC, there is incomplete ovarian suppression. This may be the reason bone density is preserved but irregular ongoing bleeding persists. This is in contrast to the complete amenorrhea seen with long-term DMPA use. Following removal, levels quickly fall and in 48 hours the progestin is no longer detected in the serum.

Efficacy

Implanon® is a highly effective contraceptive method. The most common reason for a pregnancy is a pregnancy undiagnosed at the time of insertion or a pregnancy occurring directly following insertion. According to the manufacturer of Implanon®, the cumulative Pearl Index is 0.38 pregnancies per 100 women years of use.

Implanon ® is a single rod, 4 cm in length and 2 mm in diameter, implant system made of an ethylene vinyl acetate (EVA) copolymer containing 68 mg of etonogestrel (ENG). The initial daily release rate of 60-70 mcg ENG produces a maximum mean serum level of ENG of 813 pg/ml by 4 days. This level declines slowly to a mean serum level of 196 pg/ml ENG by one year and 156 pg/ml at the end of year three. In vitro studies show a serum ENG release level of 20-30 µg/day will block ovulation. At the end of 3 years the mean in vitro release rate was 40 µg/day. [2]

The only statistically significant difference between users of ENG implants as compared to women using Norplant is that women using ENG experience higher rates of amenorrhea.[3] There has not been a measured increase in prothrombotic effect or problem with this ENG system, although use in women with estrogen contraindications has not been studied.[4] Insertion of the single implant took a mean time of 1.1 minutes and removal took 2.6 minutes.[5]

Benefits

- Three years duration of action
- Easily reversible
- Decreased menstrual blood loss, cramps, ovulatory pain, and anemia
- Very high effectiveness
- Does not contain estrogen so can be used by many women
- High continuation rate, especially in adolescent populations
- Not dependent on the user for efficacy
- Low dose of progestin exposure

Absolute Contraindications

For women with any of the following, the implant system should NOT be inserted:

- Suspected or diagnosed **pregnancy**, although unlikely the implant system would cause birth defects or abortion, it could delay diagnosis or care of the pregnancy.
- Known or suspected **breast cancer**.
- **Undiagnosed vaginal bleeding** that is suggestive of a serious condition. The implant system is associated with changes in menstrual bleeding and could make evaluation and management of abnormal bleeding difficult.

Organon lists two additional contraindications:

- A history of **thrombotic disease**. Research has documented that the progestin-only systems do not change coagulation factors, lipoproteins, cholesterol, or lipid profiles; hence it is unlikely they are prothrombotic. However, because of the package labeling, patients should be counseled that there could be a small unknown risk of a repeat thrombosis. If thrombosis does occur with implant use, remove the implant and notify the FDA MedWatch system using the pharmacy guidelines.

- **Allergy** to the implant: The EVA (vinyl of the implant) or the etonogestrel.

Precautions

According to the World Health Organization, (WHO) several conditions exist in which the method is not recommended unless other more appropriate methods are not available or not acceptable, (Category 3):

- Severe cirrhosis
- Benign and malignant hepatic tumors
- Active viral hepatitis
- The women is less than 6 weeks post-partum (primarily due to the lack of studies showing an absence of long-term effects related to neural development)
- An active DVT/PE
- Migraine with aura[6]
    - http://ihs-classification.org/en/02_klassifikation/02_teil1/01.02.00_migraine.html

- Use of anticonvulsant medication or other hepatic enzyme inducing medications (This link is to a table listing the most commonly used, but not an exhaustive list of drugs that may affect progestin metabolism). Though documented pregnancies have not occurred in women using implants and taking these medications, there is a possibility of reduced contraceptive efficacy in women taking these medications without the concurrent use of a back-up method.

If any of the conditions listed above are present in a woman requesting Implanon®, please discuss the safety of insertion with her primary care provider and the Family Planning Medical Director.

Women who are Overweight

It is also worth noting that Organon did not include in their study women over 130% ideal body weight. Ideal weight is defined as 100 lbs at 5 ft and an additional 5 lbs for every inch above that. The WHO does not consider a BMI > 30 kg/m^2 to be a contraindication to Implanon® use.[7]
In a study examining the pharmacokinetics of Implanon®, the author hypothesized the risk of pregnancy in heavier women who are using Implanon® is less than in heavy women using Norplant. This is due both to differences in serum binding properties and the fact that

ovulation inhibition remained present in the majority of women using Implanon® at 3 years.[2]

Key Counseling Point

While patient counseling needs to cover a variety of points, it is important that women are counseled carefully regarding their ability to tolerate **irregular, frequent bleeding**. Documentation of this understanding in addition to other areas covered should be included at the time of counseling and/or insertion.

- The patient must be aware that irregular bleeding is expected during implant usage. It is common to experience 15 to 20 bleeding or spotting days in the first 3 months of use, although amenorrhea can occur in 20% of women. In international studies, up to 30% of women discontinuing use of an implant cited bleeding as the reason.[3] According to the manufacturer of Implanon ®11% of women reported bleeding irregularities as the reason for discontinuing use before the end of 3 years, (104/942 participants).

History

Patients who are considering the use of Implanon® should be given the PHSKC patient education handout titled Contraceptive Implant Patient Handout. They should also receive the manufacture package materials to help inform their decision. If the patient decides to proceed with the method, a careful medical history should be obtained to rule out any contraindications or concerns about proceeding. The client should be informed about the risks and benefits of their choice and reminded of alternate contraceptive methods. The Contraceptive Implant Consent for Insertion or Removal Form should be completed and signed prior to the procedure.

Examination

Title X and Take Charge guidelines should be followed regarding the need for annual pelvic and breast examinations in patients receiving Implanon®. Women not on these programs should have an annual breast and pelvic exam as deemed appropriate by the provider doing the insertion. Considerations should include the client's age, past sexual/reproductive history and previous cytology results if obtained. The non-dominant upper inner arm between the biceps and the triceps is the site of the insertion. If a tattoo is present at the planned site of insertion, discuss with the patient whether or not it is acceptable to place it there or if they would prefer to have it placed on the other arm.

Laboratory Testing

Confirm by history, the need to perform a pregnancy test. Hematocrit or hemoglobin testing to document a baseline value may be indicated if the patient has a menstrual history suggestive of more than normal blood loss or a past history of anemia.

Who May Perform Implanon ® Insertions?

Only those providers trained through Organon are allowed to prescribe and insert Implanon. Training should be documented by sending a copy of the completed training certificate to the Family Planning Medical Director. If clinicians are comfortable with independent insertion after the training, they may proceed with the procedure. If any clinician would like assistance, review of the procedure or a chance to watch an insertion on a patient, prior to placing the implant independently, they may contact the Family Planning Medical Director and arrange a time to do so.

Who May Perform Implanon ® Removals?

Only those providers trained through Organon are allowed to remove Implanon.® If the provider has previously removed Norplant implants or feels confident about their procedural skills, they may proceed independently. If a provider has not previously removed Norplant capsules or does not perform procedures with some frequency, they should schedule the first Implanon ® removal when the Family Planning Medical Director or another provider skilled in implant removal is available.

When to Schedule the Insertion and the need for Back up Contraception*

Current Method	Insert Implanon®	Backup
No effective contraception in current cycle	Anytime in cycle if client is reasonably certain she is not pregnant If there is concern pregnancy is possible, perform a pregnancy test. If negative and patient wants to proceed, counsel regarding the risks of insertion with an early pregnancy, proceed with insertion and have the patient return in 2 weeks to repeat a pregnancy test.	If > 5 days since menses, backup for 7 days
Correct use of any hormonal contraceptive, (excluding Mirena)	Any time in cycle including the hormone-free period	Finish the current cycle
DMPA	On or before next injection is due	None
Mirena in place	Anytime in cycle	If inserted before or on day of removal, no backup needed
Paraguard	If IUD removal and Implanon® insertion occur < 5 days after the onset of menses If Implanon® is inserted > 5 days after the onset of menses and IUD removed at the same time	None Backup for 7 days

	If Implanon® is inserted > 5 days after the onset of menses and IUD not removed until next menses	None
Post-surgical abortion or post-spontaneous pregnancy loss	Within 5 days of procedure After 5 days and any time before onset of intercourse Organon recommends waiting 4-6 weeks after a second trimester loss or termination. Earlier insertion may be appropriate. Discuss with the Family Planning Medical Director.	None Backup for 7 days
Post- medical abortion	Since Implanon can interfere with a medical abortion, insertion should only take place after the process is complete. Usually at or after the follow up exam.	Backup for 7 days
Postpartum Nursing Non-nursing	Immediately If inserted > 21 days postpartum, follow guidance listed above for when no effective contraception in current cycle used	If given within 21 delivery, no back up

*Adapted from guidelines developed by Planned Parenthood of Western Washington

Please Note: In the unusual case of proceeding with an insertion in spite of the history of unprotected sex additional documentation of the counseling regarding the risk of pregnancy, the need for a repeat pregnancy test in 2 to 4 weeks depending on sexual activity, and the caution regarding ectopic gestation risk if method failure is required. If the woman is subsequently found to be pregnant the implant system should be removed, unless the pregnancy is terminated, to avoid exposure to the fetus. Even though it is unlikely to be teratogenic, it is not reasonable to leave the system in place in the setting of a desired pregnancy.

Insertion Visit

The insertion procedure is done in the clinic under local anesthesia and takes approximately 5 minutes if the consent and counseling have already been done. If there has been an interval of time since the counseling, confirm that there is no risk of pregnancy and repeat the pregnancy test on the day of the insertion if indicated. Set up the procedure by using the Implant Insertion or Removal Set-up and Prep Form.

The insertion documentation should include:

- Contraceptive Implant Consent for Insertion or Removal Form
- Contraceptive Implant Insertion or Removal Procedure Form
- The device consent form supplied by the company documenting the client read the company materials.

The chart sticker supplied by Organon, should be placed in the patient's chart on the medication tracking page. Use the supplies and procedure set-up information list when setting up for a procedure. Access to emergency supplies and treatment for allergic reaction or fainting should be available for these procedures. After insertion it is essential to have both the provider and patient palpate the implant. The client is given the Post Implant Insertion or Removal Patient Handout and the warning signs of infection are reviewed with her. Women should also be given the bleeding diary which accompanies the packaging to use if they begin to experience a bleeding pattern they are concerned about. Women should be advised that the implant system does not provide protection against sexually transmitted diseases.

Coding for Implanon®

Procedure	CPT	ICD-9
Insertion	11981	V25.5
Removal	11982	V25.43
Removal and re-insertion	11983	V25.43
Norplant Removal	11976	V25.53
Implant Insertion	11981	V25.5

Also add **S0180** for the implant & supplies

Follow-up Visits

Four to six weeks after insertion, the client should return to assess side effects, answer questions and evaluate any problems. The insertion site should be inspected for infection, phlebitis, expulsion or other problems. The clinician should ensure the implant is palpable and record this in the patient record.

Possible Side Effects

- **Heavy or Prolonged Bleeding:** Obtain a history of the amount (pads/day) and duration of bleeding. Encourage the use of the Menstrual Diary Card to document the bleeding pattern. Reassure the client that irregular bleeding is expected with the implant system. Check a hematocrit or hemoglobin and give iron as indicated. Do a pelvic examination and test for pregnancy or infection as appropriate. Estrogen supplementation has not been proven to help with bleeding. In randomized studies, NSAIDs, in a dose similar to Naproxen 550 mg bid for 5 days, significantly decreased the spotting episodes and reoccurrence with Norplant use. As with all menstrual symptoms NSAIDS medications can decrease cramping, duration, and amount of flow.

- **Amenorrhea:** Test for pregnancy. If the client is pregnant and planning to continue the pregnancy, then plan for removal of the implant system. If the pregnancy test is negative, reassure the client that amenorrhea is common (20% of Implanon® users have amenorrhea in any given 90 day period).

- **Infection of Implant Site:** Examine the site for swelling, redness, inflammation or expulsion of implants. Advise the client to apply warm moist compresses for 10 to 15 minutes 3 times a day, elevate and rest the arm as appropriate, and go emergently for

possible incision and drainage if no response in 48 hours. For significant induration and erythema consider prescribing an antibiotic with staph and/or strep coverage. If there is any purulence, obtain a wound culture and treat empirically for MRSA. Re-evaluate the site in two to five days to assure infection has resolved and implant system has not been expelled. Significant infection may require removal of the implant. Make a note in the chart regarding the infection because at the time of removal one may expect more difficulty with scar tissue.

- **Implant site scarring or hyperpigmentation:** While rare, this can happen. If it does, even removal of the implant system is unlikely to reverse any changes in the dermis.

- **Expulsion:** Use backup contraception. Replace the missing implant system if the patient chooses. Contact the company to see if a replacement kit can be provided at no cost.

- **Headache:** Evaluate stress and other factors, which may cause headaches. Reassure the client headaches often resolve in two to three months. Advise NSAIDS, relaxation techniques and have her keep a Headache Diary to find inciting events which could be reduced. If headaches are severe emergent referral to a hospital may be needed. If they are more chronic in nature refer to her primary care provider for management and evaluation. Removal of the implant system may be necessary if no other cause is identified. There is a rare condition, pseudotumor cerebri, which has been reported to be increased in women with use of the Norplant system. The fluid in the brain increases and causes pressure which can present as worsening and persistent headache for which hospitalization and treatment may be needed.

- **Progestin hormone side effects:** like mood changes, irritability, fatigue, acne, or hair loss can occur in the early months of implant system use. Usually these will resolve. If not, refer to a primary care provider for evaluation of other possible etiologies, like thyroid disease.

- **Weight Gain:** Long-term studies have shown most women have no weight change with implant use. Use the Getting Fit Handout to discuss diet and exercise habits.

- **Ovarian Enlargement or Cysts:** Implants do not suppress ovarian function to the same degree as seen with combination oral contraceptive pills. Consequently there may be the development of functional ovarian cysts just as found in normal cycling women. Most cysts will resolve in six weeks. Only refer for ultrasound if a palpable pelvic mass persists.

Reporting Problems from the Implant Systems to the FDA

Any complications such as allergic responses, site or product problems, unusual reactions or significant medical problems (e.g. thrombosis) while using the implant system should be reported to the FDA at 1-800-FDA-1088, or fill out the form online at http://www.fda.gov/medwatch/report/hcp.htm.

Discontinuation of the Implant
The implant system should be removed at 3 years. The implant should also be removed when the side effects cannot be managed to the client's satisfaction or if she is planning a pregnancy. The implant may be removed at any time of the menstrual cycle, and unless pregnancy is desired, **alternate contraception should be started immediately**. Hormonal contraception can be begun on the day of removal but because it is possible for ovulation to occur with implant systems, back up contraception should be provided or practiced for the 7 days to allow the new hormonal method time to equilibrate. If the woman is seeking pregnancy, consult the preconception guidelines. Advise her to wait until she has had at least one normal menstrual cycle after the implant is removed. This is to allow the endometrial lining to recover from the atrophy present with implant use.

A **new implant system** may be inserted at the same visit if desired by the woman. Insert the new implant system into the prior site and use the same incision unless the client prefers an entirely new site for placement.

Removal Visit

Implanon® system implants can usually be removed in less than 5 minutes. The implant system should be removed only by trained providers. With removal, the implant should be shown to the client. The Implant Removal Consent, Procedure and Patient Information forms should be used and placed in the chart when completed. Use the list at the end of this chapter to set the supplies and equipment for the procedure. If an implant cannot be palpated imaging to localize the implant may be necessary before making an incision. The Implanon® system is not radio opaque and cannot be seen by x-ray. Ultrasound using a high frequency linear-array transducer and in some cases MRI is required for localization.

Forms

Contraceptive Implant Patient Education Form

Implant Insertion or Removal Set-up and Prep Form

Contraceptive Implant Consent for Insertion or Removal Form

Contraceptive Implant Insertion or Removal Procedure Form

Post Implant Insertion or Removal Patient Information Handout

Menstrual Diary Card

Headache Diary

Getting Fit Handout

Potential Drug Interactions in Women Using Implanon®*

Drugs known to increase liver enzyme metabolism/ decrease contraceptive effectiveness	Drugs with questionable effects	Drugs known not to affect liver enzyme metabolism or contraceptive effectiveness
Anti-epilepsy drugs (AEDs) may also be used to treat certain psychiatric illnesses, headaches, chronic pain, and other conditions. WHO, 3		
carbamazepine (Tegretol) oxcarbazepine (Trileptal) phenobarbital phenytoin (Dilantin) primidone (Mysoline) topirimate (Topamax)-mild ↓ modofinil (Provigil)	toglitazone (Rezulin) felbamate (Felbatol)	lamotrigine (Lamictal) gabapentin (Neurontin) tiagabine (Gabitril) levetiracetam (Keppra) valproic acid (Depakote) zonisamide (Zonegran) vigabatrin (Sabril) ethosuximide (Zarontin) benzodiazepines
Anti-mycobacterials (used to treat tuberculosis) **WHO, 3**		
Rifampin rifampicin rifamate		INH (not in combination with rifampin)
Others		
St. John's Wort (Hypericum perforatum) – herb		Ketaconazole (antifungal) Fluconazole (antifungal)

Anti-HIVs (HAARTs) The list of drug interactions below can be found in Annex 1 of the 3rd edition of the Medical Eligibility Criteria for Contraceptive Use. **WHO, 2** For information from other sources go to: http://hivinsite.ucsf.edu/arvdb?class_id=12&page=ar-00-02&post=10&submit=Submit or http://www.medicine.iupui.edu/flockhart/table.htm (Accessed May 2007)

↓ Steroid levels/ ↓ Effectiveness May ↑ side effects		↑ Steroid levels/ No efficacy concern		
No effect on HAART	**No data on HAART**	**No effect on HAART**	**No data on HAART**	**Reduces HAART Levels**
Nevirapine	Nelfinavir Ritonavir Lopinavir/Ritonavir	Efavirenz	Indinavir Delavirdine – ? ↑ steroid levels	Amprenavir

Saquinavir levels do not change when a contraceptive steroid is added but there is no data regarding contraceptive effectiveness when combined with Saquinavir.

*** Table created for use by Planned Parenthood of Western Washington**

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4. Egberg, N, van Beek, Agaath, Gunnervik, Christina, Hulkko, Seppo, Hirvonen, Erkki, Larsson-Cohn, Ulf and Bennink, Herjan Coeligh. Effects on the Hemostatic System and Liver Function in Relation to Implanon® and Norplant®. A Prospective Randomized Clinical Trial. Contracteption 1998;58: 93-98.

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Intrauterine Device (IUD)

Overview

Intrauterine placement of a foreign body has a long contraceptive history. The current devices consist of a plastic frame with either a copper (T380A) or progestin (LNG IUD/Mirena®) added to the design. Both copper and progestin change the endometrium and cervical mucous to interfere with sperm motility and prevent fertilization of the ovum. Only when the copper IUD is used as an EC (emergency contraceptive) and inserted after fertilization does it act to possibly interrupt implantation. Although there have been no recent studies and if there is a true concern, it would be prudent to prescribe ECP as a back up measure. The primary contraceptive effect is to prevent fertilization. The IUD efficacy is one of the best of all the reversible contraceptive methods (failure is 1/200 in the first year and 1/500 after that) and it does not depend on compliance. However, all IUDs have a risk of expulsion (T380A is 2.3% in the first year and LNG IUS is 4.9% over 5 years) and 10% to 20% of the time this can be without symptoms (bleeding, pain, and vaginal sensation of string or device). Overall, if the IUD is in place, it is reported to be as effective as female sterilization.

Who May Use an IUD?

The ideal IUD user has been described as age 25, multiparous, monogamous, and having no dysmenorrhea history. However, many women may not be "ideal" yet may still choose the IUD as their contraceptive method. Diabetic women may use the IUD, due to their increased risk of cardiovascular disease; the IUD is a better choice than estrogen containing contraceptives. The copper IUD may also be placed 5 days following unprotected intercourse to prevent implantation as an emergency contraceptive.

Benefits

- Reliable long term reversible contraception;
- No interference with sex;
- If copper IUD used then no hormonal effects and women would have the same menstrual cycles as if no contraception were used;
- Progestin LNG IUD releases a very low dose so few systemic side-effects. The Mirena®, the new levonorgestral IUD, contains 52 mg Levonorgestrel (LNG) and releases 20 mcg every 24 hours with only ½ of this absorbed into the serum, or about 10 mcg of LNG systemic exposure, which is 1/10 the progestin dose found in the current 20 mcg LNG birth control pill.
- Low cost. If the Copper IUD is used for 10 years it is the cheapest contraceptive method available.
- The T380A IUD is labeled for 10 years of use. But a large study suggests it could be used up to 12 years. (*Longterm Reversible Contraception*. 12 years experience with the T380A and Tcu220C. World Health organization. Contraception 1997;56:341-52). They studied 1396 women with the T380A for 7159 woman years with a failure rate of 1.9% and no pregnancy after 8 years of use up to 12 years of observation. However, clients choosing to use after 10 years need to understand the failure rate may increase to 1-2% depending on if the copper has dissolved, which can only be determined if the device is removed. It is best to individually counsel the patient. A woman over 35 has decreased fertility and use up to 12 years may be a choice if consented (**Birth Control Method Specific Informed Consent**

Form). The LNG IUD is effective for 5 years and in women older that 35 at insertion, it could work for 7 years.

- The LNG IUS, because of the progestin, will induce endometrial atrophy, prevent hyperplasia and endometrial cancer. It has been used in women on tamoxifen and even as a treatment for hyperplasia or menorraghia.

Absolute Contraindications

- **Uterine anomaly** since the IUD relies on a normally sized uterus for contraceptive effectiveness. The uterine cavity must be able to accommodate the IUD so the uterus must sound to between 6 to 9 cm in depth. If a woman has a bicornuate or two uterine horns she would need a device in each cavity to ensure adequate exposure of the endometrium to copper or LNG (although this has not been studied) and likely there would be a higher rate of insertion difficulty and expulsion.
- Active **cervicitis or vaginitis** infections need to be treated prior to insertion.
- **Silicone, levonorgestrel, or polyethylene allergy** if LNG IUD to be used.
- **Wilson's Disease or Copper allergy** if an IUD containing copper is to be prescribed. These allergies are rare but have been reported with IUD use and resulted in systemic symptoms and rash. Copper allergy can be pre determined with appropriate skin testing. (Contact Dermatitis 1985; 13:343)(Ann Allergy 1978; 41:194)
- Undiagnosed vaginal bleeding with suspected **uterine or cervical malignancy** if treatment may be a hysterectomy, since contraception is then unnecessary.
- **Pregnancy and/or suspected fertilization**. The Copper IUD can be used as an EC if inserted within 5 days of the unprotected intercourse but ECP should be prescribed as well to maximize pregnancy protection. A negative HCG on the day of insertion must be documented, and the client must return in 2 weeks to repeat the pregnancy test as there is a risk of ectopic gestation with an IUD.
- **Anemia** with hematocrit less than 32% unless inserting the LNG IUD and in that case the LNG IUD can be a treatment for anemia. The copper IUD may increase the menstrual flow by 2 days and 1 pad or tampon in some women but others notice no difference.

Relative Contraindications

The following conditions need documentation prior to insertion. Counseling and documentation needs to be done regarding the risks or possible consequence of IUD insertion and usage. The **Birth Control Method Specific Informed Consent Form** should be completed when indicated.

- **History of ectopic gestation**. IUDs are better at preventing intrauterine pregnancies and a woman with a history of an ectopic already has a 1 in 12 chance that a pregnancy could be ectopic and women using the IUD, if a failure have a 30-50% risk of that failure or pregnancy being ectopic in location. However, the best prevention of an ectopic pregnancy is to use effective contraception and the IUD may be used in these women but the women needs to know if she thinks she is pregnant to see care immediately as her risk for an ectopic is quite high.
- If menorrhagia, metrorrhagia, or severe dysmenorrhea, consider LNG IUD.
- **Known abnormal pap** not yet treated or evaluated because if cancerous, than a hysterectomy would obviate the need for contraceptive. Consult with the Family Planning Medical Director prior to insertion if there are questions.
- **Immunodeficency disease**, HIV, cancer chemotherapy, or chronic high dose steroids (oral cortisone 20 mg or more daily). These women should not have copper IUDs and only the LNG IUD if uterine bleeding treatment needed. There is no proof that the use of the IUD

leads to systemic infection or a worsening of an immune disease but these are labeled contraindications and documentation of the discussion of theoretical risk needs to be performed.

- **Anticoagulation** therapy, platelet disorders, or any condition reducing the client's ability to make clots if using the copper IUD. It has been reported that use of the LNG led to a worsening of menorrhagia with Von Willebrand's which is a disorder of platelet function found in 1% of the population, 75% of cases are mild and can be treated with OCP, avoidance of NSAIDS, and occasionally intranasal desmopressin. (Obstet Gynecol 2005; 105:1223-6)
- **Multiple sex partners**, or partner with multiple partners since the risk of acquiring PID is greater and may mean removal of the IUD to evaluate pain complaints or if no improvement with antibiotics after 2 to 3 days, may need device removal to treat PID. The IUD does not prevent sexually transmitted infections.
- **Nulligravidity** (no prior pregnancy). Intrauterine contraception is generally not the method of choice for the woman who has never been pregnant. Reasons include risk of infection, infertility, severe pain or syncope, and a higher risk of IUD expulsion.
- **Age greater than 50** because it is unlikely there will be more than a few years of fertility, it is not cost effective and the insertion may be more difficult. However, older women may not be good candidates for hormonal contraceptives and the IUD may be her only contraceptive choice. In addition, if a woman is choosing the LNG IUD and is planning to use HRT when she is menopausal, this IUD could be beneficial.
- Already **has an IUD** but it is either an **unknown type** or known to be un-medicated (i.e. Lippes loop). Clients need to know old un-medicated IUD's have higher failure rates although if only a few years of fertility left it may not be as beneficial to change. An x-ray can help determine the type of IUD and if unable to determine it may be prudent to switch (consult Family Planning Medical Director).

Types of IUDs:

- **TCu-380-A (ParaGard)** - Available 1988 to present, life span 10 years and could use up to 12 years if consents, contains copper, 2 thin, white strings.
- **Levonorgestrel IUD (Mirena®)** - owned by Berlex, FDA approved 12/2000 2 stiff dark brown strings, releases 20mcg of levonorgestrel every day, compared to Copper IUD in one study fewer PID infections, amenorrhea in 20% of users, 90% menstrual volume reduction for some women, is indicated for use in anemia and women with menorraghia. Life span is labeled as 5 years but it has been shown to be active for 7 years in women older than 35 at insertion.
- **Progestasert** - Available 1976 to 2001, life span is 1 year, contains progesterone, 2 thin, blue-black strings. Failure rate was 3% to 5%.
- **Lippes Loop** - Available 1964 to 1985, life span indefinite, all plastic, 1 thick or 2 thin strings, A: blue, B: black, C: yellow, D: white.
- **Saf-T-Coil** - Available 1967 to 1983, life span indefinite, all plastic, 2 thin, green strings.
- **Copper-7 (Cu-7)** - Available 1973 to 1986, life span was 3 years, contains copper, 1 thin, black string.
- **Copper-T (TCu-200)** - Available 1976 to 1986, life span 4 years, contains copper, 2 thin, various (often light blue) color strings.
- **Dalkon Shield -** Available 1970 to 1975, life span was indefinite, all plastic, 1 thick, black string with knot. Remove due to risk of PID.

History
The standard medical history should include menstrual, STD, partner, pregnancy, mode of delivery, ectopic pregnancy, uterine anomaly or surgery, and allergy history. **The IUD Insertion Procedure Chart Form** is to be used for all PHSKC insertions to document appropriately.

Examination
Prior to IUD insertion the client needs to undergo a pelvic examination to confirm no cervicitis, vaginitis, or uterine anomaly detected. On the day of insertion, a baseline pulse and blood pressure should be recorded.

Lab Tests
A normal **Pap test** should be recorded on the chart within the past year. IUD use does not cause abnormal cervical cytology but treatment for abnormal cytology may be more difficult with an IUD string within the cervical os. If there is a possibility of exposure or risk, then a **gonorrhea** and **chlamydia** test should be done one to six weeks before insertion and results recorded on chart. A **wet mount and vaginal pH test** should be performed prior to insertion and if bacterial vaginosis is diagnosed, it should be treated before insertion, even if asymptomatic. If there are any concerns, pregnancy testing needs to be performed on the day of insertion to document a negative **HCG test** as well as a follow up test two weeks later if any instances of unprotected intercourse are reported. A recent **hematocrit or hemoglobin** result, within one to two years of insertion date, should be documented if a history of heavy menses.

IUD Consent Process
The screening history, examination, laboratory tests, and consent form are reviewed with the client prior to the insertion visit. The consent brochure from the manufacturer should be sent home with the client prior to insertion. To document counseling the **IUD Insertion procedure Consent Form** is signed for the procedure risks and the manufacturer or **IUD Device Consent Form** supplied with the IUD package is signed for the device risk. Key points should be emphasized and documented using the **IUD Insertion Procedure Chart Form**. If necessary, the **Birth Control Method Specific Informed Consent Form** needs to be signed at insertion and at every annual visit. This allows documentation that the high-risk user was offered other contraceptive methods or removal every year.

Manufacturer's Brochures
The manufacturer's brochure must be read by all potential patients interested in either the T380A or LNG IUD. The ParaGard T380A Manufacturer's Brochure is available to print from the Family Planning website. The brochures can also be ordered from the Paragard website at http://www.paragardiud.com/pi/index.htm. Manufacturer's brochures for the Mirena LNG IUS can be obtained by calling 1-888-BERLEX and speaking to a representative or by talking to the sales associate assigned to the facility or email request with complete delivery address to mirenabooklets@yahoo.com. If specified Spanish versions of the materials can be obtained as well.

Time of Insertion
Insertion during the first seven days of the menstrual cycle is preferable because the cervix is more open and an early pregnancy is less likely. However, research has shown there can be fewer expulsions and insertion infections when the IUD is placed later in the cycle. So there is no requirement that the IUD be placed during the menses as long as absence of pregnancy can be documented or counseling provided about the IUD acting as an emergency contraceptive and

plans made for pregnancy testing in 2 weeks following insertion. If unprotected intercourse is reported within the previous five days consider prescribing ECP or even rescheduling if multiple episodes of unprotected intercourse have taken place and there is concern about the possibility of pregnancy. The LNG IUD has not been proven to work as an EC to prevent implantation and should only be used as such with careful informed consent and in combination with ECP. The LNG IUD takes up to seven days to change the cervical mucous and therefore if it is not inserted in the first seven days of cycle, then a back up method for one week is necessary (pelvic rest advised, so abstinence for 1 week should be enough). If the client has been using Mirena, low dose OCPs, DMPA, or cervical stenosis is suspected consider having the client use a COC with 30-35 mcg EE for 1-2 cycles and then plan the insertion during the withdrawal week which can be scheduled by asking the patient to stop the OC 2-3 days prior to the insertion.

Preparation for Insertion

Advise the client to take ibuprofen 600 mg or another NSAIDS medication 1 to 2 hours prior to the insertion. The client should eat within 4 hours of the procedure, as it will minimize their nausea if they have a vasovagal reaction and ibuprofen taken on an empty stomach will cause nausea. Doxycyline 200 mg or Azithromycin 1 gm one hour prior to insertion has been studied and it has not been shown to decrease IUD insertion infections however some providers may choose to use a single dose as antibiotic prophylaxis. If the client normally has antibiotic prophylaxis to prevent bacterial endocarditis, such as when she has dental work done, then she may want the same antibiotics prior to IUD insertion, usually amoxicillin 2 grams one hour prior to the insertion. The American Heart Association states that no antibiotics are necessary for IUD insertion *(JAMA 1997; 227: 1794-1801)*, however, some patients and providers insist on using prophylactic antibiotics. If necessary, consult the list below.

1997 AHA Prophylactic Regimens

- Amoxicillin 2.0 gm PO 1 hour prior to procedure
- Ampicillin 2.0 gm IV or IM 30 minutes prior to procedure
- Clindamycin 600 mg PO 1 hour or 600 mg IV 30 minutes prior to procedure
- Cephalexin 2.0 gm PO 1 hour prior to procedure
- Azithromycin 500 mg PO 1 hour prior to procedure
- Cefazolin 1.0 gm IV 30 minutes prior to procedure

It is estimated that 5 to 15% of the USA population is allergic to penicillin and about 8 to 10% of those individuals are also allergic to cephalosporins. If respiratory problems or swelling/hives are reported with penicillin use, then use non-penicillin medication or no prophylactic.

IUD Insertion Procedure

Use the list at the back of this chapter for how to stock and set-up the equipment and supplies which will be needed. IUD insertion may be done by non-physician providers specifically approved by the Family Planning Medical Director using the IUD Insertion Skills Documentation Form. The providers are trained to insert IUDs during supervised insertions with the Family Planning Medical Director who will then decide what further training is needed. The provider is responsible for completing the IUD Insertion Skills Documentation Form, which is then to be given to the site supervisor who will keep it as part of the employee's file. If any insertion procedure is felt to be too difficult then the provider is strongly encouraged to stop the procedure and allow the Family Planning Medical Director to reassess the patient and perform the insertion. All nulliparous clients are to be inserted only by a physician or the Family Planning Medical Director. Only prepackaged, sterile devices will be used and the lot number and expiration date recorded on the chart and the **Pharmacy Implant and Intrauterine System**

Log. A paracervical block could be provided to the patient for the insertion if the provider has been trained. If a paracervical block is to be done, document the patient has no lidocaine allergy, chart the procedure on the procedure form, use the IUD set-up instructions, and infiltrate no more than 20 ml of 1% lidocaine solution divided and injected at the cervical tenaculum site and at 4:00 and 8:00 of the paracervical vaginal reflection. For all IUD insertions, a support staff should attend the provider as an assistant and in case of an emergency. All sites providing IUD insertion procedures need to insure ammonia inhalant and emergency resuscitation supplies, including atropine is readily available and these emergency procedures are using the PHSKC emergency protocols in addition to these. Verify and document if any allergy to the antiseptic and if allergic to both betadine and hibiclens then use no antiseptic.

IUD Insertion Procedure Sequence

The typical sequence of events for the insertion procedure include the following:

- Bimanual exam to assess for nontender non enlarged uterus and position.
- Speculum to visualize cervix and antiseptic swabbing of ectocervix.
- Change gloves to sterile gloves, load IUD if easy insertion anticipated.
- If risk of intolerance to sounding or stenosis then wait to open IUD package.
- Tenaculum to cervix (anterior if anteflexed, posterior if retroflexed).
- Uterine sound passed, slow gentle pressure, depth measured.
- IUD package opened and loaded (if not already) and inserter guard depth set.
- Insert IUD.
- Cut strings.
- Remove speculum, observe for 5-10 minutes.
- If abnormal pain consider removal of the IUD as it may be malpositioned or has uterus intolerant to the device (still bill for procedure and device since these were performed).
- If perforation of the uterus occurs do not insert the device, monitor vital signs, hematocrit, and consider emergent referral to a hospital. Often midline uterine perforations do not require surgery, yet it is possible if there is bleeding or hemoperitoneum surgery may be needed. Do not insert the IUD device if perforation is suspected. If perforation is later diagnosed and the IUD is outside of the uterus, referral for surgical removal is needed because both the copper and the LNG IUS can increase inflammation, adhesions and possible bowel perforation. (Human Reproduction 2003; 18:990-3)

Insertion Documentation

The **IUD Insertion Procedure Form** is to be used. The outside of the chart is then labeled to denote that the client's chart needs to be kept for the life of the device or 15 years from the insertion date for medicolegal reasons (with the Unique Retention Stickers). The **Pharmacy Implant and Intrauterine System Log** should be kept on site to record the lot number and patient, should a recall occur.

Post-IUD Teaching and Instruction

- Instruct the woman in the importance of feeling for the IUD strings after each menses and teach the technique prior to leaving the clinic. Strings should be lightly touched and not pulled on. If the partner reports feeling strings then instruct to see the provider back. If cut too short it can be like a bristle but also if too long they can be more irritating. Rarely, it may be needed to cut the strings to just inside the external cervical os and this should be documented so later removal technique can accommodate this change.
- Tampon use will not remove the IUD.
- Pulling on the strings can remove the IUD or dislocate it from the fundus, and cause method

failure.

- Expulsion of the device occurs in 3 to 5 % of users, luckily many of these are symptomatic (pain, bleeding, frame felt with finger or sensation in the vagina of longer strings). More frequent string checking is indicated in the first few cycles and follow up visit should be scheduled for 6 weeks after insertion to perform an exam and assess for problems or expulsion.
- Remind women that irregular bleeding is common for first 3 months with LNG IUD use and amenorrhea can happen to 20% of women by one year of use and to up 60% of women after 12 years of continuous use of this method (new device at 7 years). The copper IUD may increase the menstrual period on average by 2 days and volume by 50% in some users.
- If cramping is bothersome, recommend an analgesic such as ibuprofen, aspirin, or acetaminophen;
- Suggest use of iron-rich diet and iron supplements as indicated for Copper IUD users. The **Iron in the Diet Patient Handout** is available if needed.
- Advise no vaginal penetration for 1 week post-insertion.
- Advise back-up contraceptive method if sex sooner than 7 days post insertion, especially if not inserted in first seven days of menstrual cycle.
- Remind users that if pregnancy happens, 1/3 to 1/2 can be ectopic, so early medical consultation is important.

Follow-Up Visits

Pelvic examination 6 weeks following insertion, preferably after the next menstrual period, offers the best chance of detecting an early expulsion. It is also important the client report back at the follow-up exam any detection of the IUD strings by her partner during coitus. The LNG IUD strings have been impregnated with iron for easy visibility but also may be a little stiffer and it is important at insertion that strings be left long enough to curl behind ectocervix to prevent pelvic discomfort.

Long Term Follow-Up

The Copper T380A device should be replaced every 10 years unless the woman consents to keep it for 12 years and signs the **Birth Control Method Specific Informed Consent Form**. The Mirena®/LNG IUD device must be replaced every 5 years. A woman older than 35 at insertion may choose to keep the LNG IUS for 7 years if she signs the Birth Control Method Specific Informed Consent Form. If a woman with a T380A is in her 10th year of use and she is over age 45, it is probably better not to subject her to an IUD change (new device). Decreased fertility due to age as well as the continued effectiveness of the IUD will likely make a change unnecessary, however consultation with the Family Planning Medical Director may be appropriate. All women need their IUDs removed at menopause, except LNG IUD users who could choose to keep for endometrial cancer prevention if using ERT, but this is a decision she would make with her regular provider that will assume her health care at menopause. Although the LNG IUD/Mirena® was not labeled for HRT use, it has been used effectively for this purpose. Insertion or use of the LNG IUD for HRT is not to be done by the Family Planning program. Annual pap tests and pelvic exams are recommended for all IUD users.

Side-Effects and Complications

Adverse Reaction during Insertion: Consult the site PHSKC Administrative Guidelines in the Emergent Section. IUD insertion may produce enough pain and vasovagal stimulation to result in syncope, cardiac arrhythmias, seizures, or even cardiac arrest. These are rare events, but

the client should lie on the exam table until she feels capable of standing, and then be requested to wait in the clinic for at least 10 minutes post-insertion. If any dizziness is reported, the client's blood pressure should be checked, and if significantly lower than pre-insertion, she should rest in the clinic until it is back to normal. Sometimes ammonia inhalant can be used to help make the patient aroused while vital signs are taken and preparation for atropine is done.

If severe syncope occurs (BP under 70 systolic or pulse under 50):

- **Call for help.**
- Don't leave client unattended.
- Place client in shock position.
- If symptomatic bradycardia (pulse 40 or less), administer atropine 0.4-0.5 mg in a subcutaneous injection. Can repeat in 5 minutes if no response.
- Remove IUD if symptoms persist.
- If asystole, begin CPR, administer epinephrine SQ (0.5 ml of 1/1000), call 911.

Bleeding starting soon after insertion: Rule out anemia, infection or pregnancy. Consult anemia guidelines. Naprosyn 500 mg BID for 5 days or Ibuprofen 400 to 800 mg three times a day for five days may help diminish blood loss if begun before menstrual flow like on the first day of the menses. NSAIDS will decrease the release of prostaglandins and that will in turn decrease blood loss by 50% in some studies. Reassure the client that bleeding usually decreases after a few months. If the bleeding is between menses, check for infection and pregnancy. An empiric trial of metronidazole 500 mg BID for 14 days is reasonable to try because a subclinical endometritis can cause persistent spotting. However if the bleeding continues at 6 months post insertion, then referral to primary care or gynecology clinic is suggested for possible pelvic ultrasound and endometrial biopsy to see if hyperplasia, submucous uterine fibroids, or other etiology such as a platelet or coagulation factor disorder is present.
Cramping or pain: Pain associated with insertion or dysmenorrhea may be relieved by ibuprofen or other medication. Cramping during the first three months post insertion is common and is probably due to uterine muscle spasm. Check for possible perforation or partial expulsion by bimanual pelvic exam to assess for pain and looking at the string length. If the IUD is partially expelled remove the IUD and replace with a new IUD as appropriate. Rule out infection such as PID and perform a pregnancy test if any concern over irregular bleeding or missed menses. One-third to ½ of pregnancies in IUD users are ectopic.

Missing IUD Strings:

- May be due to expulsion, pregnancy, or perforation of the uterus or retraction into the nonpregnant uterus. Tell the woman to use an alternate method of contraception and come into clinic for an exam. If her period is late, she should come in emergently.
- When the client comes into clinic often the strings may be visible in the cervical os. If no strings are visible, insert the IUD string retriever or cytobrush gently into the cervical canal to feel for the IUD strings. Do not go into the uterine cavity unless the client wants the IUD removed because entering the uterine cavity may disrupt or cause an infection of the device.
- If the IUD strings are located, the strings may be fished through the os. If they cannot be found, the client should be referred for pelvic ultrasound to localize the IUD in the intrauterine cavity. The strings are not essential to contraception and many IUDs used in other parts of the world do not have strings. A client wanting ongoing contraception does not need to have strings to use the IUD and after confirmation by ultrasound or x-ray she should be advised additional imaging is not needed unless a change in menses or pain.

- To remove an IUD without strings use an IUD hook or alligator clamp or if the provider has not been trained to perform an intrauterine removal, then refer the client to the Family Planning Medical Director for removal.
- If the frame of the IUD is in the cervical canal, the IUD must be removed, as it will not provide contraception and is probably causing pain.

Expulsion occurs in about 3% to 5% of women over the lifetime of the device. If the IUD has been expelled a new IUD may be inserted if client desires, using the same guidelines as used for all insertions. Because there has been one expulsion, the risk of a second expulsion is slightly higher but often the reason for the expulsion was lack of fundal placement or uterine spasm. If this is a good method for the client, then it is worth a re-insertion. If it has been less than 90 days from insertion, then apply for a refund using the IUD Refund Pharmacy Request Form even if the device was lost, because the program can get either a refund or a replacement system.

Pregnancy with a device in situ: The possibility of ectopic pregnancy must be considered. In the event of an intrauterine pregnancy the IUD should be removed as early in pregnancy as possible if the strings are visible. This measure will decrease the risk of infected abortion. However, if the pregnancy is beyond ten weeks and the strings are still visible, refer for an emergent pelvic ultrasound to rule out a placenta previa or the possibility that the IUD is implanted in the placenta. If the IUD strings are not visible when pregnancy is detected, recommend referral for emergent ultrasound examination and gynecology consult, as the IUD removal will probably be complicated or not possible. The LNG IUD has not been associated with birth defects according to the package label but it does release hormone and best to not expose a pregnancy. IUD removal, if an abortion is planned, can be referred to the physician performing the procedure. If an ectopic pregnancy is diagnosed with an IUD in place, the IUD should also be removed as it is likely it is ineffective since pregnancy happened.

Uterine infection: A large study of IUD's and infection found 1 in 1000 women getting an IUD get PID in the first 20 days from the insertion. After that time, PID is not the result of the IUD but of being exposed to an infection. The IUD does not increase pelvic infections but the presence of a foreign body may complicate treatment and if the infection has not improved with antibiotics in 72 hours, the IUD should probably be removed after consultation with the Family Planning Medical Director.

Mucopurulence: It is common to see cellular debri, calcifications, and even purulence associated with the IUD string at the ecto cervix. The strings are a foreign body and stimulate a response. If the woman is asymptomatic there is no need to do anything unless chlamydial screening is indicated. If the woman is symptomatic cutting the string to inside the external cervical os may be needed as it is unlikely antibiotics can treat the string. Symptomatic (pain or bleeding) then consider frank cervicitis, PID, partial expulsion, or even pregnancy as an alternative diagnosis.

***Actinomyces* on Pap Test:**
Actinomyces species are normal inhabitants of the human gastrointestinal tract, in both the oropharynx and the bowel. Under ordinary circumstances, *Actinomyces* species do not cross mucosal barriers. The asymptomatic patient may choose to keep the IUD if the *Atinomyces* is persistent (2 paps 12 months apart) and understands this could lead to a serious infection if not treated early so important to return if bleeding or pain. When removal of the IUD is done, no culture of the device is needed and re-insertion of a new device two to six weeks later without a

repeat Pap test is acceptable. *Actinomyces* is a rare problem. These bacteria can be found in many women not using the IUD, and changing the IUD is often more risky than following the asymptomatic woman. Consult the Family Planning Medical Director in these cases.

Condition	Action
Pap smear showing Actinomycosis-like organisms:	
a. No symptoms (no abnormal bleeding and no uterine pain on examination)	• Repeat the pap smear in 1 year • If *Actinomyces* are present on the repeat pap smear: a) Remove the IUD, wait one menstrual cycle and re-insert another IUD (give the patient alternative contraception during this time) b) Treat the patient with the IUD in place: give doxycycline 100mg bid for 14 days, then repeat the pap smear in 3 months c) Do nothing, and have the patient return if she develops symptoms of PID or bleeding between periods
b. Symptoms of PID present	• Remove the IUD after pre-loading the patient with an antibiotic (amoxicillin 500mg tid for 14 days) • Treat the PID • If the infection is severe, hospitalize the patient • Consider an ultrasound to rule out an abscess

Adapted from Contraceptive Technology, 17th edition, page 539.
Peipert JF. Actinomyces: normal flora or pathogen. Obstet Gynecol 2004;104:1132-3.

Removal of the IUD

- Removal is indicated if the IUD failed and pregnancy occurred. For example, an ectopic pregnancy with an IUD, even if treated medically, the IUD needs to be removed or at least replaced.
- This may be necessary because of severe cramping, bleeding, infection or simply on request.
- All women entering menopause after about six months of amenorrhea should have their copper IUDs removed, as it is easier to do before the loss of estrogen. The LNG IUD can be used in menopause so a woman could choose to keep it if it has been less than seven years of use. Any other postmenopausal woman seen with an IUD in place should have the IUD removed if it can be done in the clinic.
- It is safer and easier to remove the IUD during menses, but the device may be removed at other times in the cycle if indicated. Removal midcycle could permit implantation of a fertilized ovum that is in the fallopian tubes at the time of removal. If removed after day 7 of the cycle there is a very small risk (about 1% on day 14) of method failure from coitus within 72 hours prior to removal and ECP might be considered. For this reason, a woman could begin a hormonal contraceptive method one to two weeks prior to planned IUD removal.

- If a woman is planning to get pregnant it is prudent to advise her to wait till after one menstrual cycle to regenerate an endometrial lining without any copper or LNG exposure before conception is planned. Although there is a no evidence this is necessary or evidence of increased rates of miscarriages. Evaluate the need for prenatal vitamins with the patient.
- Grasp the strings with a forceps and apply gentle steady traction. If removal is difficult, a sound may be placed in the endocervical canal for about 30 seconds to effect dilation. If removal is still difficult, the client should be referred to the clinic physician.
- Refer women with an IUD without a string to the Family Planning Medical Director for removal with an IUD hook or a long straight alligator forceps if the provider has not been trained to use the hook or forceps.
- If there is early removal or expulsion of the device before 90 days, the IUD Refund Pharmacy Request Form should be completed and the clean but used device should be returned to the vendor representative directly as soon as possible and within 3 months of the event so the clinic can get a replacement IUD kit. This possible replacement kit benefits the program but not the client as we have no guarantee of a replacement and charges cannot be refunded or reversed because an insertion procedure was still performed and product used.

The Berlex Company, makers of the Mirena® or LNG IUS provided a grant to the ARCH Foundation, Patient Assistance Program for Mirena, P.O. Box 220908, Charlotte, NC 28222-0908, phone 877-393-9071, and fax 704-357-0036, to provide free LNG IUS to women unable to pay for the device. The woman must complete the ARCH Mirena Form by printing this form from the ARCH Foundation website: http://www.archfoundation.com/Application.htm verifying she has no insurance coverage for the device and that she meets the financial eligibility criteria. The form is faxed to the ARCH Foundation and a device is mailed to the site usually within the week. The Paragard company (FEI Women's Health runs www.paragard.com) also has a patient assistance program (1-800-322-4966) and the form is posted on the PHSKC website Paragard Patient Assistance Program Form. If the patient is going to use a device supplied by the company through an assistance program then it is important that the encounter form note this by a specific billing code and keep the originals of the application form in the chart to document this was done.

IUD INSERTION SET-UP & PREPARATION

Supplies needed:

IUD insertion instruments, pre-packaged and sterilized to include:

- Single tooth tenaculum with 2x2 gauze clamped between the teeth
- Medium Graves metal speculum
- Uterine sound with gauze or material wrapped around the pointed end to prevent piercing of paper and kit contamination
- Ring forceps
- Scissors – preferably long handled and monitor sharpness
- 4 long cotton swabs and 2 small swabs for the endocervical canal, all with tape over the ends of shafts to keep from tangling (Antiseptic is poured over the swabs)

Blue pad (or some absorbent pad) for exam table end
Sterile gloves
Betadine solution
Exam lubricant to do bimanual exam
Working gooseneck or standing lamp
Sanitary pad for patient
Do Not Purge sticker
IUD package, patient sticker applied to Pharmacy Implant and Intrauterine System Log and record lot number, expiration, and insertion date. Record this information on procedure form as well.

Supplies if paracervical block

1. 1% lidocaine no more than 10 ml, use 18G needle to draw up into 10 ml syringe
2. Stainless steel 3 inch metal needle extender sterilized
3. 25G 1 ½ inch needle

Supplies for IUD removals or complicated insertions:

Ring forceps is the only instrument needed if a string is visible. For difficult removals, an IUD hook, string finder or cytobrush, alligator clamp, and tenaculum should be available. For cervical stenosis schedule during menses and if necessary use a method with estrogen to time the period. In rare cases it may require use a 4-5 / 5-6 metal Hegar dilator if trained for this.

When putting patient into the room, make sure:

1. Pregnancy test is negative and documented on FP Flow Chart.
2. Weight, BP, pulse, and LMP documented on procedure form and FP Flow Chart.
3. Query about any UPIC in the past two weeks.
4. Lot number and expiration date of the IUD kit written on the form prevents the insertion of IUD kits that are expired.
5. All supplies laid out on the counter and Mayo stand covered with paper drape.
6. IUD consent form and procedure form labeled and 2 holes punched at the top. Forms on top in chart. Verify patient has a copy of the manufacturer brochure in appropriate language and has read it, if not, get a copy to her.
7. "Unique Retention sticker" on counter ready to put on chart if insertion done.
8. Make sure crash cart on site, specifically ammonia inhalants and atropine if the patient faints and or experiences a vasovagal reaction.

Lactational Amenorrhea Method

Breastfeeding should be encouraged and supported by the family planning program. Many women can breastfeed and providers need to query regarding lactation in any woman with infants or small children. The American Academy of Pediatrics recommends babies be exclusively breastfed for the first six months of life. But the national average for mothers who meet this goal is very low at 14% according to a CDC report in 2004. Breastfeeding can prevent diarrhea, ear infections, and respiratory infections in the child. Breastfeeding can reduce a woman's relative lifetime risk for breast cancer (Lancet 2002; 360: 187-95). Lactation will burn calories and help the woman return to her pre-pregnancy weight. Consult the PHSKC obstetrical guidelines regarding specific lactation questions.

The Lactational Amenorrhea Method (LAM) is an effective contraceptive method. Lactational amenorrhea is by definition a woman who is breastfeeding her child and has amenorrhea. For up to the first 6 months post partum, this method can be 99% effective. To be considered 'fully breastfeeding,' a woman should breastfeed on demand with no nipple or nutritional supplementation to the child (no pacifier, bottles, or cereal). Usually the breastfeeding occurs at a minimum of every 6 hours. It is not known if pumping the breast manually provides the same degree of feedback and ovulation suppression.

Because ovulation can occur before the menses resumes, it is prudent to begin another contraceptive method at 6 months post partum or sooner is someone is not fully breastfeeding. It is also possible to have ovulation happen prior to menstruation and this is common in the setting of LAM and for this reason after 6 months additional contraception should be practiced.

Estrogen in the birth control pill can sometimes suppress milk production so progestin only or non-hormonal methods are best until milk production is well established but this can be as early as 6 weeks post partum. In fact a recent review (Contraception 2003; 68:233-238) found there was little evidence with current low estrogen dose combination OC's (COC), and if a women had well established lactation she could try the COC and if milk production declined then return to the progestin only method. Effective contraception is important to space children 3 years apart and to allow time for lactation. Remember, any women with LAM, meaning fully lactating and with amenorrhea, likely does not need another contraceptive in the first 6 months.

LAM induces a hypoestrogenic state and it is common to have women complain of introital dyspareunia or genital irritation. Sometimes a water-soluble lubricant is helpful, or if condom use is not needed then a vegetable oil can be used. Rarely, topical estrogen could be used (conjugated estrogen cream, 0.625 mg/dose, apply topically at HS 3 to 7 times a week for 1 month, no refills).

Although it is true that most women can breastfeed, there are exceptions. Women who should not breastfeed are those who:

- Take street drugs or do not control alcohol use
- Have an infant with galactosemia
- Are infected with the human immunodeficiency virus (HIV) and live in the U.S. with access to adequate alternative nutrition for their child
- Have active, untreated tuberculosis
- Are undergoing treatment for breast cancer
- Take certain medications
- Women positive for Hepatitis B antigen can breast feed although the infant should be given prophylaxis and vaccination and many women with Hepatitis C infection can also breastfeed provided the viral titers are low. Specific risk assessments for individual patients should be done by the primary care or obstetrical and pediatric providers and not family planning.

Taking Medications While Breastfeeding
Approximately 10% of drugs are passed into breast milk. Advise clients to minimize drug exposure while lactating. Women can discard their milk, if necessary, as pumping will maintain lactation intervals, so they have more frequent feeds which will help prevent sequestration of the drug in the milk. Also, women can ingest the medication while breastfeeding, because milk is made constantly it may decrease infant exposure to peak drug levels.

Antibiotics to avoid:
- Ciprofloxacin
- Doxycycline
- Norfloxacin
- Ofloxacin
- Podophyllin
- Podophyllox
- Tetracycline
- Trimethoprim

Also avoid these antibiotics until infant hepatic maturation (6 weeks post partum) especially if the infant was preterm:
- Sulfamethoxazole
- Sulfisoxazole

Medications Absolutely Contraindicated During Breastfeeding

Medication	Reason
Bromocriptine	Suppresses lactation, may be hazardous to the mother
Cocaine	Cocaine intoxication
Cyclophosphamide	Possible immune suppression; unknown effect on growth or association with carcinogenesis; neutropenia
Cyclosporine	Possible immune suppression; unknown effect on growth or association with carcinogenesis
Doxorubicin	Possible immune suppression; unknown effect on growth or association with carcinogenesis
Ergotamine	Vomiting, diarrhea, convulsions (at doses used in migraine medication)
Lithium	One third to one half of therapeutic blood concentration in infants
Methotrexate	Possible immune suppression; unknown effect on growth or association with carcinogenesis; neutropenia
Phencyclidine	Potent hallucinogen
Phenindione	Anticoagulant; increased prothrombin and partial thromboplastin time in one infant; not used in the United States
Radioactive iodine and other radiolabeled elements	Contraindications to breastfeeding for various periods

(from American Academy of Pediatrics, American College of Obstetricians and Gynecologists for perinatal care, 4th edition. Elk Grove Village, Illinois: AAP; Washington, DC: ACOG, 1997)

Medication Exposures During Pregnancy and Lactation

Every woman in the general population has a 3 – 5% risk of having a child with a birth defect or mental retardation. Birth defects are the leading cause of infant mortality in the United States. Two important factors to consider when assessing the teratogenic potential of a medication are the stage of pregnancy at which the exposure occurred and the amount of medication taken. It is critical to evaluate each exposure on a case-by-case basis in order to give an accurate risk assessment.

If you have a pregnant or breast feeding patient who is currently taking, or considering taking, a medication, the patient needs to be counseled about potential adverse effects the medication could have on her fetus or infant. This counseling needs to be documented in the patient's chart. Providers and patients may contact CARE Northwest toll free at 1-888-616-8484 for consultation regarding possible teratogenics.

Some Human Teratogens: Proven, Possible, and Unlikely

February 2001

From: Shepard TH. Catalog of Teratogenic Agents, 10th ed. Baltimore: The Johns Hopkins University Press, 2001: xxv

Adapted from 10/03 Care Northwest Brochure

Some Known Teratogens

Radiation	Maternal & Metabolic Imbalance	Drugs & Environmental Chemicals	
Atomic Weapons	Alcoholism	ACE inhibitors (benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, quinapril, ramipril, trandolapril)	Isotretinoin (Accutane)
Radioiodine	Amniocenteses (before day 70 post-contraception)		Lithium
Therapeutic radiation			Mercury, organic
			Methimazole
Infections	Chorionic villus sampling (before day 60 post-contraception)	Aminopterin	Methotrexate (methylaminopterin)
Cytomegalovirus		Androgenic hormones	Methylene blue (via intra-amniotic injection)
Herpes simplex virus I / II		Busulfan	
Parvovirus B-19 (Erythema infectiosum)	Cretinism, endemic	Chlorobiphenyls	
	Diabetes	Cigarette smoking	Misoprostol
Rubella virus	Folic acid deficiency	Cocaine	Penicillamine
Syphilis	Hyperthermia	Coumarin anticoagulants	Phenytoin
Toxoplasmosis	Myasthenia gravis	Cyclophosphamide	Tetracyclines
Varicella virus	Phenylketonuria	Diethylstilbestrol	Thalidomide
Venezuelan equine encephalitis virus	Rheumatic disease	Etretinate	Toluene (abuse)
	Sjogren's syndrome	Fluconazole (high doses)	Trimethadione
	Virilizing tumors	Iodides	Valprioc acid

Some Possible Teratogens

Binge drinking	Ergotamine	Primidone	Vitamin A
Carbamazepine	Glucocorticoids	Quinine (suicidal doses)	Zidovudine (AZT)
Colchicine	Lead	Streptomycin	Zinc deficiency
Disulfiram			

Some Unlikely Teratogens

Agent Orange	Bendectin (antinauseant)	Medroxyprogesterone	Rubella vaccine
Anesthetics	Electromagnetic waves	Metronidazole	Spermicides
Aspartame	Hydroxyprogesterone	Oral contraceptives	Video display terminals
Aspirin (but aspirin in the 2nd half of pregnancy may increase cerebral hemorrhage during delivery	LSD	Progesterone	Ultrasound
	Marijuana	Lamivudine	

Lunelle

Overview

Lunelle is the brand name for a combination injection contraception that contains both a microcrystalline suspension of medroxyprogesterone acetate (MPA) (25 mg), a first generation 21 carbon progestin made for slow release, and estradiol cypionate (5 mg). The E_2C is metabolized quickly to 17-B-estradiol with a half life of 4 days so by five half lives or 20 days the E_2C is gone unlike MPA which has a half life of 14 days and is cleared much later. After injection as the estrogen levels fall the woman bleeds 2 weeks later and this becomes her period week, if she gets her shot every 28 $\pm$ 5 days then her period week is typically 2-3 weeks after each shot. It is very effective with a perfect user failure rate of 1 pregnancy per 200 women using Lunelle in the first year. The injection prevents ovulation and suppresses, but does not atrophy the endometrium and monthly bleeding happens in 96% of women, but amenorrhea does happen in up to 4% of cycles. MPA serum levels can persist up to 63 to 112 days, which means ovulation can be delayed after use up to 4 months.

Contraindications

For women with any of the following, Lunelle ***should not*** be injected:

- **Allergy** to Lunelle or Depoprovera in the past. There are chemicals in the injection preparation that can trigger rare allergic reactions.
- **Known pregnancy**, although there is no evidence of teratogenesis in women who inadvertently receive Lunelle early in pregnancy, they could delay entry into prenatal care because they do not recognize the pregnancy;
- Less than **6 weeks postpartum** from a term delivery;
- A **girl that has never had a menses** because estrogen will stop her bone growth. Once menarche is reached, even one menses, then endogenous estrogen levels have begun and exogenous estrogen is safe.
- Undiagnosed **abnormal vaginal bleeding**;
- Known or suspected **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of Lunelle could worsen their prognosis.
- Any condition that could worsen with **increased cerebral fluid** in the **brain** like a meningioma, brain tumor, or pseudotumor cerebri.
- **Use of aminoglutethimide (Cytadren):** This drug used rarely to treat adrenal tumors or Cushing's disease interrupts the synthesis of cortisol, aldosterone, and estrogen by inhibiting cholesterol conversion. The drug induces metabolism of the DMPA, which may reduce the bioavailability of the DMPA, hence decrease effectiveness.

All known **estrogen contraindications** apply to this method because the injection causes serum estradiol levels to become quite high (200 to 400 mg) albeit for only 2 weeks. For women with any of the following, Lunelle, **should not** be injected:

- Women with a **personal history** of a blood clot or **thrombolic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.

- Women with a **first degree relative with a history of thrombosis** that occurred spontaneously (no injury), during OCP use, or pregnancy may have inherited a thrombophilia. If they have **never taken estrogen or had a pregnancy** then Lunelle might trigger a thrombosis or blood clot.
- Women **35 or older who smoke** tobacco. Women smokers aged 35 to 44 may use 20 mcg OC pills only if they sign the **Birth Control Method Specific Informed Consent Form**. But, they cannot use Lunelle, because the high estrogen peak could be dangerous for these women.
- Women **older than 50**, because the risk for thrombosis or breast cancer may be greater that the risk of pregnancy.
- Women with **diabetes and microvascular disease** such as retinal or renal damage proven or suspected.
- Women with **hypertension,** even if treated, have an increased cardiovascular risk with the use of estrogen injection.
- **Active hepatitis with jaundice**, liver failure, and hepatic malignancy
- **Chronic active hepatitis** with abnormal liver enzyme levels. Often the result of a viral etiology likes hepatitis B or C, but also a history of jaundice during pregnancy or chronic liver disease like Gilbert's disease. The high dose of estrogen might not be metabolized if the liver is not working.
- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas, which could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose OC pills have not had this problem but Lunelle with the rapid high estrogen levels could do this.
- In women with **epilepsy**, Lunelle may be less effective due to **seizure medication** (except valproic acid) use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital. Estrogen lowers the seizure threshold in the brain and can increase the number of her seizures and the high estrogen levels could worsen her disease. The IUD or DMPA injections are the preferred hormonal contraceptive methods in women on antiepileptic medications.
- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and could make Lunelle less effective.
- **Chronic medication use** that induces the **p450 hepatic** enzyme system may result in decreased Lunelle efficacy. Examples include some antiretroviral drugs used to treat HIV, troglitazone (Rezulin) an oral hypoglycemic medication, and cyclosporine, an anti-inflammatory drug used for transplant patients.
- Use of **oral antifungal** agents including griseofulvin, ketoconazole, fluconazole, and itraconazole may induce hepatic metabolism and may make Lunelle less effective.
- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days, or a long surgery for greater than two hours which will predispose to thrombosis. Need to discontinue Lunelle use 4 weeks prior.
- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing method because there may indeed be a risk not discussed in the guidelines.

- Known or suspected uncomplicated **migraine headaches**. Have the woman keep a diary of her headaches using the **Headache Diary** and if she notices the headaches are worse during Lunelle use, then discontinue the method. If frequent **vascular symptoms** like blindness or numbness, then refer to neurology if no prior evaluation and do not prescribe Lunelle as it could cause a stroke.
- **Active gall bladder disease**. Estrogen use can worsen stone formation and dilation of the bile ducts and Lunelle should not be used. If they have had their gallbladder removed then there is no risk with Lunelle use.

Precautions

Women with the following ***may be given*** Lunelle if an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Plans for pregnancy within one year:** Client must understand that they may have amenorrhea, irregular menses, and may be unable to get pregnant for 6 to 9 months after the last shot was given.
- **Inability to tolerate irregular, frequent bleeding:** Client must be aware that irregular bleeding is common and expected during the first 3 to 6 months of Lunelle use. The average duration of menses with Lunelle is 6 days and the interval between periods averages 20 days.
- **Inability to make frequent clinic visits**, the injections must be given every 28 $\pm$ 5 days and can not exceed 33 days between shots.
- **Lactation,** although estrogen can decrease the quantity – quality of milk the Lunelle injection because of metabolism may result in less estrogen exposure than a 30 mg COC pill. If lactation is well established Lunelle could be tried after 4 weeks postpartum.

Benefits

- Highly effective
- Has estrogen which could preserve bone density for teenagers, in particular those who are in their peak years to attain bone density.

When to Administer

When beginning Lunelle, it is best to administer the first dose within five days of the onset of menses, so the woman will be fully protected from the time of the injection. If Lunelle is given more than 5 days from the start of the cycle, ovulation can occur. Lunelle will not act as an Emergency Contraception to prevent implantation because, with the slow release of progestin, there is no high progesterone dose effect. It takes one week for the progestin effects on the cervical mucous and endometrium to be established. Lunelle can be given at the time of abortion, both first and second trimester.

Women not sexually active, consistently using oral contraceptives, using an implant or an IUD may have an injection at any time in the month. For other women, the first injection can be that day only if a negative UCG test is documented and the **Contraceptive Revisit Form** is used documenting that the woman agreed to use a back-up method for two weeks, understands the possible risk of false negative HCG test if unprotected sex in last 11 days, and agrees to return for a four week follow-up pregnancy test.

Postpartum Lunelle should not be given until 6 weeks postpartum to avoid increased thrombosis. Lunelle will also suppress milk production and should be avoided with lactation.

History and Examination

The standard **Medical History Form** should be used and reviewed for risk factors. The physical examination is performed and recorded to include weight, blood pressure, cervical, breast, and pelvic examination. If delayed pelvic option is used, the pelvic must be done prior to the ninth injection or after 9 months of use or else they must sign the **Birth Control Method Specific Informed Consent Form**, using the Delayed Pelvic section of the guidelines. The client should be educated about the risks and benefits of Lunelle and alternate contraceptive methods. Complete the appropriate **Contraceptive Revisit Form** with each following visit.

Lab Tests

Pregnancy testing should be documented for most Lunelle starts or restarts and it is mandated prior to the second injection if there has been no vaginal bleeding since the initial shot. Because amenorrhea is rare with Lunelle, always consider a HCG test if there has been no bleeding. A hematocrit may also be indicated if the client has been experiencing heavy bleeding.

Injection Technique

The provider will write a drug order prescription for "Lunelle (DMPA 25 mg and Estradiol Cypionate 5 mg) injection monthly (28 days ± 5 days not to exceed 33 days) for one year or until annual exam due." A registered nurse can give the injections using a vial or prefilled syringe. The company will be selling it as a vial to start. **Shake the solution** well just before injecting with a 21 to 23-gauge needle into the deltoid muscle or gluteus muscle. Upjohn affirms both deltoid and gluteus sites are equally efficacious. For gluteal injection use a 1.5-inch needle. For deltoid injection use the non-dominant arm. If client's weight is less than 60 Kg (142#, use a 5/8 inch or even ½ inch needle to achieve muscle penetration of 5mm. If weight is between 60 and 90 Kg (142# and 198#, a 1 inch needle should suffice, and if greater than 90 Kg (198#, a 1.5 inch needle is required to ensure intramuscular administration. If patient is obese, greater than 70 kg and not tall, then strongly recommend deltoid injections to maximize contact with muscle tissue rather than adipose tissue. **DON'T MASSAGE THE INJECTION SITE**. There is no need to rotate the site, as injections usually do not scar. Give the client a copy of patient product insert. Document the dose, date, site, lot number and expiration date in chart and record date of next planned on the **Menstrual Calendar Reminder Card** for the client's use and in the chart.

Follow-up Visits

28 days ± 5 days after the first injection and no more than 33 days between injections the client should return for another injection. The **Lunelle Perpetual Calendar** can be used. Clients can sign up for email reminders using the Lunelle website at http://reminder.lunelle.com/. Document and evaluate any side effects using the **Contraceptive Revisit Form**. Weight and BP should be done at the first 3 injections and yearly thereafter unless an abnormal trend is documented. Remember Lunelle contains estrogen and this can increase the blood pressure in some women. Check the weight at subsequent visits on all women who complain of weight change or who had significant change at the prior visit. Do a pregnancy test before the second injection, if she was a

same day start, has not had any bleeding since the first injection, or if she did not use a back up method for 2 weeks if needed. The client can use the **Menstrual Calendar Reminder Card** to document her bleeding patterns. Counsel woman to expect irregular bleeding the first few cycles but with time her period week will be regular. The bleeding will typically happen around 2-3 weeks after each injection when the estrogen levels fall. Using Lunelle for menstrual suppression has not been studied and should not be done.

If a woman is 5 days late, making it more than a 33-day interval, she may receive an injection that day only if the sensitive pregnancy test (25 mIU) is negative. The **Contraceptive Revisit Form** should be used documenting that she agreed to back-up contraception for two weeks, understood the small possibility of a false negative pregnancy test if unprotected intercourse in the prior 11 days, and agreed to return in four weeks for a repeat pregnancy test.

Possible Side-Effects

Heavy or Prolonged Bleeding: About 45% of women will have prolonged (more than 7 days/month) bleeding and 20% of women will have very prolonged (more than 15 days/month) bleeding after the first injection.

- Obtain a history of the amount (pads/day) and duration of bleeding.
- Encourage use of **Menstrual Calendar Reminder Card** to document bleeding pattern.
- Reassure client that irregular bleeding is expected with Lunelle.
- Do a hematocrit and give iron as indicated.
- Do a pelvic examination, do current normal cytology and infection tests if not current.
- Test for pregnancy as appropriate.
- Assure women that bleeding becomes more regular (around 6 days per month beginning 2 to 3 weeks following injection) after repeated injections of Lunelle.

Amenorrhea. Not bleeding on Lunelle happens for up to 4% of cycles and women should be reassured if pregnancy has been ruled out.

Excessive Bleeding with use can be managed with**:**

- Naproxen 500 mg 3 times daily for 5 days or Ibuprofen 400 to 800 mg three times daily for 5 to 10 days can decrease bleeding.
- Consider switching to DMPA injection to decrease estrogen to accelerate uterine endometrial lining atrophy.
- One or two cycles of oral contraceptive pills with weak progestin like norethindrone may be prescribed instead of a repeat Lunelle injection, to try and regulate bleeding although not proven to work.
- If bleeding continues, consider infection evaluation (gonorrhea and chlamydia tests) and referral for possible pelvic ultrasound and endometrial biopsy as submucosal uterine fibroids, tumor, or endometritis should be ruled out.

Inflammation of Injection Site: Examine the site for swelling, redness or infection. Advise warm compresses, elevation, and rest the area as appropriate. For significant cellulitis, antibiotics targeting strep or staph skin flora pathogens may be prescribed for 3 to 5 days but if no improvement in 48 hours she may need referral for additional antibiotics and/or surgical treatment.

Weight Gain: A steady weight gain of about 2 to 4 pounds a year is common on Lunelle. The cause is probably the increased appetite and sedation (lack of exercise) from progestin use.

Headache: Evaluate stress and other factors, which may cause headaches. Advise ibuprofen, aspirin or acetaminophen, relaxation techniques, or other measures to control headaches. If headaches are severe or with neurological symptoms, referral to neurologist is appropriate and discontinue Lunelle.

Allergic reaction: There are rare cases of hives or respiratory reactions following Lunelle or DMPA injections. Usually the allergy is to the vehicle and not the hormone but an allergic reaction can be life threatening. This would be a contraindication to Lunelle and DMPA and future injections should be avoided. Report these to Upjohn at 1-800-253-8600.

Discontinuation of Lunelle Injections

The client should understand that menses might be absent or irregular for over 6 to 9 months after the last injection. If pregnancy is not desired, alternate contraception should be started within 33 days of last injection. Infertility evaluations should not be begun until 9 months from last injection. Amenorrhea evaluation should be begun if still no menses 6 months from last injection. At age 50 women should not be using Lunelle for contraceptive purposes and Lunelle should be discontinued because the effect of Lunelle on breast cancer in older women is unknown and could be undesirable given the elevated hormonal peaks.

Reporting Problems from Lunelle Injection to Upjohn and the FDA

Since widespread Lunelle use is still relatively new, any problems like allergic responses, site, product, or unusual reactions or problems detected while using Lunelle should be reported to Upjohn at 1-800-253-8600. You should also call the FDA at 1-800-FDA-1088 or fill out the form online at http://www.fda.gov/medwatch/report/hcp.htm. DMPA has never been shown to cause birth defects but the original androgenic, high dose OCPs did cause some genito-urinary anomalies hence the DMPA and Lunelle labeling. There is also a single study of women with DMPA injection in pregnancy having smaller infants but this could have been due to late diagnosis of pregnancy and late prenatal care.

Oral Contraceptive Pills

Overview

The **Oral Contraceptive Pill (OCP)** is used by millions of women. At any one time, 1 out of 4 women in America using birth control are "on the pill" and 85% of American women have used OCPs at some time. They were first available in 1960 and at that time the pill contained the equivalent of 120 mcg of Ethinyl Estradiol (EE) and 10,000 mcg of an estrane progestin. The current **Combination Oral Contraceptive (COC)** pills contain 20 to 35 mcg of EE and only 1000 mcg (some only 100 mcg) of progestin (see **Hormonal Products Comparison Chart** at the end of this chapter). **Progestin Only Pills (POPs)** contain less than half the progestin dose in a COC pill and no estrogen.

The progestin component is responsible for the contraceptive action of the COC. Progestin blocks ovulation, causes thickening of the cervical mucus, and atrophies the endometrium so sperm cannot survive or get to the fallopian tubes for fertilization. Ovulation is reduced by 75% with cyclic sub 50 mcg EE COC cyclic pill use. The estrogen component of the pill stabilizes the endometrium to minimize irregular bleeding, allows lower progestin dosing, and increases the serum hormone binding globulin (SHBG) levels to decrease free testosterone and circulating androgen levels.

If COC pills are taken every day within 4 hours of the scheduled time, with no missed pills, no vomiting or diarrhea, no antibiotic or other medication use which can change absorption or OCP metabolism, then the pregnancy rate is only 1 out 1000 women using the pill for the first year. However, users usually miss some pills or restart late after the pill-free interval making the actual failure rate 5% or 5 women out of 100 users get pregnant in the first year of use. Progestin only pills have a "perfect user" failure rate of 0.5% or 1 woman out of 500 users and the same "typical" failure rate of 5% in the first year. Progestin only pills contain only progestin at approximately 1/3 of the COC dose, so 50% of women ovulate while using the POP hence cervical mucus is the primary barrier to conception. POPs need to be taken every day within 3 hours of the same time with no pill-free interval or scheduled withdrawal bleeding days. The progestin dose is so low the cervical mucus could change to allow sperm penetration if the progestin levels fall with late POP pill use.

Benefits

- Decreased cancer - ovarian and endometrial cancer risk decreases by 40% after 1 year of total OCP pill use and 80% reduction after 10 years of use *(JAMA 1987; 257:796-800)*. This protection lasts at least 15 years and most likely persists for a lifetime. Conversely, if a woman has been ovulating for 35 or more years then her risk of ovarian cancer increases by 300% (from 1% to 3%) lifetime risk. The protection against ovarian cancer is thought to be from the reduction in ovulation and the use of progestin induces apoptosis or cell death of abnormal ovarian epithelial cells.
- Decreased breast changes like cyclic and fibrocystic complaints, fibroadenoma
- Decreased benign ovarian tumors and cysts
- Decreased pelvic inflammatory disease
- Decreased rheumatoid arthritis
- Regulates and reduces menstrual bleeding
- Decreased endometriosis
- Decreased osteoporosis
- Decreased anemia
- Decreased menstrual cramps, ovulation pain & premenstrual tension
- Decreased acne and hirsutism
- Can adjust menses for vacations or if conditions require amenorrhea

- No interference with coitus

Pills are very safe and to put it into perspective, an interesting table was developed for risk comparison by Contraceptive Technology (17th edition, 2000), listed here below. Indeed, even things like using a ladder are far more dangerous than taking the modern low dose OCP; in the UK in 2002 approximately 35,000 people sought medical care for falling off a ladder and approximately 50 died. (Lancet 2004; 363: 1252).

Risk of death in a year for men and women who participate in…
Motorcycling .....1 in 1,000
Automobile driving.....1 in 5,900
Rock climbing .....1 in 7,200
Playing football .....1 in 25,000

Risk of death per year for women aged 15 to 44 from:
Using tampons .....1 in 350,000
Having sexual intercourse (PID).....1 in 50,000

Risk of death per year for women from:
Undergoing sterilization.....1 in 38,500
Continuing a pregnancy .....1 in 10,000
Legal abortion:
Before 9 weeks .....1 in 262, 800
Between 9 and 12 weeks.....1 in 100,100
Between 13 and 15 weeks.....1 in 34, 400
After 15 weeks .....1 in 10,200
Using oral contraceptives:
Nonsmoker .....1 in 66,700
Age less than 35 .....1 in 200,000
Age 35-44 .....1 in 28,600
Heavy smoker (25 or more cigarettes per day).....1 in 1,700
Age less than 35 .....1 in 5,300
Age 35-44 .....1 in 700

COC Pill Absolute Contraindications
For women with any of the following, COC pills (OCPs with estrogen), should not be prescribed by the PHSKC Family Planning Program.

- Women with a **personal history** of a blood clot or **thrombolic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.
- **Known pregnancy** or less than 3 weeks postpartum following a gestation of 24 weeks or greater.
- Known **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of COC pills could worsen their prognosis. A recent study of 4575 women with breast cancer and 4682 controls without breast cancer did not find any elevation of risk for being diagnosed with breast cancer from using the OCP *(NEJM 2002; 346: 2025-32)*. This study provides reassurance that the use of the OCP will not increase a lifeline woman's risk of getting breast cancer.
- **Active hepatitis with jaundice**, liver failure, and hepatic malignancy because they cannot metabolize the OCP.
- Women **45 or older who smoke** tobacco. Women smokers aged 35 to 44 may only use 20 mcg pills if they sign the Birth Control Method Specific Informed Consent Form and are counseled to reduce to 15 or less cigarettes a day.
- A girl that has **never had a menses**, since estrogen will stop her bone growth. Once menarche is

reached, even one menses, then endogenous estrogen levels have begun.

- Known **migraine headaches with focal neurologic symptoms** like blindness, numbness, or vomiting, which make the risk of a stroke high, especially with estrogen use.
- Known carrier of a **hereditary thrombogenic mutation** like Factor V Leiden or Protein S or C deficiencies.

Progestin Only Pill Absolute Contraindications

For women with any of the following, progestin only pills should not be prescribed by the SKCDPH Family Planning Program.

- Known **malignancy of the breast or endometrium**.
- **Known pregnancy**
- Seizure medications, rifampin, and many chronic medications could accelerate the metabolism of the already low progestin dose rendering the pill ineffective.

COC Pill Relative Contraindications

For women with any of the following, oral contraceptives containing estrogen should not be prescribed unless the client insists COC pills are the only method she will use. She must then sign the Birth Control Method Specific Informed Consent Form and the provider must document the discussion about alternative methods offered and the client accepting the risk from estrogen containing pills. In addition, the 20 mcg EE pill dose should be prescribed unless documented intolerance and the patient understands her risk may be increased with increased estrogen.

- Women **under the age of 35 and heavy smokers** (more than 15 cigarettes a day) have an increase in cardiovascular events on estrogen and women could be asked to sign the Birth Control Method Specific Informed Consent Form particularly if there are other risk factors such as family history or obesity. At a minimum counseling regarding tobacco cessation should be documented.
- Women age **50 or older** need mammogram, lipid, menopause, and possibly bone density screening to adequately manage a hormonal prescription. For these reasons it is not a part of the routine family planning program services. We also recognize women over 50 can become pregnant but a non-hormonal method can be used or management with an outside provider.
- Women with a **first degree relative with a history of a thrombosis** that occurred spontaneously (no injury or pregnancy, and especially if clotting event when young) may have inherited a thrombophilia. If the woman wanting COC pills has **never taken estrogen or had a pregnancy** then a COC pill might be her first exposure to exogenous estrogen and it could trigger a clot. Remember many women could have an inherited decrease in the ability to stop a clot and yet they may never have a problem with a blood clot. One calculation published by an Italian research group stated that COC pills would have to be withheld from 90,000 women to prevent one DVT. Since only 1% of DVTs cause death, it makes no sense to withhold COC pills to women for just a family history. A study of women with blood clots found very few had a family history, which suggests family history will not predict many events. Even if these women with a family history had the $300 worth of tests done to see if they inherited the gene, half the time the tests will be negative and she could still have a hereditary propensity to clot. Use the Birth Control Method Specific Informed Consent Form if a worrisome family history and no prior estrogen exposure to document she was told of the unknown and probably very small risk of blood clots when using estrogen. To put the risk of getting a blood clot in perspective, if one followed 100,000 women for one year, five of them would get a DVT (1% are fatal). If you then gave all these women COC pills, then 10 to 30 of them would get a DVT during the year, but if they were all pregnant, 60 to 100 of them would get blood clots. Increased venous thrombosis has been reported in OCP users of pills containing desogestrel. A recent study of clotting found a significant increase in clotting in women on desogestrel compared to other progestins. For this reason, avoid desogestrel in obese women, women who are relatively immobile, new pill users or women with no prior estrogen exposure, or women with other risk factors for clots. Desogestrel significantly increases SHBG over Levonorgestrol use and it is in the label that this progestin

increased DVT risk 1.7 over other progestins (Am J Obstet Gynecol 2004: 190: 332-7). A discussion paper on the cardiovascular risks also concluded that these "third generation" or low androgenicity progestins increased the inflammatory markers and the thrombotic risk over other progestins (Atherosclerosis 2004; 172: 281-6). You may refer for familial thrombophilia evaluation if client has first-degree relatives with a history of blood clots especially if an affected relative can also attend the visit, to the Hematology Clinic at Harborview Medical Center (see Information About Referral to Harborview Medical Center Handout).

- Known or suspected **migraine headaches**, which may be worsened on OCP use then estrogen is not advised. If frequent vascular symptoms like blindness or numbness then refer to neurology and do not prescribe COC pills. If migraines with vascular symptoms that are rare or in the distant past, give only 3 cycles and evaluate for exacerbation and consider using 20 mg EE2 products to lesson the estrogen withdrawal trigger for a headache. Have the woman keep a diary of her headaches using the Headache Diary and if she notices the headaches are worse during the pill free interval then consider estrogen withdrawal etiology and consider extended cycles or skipping the pill free intervals. Use of a 20 mcg ethinyl estradiol pill with continuous COC pill use can be considered using the Menstrual Supression Guidelines.
- **Chronic active hepatitis** usually from a viral etiology like hepatitis B or C or a history of jaundice during pregnancy or chronic liver disease. Question the client and if she reports jaundice or documented hepatitis with abnormal liver enzymes within past three years then send a liver panel. If she has had no jaundice or documentation of elevated liver enzymes in past three years, then the prescription can be begun on the same day as the baseline liver enzyme panel. If the liver enzymes on the baseline lab test are double the normal values then plan to repeat liver panel in 3 months and after one year of use. Refuse a COC pill refill if enzymes have worsened until consultation with Family Planning Medical Director. If the enzymes were more than double the normal value, a woman has impaired liver function and her liver cannot metabolize her COC pill. Estrogen is not toxic to the liver and it will not worsen liver function, but a low dose pill will become a high dose estrogen pill because metabolism is impaired and she is then exposed to the risks of thrombosis. The process of metabolizing the estrogen could possibly worsen her liver function.
- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas because estrogen likely induced proliferation and these could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose pills have not had this problem but any estrogen containing prescription label will contain this warning. If someone has a known diagnosis of hepatic adenoma, estrogen is contraindicated.
- Suspected **pregnancy,** although there is no evidence of teratogenesis in women who inadvertently took low dose oral contraceptives during the first four months of pregnancy.
- Women with **diabetes and microvascular disease**, such as retinal or renal damage proven or suspected is an absolute contraindication to COC pill use. Retinal vessel damage is not usually seen till after 10 years of insulin use and is very rare in non-insulin users. Diabetic women on insulin are followed by primary care providers and should have regular eye, renal and lipid evaluations with these providers. Estrogen and progestin use may change slightly the insulin dose needed but COC pill use is safe, will not worsen their diabetes, and is preferable to pregnancy.
- Women with **hypertension,** even if treated, have an increased cardiovascular risk with the use of estrogen. Consider changing to a method with no estrogen, or if unacceptable, the 20 mcg estrogen pill with the Birth Control Method Specific Informed Consent Form. If the blood pressure remains elevated or worsens after 3 months, then COC pill use should cease. Estrogen can increase blood pressure and fluid retention. This means COC pills can interfere with hypertension medications and treatment.
- In women with **epilepsy**, pills may be less effective due to **seizure medication** use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital (see later in chapter table on drug interactions). The Family Planning Program will not be prescribing 50 mcg estrogen dose pills because estrogen absorption and metabolism is very different in individual women. The woman on a high dose estrogen pill is exposed to potentially higher thrombotic risks. Estrogen also lowers the

seizure threshold in the brain and can increase the number of seizures. The IUD or DMPA injection are the preferred hormonal contraceptive in women on antiepileptic medications.

- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and will make the pills less effective. During short-term therapy such as meningitis prophylaxis, continue the oral contraceptive but use a back-up method as rifampin use has been associated with many pill failures;
- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days or a long surgery (greater than two hours) will predispose to thrombosis and consider stopping the COC pills 4 weeks prior.
- **Airline travel**, especially if the flight is 8 hours or longer, has been found to increase the risk of blood clot in COC users 14x higher than non-users not traveling.
- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing OCP because there may indeed be a risk not discussed in the guidelines.
- **Metabolic diseases** like lactose intolerance or celiac sprue. If a woman has an inability to metabolize something the package labeling for the pills should be read carefully for any other ingredients contraindicated for that patient. For example, many tablets might use lactose, starch, or cellulose for binding the pill so it holds together. These ingredients are listed in the first section of the package insert where the pill is described. No OCP appears to have phenylalanine so women with PKU are safe in using OCPs however the package labeling should still be scanned for that particular tablet's ingredients including the spacer pills. The amount of lactose in the OCP tablets with lactose is quite small however if a woman developed a worsening of her diarrhea or lactose intolerance complaints, the provider could try and find an OCP with no lactose listed in the ingredients. It is important to remember each pill brand can be formulated differently and a generic version of the pill could still have different ingredients for formulation or holding the pill together.
- **Hydatidiform mole or choriocarcinoma** currently being treated, with elevated serum HCG levels, should not have COC pills until the HCG levels are normal. A large case study of women with choriocarcinoma found that women given COC pills while their HCG levels were elevated were significantly more likely to require chemotherapy than those that did not use exogenous hormones until the HCG level had returned to normal (which would be close to zero).
- **Obesity.** Women with a BMI of $\geq$ 30 kg/m ^{2} are at more risk for thrombosis and the use of estrogen can increase this risk. Women weighing more than 70 kg may also have higher OCP failure rates according to a study *(Obstet Gyneco/2002; 99: 820-827)*. This has not been shown in other OCP studies but it is possible because obese women have a larger volume of distribution and a higher rate of medication metabolism and clearance. Norplant failures were 5x higher in obese women and the patch failed in 8% of obese women compared to only 1% of normal weight woman. Obesity is also the linked to fertility and parity and perhaps these women have a higher threshold and need higher doses for ovarian suppression. It is possible phasic pills or even cyclic 20-25 mcg EE_2 OCP's should be avoided especially if prior OCP failure and instead prescribe 30 mcg EE_2 pills or consider continuous use of 20 mcg EE_2 pills using the menstral supression guidelines.
- **Allergy** to other pill components found in the pill tablet like lactose, iodine, or dye for example. Each pill brand, including generics can have very different ingredients use to hold the pill together. These ingredients can be found in the package insert labeling.

COC Pill Precautions

Women with the following may be given COC pills if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Undiagnosed vaginal bleeding** until diagnosis is established and managed. Although often COC

pills can be used to regulate irregular menses. If the COC pills regulate the menses there is usually no further need for diagnostic tests. A 3 to 6 month trial of COC pills can be a diagnostic maneuver, proving that the history of irregular menses was most likely caused by lack of regular ovulation.

- **Lactation:** The amount and possibly the quality of milk may be lessened with the use of estrogen in the first few months post partum, or before lactation and "let down" are well established. A recent review pointed out that the evidence for COC contraindications with lactation is scanty and recent studies with current 20-30 mg EE2 doses has not been performed. If weaning is desired, COC pills may be used to decrease the flow of milk. A progestin-only hormonal contraceptive is preferred, but if lactation is well established then a change to COC pills is possible and may be best to prevent pregnancy and if there are problems, change back to progestin only. In a women with lactational amenorhea consult the Lactation Guidelines chapter as many of these women do not need another method especially in the first 6 months.
- **Active gall bladder disease**. Estrogen use can worsen stone formation and dilation of the bile ducts. If the gallbladder has been removed then there is no risk with COC pill use.
- **Chronic yeast vaginitis.** This may possibly be worsened by cyclic estrogen use. There is a study that found DMPA use, which reduces estrogen levels, decreased the number of yeast infections.
- Use of **oral antibiotics** in particular metronidazole, amoxicillin, ampicillin, and tetracycline, have been associated with case reports of COC pill failure while taking these and other antibiotics. The mechanism for the failure is probably a change in the gut flora so the entrohepatic absorption and circulation of the estrogen and progesterone change resulting in subtherapeutic levels. The most conservative advice is to use a back-up method for the duration of antibiotic use (see OCPs and Antibiotic Use Handout) although the current Contraceptive Technology edition does not think this is necessary with COC pill use, POP users should consider a back-up method. If the woman is on chronic, daily low dose antibiotics (like acne suppression with tetracycline or nightly Septra for pylonephritis prevention) use the Birth Control Method Specific Informed Consent Form advising the pill method may not be as effective as in a non-antibiotic user, but likely if no break through bleeding or diarrhea then most likely there are effective hormone levels. Do not begin these chronic antibiotic users on a 20 mcg COC pill since these are usually women being treated for acne and would benefit from 30 mcg of estrogen and potentially the daily antibiotic could make the estrogen level even lower.
- **Gilbert's Disease** (hyperbilirubinema because of a reduced uptake of bilirubin). Gilbert's Syndrome is a common hereditary condition, which results in abnormal or delayed clearance of bilirubin by the liver so a mild unconjugated hyperbilirubinemia results, usually with normal liver enzyme function/levels and liver histology. Fatigue, stress, alcohol, starvation, and illness can trigger an increase in the bilirubin and mild jaundice but icterus is rare. Phenobarbital or other hepatic enzyme inducers can decrease these bilirubin levels. This condition is found in 8% of the US population with more men than women affected. It is prudent to avoid drugs cleared by glucouronidation, which would include hormonal contraceptives if the condition is severe such as current jaundice. However, hormonal contraceptives are not toxic to the liver and have been used by many women with only a mild impairment. It is reasonable to check the bilirubin at baseline and following a month or two of use to insure the level is stable.

How Some Drugs Reduce OCP Efficiency

There are several mechanisms by which therapeutic drugs can alter OCP effectiveness. The result of each of these mechanisms is reduced estrogen and progestin levels and, therefore, increased likelihood of ovulation and subsequent pregnancy. Five of the primary mechanisms are listed below.

- **Liver enzyme induction**. Some medications increase the activity of the liver enzymes that metabolize hormonal steroids. This enhanced metabolism reduces the level of steroids in the blood stream.
- **Elevated Albumin or protein** which bind the OC steroids. Some medications may enhance the production of these proteins which could bind with progestins in the blood, therefore a decrease in

the amount of free progestin available to suppress ovulation.

- **Vomiting or diarrhea or loss of small intestine surface area**. Medications that cause vomiting or diarrhea could decrease the absorption of oral contraceptive steroids. Surgical removal of bowel or diseases which change the intestines' ability to absorb steroids could reduce the serum drug levels.
- **Reduced levels of intestinal bacteria**. Medications that reduce the levels of intestinal bacteria may cause vomiting or diarrhea; this may decrease the amount of OC steroids absorbed through the intestine. Reduced levels of intestinal bacteria also can affect the body's ability to reabsorb estrogen. Estrogen passes through the liver into the bile and is then secreted into the intestines; there it is reabsorbed back into circulation. The re-circulation of estrogen is important to maintaining stable hormone levels.
- **User factors**. Side effects of some medications may cause a woman to decide not to take her OCPs. For example, side effects such as nausea may cause the client to miss taking her pill for one or more days, a particularly crucial event is she is using a lower dose OCP and if missing pills extends the pill-free week. Also, a user may become concerned about spotting or breakthrough bleeding due to a medication/OCP interaction and decide to discontinue the method.

***Oral Contraceptive Pill Use and Possible Drug Interactions**

Interacting Drug	Possible Effect	Recommendation
Rifampin	Demonstrated compromised OCP efficacy	Consensus that use of this potent hepatic enzyme inducer requires alternative contraception
Griseofulvin	Hepatic enzyme inducer	Demonstrated compromised OCP efficacy
Ketoconazole, itraconazole, fluconazole	Inhibitors of hepatic enzymes	Increased levels of EE, delayed withdrawal bleeding. Chronic use could decrease efficacy.
Phenobarbitol, primidone, phenytoin, carbamazepine, felbamate, oxcarbazepine, topiramate, vigabatrin, primidone, ethosuximide, modafinil. lamotrigine	Reduced steroid levels. Hepatic mfo enzyme inducers.	No data have demonstrated reduced suppression of ovulation but caution still strongly advised
Troglitazone, cycloporine	Hepatic mfo inducers	Possibly reduce pill efficacy
Diazepam, chlordiazepoxide, tricyclic antdepressants, theophylline, buprenorphine	Prolonged elimination half-life and increased plasma levels of these agents	Suggest lower doses may achieve desired therapeutic effect in OCP users
Acetaminophen, aspirin	Increased clearance of NSAIDS	Some clinicians believe higher doses of NSAIDS may be required for adequate therapy
Some antiretroviral drugs: nelfinavir, ritronavir, amprenavir, and nevirapine	Hepatic mfo inducing so increased progestin metabolism	Could decrease COC efficacy
St. John's wort	Inhibitor of cytochrome P450 isoenzymes	Breakthrough bleeding
Valproic acid, gabapentin, tiagabine	No change	OCP efficacy unchanged, seizures could still change from EE use
Tetracycline, doxycycline, ampicillin, metronidazole, quinolone	Rare case report	Consensus that risk is not increased if only monotherapy and COC pill. POP risk much greater since lower progestin level
Acyclovir and AZT related drugs, Indinavir, Saquinavir	None documented	Can be used with OCPs

*The information on this table was obtained from the Micromedex.com site September 2004. It is possible this information can change, and it is the provider's responsibility to verify the information has not changed.

- **Use of higher dose estrogen pill**, more than 35 mcg of ethinyl estradiol, will not be prescribed unless the Family Planning Medical Director has been consulted and the client signs a Birth Control Method Specific Informed Consent Form.
- Yasmin is different from other birth control pills because it contains the progestin drospirenone. This progestin is similar to natural progesterone and the drug spironolactone, which is listed as a

teratogen. In addition this newer progestin which has no androgen binding may have the same problems as seen with other newer progestins like desogestrel and gestodene in that the lack of androgen effect and increased estrogen effect (SHBG increase) could increase thromobotic risks and this has been reported (BMJ 2002; 324: 869). Drospirenone can also increase potassium levels. Women should not take Yasmin if they have kidney, liver or adrenal disease because this could cause serious heart and health problems. Other drugs may also increase potassium. After the first month of using Yasmin, a potassium level should be checked for women using Yasmin and the following medications:

- NSAIDs (ibuprofen {Motrin, Advil}, naproxen (Naprosyn, Aleve, and others) when taken long-term and daily for treatment of arthritis or other problems)
- Potassium-sparing diuretics (spironolactone and others)
- Potassium supplementation
- ACE inhibitors (Capoten, Vaotec, Zestril and others)
- Heparin

Progestin Only Pill Precautions

- Irregular bleeding
- Weight gain if appetite increases
- Increased acne possible since progestin only
- Inability to keep a regular schedule as these pills **must be taken within 3 hours** of the same time every day and if not then the woman needs a backup method for 2 days and if she misses 2 days of pills then backup for 7 days.

History and Consent

The standard medical history is reviewed by the clinician to confirm absence of absolute and relative contraindications. Counseling should be provided to ascertain ability to comply with daily pill taking. If contraindications do exist then document other methods discussed, patient's decision to not use other methods, and if appropriate sign the Birth Control Method Specific Informed Consent Form. If the client has signed this consent form then she needs to sign it every year when she is given a prescription for the COC pills. Her risk profile may change and there needs to be documentation that she was offered other methods every year and continues to choose COC pills.

Examination

Baseline blood pressure, weight, and pregnancy testing (if needed) should be performed prior to OCP prescription. Although there is no increase in the risk of breast cancer with pill use **annual breast exam** should be performed to emphasize the importance of early detection and screening. There is a small possibility that cervical cancer, increased in long-term COC pill users due to the estrogen proliferative effect on HPV persistance cervical ectopy or glandular epithelium of the cervix, and for this reason **cervical cytology** should be considered for women at risk and the Cervical Cancer Screening Guidelines should be used. There is an option of delaying the pelvic exam and the Delayed Pelvic Guidelines should be consulted. Progestin thickens the cervical mucous and atrophies the endometrium and this can decrease the ascent of bacteria to the upper genital tract, thus one can find asymptomatic chlamydial infections in OCP users. All OCP users should be offered STD screening as per the PHSKC STD guidelines.

Prescribing Pills

Prescription medication can usually only be dispensed by pharmacies. Washington pharmacy code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at Family Planning Clinics. However OCPs cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority.

- **First time COC pill users** can only get an initial supply of three cycles. This 3 month revisit is to ask

about complaints and to measure the weight and the blood pressure. These are to be recorded by a clinic nurse and any significant problems evaluated by the clinician. Make sure the client is taking pills correctly. Use the Female Family Planning / STD Visit Form or similar note at visit. She can then be given the rest of the year's supply, usually 10 (total of 13 cycles for a year's supply).

- **Ongoing OCP users or prior OCP users**, who have been on oral contraceptives for at least three months at the time of the initial or annual visit, are without problems, and have documentation of a normal blood pressure after 3 months of estrogen use in the past, may then be give a supply sufficient (13 months total prescription between annual exams) to last until her next annual exam.
- If **late for annual exam**, provision of additional pill cycles, two sets of 3 cycles or up to 6 cycles, can be given with provider discretion because the risk of pregnancy is greater than the risk of an abnormal exam. An emergency refill of pills (3 packages) may be given or phoned into a pharmacy for regular clients without problems. This must be recorded on client chart.
- If **outside records** are needed, OCPs can be prescribed after complete medical history, weight, blood pressure measurement, and if appropriate, pregnancy screening. Outside records should be reviewed and if the records document the client is current with her annual exam then she may be prescribed the year's supply of pills. She should not get a second year's supply without an annual exam with the Family Planning Program.

When to begin COC pills

- COC pills should ordinarily be **started on the first day of the next menses or** the **first Sunday closest** to the onset of menses. For Sunday start: if menses begins on a Monday the client should take 2 pills that day so it is a "Sunday" start rather than wait until Sunday at the end of the week; if the menses begins on or after a Wednesday then wait to begin on that Sunday. The Sunday start was designed to give women period bleeding during the week so by the weekend bleeding has stopped. However, Sunday start can be bad because women run out of pills on the weekend and may have a late restart on a Monday or later. A first menstrual day start may induce faster and more complete ovarian suppression and is recommended for more effective contraception but a day one start has been associated with more irregular bleeding when compared to a cycle day 5 start. Perhaps if the endometrium is built up and ready for menses it does need to shed to then be easily suppressed. If continuous OCP use for menstrual suppression is being prescribed shedding the endometrium first may help minimize irregular bleeding and a cycle day 5 start may be best.
- **Same Day Start/Restart** may be done if the patient understands and consents. This means the first pill is taken the day of the clinic visit and can even be done there in the clinic with teaching. This may be appropriate in women taking ECP, or who has recently been on pills and missed more than 3 days of pills, or who has had a history of irregular menses and waiting until menses will increase the risk of pregnancy. Documentation of a negative HCG test is required. Consider if the client also needs an EC prescription because regular dose OCPs will not act as an EC. The client must understand the need for a backup method for 7 days and that a pregnancy test should be done if indicated in 4 weeks, especially if no bleeding. Provide counseling to the client that when beginning OCPs it is very common to have irregular bleeding for 3 months and it has been shown to be no worse than when starting the OCP outside of the menstrual week. After 3 months of OCP use typically the cycles are regulated.
- **Rule of Seven's** is a simple way to teach patients regarding pill use. Basically, after 7 days of active pill or progestin use, cervical mucus is changed and ovulation blocked so after 7 days no back-up is needed. Conversely, a woman should never go more than 7 days without progestin use or she then needs back-up contraception.
- If **switching pill formulation or dose**, especially from a higher to a lower dose OCP it is prudent to recommend 7 days of back-up contraception in case the dose change results in hormone level change.
- Women starting COC pills **after the 1st day of menses** should use added protection for 7 days. If starting before or on the 1st day of menses then no additional protection is needed for that cycle.
- It is possible break through or irregular bleeding during the first cycle of the OCP may be reduced by

starting the OCP on day 5 rather than day one of the cycle. It is possible the menstrual bleeding is not completed as well with the day 1 start and results in later in the cycle bleeding (European J Contraception and Reproductive Healthcare 1998; 3:121-3).

- COC pills may be started **21 days post partum** in women choosing not to breast feed or on the **day of an abortion** for any pregnancy **less than the second trimester**. After 24 or more weeks gestation, do not start estrogen use until three weeks post-delivery or abortion to minimize the risk of increased thrombosis post delivery. By 2 to 3 weeks post partum, 30% of non-breast feeding women will ovulate and could potentially get pregnant.
- If using the **OCP for Withdrawal Bleeding Manipulation** then consult the Menstrual Suppression Clinical Guidelines.

When to Begin POPs

- Any time postpartum or post-abortion.
- The cervical mucus change takes 7 days, so backup contraception is needed for 7 days since ovulation is often not suppressed.
- It is very important that POPs be taken every day within three hours of the same time because 50% of POP users ovulate and the contraceptive protection is from cervical mucus changes. If not, the woman needs to use a back-up method for two days while she resumes regular pill taking.

Product Brochure

The manufacturer's patient product labeling is to be given to the client each time pills are dispensed. The PHSKC patient brochure on oral contraceptives (Birth Control Pill Patient Handout) is appropriate to give out to clients beginning OCP use.

Possible Side Effects

- **Nausea.** Taking the pill just prior to sleep, for example at the time of tooth brushing could help. The nausea is centrally mediated and is the result of the estrogen effect on the brain. The nausea is not the result of a local effect on the stomach but because the estrogen is working on the brain to cause nausea. Taking the pill in the morning may end up producing a "morning sickness" effect. Taking the pill at night makes the estrogen peak while one sleeps. Progestin methods usually do not cause nausea. If a pill change seems necessary, a 20 mcg estrogen pill could be selected. A progestin-only method of contraception may be needed if the estrogen is not tolerated.
- **Weight Gain.** In studies of large numbers of women OCPs did not significantly increase the weight of the population however individual women may respond differently to pill use. Weight gain is usually from increased food consumption and decreased activity. However estrogen use can cause some fluid retention in some women and then it is appropriate to try a 20 mcg estrogen pill and educate about exercise and a low-salt diet. Drosperidone is a new progestin derived from a spirinolactone like molecule which is a diuretic, however, in studies there is no prolonged effect on weight and at one year a small increase in weight; perhaps because it is a progestin similar to natural progesterone and medroxy progesterone acetate, which can increase appetite and sedation (less activity). There is no proven OCP with a "better" weight profile than another OCP.
- **Breakthrough Bleeding (BTB) or Spotting.** BTB is when the woman reports having bleeding between the pill free days or scheduled withdrawal bleeding. BTB is defined as enough bleeding to need a hygiene product like pads or tampons and spotting is when no protection was needed. In the first 3 months of COC pill use and for the first year of POP use these events are very common and worse with missed or late pills. Continuation on the same pill for three cycles before switching brands should be encouraged.

BTB During First 3 months of pill use:

- **Reassure client** this is very common when first beginning OCPs and is often because the uterine lining is shrinking and shedding under hormonal influence.

- Be certain that the pill is being taken at the **same time or within 4 hours,** if COC pill, and 3 hours if POP, of a set time every day, and there have been no missed pills. Missed or late pills are the usual reasons for BTB or spotting.
- **Rule out other causes** of bleeding as appropriate by history and exam such as pregnancy, polyps, cervicitis, or other medication use.
- **Ibuprofen,** 400 to 800 mg three times daily or Naprosyn 500 mg twice a day beginning with menses, can reduce the amount of menstrual flow and the frequency of BTB or spotting. Menses or menstrual withdrawal bleeding is triggered by a drop in progesterone, which results in prostaglandin production. These chemicals then shed the endometrium by vessel spasm hence the pain and cramps.
- For early or midcycle spotting, a higher **estrogen** or phasic pill with increased estrogen midcycle could be tried after three cycles.
- For late-cycle bleeding consider a **progestin** with a longer half life pill such as one with levonorgestrel or norgestrel if already three months of OCP use.
- **Recent history of DMPA:** Injections could interfere with the OCP levels since DMPA is not completely cleared for 6 months after use. Because of DMPA's progestin effect on the endometrium to cause atrophy increasing estrogen may suppress BTB or spotting. An estrogenic pill like a 30 or 35 mcg pill or a weaker progestin pill may help. There are no published studies on the best formulation to transition women from DMPA to COC pills.
- **Vitamin C:** 1000 mg at the time of taking the COC pill for a week for some women may help if it increases the absorption of estrogen. Conversely if the woman is a regular Vitamin C user and then stops taking Vitamin C it may cause her endometrium to experience a drop in estrogen and this could trigger spotting.
- **Alcohol use** can also change the metabolism of estrogen so that the estrogen is metabolized slower giving higher estrogen levels. Using alcohol daily, binge drinking or stopping alcohol consumption could trigger some transitory BTB or spotting.
- **Tobacco use** induces metabolism of estrogen making some smokers more vulnerable to breakthrough bleeding and spotting.

After 3 months of OCP use:

- The endometrium has atrophied and the most likely etiology is missed or late pills, and irregular pill taking. For this reason **pregnancy testing** is advised if the woman presents with bleeding complaints.
- If unexplained breakthrough bleeding occurs in women established on the pill, do an **infection check** and evaluate for other sources of bleeding before pill change. If no etiology is found and the BTB or spotting persists after two cycles, referral is indicated to gynecology clinic to evaluate for uterine or ovarian pathology.
- In a randomized study of DMPA users, **supplemental estrogen did not help BTB**. This has not been studied in OCP users, but it is unlikely to help except acutely and since estrogen causes proliferation it could be counter productive with increased bleeding when the supplemental estrogen is stopped. Switching to a COC pill with a decreased EE2 dose for ongoing use might be considered since less estrogen means less blood lining to bleed from.
- **Breast Tenderness.** This will usually disappear within three cycles. If not, lower doses of estrogen may help. Instruct in obtaining and using proper bra. Discuss the possible role of caffeine. Some women may benefit from vitamin E 400 IU daily.
- **Headache.** Allow two to three cycles for adjustment and recommend aspirin, ibuprofen or acetaminophen. Use the Headache Diary. Consider discontinuing oral contraceptives if headaches worsen with continued use. Milder headaches may improve with a change of pill formulation to one with less estrogen. If severe, persistent, or vascular symptoms like blindness or numbness develop, stop COC pill use and refer to primary care provider and possibly neurologist. Estrogen withdrawal headaches can decrease with cycle elimination and taking a 20 mcg OCP continuously without a

break for menses is an option using the menstral suppression guidelines.

- **Watery vaginal discharge.** If excessive vaginal discharge is still present after two to three cycles, a lower estrogen pill may be tried. Rule out vaginitis or cervicitis.
- **Oligomenorrhea and Amenorrhea.** These are common with low-dose pills over time, due to lack of estrogen proliferation of endometrium. Menstrual changes are not harmful and the client needs only reassurance. If the woman strongly desires to have periods, a higher estrogen 35 mcg, dose pill may be tried. If there is any reason to suspect pregnancy (forgotten pills, symptoms, suspicious pelvic exam, etc.) or two missed menses successively, then a pregnancy test may be done as appropriate.
- **Depression and Irritability.** A low sodium diet may help if premenstrual mood changes. Hepatic metabolism of estrogen can deplete vitamin B6 (pyridoxine) so a 50 to 100 mg daily dose can be tried to see if mood improves. A lower estrogen and/or progestin dose pill may also help. If mood changes appear to be cyclic, then extended or continuous cycles could be tried.
- **Increased Blood Pressure.** Repeat measurement after a brief rest in the clinic. If the increase is sustained, consult and use the Family Planning Hypertension guidelines. If diastolic continues to be 85 mm or greater then the client can use COC pills only after signing the Birth Control Method Specific Informed Consent Form, switch the client to a 20 mcg estrogen pill and repeat visit in 3 months with COC pill discontinuation if still hypertensive.
- **Acne and oily skin.** COC pills or estrogen cause an increase in hepatic production of Serum Hormone Binding Globulin (SHBG). SHBG then binds to free testosterone and androgens effectively reducing the free, which are the active, androgenic hormones. This is why all COC pills can reduce acne and hirsuitism. Studies to get marketing labeling for acne reduction compare the OCP to placebo and not to another COC pill, so it is not a fair trial since other COC pills will also reduce acne. Probably the best pill to reduce acne would be a pill with 35 mcg of EE and low dose of a weak nonandrogen binding progestin like NET (Ovcon 35).
- **Decreased Libido.** This may be related to decreased circulating androgens or a decline in the natural estradiol surge mid-cycle (ovulation). There is one study that reported Triphasil improved libido and this may actually be related to the increased estrogen to progestin ratio during part of the cycle. Some women report more libido on higher dose estrogen OC's but this has not been well studied. Vaginal dryness may be managed with lubricants or increased estrogen dose. A review of sexual arousal and taking a sexual history is also important.
- **Chloasma** (melasma). Hyperpigmentation areas on the face are a great cosmetic concern. Occurrence is related to sun exposure, family history, and pregnancy, and can be due to estrogen levels especially pregnancy and COC pill use. Pigmentation can be reduced by avoiding all exposure to the sun. Use of a high potency sunscreen especially on the affected areas may benefit. Bleaching agents such as hydroquinone, or tretinoin in topical creams are frequently helpful. DO NOT prescribe these, only refer. If a woman develops chloasma during pregnancy or with COC pill use she is at risk to develop it with repeated COC pill use or pregnancy. Sometimes the skin changes are permanent even after pill discontinuation so women may choose to discontinue use of COC pills to prevent further discoloration.

Hormonal Product Comparison Table

The table at the end of the chapter compares the dose of estrogen and progestins of the different OCPs available. Consult the Family Planning Program 28 Pharmacy Medication Order Form for OCP brands currently on the PHSKC Formulary List and comparative price list. All the OCPs listed have similar efficacy in preventing pregnancy; however when switching formulations or doses it is prudent to advise backup contraception for 7 days. Use the **Hormonal Product Comparison Chart** at the end of this chapter to help make pill brand switches depending on the types of side effects. Generic OCPs are not on our formulary due to cost but OC generics are rated AB, meaning good therapeutic bioequivalence with serum levels of the drug that can vary 20% from name brand but this is still effective and most women do not notice any difference although the packaging and pill color can vary from brand product.

Choice of Oral Contraceptive Pill Type

- For **new starts** prescribe a pill on our PHSKC formulary pill which is low cost. The preferred starter pill for the program depends on the contract pricing and is typically the lowest estrogen dose pill at the cheapest price. There are very few studies comparing women on different pill brands but there are very few differences. If a woman is obese (BMI $\geq$ 30) or weight > 70 kg, consider avoiding phasic or 20 mcg EE_2 products unless used daily as it is possible obese women need higher doses although if the patient has not had an OC failure and is stable on a certain brand then it can be her choice to stay on the very low dose product.
- Use the Menstrual Calendar Reminder Card to help patients track their bleeding and spotting.
- Because there is a significant increase in clotting in women on desogestrel compared to other progestins avoid desogestrel in obese women, women who are relatively immobile, new pill users or women with no prior estrogen exposure, or women with other risk factors for thrombosis.
- With **ongoing** pill users, if possible, refill with a pill prescription most like the one she "likes" or has been using.
- **Triphasic and Biphasic** preparations vary the doses of the two hormones in the pills depending on the time in the cycle. There is no medical reason to prefer phasic preparations and evidence suggests phasic OCPs have more BTB due to varying hormone levels. Phasic products are not recommended for extended or continuous use. In addition, phasic OCPs should not be used if a client is on a chronic medication that requires stable serum levels like a tricyclic antidepressant or an antibiotic.
- **No 50 mcg** estrogen containing pill should be prescribed without consulting the Family Planning Medical Director.
- If a pill **change** is made **for side effects** prescribe only 3 cycles of the new pill and having the client return to evaluate the effect of the change. Usually pill changes do not result in significant problems. For example, the PHSKC formulary changes frequently for cost reasons and almost all of the women changed do not return with problems. When making changes for side effects remember **estrogen** decreases spotting and acne but can worsen nausea, bloating, breast tenderness, and headaches while **progestins** decrease the amount of menses but can increase appetite, sedation, acne, and mood changes. Interestingly, in placebo versus OC studies the only side-effects reported to be different in OC users compared to placebo users were breast tenderness and nausea. So perhaps only estrogen dose is a measurable difference between pill brands. But women are individuals and many side-effects are subtle and difficult to measure.

Hormonal Product Comparison Table

*Brand Name	Estrogen				Progestin		
		Dose (µg)	Cycle Days	Type	Dose (µg)	Cycle Days	
MONOPHASICS							
FemHRT	PD	EE	5	1-28	NET	1000	1-21
Activella	PU	17B, E2	1000	1-28	NETA	500	1-28
PremPro	W	CE	625	1-28	MPA	2500	1-28
PremPro5	W	CE	625	1-28	MPA	5000	1-28
Alesse/Levlite/Aviane/Lessina	W/BE/DM/BA	EE	20	1-21	LNG	100	1-21
Loestrin 1/20 /Microgestin 1/20	PD/WAT	EE	20	1-21	NETA	1000	1-21
Mircette/Kariva/*Mercilon*	OR/BA	EE	20/10	1-21/24-28	DES	150	1-21
Minesse/Melodia		EE	15	1-21	GEST	60	1-21
Meliane/Harmonet		EE	20	1-21	GEST	75	1-21
Yasmin	BE	EE	30	1-21	DSP	3000	1-21
Desogen/OrthoCept/Apri/*Varnoline*	OR/O/WAT	EE	30	1-21	DES	150	1-21
Nordette/Levlen/Levora/Portia/*Minidril*	M/BE/WAT/BA	EE	30	1-21	LNG	150	1-21
Seasonale	BA	EE	30	1-84	LNG	150	1-84
Loestrin Fe 1.5/30 /Microgestin 1.5/30	PD/WAT	EE	30	1-21	NETA	1500	1-21
Lo/Ovral/Cryselle/Low-Ogestrel	W/BA/WAT	EE	30	1-21	NG	300	1-21
Minulet/Moneva		EE	30	1-21	GEST	75	1-21
Ovcon-35	BMS	EE	35	1-21	NET	400	1-21
Brevicon/Modicon/Necon/ Nelova/Nortrel/Genora	WAT/O/WAT/ WC/BA/RU	EE	35	1-21	NET	500	1-21
Ortho-Novum 1/35/Nelova 1/35E/Nortrel 1/35/Norethin 1/35/ Norinyl 1+35	O/P/WAT/WC/ BR/RO/SE	EE	35	1-21	NET	1000	1-21
Ortho-Cyclen/Sprintec/*Cilest*	O/BA	EE	35	1-21	NGM	250	1-21
Demulen 1/35/Zovia	SE/WAT	EE	35	1-21	EDDA	1000	1-21
Demulen 1/50 / Zovia 1/50	SE/WAT	EE	50	1-21	EDDA	1000	1-21
Ortho-Novum 1/50 /Genora 1/50 / Nelova 1/50M /Norinyl 1+50 /Ovcon 50	O/RU/WC/SE/ BMS	ME	50	1-21	NET	1000	1-21
Ovral	W	EE	50	1-21	NG	500	1-21
Evra® Patch	O	EE	20	1-21	D-Acyl NGM	150	1-21
NuvaRing®	OR	EE	15	1-21	ENG	120	1-21

*Generic formulations may produce serum levels within 20% of brand name formulations, are packaged differently, pills a different color even, but are as effective as brand product.
Italics represents a brand available internationally outside of the US.

Manufacturer

BA = Barr
O = Ortho / Monarch = M
R = Roche
OR = Organon
DM = Duramed
WC = Warner Chilcott
RU = Rugby
PD = Parke Davis/Pfizer
WAT = Watson
BE = Berlex
W = Wyeth
P = Pharmacia
BMS = Bristol Myers Squibb

PHASICS	Estrogen				Progestin		
			Dose (µg)	Cycle Days	Type	**Dose (µg)**	Cycle Days
OrthoPrefest	O	17B/E2	1000	1-28	NGM	90	3 days/on 3 days/off
Ortho-Novum 10/11 Necon 10/11/Jenest-28	O/WAT/OR	EE	35	1-21	NET	500 1000	1-10 11-21
Estrostep 21	PD	EE	20/30/35	1-5/6-12 /13-21	NET	1000	1-21
Cyclessa	OR	EE	25	1-21	DSG	100/125/250	1-7/8-15/416-21
Ortho Tri-Cyclen/ Trinessa/Trisprintec	O/ W/B	EE	35	1-21	NGM	180/215/250	1-7/8-15/16-21
Ortho Tri-Cyclen Low	O/W/B	EE	25	1-21	NGM	180/215/250	1-7/8-15/16-21
Triphasil/Tri-Levlen/ Trivora/Enpresse	W/BE/WAT/BA	EE	30/40/30	1-6/7-11/ 12-21	LNG	50/75/125	1-6/7-11/12-21
Ortho Novum 7/7/7 / Nortrel	O/BA	EE	35	1-21	NET	500/750/1000	1-7/5-16/17-21
Tri-Norinyl	WAT	EE	35	1-21	NET	500/1000/500	1-7/8-16/17-21
PROGESTIN ONLY							
Micronor (28 day)/Errin/Jolivette	O/BA/WAT				NET	350	
Nor-QD (28 or 42 day)/Camila	R/BA				NET	350	
Ovrette (28 day)	W				NG	75	
Aygestin	L				NETA	5000	
Cycrin	W				MPA	2500/5000/10000	
Cerazette	OR				DSG	75	

EE—ethinyl estradiol; ME—mestranol; 17BE2–17-beta-estradiol; CE–conjugated estrogens; LNG—levonorgestrel; NE = NET—norethindrone; EDDA–ethynodiol diacetate; NETA—norethindrone acetate; NG—norgestrel; NGM—norgestimate; D-AcylNGM-norelgestromin; MPA–medroxy progesterone acetate; DSG–desogestrel; 3-Keto-DSG-etonorgestral(ENG); DSP–drospirenone, GEST-Gestodene

Metabolism

1) ME→EE active metabolite
2) EDDA & NETA→NET active metabolite
3) 50% NG & 20% of NGM→LNG
4) NGM→Dacy/NGM
5) DSG→3 Keto DESO(ENG) – Like LNG only one carbon different
6) EE, CE, NET, DSP, MPA, ENG, D-acetyl NGM, and LNG are all active and do not need metabolism to work

Progestin with Estrogen activity

Weak EDDA & NETA with 10% EE2 activity (1000 mcg NETA=5 mcg EE2)

T ½ drug half life

NET = 4 - 13 range or 7 hours
Lng = 11 - 45 range or 15 hours
NGM = 12 – 30 range or 12 hours
DES = 14 – 38 range or 12 hours
DSP = 30 hours
MPA = 30 hours

Progestin binding – rabbit endometrium

Gestodene (not in U.S.A.) > Deso & Lng > NGM > NET & EDDA

Potency (dose needed for ovulation suppression and as potency increases less drug is needed)

GEST> Deso & Lng > NGM > NET & EDDA > DSP & MPA

Androgen binding at doses 50x ovulation suppression doses

DHT = 1.0 NGM = .003 MPA, DSP, NET = none Lng = 0.2

Mineralcorticoid activity

DSP potassium monitoring is needed and hepatic, cardiac, renal disease, or chronic use of NSAIDS contraindicated.

Spermicide

What is a Spermicide?

By definition, a spermicide is a chemical that kills sperm. Nonoxynol-9, or N9, is the most common spermicide, a substance that can destroy sperm. N9 is a chemical detergent that breaks the cell membranes of the sperm. Unfortunately, N9 can also irritate and disrupt the vaginal epithelium. Spermicide strength varies greatly and extensive tests by the manufacturers are currently not required. The dose of N9 needed to destroy sperm is thought to be around 100 to 150 mg. A large NIH comparative trial found failure rates of 10-22% over 6 months and concluded N9 products under 100mg should not be used (Obstet Gynecol 2004; 103: 430-9). An earlier study of women using a 70mg N9 product multiple times a day did not appear to reduce pregnancy rates and these women also had much higher rates of HIV acquisition. Consequently, clients should be advised that high dose products, like the 1000mg sponge, or repeated dosing causes vaginal irritation and even mucosal ulceration. There is also concern that N9 can react with latex condoms and cause more release of the latex proteins, which could then increase the risk of latex allergy. The use of the spermicide N9 should not be promoted to reduce the transmission of bacteria or viruses that cause STD's and in fact the use of N9 may increase these conditions. Condoms with N9 are not recommended and do not add benefit.

History and Examination

Initial Clinic Visit

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The minimum required physical examination is performed and recorded, and if needed, additional examination done as indicated by the history. Minimum laboratory tests are obtained and reviewed. Inform the client about male and female condoms as superior alternatives. Advise the client about emergency contraception and for most clients a package of EC should be prescribed and dispensed prophylactically.

Subsequent Clinic Visits

The client should return if they have problems or as needed for supplies. At every visit, document alternative superior contraceptives were offered to the client. An annual exam should be offered yearly.

Contraindications and Precautions

- Allergy to spermicide or ingredients in base.
- Recurrent urinary tract infections.
- The failure rate for spermicide alone is very high with 28% of women experiencing a pregnancy within the first year of use.
- Spermicides cause irritation and increase mucosal damage and potentially facilitate the transmission of blood borne viral infections like HIV and Hepatitis.
- Should never be used in the rectum.
- The sponge is significantly less effective than the diaphragm with spermicide with 17-24% of women pregnant at one year of sponge use and only 10-12% of diaphragm users *(Contraception 2003; 67: 15-18).*

Benefits

- Available without prescription
- Non-hormonal
- Reversible
- Controlled by the woman

Possible Side Effects

- **Allergy to spermicide:** If a rash, women may use cortisone cream (ointment is better as there is no alcohol as in creams) on her vulva for a few days. She could try a different type (cream versus gel or film versus suppository), different brand, or different spermicide (octoxynol versus nonoxynol-9). Remember some of these products cannot be used with latex condoms as they may weaken and cause breakage of the condom. One possibility is to rinse off the outside of the vulva with water, not a douche but with fingers, and then in six hours remove the spermicide from the vagina. However, remind the client that current spermicide chemicals act as detergents and it is difficult for it to work unless it has irritant properties. Lastly, it may be best for the client to consider a different contraceptive method.
- **Increased vaginal infections:** Examine for yeast, bacterial vaginosis, etc. The client can try using condoms as well as spermicides. If problems persist, the client may need to change methods.
- **Increased urinary tract infection:** Advise women to drink fluids, to urinate both before and after intercourse, and to wipe from front to back with toilet paper use.

Dispensing/Patient Education

- Spermicide products are bought over the counter and vary from 60mg to 1000mg of N9 per application.
- Routinely give spermicide cream or jelly with a diaphragm or a cervical cap as part of the combination method. Also provide an applicator to add additional spermicide. For women using the method alone educate about the lower effectiveness and suggest a higher dosage of at least 150mg of N9 per act of intercourse. Repeat foam application with each act of intercourse.
- When using suppositories or film, the couple needs to wait 15 minutes after insertion for the suppository or film to dissolve before sexual intercourse. Foams, creams and jellies are usually effective immediately.
- The Today brand of sponge with 1000mg N9 can be bought in Canada and is left in place for repeated acts of intercourse over 24 hours. Women need to be advised of the possible risk of toxic shock syndrome, difficult removal, and risk of vaginal irritation from the high dose of N9.
- Canada also sells another type of sponge called Protect Aid, which uses F-5 Gel (contains N9, benzalkonium chloride, and sodium cholate), which permeates a polyurethane foam disc.
- Both sponges use a polyurethane foam material with a metabisulfite or sulfur like material for a preservative. The sponge needs to be left in place for at least 6 hours after the last act of intercourse to provide efficacy. Either sponge can be used for repeated acts of intercourse but for only 12 hours if the Protect Aid brand and up to 24 hours if the Today sponge.
- The client needs to read the package instructions carefully.
- If the woman is seeking a sexual lubricant then a N9 or spermicide product is not necessary and has not been shown to be beneficial.

Sterilization

Sterilization is permanent contraception usually accomplished by a surgical procedure. In men, the vas deferens are interrupted and in women, the fallopian tubes. Hormonal production can continue, in women with menstrual cycles unaffected, and in men, ejaculation is unchanged. In women, ovulation continues but due to tubal interruption fertilization by sperm is greatly reduced. The failure rate for vasectomy is less than 1 in 1000 if the semen sample 12 weeks after the surgery has no sperm in the ejaculate. A recent study suggests half of vasectomy failures happen in the first 3 months (Obstet Gynecol 2004; 103: 848-50). The 10 year failure rate for female sterilization is 0.8% for postpartum partial salpingectomy and can be as high as 2% for interval laparoscopic methods involving cauterization, clips, or bands. Women under the age of 28 have a higher rate of failure and 15% to 40% incidence of regret, but only 1% actually seek and obtain reversal. In the U.S., over 1 out 4 couples seek sterilization, with approximately 2 women sterilized for every man. An excellent review of sterilization can be found in the September 2003 ACOG Practice Bulletin No. 46.

Consent

The consent must be signed by both the patient and the provider obtaining the consent at least 30 days prior to performing a tubal ligation (although there is an exception if delivery occurs before 37 weeks) or a vasectomy. Any woman who is considering postpartum tubal ligation should be thoroughly counseled about this option during pregnancy and sign the consent as soon as their decision has been made. Consent forms for sterilization, as well as patient education brochures, can be ordered using the Office of Population Affairs Publications Clearinghouse Order Form. The State has a document describing the consent process and this is an important resource (Sterilization Consent Procedure). Instructions for Take Charge Sterilization Referral and Billing Information Cover Letter should be used. Providers can also provide the Female Sterilization Referral List or Vasectomy Referral List but these lists are only representative of the local providers and do not imply endorsement. All providers on the list agreed at the time of the data collection to provide Medicaid services.

Counseling for sterilization should include:

- Explore other contraceptive methods including long term reversible methods such as pills, injections, implants, and the IUD.
- Explain that sterilization must be considered permanent and irreversible with 15% regret and 40% if under age 30. Even with very expensive surgery to put the vas deferens or fallopian tubes back together, fertility (ability to get pregnant) can be less than 50%.
- Explain that the female sterilization failure rate is approximately 2% or 2 out of 100 women pregnancies over 10 years
- Discuss the possibility of future ectopic pregnancies (one third of all failures) with female sterilization and the need to seek care promptly if she suspects pregnancy after having had a tubal ligation performed
- Describe the surgical procedure:
    - Postpartum tubal ligation is usually performed the day after a vaginal delivery. A small incision is made at the umbilicus. Each tube is located, the middle portion removed,

and the separate ends tied. This procedure can also be performed at the same time as a Cesarean delivery. Postpartum tubal ligation requires anesthesia, usually spinal or epidural.
    - Interval tubal ligation is performed more than 6 weeks after delivery, using a laparoscope to visualize the tubes. The tubes are cauterized or occluded with a clip or ring. This procedure usually requires general anesthesia and takes 30 to 60 minutes. Women go home that day.
    - It is rare but approximately 4 deaths occur per 100,000 sterilization procedures.
    - A new devise, Essure, was FDA approved in 2002. These metal and dacron coils can be placed using hysteroscopy under local anesthesia. But 10% of the time the surgery can not be done, 4% of women need to wait an additional 3 months or have the procedure repeated, and all women getting these coils placed need a hysterosalpingogram to verify tubal scarring was successful (Obstet Gynecol 2003: 102: 59-67).
    - If a vasectomy, the procedure is done in the office under local anesthesia with the skin over the scrotum opened and the vas deferens located for ligation. After a vasectomy, clients will still need a back-up contraceptive method until the sperm test is negative (can be up to 3 months).
- A vasectomy or tubal ligation do not reduce the risk of STDs, a condom is still needed for protection.
- Vasectomy does not increase the risk of prostate cancer even after 25 years according to a large population – based age control study (JAMA 2002; 287: 3110-3115),

Post Vasectomy Semen Evaluation

If a vasectomy is done by PHSKC then use the Vasectomy Information and Consent Form. A man presenting after a vasectomy should be advised that a semen sample should be checked for the presence of sperm first at 6 to 8 weeks and then 4 weeks later or with a single negative specimen 12 weeks later was found to be the best predictor of efficacy. The man should have at least 12 to 20 ejaculations following the procedure before the first assessment to ensure the clearing of the sperm already in the vas deferens tract. The sample is collected in a sterile container and should be evaluated as soon after ejaculation as reasonable to best detect motile or live sperm (which would be worrisome for an incomplete transection of the vas deferens or a fistula).

The semen sample should be well-mixed and placed directly on a glass slide with coverslip. Examine for presence of spermatozoa under low then high power, covering all areas of the coverslip and report as number of spermatozoa seen per hpf. Remark on absence or presence of sperm and if motility is present.

Any man testing positive for any spermatozoa should be advised he is not infertile and needs to continue alternative contraception and to bring another semen sample in 4 weeks (advise ejaculations at least 2 to 3 times per week). A man testing positive at the second test should be referred back to the surgeon for consideration of a repeat vasectomy procedure.

Transdermal Contraceptive Patch

Overview

The FDA approved the Ortho Evra™ contraceptive patch November 2001. The Ortho Evra™ transdermal contraceptive system (TCS is the abbreviation) or patch contains both estrogen and progestin. The patch is applied to the skin with a new patch each week for a total of 21 days followed by a patch free week. Because this patch is the only patch available on the US market for the remainder of the chapter when the word patch is used it will refer to the Ortho Evra™ patch or the patch.

The patch is 20 cm^2 (roughly 2 inches by 2 inches) and consists of 3 layers: an outer flesh colored protective polyester layer, a medicated adhesive middle layer, and a clear polyester liner sheet which is removed prior to application. The patch releases 20 mcg of ethinyl estradiol and 150 mcg of norelgestromin (also known as 17-deacetylnorgestimate) daily. This prevents ovulation and is the primary contraceptive mechanism. Absorption of the estrogen is almost 100% and serum estrogen levels are actually very similar to that of a 30-35 mcg orally administered COC pill. This might explain why the reported patch side-effects may be estrogenic in nature for some women. As of 2004 approximately 4 million American women from 8/2002 to 9/2004 had used the patch and there were at least 8 deaths reported in young healthy women, primarily from stroke or thrombosis. While this risk is not greater than a COC pill it is likely the adverse events are underreported. Because this is still a relatively new method if any patient in the PHSKC has a blood clot while using the patch this should be reported with the FDA MedWatch form.

The patch is to be placed on day one of the cycle and then replaced with a new patch every 7 days for a total of 3 weeks. Then a patch free week induces withdrawal bleeding. Because of the higher estrogen levels and the relatively weak progestin ratio this product should not be used for menstrual suppression or continuously. It is unknown if endometrial hyperplasia can be prevented or if extended use would induce hypercoagulability not seen with cyclic use, besides not being FDA approved for extended use. The patch hormones will accumulate within the skin and the hormone levels are higher in the third compared to the first week of use so it may be important to have the patch free week.

The patch is applied to one of four sites: buttock, lower abdomen, upper outer arm, or upper torso. The patch should never be applied to the genitals or breasts. The patch site should be rotated and a new patch needs to be applied to a new site. Oils, creams, or cosmetics should not be applied to or around the patch with 3% of patches partially lifting and 2% of patches falling off and needing replacement during studies. Once the patch has adhered the woman may shower, bathe, swim, and use a hot tub. Approximately 2.6% of users quit because of problems with the patch and 20% overall reported some site reaction at some time during the studies.

User compliance with the patch was 90% in the studies, which is better than with pill use. Overall fewer pregnancies happened in the patch users but statistically it was not significant. The method failure rate was similar to the OCP during the clinical trials with less than 1% of women experiencing a pregnancy with perfect use and less than 2% failure overall. However many of these failures or pregnancies were in obese women and women weighing 90 Kg (198 pounds) or more had an 8% failure rate while using the patch (Smallwood GH et al. Efficacy and safety of a transdermal contraceptive system. Obstet Gynecol 2001;98:799-805). The FDA noted this when the patch was approved and although the studies are still inconclusive it is prudent to recommend the patch to women weighing more than 90 kg only with

additional consent until there are more reassuring findings.

Benefits

- The same benefits as the OCP including a reduction in menstrual flow, anemia, and ovarian cysts for example. Although compared to Triphasil OCP in a RCT the patch users reported more dysmenorrhea (Audet MC et al. Evaluation of contraceptive efficacy and cycle control of a transdermal contraceptive patch vs an oral contraceptive. JAMA 2001;285:2347-2354).
- Do not have to remember a pill every day.
- Once the patch is in place then nothing needs to be done for 7 days.
- Increased method compliance compared to the birth control pill especially in young women.
- The contraceptive steroids are absorbed from the skin and this delivery system avoids the gastrointestinal tract and first pass hepatic metabolism seen with oral administration. The patch delivers the steroids continuously so the peaks and troughs with oral administration are not present.

Absolute Contraindications

For women with any of the following, methods with estrogen like the patch should not be prescribed.

- Women with a personal history of a blood clot or **thrombolic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.
- **Known pregnancy**
- Known **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormones could worsen their prognosis.
- **Active hepatitis with jaundice**, liver failure, hepatic adenoma, and hepatic malignancy
- Women **35 or older who smoke** tobacco. Women smokers aged 35 to 44 may only use 20 mcg pills or the ring if they sign the Birth Control Method Specific Informed Consent Form and are counseled to reduce to ≤15 cigarettes a day. Do not give the patch to these women, the estrogen exposure is greater.
- A girl that has **never had a menses**, since estrogen will stop her bone growth. Once menarche is reached, even one menses, then endogenous estrogen levels have begun.
- **Allergy** to adhesives or other transdermal delivery systems. It is very probable the contraceptive patch would contain some of the same ingredients as other adhesives.

Relative Contraindications

For women with any of the following, methods containing estrogen like the patch should not be prescribed unless the client insists this is the only method she will use. She must then sign the Birth Control Method Specific Informed Consent Form and the provider must document the discussion about alternative methods offered and the client accepting the risk from estrogen. In addition, the 20 mcg EE pill dose or the ring should be prescribed unless documented intolerance and the patient understands her risk may be increased with increased estrogen dose from the patch.

- Women with more than one **first degree relative with a history of a thrombosis** that occurred spontaneously (no injury or pregnancy, and especially if clotting event when young) may have inherited a thrombophilia. If the woman wanting an estrogen method who has **never taken estrogen or had a pregnancy** then this may be her first exposure to sustained estrogen and this could induce a clot. Remember many women could have an inherited decrease in the ability to stop clotting and yet they may never have a problem. One calculation published by an Italian research group stated that COC pills would have to be withheld from 90,000 women to prevent one DVT. Since only 1% of DVTs cause death, it makes no sense to withhold COC pills to healthy young women for just a family history. A study of women with blood clots found very few had a family history which suggests family history

will not predict many events. Even if these women with a family history had the $300 worth of tests done to see if they inherited the gene, half the time the tests will be negative and she could still have a hereditary propensity to clot. Use the Birth Control Method Specific Informed Consent Form if family history and no prior estrogen exposure to document she was told of the unknown and probably very small risk of blood clots when using estrogen. To put the risk of getting a blood clot in perspective, if one followed 100,000 healthy young women for one year, 5 of them would get a DVT (and only 1% are fatal). If you then gave all these women COC pills, then 10-30 of them would get a DVT during the year, and if the person had half of the gene (heterozygote) for a clotting problem (Leiden Factor) then the rate would be three times that of normal women with around 30 to 90 of women getting a blood clot during that year which is the same as if the women were all pregnant for that year. If the woman had inherited both genes (homozygote) then her risk for a blood clot is very high and if this is known then these women should not use estrogen. You should refer for familial thrombophilia evaluation prior to estrogen use if client has two first-degree relatives with clots especially if an affected relative can also attend the visit, to the Hematology Clinic at Harborview Medical Center (see Information About Referral to Harborview Medical Center Handout).

- Known or suspected **migraine headaches**, which may be worsened. If frequent vascular symptoms like blindness or numbness then refer to neurology and do not prescribe the patch. If migraines with vascular symptoms that are very rare or in the distant past, give only 3 cycles and evaluate for exacerbation. There have been reports of strokes and deaths in young women with patch use and this risk is increased in women with a history of migraines. If headaches begin or worsen during patch use then stop the patch.

- **Chronic active hepatitis** usually from a viral etiology like hepatitis B or C or a history of jaundice during pregnancy or chronic liver disease like Gilbert's Disease. Question the client and if she reports jaundice or documented hepatitis with abnormal liver enzymes within past three years then send a liver panel. If she has had no jaundice or documentation of elevated liver enzymes in past three years, then the prescription can be begun with one package on the same day as the baseline liver enzyme panel. If the liver enzymes on the baseline lab test are double the normal values then plan to repeat liver panel in 3 months and after one year of use. Refuse a refill if enzymes have worsened until consultation with Family Planning Medical Director. If the enzymes were more than double the normal value, a woman has impaired liver function and her liver cannot metabolize the estrogen. Estrogen is not toxic to the liver and it will not worsen liver function, but a low dose estrogen exposure will become a high dose exposure because metabolism is impaired and she is then exposed to the risks of thrombosis. The process of metabolizing the estrogen could also possibly worsen her liver function and ability to metabolize other medications.

- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas, which could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose pills have not had this problem but any estrogen containing prescription label will contain this warning. If someone has a known diagnosis of hepatic adenoma, estrogen is contraindicated.

- Suspected **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormonal products could worsen their prognosis.

- Suspected **pregnancy,** although there is no evidence of teratogenesis in women who inadvertently took low dose oral contraceptives during the first four months of pregnancy.

- Women with **diabetes and microvascular disease** such as retinal or renal damage proven or

suspected is an absolute contraindication to estrogen use. Retinal vessel damage is not usually seen till after 10 years of insulin use and is very rare in non-insulin users. Diabetic women on insulin are

followed by primary care providers and should have regular eye, renal and lipid evaluations with these providers. Estrogen and progestin use may change slightly the insulin dose needed but it is safe, will not worsen their diabetes, and is preferable to pregnancy.

- Women with **hypertension,** even if treated, have an increased cardiovascular risk with the use of estrogen. Consider changing to a method with no estrogen, or if unacceptable, the 20 mcg estrogen pill or ring with the Birth Control Method Specific Informed Consent Form. If the blood pressure remains elevated or worsens after 3 months, then COC pill or ring use should cease. Do not prescribe the patch to women with hypertension. Estrogen can increase blood pressure and fluid retention and can interfere with hypertension medications and treatment.

- In women with **epilepsy**, the patch may be less effective due to **seizure medication** use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital. The Family Planning Program will not be prescribing 50 mcg estrogen dose pills because estrogen absorption and metabolism is very different in individual women. The woman on a high dose estrogen pill is exposed to potentially higher thrombotic risks. Estrogen also lowers the seizure threshold in the brain and can increase the number of seizures. The IUD or DMPA injection are the preferred hormonal contraceptive in women on antiepileptic medications. There have been no reports of the use of the patch in women taking these medications and it is a labeled contraindication. While it is possible the patch could provide a steady state of contraceptive hormones and thus be effective and not interfere with the seizure medications, it is also possible the estrogen levels could interfere with seizure suppression although natural menstrual cycles or pregnancy could be worse. Consult the Family Planning Medical Director, use the Birth Control Method Specific Informed Consent Form, and if possible consult and follow the patient with her primary provider managing her seizure disorder.

- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and will make the method less effective. During short-term therapy such as meningitis prophylaxis, continue the patch but use a back-up method also as rifampin use has been associated with many OCP failures;

- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days or a long surgery, greater than two hours, planned, etc., which will predispose to thrombosis. Need to discontinue patch use 4 weeks prior.

- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing method because there may indeed be a risk not discussed in the guidelines.

- **Hydatidiform mole or choriocarcinoma** currently being treated, with elevated serum HCG levels, should not have COC pills and perhaps not use the patch since similar hormonal medication until the HCG levels are normal. A large case study of women with choriocarcinoma found that women given COC pills while their HCG levels were elevated were significantly more likely to require chemotherapy than those that did not use exogenous hormones until the HCG level had returned to normal (which would be close to zero).

- **Chronic skin or dermal conditions** (for example eczema or psoriasis). It is possible the adhesive product could exacerbate or trigger a rash. Although it is unlikely to be life threatening the chart should still contain a documented warning to the client that the method relies on adhesion to deliver the contraceptive steroids and studies have not been done in women with chronic skin conditions. Approximately 1-2% of women using the patch will report some hyperpigmentation of the skin where patch use has been and this may not be reversible.

- **Obesity.** A weight greater than 90 kg or 198 pounds is a relative contraindication to the method due to decreased effectiveness (8% failure versus 1% failure). The 3319 women during 22,155 patch cycles or up to 1 year of patch use were used to determine efficacy resulted in 15 pregnancies. Five of these were in the 3% of women weighing 90 kg or more. The other 10 pregnancies were evenly distributed over body weights below 90 kg including 1 in women 80-84 kg and 1 in women 85-89 kg. Therefore, it is a small possibility women close to 90 kg might even have a small risk of failure but it is unknown.

- **Chronic headaches.** Have the woman keep a diary of her headaches using the Headache Diary and if she notices the headaches are worse during patch use then consider stopping patch use however if the headaches appear to only happen in the patch free interval then consider estrogen withdrawal etiology and consider switching to a 20 mcg dose OCP for continuous use and consult the menstrual cycle suppression chapter. Do not recommend or prescribe the patch for continuous use.

Precautions

Women with the following may be given a patch prescription if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Undiagnosed vaginal bleeding** until diagnosis is established and managed. Although often COC pills or the patch could be used to regulate irregular menses. If the COC pills regulate the menses there is usually no further need for diagnostic tests. A 3 to 6 month trial of COC pills or patch can be a diagnostic maneuver, proving that the history of irregular menses was most likely caused by lack of regular ovulation.

- **Lactation:** The amount and possibly the quality of milk will be lessened with the use of estrogen especially in the first 6 months post partum. If weaning is desired, COC pills or the patch may be used to decrease the flow of milk. A progestin-only hormonal contraceptive is preferred and can actually increase the amount of milk produced. If lactation is well established and greater than six months, then a change to COC pills is possible but if there are problems, change back to POP. Use of the patch in lactation has not been studied and is not recommended because of the relatively high estrogen levels induced with patch use.

- **Active gall bladder disease**. Estrogen use can worsen stone formation and dilation of the bile ducts. If they have had their gallbladder removed then there is no risk with patch use.

- **Chronic yeast vaginitis.** This may possibly be worsened by cyclic estrogen use. There is a study that found DMPA use, which reduces estrogen levels, decreased the number of yeast infections.

- Use of **oral antibiotics** in particular metronidazole, amoxicillin, ampicillin, and tetracycline, have been associated with case reports of COC pill failure while taking these and other antibiotics. The mechanism for the failure is probably a change in the gut flora so the entrohepatic absorption and circulation of the estrogen and progesterone change resulting in subtherapeutic levels. It is unknown

at this time if the patch because it delivers the hormones via the dermis would be unaffected by antibiotic use and at this time it is prudent to give the same advise as given with OCP use. The most conservative advice is to use a back-up method for the duration of antibiotic use (see OCPs and Antibiotic Use Handout) although the current Contraceptive Technology edition does not think this is necessary with COC pill use, POP users because of lower progestin dose should consider a back-up method. If the woman is on chronic, daily low dose antibiotics (like acne suppression with tetracycline or nightly Septra for pylonephritis prevention) use the Birth Control Method Specific Informed Consent Form advising the pill method may not be as effective as in a non-antibiotic user and consider continuous and not cyclic use. There was a small study of 24 women using the patch with tetracycline 500 mg every 6 hours for 1 week and the serum levels of the hormones were not significantly changed (not published yet so actual data not seen). So it is possible the patch may be less vulnerable to antibiotic use although remember it is likely failures on antibiotics are related to

individuals. Some women have the problem because of their individual hepatic metabolic enzyme activity and others may not. If no break through bleeding or diarrhea then most likely there are effective hormone levels.

- Consult the OCP guidelines if other chronic medications as some would be contraindications to patch use and those reference tables are not duplicated here.

History and Consent
The standard medical history is reviewed by the clinician to confirm absence of absolute and relative contraindications. Counseling should be provided to ascertain ability to comply with placing and removing the patch. If contraindications do exist then document other methods discussed, patient's decision to not use other methods, and if appropriate sign the Birth Control Method Specific Informed Consent Form. If the client has signed this consent form then she needs to sign it every year when she is given a prescription for the patch. Her risk profile may change and there needs to be documentation that she was offered other methods every year and continues to choose the patch.

Examination
Baseline blood pressure, weight, and pregnancy testing (if needed) should be performed prior to prescription. Although there is no increase in the risk of breast cancer with patch use annual breast exam should be performed to emphasize the importance of early detection and screening. There is a small possibility that a rare form of cervical cancer, adenocarcinoma, is increased in COC pill users due to the estrogen proliferative effect on cervical ectopy or glandular epithelium of the cervix, and for this reason annual cervical cytology should be offered if indicated by her sexual and cervical cytology history (consult the cervical cancer screening guidelines). There is an option of delaying the pelvic exam and those guidelines should be consulted. Progestin thickens the cervical mucous and atrophies the endometrium and this can decrease the ascent of bacteria to the upper genital tract, thus one can find asymptomatic chlamydial infections in OCP users. All patch users should be offered STD screening as per the PHSKC STD guidelines.

Prescribing the patch
Prescription medication can usually only be dispensed by pharmacies. Washington pharmacy code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at Family Planning Clinics. However the patch cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority.

- **First time patch users** can only get an initial supply of 3 cycles. This 3 month revisit is to ask about complaints or difficulties with patch use and to measure the weight and the blood pressure. These are

to be recorded by a clinic nurse and any significant problems evaluated by the clinician. Make sure the client is using the patch correctly. Use the Female Contraceptive Visit Form or similar note at visit. She can then be given another 4 months supply.

When to begin patch use

Patch use should ordinarily be **started on the first day of the menses.** A first menstrual day start will induce faster and more complete ovarian suppression and for this reason no additional back up method is recommended by the labeling if begun correctly.

- Women starting the patch **after the 5th day of menses** should use added protection for 7 days. If starting on the first day of menses then no additional protection is needed for that cycle. Women **switching** from another hormonal method will be protected from the beginning of patch use if no longer than a 7 day interval from the last pill or ring or within the effective time of an injection. To alter the day of the week for patch administration may require the use of a back up method until the preferred day.

- Patch use may be started **21 days post partum** in women choosing not to breast feed (estrogen can stop lactation) or on the **day of an abortion** for any pregnancy **less than the late second trimester**. After 24 or more weeks gestation, do not start estrogen use until three weeks post-delivery or abortion to minimize the risk of increased thrombosis post delivery. By 2 to 3 weeks post partum, 30% of non-breast feeding women will ovulate and could potentially get pregnant.

- **Same Day Start/Restart** may be done if the patient understands and consents. This means the first patch is placed the day of the clinic visit and can even be done there in the clinic with teaching. This may be appropriate in women taking ECP, or who has recently been on pills and missed more than 3 days of pills, or who has had a history of irregular menses and waiting until menses will increase the risk of pregnancy. It may also be appropriate for women whom the provider thinks may benefit from actual patch use teaching. Documentation of a negative HCG test is required. Consider if the client also needs an EC prescription because regular dose OCPs will not act as an EC. The client must understand the need for a backup method for 7 days and that a pregnancy test should be done in 4 weeks, especially if no bleeding. Provide counseling to the client that beginning a hormonal method midcyle can result in increased break-through bleeding and if it is worrisome to the patient, it may be better to wait until the next menses. But in some women, like prior DMPA users, beginning a hormonal method when the client wishes to start is better than waiting for a menses. After 3 months of patch use typically the cycles are regulated and the same day start will have no lasting effect.

How to use the patch

The patch may be applied to one of 4 sites, absorption equivalent, on the skin: the lower abdomen, upper outer arm, upper torso, or buttock. The patch cannot be applied to the genital area or the breast (not known if local tissue would be effected by the high hormone levels). The patch is also to be applied to clean dry skin free of lotion or oils although no special preparation should be done. The patch should be held tightly to the skin for 10 seconds to help it adhere tightly. The patch is worn for 7 days although contraceptive levels have been proven to continue up to 48 hours if patch removal is delayed or a new patch is not applied directly following removal of the prior patch. In other words, as long as a new patch is placed within 2 days ovarian suppression should continue. Use of a single patch for more than 9 days has not been studied (very likely it will be ineffective as the levels had dropped quite low by day 9 of use) and the woman needs a backup method for 7 days and consider pregnancy testing at revisit if this reported.

The patch is to be peeled off and sticky side stuck to sticky side so hormone releasing surface is covered and can not leak into landfill and discarded in the trash not the toilet. If there is adhesive left on the skin

mineral oil can be used to remove it, being careful to apply the new patch to only clean and dry skin. A new patch is then directly applied to a new but adjacent site or perhaps a new site entirely.

If the patch does not adhere or partially detaches the entire patch must be removed. Adding tape to the patch is not an option, the drug delivery system requires the adhesive be tightly adhered over the entire patch surface to deliver the drug. In studies approximately 3% partially detached and 2% of patches had to be replaced. If a patient consistently requires additional patches then a different method should be considered. Tests were done with patch use with exercise, perspiration, hot tubs, saunas, humid environments, and cool water immersion and the delivery system was unaffected and fewer than 4% of patches detached and needed replacement. Women cannot tattoo or color the patches as this could change drug delivery.

The patch needs to be replaced every 7 days with a new patch to maintain contraception. Hormone levels drop to zero within 1 week following patch removal hence the need for a new patch after the patch free week to maintain contraception. After 3 weeks or 3 patches the woman is to have a patch free week to allow withdrawal bleeding. If a patch was accidentally left on for more than 7 days the week before the period week then either the patch free week should be only 4 days or a new patch used to skip that period week. There is no data or studies regarding extended cycles or menstrual suppression with the patch and it is possible continuous use could lead to endometrial proliferation since the ratio of the estrogen to progestin with the patch favors estrogen..

Getting An Extra Patch

Because the patch can fall off or need to be emergently replaced, women need to have access to extra patches. A woman getting her supplies from PHSKC should get 84 day prescriptions (#12 patches with 3 refills) and be advised to always make sure she has at least one patch in addition to one she is using and not to wait to get a refill only when she is using her last patch. If the patch prescription has to be filled at an outside pharmacy, then write two prescriptions, one for the year's supply and one for an extra patch. This extra patch prescription can be kept on file at that pharmacy or kept by the patient in the event of needing an urgent refill at any available pharmacy. She would go to the pharmacy with this extra patch prescription. If she pays for that patch, she can then submit this bill directly with the extra patch certificate (in the box with the extra patch) to the Ortho Evra extra patch program (www.orthoevra.com or 1-800-682-6532). If this extra patch is paid for by Medicaid insurance then no rebate can be requested.

Product Brochure

The manufacturer's patient product labeling is to be given to the client each time the patch is dispensed.

Possible Side Effects

- **Nausea.** The nausea is not the result of a local effect on the stomach but because the estrogen is working on the brain to cause nausea. For this reason even women using the patch may experience nausea from estrogen. In a comparative study the women using the patch reported significantly more nausea than the OCP user (Triphasil was being used in the study and that OCP has estrogen doses of 30 to 40 mcg). It is possible the constant sustained estrogen levels result in more estrogenic side effects like nausea and breast tenderness although with continued use these should subside. Placing the patch on the abdomen may reduce the nausea side effect according tot he patch company.

- **Weight Gain.** In studies of large numbers of women OCPs did not significantly increase the weight of the population however individual women may respond differently to hormone use. Weight gain is usually from increased food consumption and decreased activity. In the women using the patch in the clinical trials the weight gain was similar to that as measured in pill users, less than 2 pounds after one year (which was similar to the weight gain measured in placebo patch users in a small study).

- **Site reactions.** In the studies 20% of women reported some site redness or irritation although only 2% of women stopped using the patch because of problems with their skin due to the patch. It was very common for the patch site to be slightly red for an hour after patch removal. The patch sites were studied using ultraviolet light and the company states the use of the patch was not associated with phototoxicity or photo allergy. If use of the patch consistently leaves a rash or skin lesion which persists the woman might consider a different method because there is nothing that can be done to prevent a dermal reaction with future use. While short term treatment with a mild hydrocortisone cream might be offered to clients presenting with a patch related inflammation, if repeated rashes happen the method must be discontinued. Approximately 1-2% of women using the patch report some hyperpigmentation of the skin from patch use and this may not be reversible and would likely continue to occur with ongoing patch use.

- **Breakthrough Bleeding (BTB) or Spotting.** BTB is when the woman reports having bleeding when using the patch instead of during the patch free week or scheduled withdrawal bleeding. BTB is defined as enough bleeding to need a hygiene product like pads or tampons and spotting is when no protection was needed.

First 6 months of patch use:

- **Reassure client** this is very common when first beginning hormonal methods and is often because the uterine lining is shrinking and shedding under hormonal influence. In the first 2 months of patch use around 20% of women had BTB, twice what was reported by the OCP users in the comparative study. But after 2 months the rates were similar.

- Use the **Menstrual Calendar Reminder Card** to help patients track their bleeding and spotting.

- Be certain that the patch is being used as scheduled as a drop in the hormonal levels can worsen BTB and spotting. If the woman is **overweight** consider method failure and obtain a pregnancy test and if negative consider the hormone levels may not be adequate for endometrial suppression although patch study data did not analyze BTB in different weight categories.

- **Rule out other causes** of bleeding as appropriate by history and exam such as pregnancy, polyps, cervicitis, or other medication use.

- **Ibuprofen,** 400 to 800 mg three times daily or Naprosyn 500 mg twice a day beginning with menses, can reduce the amount of menstrual flow and the frequency of BTB or spotting. Menses or menstrual withdrawal bleeding is triggered by a drop in progesterone, which results in prostaglandin production. These chemicals then shed the endometrium by vessel spasm hence the pain and cramps.

- **Recent history of DMPA:** Injections could alter the ratio of hormone levels since DMPA is not completely cleared for 6 months after use. Because of DMPA's progestin effect on the endometrium to cause atrophy increasing estrogen may suppress BTB or spotting. Switching to a pill with a higher progestin dose may be tried since the estrogen dose in the patch is already quite high it is most likely the client needs more endometrial suppression (more progestin). Use of the patch while taking combination birth control pills is contraindicated. There are no published studies on the best formulation to transition women from DMPA to patch use.

- **Alcohol use** can also change the metabolism of estrogen so that the estrogen is metabolized

slower giving higher estrogen levels. Using alcohol daily, binge drinking or stopping alcohol consumption could trigger some transitory BTB or spotting.

- **Tobacco use** induces metabolism of estrogen making some smokers more vulnerable to breakthrough bleeding and spotting.

After 6 months of patch use:

- The endometrium should have atrophied and the most likely etiology is noncompliant patch use. For this reason **pregnancy testing** may be advised if the woman presents with bleeding complaints.

- If unexplained breakthrough bleeding occurs in women established on the patch, do an **infection check** and evaluate for other sources of bleeding before method change. If no etiology is found and the BTB or spotting persists after two cycles, **referral** may be indicated to gynecology clinic to evaluate for uterine or ovarian pathology. In women with persistent spotting with the LNG IUS it was found on ultrasound some had submucosal endometrial polyps. Although this is not a contraindications to hormone use and indeed hormones can suppress the irregular bleeding over time.
- In a randomized study of DMPA users, supplemental estrogen did not help BTB. This has not been studied in OCP or patch users, but it is unlikely to help except acutely and since estrogen causes proliferation it could be counter productive with increased bleeding when the supplemental estrogen is stopped. Switching to a COC pill with an increased progestin dose for ongoing use might be considered.

- **Breast Tenderness.** This will usually disappear within three cycles although may be worse than that seen with OCPs. If not, lower doses of estrogen may help meaning a switch to pills or the ring. Instruct in obtaining and using proper bra. Discuss the possible role of caffeine. Some women may benefit from vitamin E 400 IU daily.

- **Headache.** Allow two to three cycles for adjustment and recommend aspirin, ibuprofen or acetaminophen. Use the **Headache Diary** to see when the headaches occur. Discontinue the patch if headaches worsen. If severe, persistent, or vascular symptoms like blindness or numbness develop, stop patch use and refer to an emergency room if acute. If the headaches are mild and associated with the patch free week, it is possible that wearing the 3rd week's patch for the 4th week, normally the patch free week, would allow a slower decline in the estrogen levels and provide less of a trigger for a headache. This is an unlabeled use of the patch and it is unknown it this would result in irregular bleeding.

- **Oligomenorrhea and Amenorrhea.** This is very uncommon with cyclic patch use (less than 2% of users over one year). Check a pregnancy test and if negative, reassure the woman although counsel to return if still no menses in the next cycle.

- **Depression and Irritability.** A low sodium diet may help if premenstrual mood changes. Hepatic metabolism of estrogen can deplete vitamin B6 (pyridoxine) so a 50 to 100 mg daily dose can be tried to see if mood improves. There is no evidence the patch has no effect on the B6 system but it is possible the higher or sustained estrogen levels could affect mood. If mood changes appear to be cyclic, then extended or continuous cycles could be tried with OCPs or ring but not the patch.

- **Increased Blood Pressure.** Repeat measurement after a brief rest in the clinic. If the increase is

sustained, consult and use the Family Planning Hypertension guidelines. If diastolic continues to be 90 mm or greater then the client cannot use the patch.

- **Acne and oily skin.** Estrogen causes an increase in hepatic production of Serum Hormone Binding Globulin (SHBG). SHBG then binds to free testosterone and androgens effectively reducing the free, which are the active, androgenic hormones. This is why all COC pills can reduce acne and hirsuitism. Ortho Tricyclen, a Norgestimate triphasic, is a COC pill that has package labeling as a treatment for acne. A study compared this pill to placebo and not to another COC pill. It is very likely other COC pills also reduce acne. Probably the best pill to reduce acne would be a pill with 35 mcg of EE and low dose of a weak nonandrogenic progestin like NET (Ovcon 35). The patch has not been proven to reduce acne although acne was a rare complaint in the studies and it is unlikely to be different than the COC pill since SHBG levels were actually the same as the 30-35 mcg comparative pill users.

- **Decreased Libido.** This may be related to decreased circulating androgens. Vaginal dryness may be managed with lubricants or increased estrogen dose. A review of sexual arousal and taking a sexual history is also important.

- **Chloasma** (melasma). Hyperpigmentation areas on the face are a great cosmetic concern. Occurrence is related to sun exposure, family history, and pregnancy, and can be due to estrogen levels especially pregnancy and COC pill use. Pigmentation can be reduced by avoiding all exposure to the sun. Use of a high potency sunscreen especially on the affected areas may benefit. Bleaching agents such as hydroquinone, or tretinoin in topical creams are frequently helpful. DO NOT prescribe these, only refer. If a woman develops chloasma during pregnancy or with COC pill or patch use she is at risk to develop it with repeated estrogen use or pregnancy. Sometimes the skin changes are permanent even after discontinuation so women may choose to discontinue use of the patch or COC pills to prevent further discoloration.

Vaginal Contraceptive Ring

Overview

The FDA approved the NuvaRing™ October 2001. It is a Contraceptive Vaginal Ring (CVR is the abbreviation). Development of a vaginally administered hormonal contraceptive has been ongoing since the 1970's. The earlier rings contained only progestin delivered via a bulky silicone or latex rings which may have been worn for up to 6 months. The NuvaRing™ is very different. It contains both estrogen and progestin, the ring is made from vinyl, is very soft and flexible, is easily inserted and removed with no fitting or special placement, and is only worn for 21 days, then discarded. Because this ring is the only ring available on the US market for the remainder of the chapter when the word ring is used it will refer to the CVR, the NuvaRing™.

Transparent ethylene vinyl acetate copolymer is used to form the 54 mm (around 2 inches) diameter ring with a cross-sectional diameter of 4 mm (around 1/8th inch). The ring releases 15 mcg of ethinylestradiol and 120 mcg of etonorgestrel (also called 3-keto-desogestrel) daily. The progestin component is responsible for the contraceptive action of the ring with ovulation blocked even if the ring is kept in an extra 2 weeks. The bioavailability of the progestin is 100% but the estrogen only 50% hence serum estradiol levels are lower than any OCP but constant. There are still estrogen effects measured on SHBG and HDL levels indicating hypoestrogenism does not occur.

The method failure rate was similar to the OCP during the clinical trials with less than 1% of women experiencing a pregnancy with perfect use and 2% failure overall. Perfect use implies the woman inserts the ring within the first 5 days of menses when beginning use and then leaves the ring in place for 21 days. If the ring is removed it must be returned to the vagina within 3 hours or a back up method is needed for 7 days. Following the ring free week it is very important a new ring then be inserted to make sure no more than 7 days are ring free. Because the CVR is a low estrogen product, it can be used to suppress menses by using it without a ring free week.

With coitus the partner may be aware of the use of the ring. In studies approximately 75% of partners could feel the ring but it was very rare that the partner complained. The ring is small and soft so unlikely to be painful when touched by the penis. The amount of steroid hormones released by the ring is low and with the brief penile exposure (average coitus 4 minutes) the risk of hormone exposure is low especially since the penis is keratinized skin.

Benefits

- The same benefits as the OCP including a reduction in dysmenorrhea, menstrual flow, anemia, and ovarian cysts are likely.
- Do not have to remember a pill every day.
- Once the ring is in place then nothing needs to be done for 21 days.
- The contraceptive steroids are absorbed from the vagina and this delivery system avoids the gastrointestinal tract and first pass hepatic metabolism seen with oral administration.
- The 15 mcg of EE2 with only 50% systemic absorption means this ring is currently the lowest combination or estrogen containing contraceptive on the US market. This does not mean it can be

given to women with estrogen contraindications only that it may be better tolerated by those women sensitive to estrogen side-effects.

Absolute Contraindications
For women with any of the following, methods with estrogen like the ring should not be prescribed.

- Women with a **personal history** of a blood clot or **thrombolic event**, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, or coronary artery disease.
- **Known pregnancy**
- Known **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormones could worsen their prognosis.
- **Active hepatitis with jaundice**, liver failure, hepatic adenoma, and hepatic malignancy
- A girl that has **never had a menses**, since estrogen will stop her bone growth. Once menarche is reached, even one menses, then endogenous estrogen levels have begun.

Relative Contraindications
For women with any of the following, methods containing estrogen like the ring should not be prescribed unless the client insists this is the only method she will use. She must then sign the Birth Control Method Specific Informed Consent Form and the provider must document the discussion about alternative methods offered and the client accepting the risk from estrogen. In addition, the 20 mcg EE pill dose or the ring should be prescribed unless documented intolerance and the patient understands her risk may be increased with increased estrogen.

- Women **35 or older who smoke** tobacco. Women smokers aged 35 to 44 may only use 20 mcg pills or the ring if they sign the **Birth Control Method Specific Informed Consent Form** and are counseled to reduce to ≤15 cigarettes a day.

- Women with more than one **first degree relative with a history of a thrombosis** that occurred spontaneously (no injury or pregnancy, and especially if clotting event when young) may have inherited a thrombophilia. If the woman wanting COC pills or the ring who has **never taken estrogen or had a pregnancy** then a COC pill or the ring might be her first exposure to sustained estrogen and could induce a clot. Remember many women could have an inherited decrease in the ability to stop a clot and yet they may never have a problem with a blood clot. One calculation published by an Italian research group stated that COC pills would have to be withheld from 90,000 women to prevent one DVT. Since only 1% of DVTs cause death, it makes no sense to withhold COC pills to women for just a family history. A study of women with blood clots found very few had a family history which suggests family history will not predict many events. Even if these women with a family history had the $300 worth of tests done to see if they inherited the gene, half the time the tests will be negative and she could still have a hereditary propensity to clot. Use the **Birth Control Method Specific Informed Consent Form** if family history and no prior estrogen exposure to document she was told of the unknown and probably very small risk of blood clots when using estrogen. To put the risk of getting a blood clot in perspective, if one followed 100,000 women for one year, five of them would get a DVT (1% are fatal). If you then gave all these women COC pills, then 10 to 30 of them would get a DVT during the year, but if they were all pregnant, 60 to 100 of them would get blood clots. Increased venous thrombosis has been reported in OCP users of pills containing desogestrel. The ring contains the metabolite of desogestrel consequently these precautions apply to the ring. A recent study of

clotting found a significant increase (2x risk) in clotting in women on desogestrel compared to other progestins. For this reason, avoid desogestrel in **obese women (BMI >29)**, women who are **relatively immobile**, women with a **family history of clotting** who are to be new pill users or women with no prior estrogen exposure, or women with other risk factors for clots. You may refer for familial thrombophilia evaluation if client has two first-degree relatives with clots especially if an affected relative can also attend the visit, to the Hematology Clinic at Harborview Medical Center (see Information About Referral to Harborview Medical Center Handout).

- Known or suspected **migraine headaches**, which may be worsened. If frequent vascular symptoms like blindness or numbness then refer to neurology and do not prescribe COC pills or the ring. If migraines with vascular symptoms that are rare or in the distant past, give only 3 cycles and evaluate for exacerbation. Have the woman keep a diary of her headaches using the Headache Diary and if she notices the headaches are worse during the pill or ring free interval then consider estrogen withdrawal etiology and consider extended cycles or skipping the pill or ring free intervals. If continuous ring use is prescribed counsel and document using the menstrual suppression chapter of the guidelines being careful to document the woman was told that this is not FDA approved or labeled, could cause more ovarian suppression, to expect spotting and irregular bleeding initially, and if amenorrhea, perform HCG testing at revisit.

- **Chronic active hepatitis** usually from a viral etiology like hepatitis B or C or a history of jaundice during pregnancy or chronic liver disease like Gilbert's Disease. Question the client and if she reports jaundice or documented hepatitis with abnormal liver enzymes within past three years then send a liver panel. If she has had no jaundice or documentation of elevated liver enzymes in past three years, then the prescription can be begun with one ring on the same day as the baseline liver enzyme panel. If the liver enzymes on the baseline lab test are double the normal values then plan to repeat liver panel in 3 months and after one year of use. Refuse a refill if enzymes have worsened until consultation with Family Planning Medical Director. If the enzymes were more than double the normal value, a woman has impaired liver function and her liver cannot metabolize the estrogen. Estrogen is not toxic to the liver and it will not worsen liver function, but a low dose exposure will become a high dose exposure because metabolism is impaired and she is then exposed to the risks of thrombosis. The process of metabolizing the estrogen could also possibly worsen her liver's ability to metabolize other medications.

- **Hepatic adenoma**. The old high dose pills used to be associated with benign hepatic adenomas, which could sometimes distend, enlarge the liver, and rupture causing bleeding. Recent literature states the low dose pills have not had this problem but any estrogen containing prescription label will contain this warning. If someone has a known diagnosis of hepatic adenoma, estrogen is contraindicated.

- Suspected **malignancy of the breast or endometrium** because these tumors have estrogen and progesterone receptors and use of hormonal products could worsen their prognosis.

- Suspected **pregnancy,** although there is no evidence of teratogenesis in women who inadvertently took low dose oral contraceptives during the first four months of pregnancy.

- Women with **diabetes and microvascular disease** such as retinal or renal damage proven or suspected is an absolute contraindication to estrogen use. Retinal vessel damage is not usually seen till after 10 years of insulin use and is very rare in non-insulin users. Diabetic women on insulin are followed by primary care providers and should have regular eye, renal and lipid evaluations with these

providers. Estrogen and progestin use may change slightly the insulin dose needed but it is safe, will not worsen their diabetes, and is preferable to pregnancy.

- Women with **hypertension,** even if treated, have an increased cardiovascular risk with the use of estrogen. Consider changing to a method with no estrogen, or if unacceptable, the 20 mcg estrogen pill or ring with the **Birth Control Method Specific Informed Consent Form**. If the blood pressure remains elevated or worsens after 3 months, then COC pill or ring use should cease. Estrogen can increase blood pressure and fluid retention. This means hormonal contraceptives can interfere with hypertension medications and treatment.

- In women with **epilepsy**, pills or the ring may be less effective due to **seizure medication** use. This includes carbamazepine, primidone, phenytoin (Dilantin), and phenobarbital. The Family Planning Program will not be prescribing 50 mcg estrogen dose pills because estrogen absorption and metabolism is very different in individual women. The woman on a high dose estrogen pill is exposed to potentially higher thrombotic risks. Estrogen also lowers the seizure threshold in the brain and can increase the number of seizures. The IUD or DMPA injection are the preferred hormonal contraceptive in women on antiepileptic medications. There have been no reports of the use of the ring in women taking these medications and it is a labeled contraindication.

- Use of **rifampin** for tuberculosis increases the metabolism of estrogen and will make the pills and probably the ring less effective. During short-term therapy such as meningitis prophylaxis, continue the ring but use a back-up method also as rifampin use has been associated with many pill failures;

- **Immobility** such as need for a wheelchair, non-weight-bearing long leg cast, major surgery defined as causing immobility for more than two days or a long surgery, greater than two hours, planned, etc., which will predispose to thrombosis. Need to discontinue the ring use 4 weeks prior.

- **Any patient with acute or recent serious illness or chronic serious cardiovascular, vascular, or renal disorders** which may be aggravated by thrombosis or fluid retention such as congestive heart failure, renal dialysis, artificial heart valve for which the client is on anticoagulants, Lupus, Kawasaki disease with prior CAD, and many more conditions. If a patient has a serious medical condition it is often prudent to consult the Family Planning Medical Director prior to prescribing an estrogen containing method because there may indeed be a risk not discussed in the guidelines.

- **Hydatidiform mole or choriocarcinoma** currently being treated, with elevated serum HCG levels, should not have COC pills and perhaps not use the ring since similar hormonal medication until the HCG levels are normal. A large case study of women with choriocarcinoma found that women given COC pills while their HCG levels were elevated were significantly more likely to require chemotherapy than those that did not use exogenous hormones until the HCG level had returned to normal (which would be close to zero).

Precautions

Women with the following may be given a ring prescription if, in the judgment of the clinician, an alternative method of contraception would not be acceptable to the client or would increase the risk of an unwanted pregnancy.

- **Pelvic relaxation or prolapse** such that the ring may be expelled easily. Expulsion was rare in the studies with the ring, with fewer than 2% of women quitting because of ring expulsion, but they

excluded obese women and women with chronic constipation. Hence a woman who frequently strains when toileting may lose the ring in the toilet. The ring can be washed with warm water and if needed a mild soap, and replaced into the vagina.

- **Undiagnosed vaginal bleeding** until diagnosis is established and managed. Although often COC pills or the ring could be used to regulate irregular menses. If the COC pills regulate the menses there is usually no further need for diagnostic tests. A 3 to 6 month trial of COC pills or ring can be a diagnostic maneuver, proving that the history of irregular menses was most likely caused by lack of regular ovulation.

- **Lactation:** The amount and possibly the quality of milk will be lessened with the use of estrogen especially in the first 6 months post partum. If weaning is desired, COC pills or the ring may be used to decrease the flow of milk. If lactation is desired a progestin-only hormonal contraceptive is preferred and can actually increase the amount of milk produced. If lactation is well established and greater than six months, then a change to COC pills is possible but if there are problems, change back to POP.

- **Active gall bladder disease**. Estrogen use can worsen stone formation and dilation of the bile ducts. If they have had their gallbladder removed then there is no risk with COC pill or ring use.

- **Chronic yeast vaginitis.** This may possibly be worsened by estrogen use especially if cyclic with monthly withdrawal bleeding. Estrogen users often have yeast colonization. There is a study that found DMPA use, which reduces estrogen levels, decreased the number of yeast infections.

- **Chronic vaginitis or vaginal pain.** In the studies with the ring approximately 1/3 of the women quitting the ring did so because of complaints relating to the ring including an increase in vaginal discharge. There were no exams to confirm any pathology or comparison to other hormonal contraceptives. Several studies with the NuvaRing™ included colposcopy and cultures and there were no significant changes with ring use so it is highly unlikely the ring harms the vagina. But a woman with chronic problems may have difficulty accepting or tolerating a vaginal delivery system.

- **Spermicides** and **topical vaginal medications** did not alter the contraceptive steroid release from the ring and thus can be used when using the ring according to the package labeling.

- Use of **oral antibiotics** in particular metronidazole, amoxicillin, ampicillin, and tetracycline, have been associated with case reports of COC pill failure while taking these and other antibiotics. The mechanism for the failure is probably a change in the gut flora so the entrohepatic absorption and circulation of the estrogen and progesterone change resulting in subtherapeutic levels. It is unknown at this time if the ring because it delivers the hormones via the vagina would be unaffected by antibiotic use and at this time it is prudent to give the same advice as given with OCP use. The most conservative advice is to use a back-up method for the duration of antibiotic use (see OCPs and Antibiotic Use Handout) although the current Contraceptive Technology edition does not think this is necessary with COC pill use, others do suggest one discuss it with the woman and recommend a back up method until 7 days after the antibiotic use is completed. POP users should be told to use a back-up method. If the woman is on chronic, daily low dose antibiotics (like acne suppression with tetracycline or nightly Septra for pylonephritis prevention) use the **Birth Control Method Specific Informed Consent Form** advising the pill method may not be as effective as in a non-antibiotic user. If no break through bleeding or diarrhea then most likely there are effective hormone levels. Do not begin these chronic antibiotic users on a 20 mcg COC pill since these are usually women being

treated for acne and would benefit from 30 mcg of estrogen and potentially the daily antibiotic could make the steroid levels even lower.

- Use of other chronic medications, consult the OCP chapter as some may compromise hormonal contraceptive efficacy.

History and Consent

The standard medical history is reviewed by the clinician to confirm absence of absolute and relative contraindications. Counseling should be provided to ascertain ability to comply with placing and removing a ring from the vagina. If contraindications do exist then document other methods discussed, patient's decision to not use other methods, and if appropriate sign the **Birth Control Method Specific Informed Consent Form**. If the client has signed this consent form then she needs to sign it every year when she is given a prescription for the ring. Her risk profile may change and there needs to be documentation that she was offered other methods every year and continues to choose the ring.

Examination

Baseline blood pressure, weight, and pregnancy testing (if needed) should be performed prior to prescription. Although there is no increase in the risk of breast cancer with pill use **annual breast exam** should be performed to emphasize the importance of early detection and screening. There is a small possibility that a rare form of cervical cancer, adenocarcinoma, is increased in long term COC pill users due to the estrogen proliferative effect on cervical ectopy or glandular epithelium of the cervix, and for this reason **annual cervical cytology** should be offered. There is an option of delaying the pelvic exam and those guidelines should be consulted. Progestin thickens the cervical mucous and atrophies the endometrium and this can decrease the ascent of bacteria to the upper genital tract, thus one can find asymptomatic chlamydial infections in OCP users. All ring users should be offered STD screening as per the PHSKC STD guidelines.

Prescribing Rings

During the studies with the ring women were given the ring and did their first insertion at home and no additional teaching was done in the clinic and there were no reports of a retained or "lost" ring. However the package insert should be discussed with the client and a sample ring could be used to demonstrate the insertion and removal technique. The blue sample rings cannot be used in the vagina as they have not verified the dye is safe. The ring must be kept refrigerated prior to dispensing because once the rings are at room temperature they need to be used meaning inserted in the vagina by 4 months. For example if on October 1st one dispensed 4 rings, then by February 1st the last ring must be inserted and it is still effective for that cycle. Rings can be stored by the patient in the refrigerator but they do not need to be. A ring stored in the refrigerator can be kept for 2 years if labeling allows. The rings should not be exposed to direct sunlight or to extremes of temperature. Room temperature is defined as 59 to 86 degrees Fahrenheit per the package labeling. Prescription medication can usually only be dispensed by pharmacies. Washington pharmacy code allows dispensing of contraceptives, and only contraceptives, by non-pharmacy persons at Family Planning Clinics. However rings cannot be dispensed unless there is a valid and current prescription. A prescription can only be written or given orally by a provider with prescribing authority.

- **First time ring users** can only get an initial supply of 1 to 3 cycles. A 3 month revisit is mandated to ask about complaints or difficulties with ring use and to measure the weight and the blood pressure.

These are to be recorded by a clinic nurse and any problems evaluated by the clinician. Make sure the client is using the ring correctly. Use the **Female Contraceptive Visit Form** or similar note at visit. She can then be given another 4 months supply and because of the need for refrigeration and quality control clients cannot get an entire year's supply at one time and must return every 3 to 4 months for new rings.

When to begin ring use

Ring use should ordinarily be **started within the first 5 days of the menses.** If the woman is switching from another hormonal method like pills or injections the ring can be placed immediately with no hormone free interval or at least by the end of the pill free week. Some women report the ring can be displaced with use of a tampon and for this reason the first few days of the menses could be avoided if heavy vaginal bleeding is expected. But a first menstrual day start may induce faster and more complete ovarian suppression and is highly recommended if continuous ring use for menstrual suppression is being prescribed.

- Women starting ring **after the 5th day of menses** should use added protection for 7 days. If starting before or by the 5th day of menses then a week of back up for the 1st cycle is recommended by the ring labeling unless the woman has been using a hormonal method properly in the cycle prior.

- Ring use may be started **21 days post partum** in women choosing not to breast feed (estrogen can stop lactation) or on the **day of an abortion** for any pregnancy less than a late second trimester. After 24 or more weeks gestation, do not start estrogen use until three weeks post-delivery or abortion to minimize the risk of increased thrombosis post delivery. By 2 to 3 weeks post partum, 30% of non-breast feeding women will ovulate and could potentially get pregnant.

- **Same Day Start/Restart** may be done if the patient understands and consents. This means the first ring is placed the day of the clinic visit and can even be done there in the clinic with teaching. This may be appropriate in women taking ECP, or who has recently been on pills and missed more than 3 days of pills, or who has had a history of irregular menses and waiting until menses will increase the risk of pregnancy. It may also be appropriate for women whom the provider thinks may benefit from ring use teaching. Documentation of a negative HCG test is required. Consider if the client also needs an EC prescription because regular dose OCPs will not act as an EC. The client must understand the need for a backup method for 2 weeks and that a pregnancy test should be done in 4 weeks, especially if no bleeding. Provide counseling to the client that beginning a hormonal method midcyle can result in increased break-through bleeding and if it is worrisome to the patient, it may be better to wait until the next menses. But in some women, like prior DMPA users, beginning a hormonal method when the client wishes to start is better than waiting for a menses. After 3 months of ring use typically the cycles are regulated and the same day start will have no lasting effect.

How to use the ring

The foil sachet is opened and after washing her hands the woman can place the ring in the vagina. There is no need for a pelvic exam or a fitting exam because the NuvaRing™ is not like a diaphragm. The ring can be placed anywhere in the vagina, "there is no wrong way to put it in". Once in the vagina the ring should not be felt and if the ring is felt the patient can just gently push it deeper into the vagina. Less than 2% of women using the ring in the studies quit using the ring because of expulsions and these were typically with defecation or bearing down and may have been only a single event. The ring is then left in place for 21 days. In the event the ring comes out it should be immediately replaced. If necessary the

ring can be rinsed off with warm (never hot or freezing) water and if necessary a mild soap. If the ring was left out for 3 or more hours then the labeling instructs the woman to use a back up method for 7 days. If the extended ring removal was in the third week of the ring use it is advised she skip the ring free week and after the 21st day just insert a new ring without a ring free week. After use of the ring, it is to be placed into the same or perhaps the next, foil sachet, sealed and discarded in the trash and never the toilet.

- Each month the client will need to remember to change the ring. One way might be to have her always take out on the 25th of the month and put a new one in on the 1st of the next month. This means the period week is of variable length but it is easy to remember and it is never more than 7 days so coverage is assured.

- Extended or continuous CVR use to suppress withdrawal bleeding. A woman could choose to do this with the CVR. The levels of hormone stay high enough to block ovulation up to 5 weeks (35 days) of use, but it is best to go no longer than 1 month of use per ring. Insert a new ring on a set day like the 1st of each month to take out old ring and insert a new ring. If the woman notices a lot of spotting at the end of each month, changing to a new ring sooner (by 4 weeks) may help. It is likely just as with continuous pill use irregular bleeding will be common in the first 6 months and less of a problem with long term use.

Product Brochure

The manufacturer's patient product labeling is to be given to the client each time rings are dispensed. Clients can also find information at www.nuvaring.com or 1-877-nuvaring. The company will be making available a monthly timer to help women remember to take out the ring on day 21 and reinsert a new ring on day 28.

Possible Side Effects

- **Nausea.** The nausea is not the result of a local effect on the stomach but because the estrogen is working on the brain to cause nausea. For this reason even women using the ring may experience nausea.

- **Weight Gain.** In studies of large numbers of women OCPs did not significantly increase the weight of the population however individual women may respond differently to hormone use. Weight gain is usually from increased food consumption and decreased activity. In the 2400 women using the ring in the clinical trials the weight gain was similar to that as measured in pill users, a little under a pound after one year.

- **Breakthrough Bleeding (BTB) or Spotting.** BTB is when the woman reports having bleeding between the ring days or scheduled withdrawal bleeding. BTB is defined as enough bleeding to need a hygiene product like pads or tampons and spotting is when no protection was needed. In the studies with the ring compared to the pill there was less BTB with the ring, but 1/3 of women were still

  bleeding at the end of the ring free week so important to tell patients to put in a new ring, even if bleeding, after 7 days of no ring.

First 6 months of ring use:

- **Reassure client** this is very common when first beginning hormonal methods and is often because the uterine lining is shrinking and shedding under hormonal influence.

- Use the Menstrual Calendar Reminder Card to help patients track their bleeding and spotting.

- Be certain that the ring is being **used as scheduled** as a drop in the hormonal levels can worsen BTB and spotting. It is possible a shorter ring free interval or no ring free interval may help but totally unproven. What is known is with time the amount of BTB will decrease.

- **Rule out other causes** of bleeding as appropriate by history and exam such as pregnancy, polyps, cervicitis, or other medication use.

- **Ibuprofen,** 400 to 800 mg three times daily or Naprosyn 500 mg twice a day beginning with menses, can reduce the amount of menstrual flow and the frequency of BTB or spotting. Menses or menstrual withdrawal bleeding is triggered by a drop in progesterone, which results in prostaglandin production. These chemicals then shed the endometrium by vessel spasm hence the pain and cramps.

- **Recent history of DMPA:** Injections could alter the ratio of hormone levels since DMPA is not completely cleared for 6 months after use. Because of DMPA's progestin effect on the endometrium to cause atrophy increasing estrogen may suppress BTB or spotting. The ring releases a very potent progestin, but only a low level of estrogen. Switching to a pill with a higher estrogen dose may be tried. Use of the ring with concomitant combination birth control pills is contraindicated. There are no published studies on the best formulation to transition women from DMPA to ring use. In a randomized study of DMPA users, supplemental estrogen did not help BTB. This has not been studied in OCP or ring users, but it is unlikely to help except acutely and since estrogen causes proliferation it could be counter productive with increased bleeding when the supplemental estrogen is stopped. Switching to a COC pill with an increased EE dose for ongoing use might be considered.

- **Alcohol use** can also change the metabolism of estrogen so that the estrogen is metabolized slower giving higher estrogen levels. Using alcohol daily, binge drinking or stopping alcohol consumption could trigger some transitory BTB or spotting.

- **Tobacco use** induces metabolism of estrogen making some smokers more vulnerable to breakthrough bleeding and spotting.

After 6 months of ring use:

- The endometrium has atrophied and the most likely etiology is noncompliant ring use. For this reason **pregnancy testing** may be advised if the woman presents with bleeding complaints.

- If unexplained breakthrough bleeding occurs in women established on the ring, do an **infection check** and evaluate for other sources of bleeding before pill change. If no etiology is found and the BTB or spotting persists after two cycles, referral is indicated to gynecology clinic to evaluate for uterine or ovarian pathology.

- **Breast Tenderness.** This will usually disappear within three cycles. If not, lower doses of estrogen may help. Instruct in obtaining and using proper bra. Discuss the possible role of caffeine. Some women may benefit from vitamin E 400 IU daily.

- **Headache.** Allow two to three cycles for adjustment and recommend aspirin, ibuprofen or acetaminophen. Use the **Headache Diary**. Consider discontinuing the ring if migraine headaches worsen with continued use. If severe, persistent, or vascular symptoms like blindness or numbness develop, stop ring use and refer to a neurologist and to an emergency room if acute. Estrogen withdrawal headaches can decrease with cycle elimination and taking a 20 mcg OCP or using the ring continuously without a break for menses may be considered.

- **Watery vaginal discharge.** If excessive vaginal discharge is still present after two to three cycles, perform a pelvic exam and rule out vaginitis or cervicitis. If it is a physiologic discharge there is no treatment and ring use might be discontinued with a follow up visit a month later to see if it has resolved.

- **Oligomenorrhea and Amenorrhea.** This is uncommon with cyclic ring use (less than 5% of users over one year). Menstrual changes are not harmful and the client needs only reassurance. If the woman strongly desires to have periods, a higher estrogen product like a pill may be tried. If there is any reason to suspect pregnancy (forgotten pills, symptoms, suspicious pelvic exam, etc.) or two missed menses successively, then a pregnancy test should be done as appropriate.

- **Depression and Irritability.** A low sodium diet may help if premenstrual mood changes. Hepatic metabolism of estrogen can deplete vitamin B6 (pyridoxine) so a 50 to 100 mg daily dose can be tried to see if mood improves. There is no evidence the ring has no effect on the B6 system and it is possible the lower dose of estrogen could also affect mood. If mood changes appear to be cyclic, then extended or continuous cycles could be tried.

- **Increased Blood Pressure.** Repeat measurement after a brief rest in the clinic. If the increase is sustained, consult and use the Family Planning Hypertension guidelines. If diastolic continues to be 90 mm or greater then the client can use the ring only after signing the **Birth Control Method Specific Informed Consent Form**, and repeat visit in 3 months with discontinuation if still hypertensive.

- **Acne and oily skin.** Estrogen causes an increase in hepatic production of Serum Hormone Binding Globulin (SHBG). SHBG then binds to free testosterone and androgens effectively reducing the free, which are the active, androgenic hormones. This is why all COC pills can reduce acne and hirsuitism. Ortho Tricyclen, a Norgestimate triphasic, is a COC pill that has package labeling as a treatment for acne. A study compared this pill to placebo and not to another COC pill. Other COC pills also reduce acne. Probably the best pill to reduce acne would be a pill with 35 mcg of EE and low dose of a weak nonandrogenic progestin like NET (Ovcon 35). The ring has not been proven to reduce acne although acne was a rare complaint in the studies and it is unlikely to be different than the COC pill since SHBG levels were actually higher in the ring users compared to the pill users.

- **Decreased Libido.** This may be related to decreased circulating androgens. Vaginal dryness may be managed with lubricants or increased estrogen dose. A review of sexual arousal and taking a sexual history is also important.

- **Chloasma** (melasma). Hyperpigmentation areas on the face are a great cosmetic concern. Occurrence is related to sun exposure, family history, and pregnancy, and can be due to estrogen levels especially pregnancy and COC pill use. Pigmentation can be reduced by avoiding all exposure to the sun. Use of a high potency sunscreen especially on the affected areas may benefit. Bleaching agents such as hydroquinone, or tretinoin in topical creams are frequently helpful. DO NOT prescribe these, only refer. If a woman develops chloasma during pregnancy or with COC pill or ring use she is at risk to develop it with repeated estrogen use or pregnancy. Sometimes the skin changes are permanent even after discontinuation so women may choose to discontinue use of rings or COC pills to prevent further discoloration.

Adnexal Masses

Guidelines

- The normal ovary in fertile-age women is up to 4 cm in diameter. The normal uterus is about 7 cm in length and 6 cm wide.
- An enlarged ovary, especially if soft or cystic, is usually because of a functional or physiological cyst. Ovulating women make follicular cysts early in their cycle and then mid-cycle, ovulate, and later in the cycle and up to the first few days of the menses, a corpus luteum cyst can often be palpated or seen by ultrasound.
- Cysts are found in over 50% of menstruating age women by ultrasound and if small and asymptomatic, they are usually of no clinical significance. Small functional cysts may even be seen by ultrasound in postmenopausal women.
- Cysts or enlargements early in pregnancy are usually the corpus luteum, which is necessary to maintain the pregnancy up to about 10 weeks.
- Cysts over 8 cm are frequently pathological, however, there are some functional cysts 6 to 8 cm in diameter which resolve by the next cycle.
- Mild uterine enlargement is normal after pregnancies. Confirm the enlargement is symmetric and stable by re-examining in 3 to 6 months and if still concerned, refer for evaluation and imaging.
- If the woman is prepubertal, postmenopausal, or if the client has been on birth control pills or DMPA injections for over 6 months, or if the enlargement is bilateral, then the enlargement is usually not due to a functional ovarian cyst. These adnexal masses should probably be referred for evaluation and imaging.

Examination

The standard medical history is reviewed and enlarged upon as necessary. Document if there is a family history of adenocarcinomas like breast, colon, or ovarian in first degree relatives. If indicated, perform HCG testing and STD testing. Obtain outside records if a prior history of ovarian or uterine enlargement on exam or ultrasound.

Management

- Rule out pregnancy. If the woman is not pregnant, three cycles of pills may be given to be started on the first day of her menstrual cycle. OCPs and DMPA will suppress ovulation and can prevent future cysts. If enlargement persists on pelvic exam after 6 to 8 weeks, refer the client to a gynecology clinic. She would then need ultrasound imaging and that should not be ordered by the Family Planning Program as we do not do the surgery or manage persistent adnexal masses.
- If the woman is pregnant, note the enlargement on the verification of pregnancy form given to the client for her clinician. Explain the signs of ectopic pregnancy if the client has risk factors like prior ectopic or infertility treatment. Refer emergently if the client is having bleeding or pain. Refer for abortion or pregnancy care as desired, but have her inform the clinician of the "cyst" when making her appointment. Reexamine the woman after termination of pregnancy, and if the cyst persists, refer for evaluation and imaging.

- If the mass is solid or is a cystic mass larger than 8 cm, do not follow and refer immediately (next available appointment) for evaluation, gynecologic work-up for possible surgery, and the referring facility should order the imaging studies, not the family planning program.
- If the records report uterine fibroids were diagnosed, then these are almost always benign. The size of the fibroids needs to be checked in 6 months from initial diagnosis and then every year to make sure there is no rapid enlargement. OCPs and DMPA are okay to prescribe. If the woman develops irregular bleeding not controlled with cyclic OCPs or rapid uterine size enlargement, then she needs to be referred for evaluation and possible surgical treatment.
- If a family history indicates there could be a familial tendency for ovarian cancer, refer the client for screening and possible genetic testing (206-616-2135 is a UW referral). All American women have a 1% lifetime risk of ovarian cancer. Women with 1 first degree relative have an increased lifetime risk of about 6% and with 2 first degree relatives the risk can be as high as 40% if the woman carries the same gene as her relatives. Sometimes women with these genes will choose to have prophylactic ovarian removal. There is evidence that the use of OCPs can prevent not only sporadic but also hereditary ovarian cancers. Use of OCPs and probably DMPA for 5 to 10 years, because of the progestin effect and ovulation suppression can decrease a woman's lifetime risk of ovarian cancer 50 to 80%.

Amenorrhea

Definitions

- **Primary amenorrhea** is when a 16-year-old has never had a menses. The Family Planning Program should not be working up primary amenorrhea. These girls should be referred.
- **Secondary amenorrhea** is when there has been no menses for six months in a woman with menses in the past.

History and Examination

The standard medical history is reviewed and enlarged upon as clinically appropriate by the clinician. The physical examination is performed to evaluate breast and pubic hair development. A urine test for pregnancy and a cervical smear for fern test documenting estrogen production may be performed in the clinic. HCG testing should always be considered. Consider referral for a prolactin test if there is long-term amenorrhea especially with galactorrhea. A level of >100mg/dL suggests a prolactinoma. A TSH could also be done if the prolactin is elevated or if there are signs or symptoms of thyroid disorders.

Treatments

It really depends on what the woman desires, if she is seeking pregnancy the plan will be very different from a woman wanting contraception.

Medroxyprogesterone may be used to induce menses when there is amenorrhea due to anovulation. Provera provides the progesterone stimulus to the estrogen-primed endometrium to begin a menses as the progestin is withdrawn. Provera will not stimulate a menses in a woman with little estrogen production.

Indications for Medroxyprogesterone

- Postpill or post partum amenorrhea of over eight weeks duration, where menses are desired.
- Postpill or other amenorrhea of six months are more to demonstrate intact hypothalamic-pituitary-ovarian uterine system.
- If DMPA injection use in the past, do not expect oral provera to always trigger a menses until 6 to 12 months after the last injection since estrogen production could still be suppressed.
- Secondary amenorrhea when pregnancy has been ruled out.
- If a client with secondary amenorrhea is seeking contraception, COC pills can also be given as a non-routine OCP start if strongly suspected oligovulation is the etiology. There is no reason to prove it and sometimes a provera withdrawal may trigger an ovulation and the client then experiences an unwanted pregnancy.

Precautions for Medroxyprogesterone

- Known pregnancy although it DOES NOT cause birth defects;
- Tumors of breasts or reproductive organs;
- The dose used will not prevent pregnancy.

To Prescribe Medroxyprogesterone Withdrawal Document

- Negative sensitive urine test (25mIU) for pregnancy.
- Normal pelvic exam in the past 12 months.
- Client is aware this is not a contraceptive method and she can still get pregnant.

Prescribing Medroxyprogesterone

Prescribe medroxyprogesterone 10 mg one daily for 10 days and counsel the client to expect menses after the pills have been taken. Teach client to use the Menstrual Calendar Reminder Card to document her cycles.

Follow-up

- An appointment should be made in two to three weeks after taking the medroxyprogesterone pills.
- If menses has occurred, this rules out hypothalamic or pituitary problems. Birth control may be instituted as desired by the client. No further testing is necessary.
- Birth control could have been started for the client without a provera withdrawal if pregnancy is not being sought, secondary amenorrhea less than 12 months, and no signs or symptoms indicative of hypothalamic or pituitary dysfunction.
- If menses has not occurred after provera, a urine test for pregnancy and a pelvic examination if not already done should be done. If these are negative and the amenorrhea has been for more than six months duration in a woman who is not nursing and is under 40 years of age, consider referral for endocrine evaluation to assess for premature ovarian failure or other endocrine disorder.

Androgen Disorders

Definitions

Androgen disorders are very common. They occur in about 10% to 22% of women and usually start during puberty. Many of the women consider themselves to be normal but some may have polycystic ovary syndrome (PCOS) or hirsutism.

Women with androgen disorders frequently present with gynecological problems including menstrual irregularity, dysfunctional uterine bleeding, amenorrhea, infertility, ovarian enlargement or frequent ovarian cysts, endometrial hyperplasia, fibrocystic breasts, or even virilization.

Dermatological manifestations include acne, especially if it is severe or cystic, oily skin, hirsutism, alopecia, seborrhea, hidradenitis suppurativa, and acanthosis nigricans. Many women shave or mask hair or skin changes and must be specifically asked about these conditions.

Congenital adrenal hyperplasia (CAH) occurs in 1/14,000 women but is more common in Ashkenazi Jews, Alaskan Eskimos, Latinos, and Yugoslavians. Consider androgen disorders in women with a large variety of presenting signs and symptoms. Any woman whose menstrual cycle varies by more than 5 days each month should be considered as possibly having an androgen disorder. Women with infertility should be referred to evaluate for adult and irregular menstrual cycle onset CAH which can reduce fertility.

Medical manifestations include the metabolic syndrome manifested by android obesity, elevated blood pressure, insulin resistance, adrenal hyperplasia, and lipid abnormalities including elevated triglycerides and decreased HDL. Divide the circumference of the waist by the circumference of the hips and if the ratio is greater than 0.85, this is the definition of android obesity and it increases the risk of long term complications and morbidity and mortality. Many women can later develop diabetes and should be screened.

Long term risks from androgen disorders include hypertension, diabetes mellitus, cardiovascular disease, endometrial cancer, ovarian cancer, and possibly breast cancer, thus the need to identify these women and prevent the consequences when possible is important.

Evaluation

Management can frequently be based upon clinical diagnosis without any laboratory testing. Endocrine tests are expensive, sometimes not diagnostic, and vary because of cyclic or diurnal changes. Assessment of hirsutism can be done with the Hirsutism Classification Chart. It is prudent to do glucose screening and lipid screening for all women over 35 with androgen disorders. Consider an HCG for amenorrhea, a hemoglobin or hematocrit for bleeding problems, and an endometrial biopsy referral in high risk women over 35 with a worrisome bleeding pattern because endometrial cancer is common with prolonged PCOS not treated with progestins.

Most women with androgen disorders do not need special endocrine tests. These should be ordered in consultation with the Family Planning Medical Director. Androgen evaluation to rule

out the very rare cases of tumors is indicated for rapid onset of hirsutism and virilization (enlarged clitoris, deepened voice, or male pattern balding). Free or total testosterone levels frequently are elevated in all androgen disorders. However, free testosterone is normal in about one-third of women with androgen disorders. Levels of testosterone well in excess of 200 mg/dL could suggest an ovarian or adrenal tumor. High levels of DHEA-S (dehydroepiandrosterone sulfate) indicate an adrenal problem and if well in excess of 700 micrograms/dL, could suggest an adrenal tumor. In PCOS the LH is typically higher than the FSH but this is highly variable and not the only result needed for diagnosis.

Treatment

If there is amenorrhea, do a withdrawal test with medroxyprogesterone acetate (Provera). If there is no bleeding, refer for endocrinological evaluation. All women with androgen disorders who are not actively seeking pregnancy should be strongly encouraged to use a combination oral contraceptive pill from puberty to menopause, except for intervals related to pregnancy. This will suppress the androgen production and relieve or treat many of the associated problems. Results often take four to six months to be noticeable to the client. Estrogen can help prevent more hair growth but it will not get rid of existing hair. These women are at especially high risk for cancer of the endometrium and cancer of the ovary and the cancer risks can be decreased 50% to 80% in these women with COC pill use.

Advise the woman to avoid drugs that can cause androgen effects including minoxidil, diazoxide, phenytoin, phenothiazines, androgenic progestins, glucocorticoids, cyclosporine, danazol, streptomycin sulfate, and anabolic steroids. An anti-androgen, Spironolactone, can be helpful in preventing further hair growth especially if used with an estrogen-containing pill like Ovcon 35. It can be prescribed in doses of 25 to 100 mg once to three times a day with the maximum daily dose of 300 mg. It is best to begin slowly. If you have never prescribed it before, consult pharmacy or other resources. Spironolactone is a diuretic, anti-hypertensive agent and long-term use of this product should involve potassium monitoring and because is it a possible teratogen it is important to use this only with an effective contraceptive.

Recommend the use of local measures for acne such as benzyl peroxide, antibacterials and retinoic acid (see Acne Handout). Hirsutism can be managed temporarily with plucking, bleaching, or shaving and permanently with electrolysis or laser hair removal. Topical 13.9% eflorithine hydrochloride (Vaniqa ™) may also help to remove unwanted facial hair growth.

When pregnancy is desired, many women with androgen disorders may have infertility problems related to oligoovulation; research has found if obese women lose 10 to 15% of their body weight, normal ovulation can often return. If the Basal Body Temperature Chart indicates anovulation, referral to an infertility clinic is indicated.

Breast Problems

History

The standard medical history is reviewed for a history of breast cancer in first degree relatives (mother, sister, daughter, or even father's sister if age ≤50 when diagnosed with the cancer). If more than one first degree relative with breast, ovarian, or colon cancer, especially if at an early age at diagnosis, then counsel client to seek genetic testing and advise about possible increased cancer risk and need for early screening. If breast cancer was diagnosed in a first degree relative, then the woman should be advised to begin mammogram screening 10 years prior to the age of the relative's diagnosis of cancer.

Examination

Complete breast examination is performed and results documented. Breast self-examination technique should be reviewed.

Management

Cyclic Mastalgia: Often inappropriately called "Fibrocystic Breasts"- these women often have tender or nodular feeling breasts. Explain and reassure the woman. Advise reduction in caffeine products and 400 mg of Vitamin E daily can help. If the client has specific concerns or abnormal findings, then referral to a breast specialist is indicated. One of the biggest causes of malpractice suits is a delay in the diagnosis for women with breast cancer. Therefore, any client that continues to have breast pain complaints needs a specialist evaluation and possibly imaging.

Nipple Rash: Suspect contact allergic reaction. Have client use cotton bras. Avoid soaps, cosmetics, lotions, etc. If macerated, use soaks. If eczematoid, use hydrocortisone cream 1% applied lightly qid. If persists, refer to breast specialist, especially in women over age 35, where Paget's disease with cancer should be considered.

Nipple Discharge:

- **Milky discharge or Galactorrhea** is significant only if spontaneous (without expressing the breast). Can be unilateral or bilateral. Galactorrhea is a common side effect of hormonal contraception. Confirm fat globules present by examining the fluid under a coverslip and low power. Confirm no visual field loss or new, worsening headaches, which would possibly signal an enlarging pituitary adenoma. Outline the role of breast stimulation, hormones (OCP and DMPA), marijuana, tranquilizers, tricyclic antidepressants, narcotics, Aldomet, reserpine, and many other medications that change estrogen/progesterone levels.

  - If the woman is trying to get pregnant, no contraceptives for one year, no pregnancy, and definitely no hormonal contraceptives should be used for 6 months if OCP use history and 12 months if DMPA past use. Consider referral as sometimes small elevations in prolactin can reduce ovulation. There are medications that can reduce the production of prolactin.

- If the woman is using contraception with regular menses, then counsel about common causes of galactorrhea and plan recheck in six months and if persists, refer to primary care provider.
- If the woman experiences amenorrhea for 6 or more months, refer her to a primary care provider or, if not possible to refer, check PRL and TSH. Refer to an endocrine clinic for imaging if the prolactin is greater than 50, although usually no imaging or treatment is needed unless the prolactin level is greater than 100.

- **Sticky, green or blue colored, or grumous discharge** is usually due to benign ductal ectasia. The woman may have periareolar pain, itching, or occasionally erythema. Do a guaiac test to rule out presence of blood. Management is hygiene, avoidance of manipulation, and reassurance.

- **Watery, bloody, serosanguinous or serous discharge** may be due to a benign condition but is also suggestive of cancer. Confirm the lack of fat globules under microscopy and giauac the fluid. Often the woman needs mammography or surgical exploration of the duct. Refer to breast specialist or primary care physician. DO NOT send cytology of the fluid as that is best done at the referral clinic and the results may be misleading.

Patient Complaint or Exam Finding of Possible Breast Mass
Evaluate and record exam findings carefully on the chart. If the area of concern is cystic, soft, irregular and not a discreet mass, schedule the client for a revisit within 6 weeks or at a different point of the menstrual cycle and if concern persists, refer to a breast specialist. If the mass is fibrous, very firm, and discreet, or if the client found the mass and the provider can also palpate the mass, then the client warrants a referral to a breast specialist or to her primary care physician for diagnosis. Imaging should not be ordered without this consultation as there can be a 10% false negative rate with mammograms and sometimes ultrasound instead of mammography would be ordered and the imaging should be ordered by the specialty clinic so they have access to the images. It is usually not necessary to withhold hormonal contraceptives during this time of evaluation, it would be worse if the client become pregnant and use of OCP or DMPA has not been shown to worsen the prognosis. If the mass is diagnosed to be of benign etiology, then continue to follow the client with annual exams, carefully documenting the size and prompt referral back to the specialty clinic if there are changes or persistent patient complaints.

Screening Mammograms
Screening mammograms may be recommended every year in women over age 40, according to the ACS and ACOG, although an NCI panel recommended not beginning until age 50 with annual screening. Studies show routine screening mammograms on women under the age of 50 yield too many false positives to be cost effective. If a woman under 50 is to get a mammogram, it should be in the first two weeks of her menstrual cycle to improve the images (more false positive studies if done in last two weeks of menstrual cycle). In women with a family history of breast cancer in a first degree relative, screening mammograms should begin 10 years before age of diagnosis of cancer in their relative. In addition, women with early breast, colon, or ovary cancers in other family members may benefit from genetic screening with a breast specialist. Additional risk factors for breast cancer include obesity, daily alcohol use, high fat dietary intake, and lack of term pregnancy and/or lactation history. Perhaps when counseling women between the ages of 40 and 50 about mammography, a woman could be told of the controversy about the benefits and possible lack of benefit when screening before 50 but then decide based on her own perception of her risks.

Breast Cancer Risk Estimates
Reprinted below is a table from an article on breast cancer risk assessment for women with a family history of breast cancer (JAMA; 273:577-85).

Table 1. – Breast Cancer Risk Estimates for Members of Moderate-Risk Families*

Affected Relative	Age of Affected Relative, y	Cumulative Breast Cancer Risk by Age 80, %
One first degree	<50	13-21
	≥50	9-11
One second degree	<50	10-14
	≥50	8-9
Two first degree	Both <50	35-48
	Both ≥50	11-24
Two second degree†	Both <50	21-26
	Both ≥50	9-16

*Adapted from Claus et al. Risk estimates are derived by incl uding age extremes from the risk tables calculated by Claus. For example, for affected relatives younger than 50 y, the lower limit is the calculated risk if the affected relative is in the 40- to 49-y age group and the upper limit is the calculated risk for a relative in the 20- to 29-y age group. Thus, these figures represent the range of risk based on age and are not confidence intervals.
† Both paternal or both maternal

This table was published by the Susan G Komen Breast Cancer Foundation regarding the overall risk for all American women with no known family history.

What Is Your Risk of Developing Breast Cancer?

By age 25	one in 19, 608	By age 60	one in 24
By age 30	one in 2, 525	By age 65	one in 17
By age 35	one in 622	By age 70	one in 14
By age 40	one in 217	By age 75	one in 11
By age 45	one in 93	By age 80	one in 10
By age 50	one in 50	By age 85	one in 9
By age 55	one in 33	Ever	one in 8

Avoid Malpractice
Failing to diagnose breast cancer is the number one cause of malpractice suits. The most frequently cited reasons for this failure in an article (1995 OBG Management) were:

- Physical findings failed to impress physician (169 of 487 malpractice suits)
- Failure to follow up with patient (150)
- Negative mammogram report (125)
- Mammogram misread (110)
- Failure to do proper biopsy (110)
- Delay in or failure to consult (75)
- Failure to react to mammogram (60)
- Distracted by other health problems (55)
- Repeat exams did not arouse suspicion (55)
- Failure to order mammogram (54)

Dysfunctional Uterine Bleeding

Definitions
Menorrhagia >7 days or 80mL
Metrorrhagia – irregular intervals
Menometrorrhagia – irregular and excessive

Differential Diagnosis of Abnormal Genital Bleeding

- Pregnancy
- Cancer
- Infections; endometritis, cervicitis
- Anatomic cause; fibroids, polyps, bleeding from other sites (anus or urinary tract)
- Systemic; thyroid, drugs, hormones, bleeding disorders, herbs

Dysfunctional uterine bleeding is common in teenagers for the first two years after menarche due to immature pituitary-ovarian axis function. In perimenopausal women it is also common, usually due to ovarian failure. In women, aged 20 to 40, polycystic ovary syndrome (PCOS) can present with obesity, hirsutism, ovarian cysts, and infertility, in addition to irregular menses. All of these women tend to have anovulatory cycles. A cycle with no ovulation produces no progestin withdrawal, hence abnormal menstrual shedding.

Physical exam should include an assessment for the following:

- Cervix – erosion, lesion, polyp, infection
- Uterus – size, shape, contour
- Adnexa – size
- Thyroid – enlargement

Diagnosis
Diagnosis includes a history of bleeding pattern, duration of the problem (menstrual calendar for past year), number of days bleeding monthly, regularity (cyclic versus intermenstrual bleeding) and amount (number of pads/tampons on heaviest day). Tests for infection and a pap smear for cervical cancer should be done. Hematocrit should always be done. UCG may be considered as ectopic pregnancy and threatened spontaneous abortion commonly present as menorrhagia rather than amenorrhea. Women over age 40 with intermenstrual bleeding should be referred for an endometrial biopsy especially of their cycles do not respond to therapy. Screen for hypothyroid symptoms and consider a TSH if indicated.

Management
If the bleeding is severe and the hematocrit under 30 or hemoglobin under 11, evaluate for postural hypotension. Check BP supine and then when standing. A significant drop of BP or severe anemia (hematocrit ≤26) is usually an indication for hospitalization. A positive HCG or other evidence of a complication of pregnancy usually requires emergent referral to a gynecologist or an emergency room.

If very heavy, prolonged bleeding, an estrogen-containing OCP taper can be used. Administer up to 200μg EE a day (Nordette 1 to 2 pills TID) until the bleeding slows, then give 1 to 2 pills BID until the bleeding stops, and then finish the pill package. This will usually stop the bleeding in two or three days. Warn women that the bleeding after they stop the pills will be heavy because the thick, overgrown lining accumulates due to her unopposed estrogen and using progestins will cause a "medical D&C." Give her a **Menstrual Calendar Reminder Card** to document the days and amount of bleeding.

Women with PCOS usually should continue with low dose oral contraceptives until they are ready to seek a pregnancy. The OCP can prevent ovarian and uterine cancer and reduce their circulating androgens. Perimenopausal women may continue OCPs until age 50 if they have no other risk factors.

Women who are not currently bleeding heavily may be started any combination monophasic pill to regulate bleeding. Women who do not need contraception and do not want to take oral contraceptives, which is the preferred treatment, may be managed with cyclic oral medroxyprogesterone (Provera) 10 mg daily for 10 days each cycle starting on day 15 of cycle or if not cycling can give day 1-10 of every month, for three months. If more than three months, this should be provided by the primary care provider because on-going Provera is more costly than OCPs and it is not a contraceptive method, hence not part of the Family Planning Program. Women seeking to get pregnant should be advised that once the bleeding begins (and lasts 24 hours) on the Provera they could stop taking it as long as they took at least 5 days of the Provera.

Women who do not respond (decreased bleeding and stop intermenstrual bleeding) after three to six months of treatment should be referred as they may require imaging, hysterosalpingography, or hysteroscopy to rule out endometrial polyps, submucous fibroids, adenomyosis, and other pathological conditions. Any women over age 40 whose bleeding does not respond after three months of hormonal management should be referred for evaluation and an endometrial biopsy if one has not already been done. If an endometrial biopsy is done, the EMB Procedure Form and EMB Consent Form need to be used. The risk for endometrial cancer is elevated in obese women, and if they have a history of PCOS or are nulliparous, this can further increase their risk.

Dysmenorrhea

Diagnosis

Dysmenorrhea is defined as cyclic pain, headaches, or bloating with menstruation. Chronic pelvic pain is present when pain is persistent for more than three months. Many women with pelvic pain also have dysmenorrhea. The Pelvic Symptom Diary may be helpful to document more details regarding the pain.

Treatment

Hormonal contraceptives, which inhibit ovulation and endometrial proliferation, can significantly decrease dysmenorrhea and PMS.

Dysmenorrhea is usually caused by prostaglandin production and the most effective treatment is taking a NSAIDS medication on the very first day of the menses before prostaglandin production has peaked. Prostaglandins are produced as progesterone levels drop which destabilizes the endometrial lining and cellular membranes degenerate releasing prostaglandins. Use of the Lng IUS or synthetic progestins (COC pills, progestin-only methods like Norplant, DMPA or pills) can all decrease the amount of endometrial proliferation hence less tissue to slough with a menses.

- For pain, suggest aspirin or 200 to 400mg ibuprofen (available without prescription) first. If severe, can prescribe:
  Ibuprofen 400 or 600 mg #40, one every six to eight hours; Start before or at onset of menstrual pain, limit to 20 pills each month, refill for one year. Also, Naproxen 500 mg bid #20 can be used, at or before onset of menstrual pain for five days.

- For severe bloating and heavy achy discomfort, prescribe (through outside pharmacy): Hydrochlorothiazide 50 mg #30, one-half to one in the morning for three to five days before each menses. Refill once only the first year.

- For premenstrual depression could try: Pyridoxine (B_6) 25 to 50 mg. daily starting seven days before each menses.

- Consider continuous or extended COC pill use if symptoms persist on cyclic OCPs.

- If chronic pelvic or abdominal pain, the Bowel Program Handout and the Are You Getting Enough Fiber? Handout may be helpful.

- If chronic bladder pain, the Bladder Discomfort Program Handout and the Bladder Health Handout may be helpful.

Infertility

Definition

Infertility is when a couple cannot conceive after one year of unprotected sex. Primary infertility means the woman or man has never been pregnant or fathered a pregnancy. Secondary infertility is when a pregnancy was possible in the past. The causes of infertility are multiple, approximately 35% of infertility is due to tubal factor, 35% male factor, 10% cervical factor, 10% unknown, and only 10% are due to ovulation difficulties amenable to clomid type therapies. As women age, their risk for infertility increases. At age 24, women have the greatest rate of successful pregnancy and women after age 35 with infertility often will require specialty services. After age 35 about 30% of women will not be able to have a successful pregnancy and this increases to 60% after age 40 (Fertility Sterility 2002; 78:215-19). As part of aging the risk for a miscarriage increases as well to 25% after age 35. The risk of a genetic abnormality is rare in women under 30 (1/500), and increases with age to 1/270 after 30, and 1/60 at age 40. Pregnancy related mortality also increases in older women (Obstet Gynecol 2003; 102:1015-21). In summary, women should be counseled that the very best age for pregnancy for good maternal and child outcome is age 24 and waiting until one is over 30 is not the best strategy.

Program Goals

According to the Title X guidelines, there are three levels of infertility service and these are quoted below:

Level I:
Initial infertility interview, education, examination, appropriate laboratory testing (hemoglobin or hematocrit, pap smear, and culture for gonorrhea), counseling and appropriate referral.

Level II:
Includes semen analysis, assessment or ovulatory function through basal body temperature and/or endometrial biopsy, and postcoital testing.

Level III:
More sophisticated and complex than level I and II services.

Title X sites must include Level I services and these are currently being done by the family planning practice guidelines under routine history and physical exam services. We believe Level 3 services are best provided in the context of an infertility service with ultrasound monitoring and referrals can be made to Harborview for clomid or other workup. Until society agrees to subsidize infertility services, we will not be able to supply much assistance since most successful treatments, like IVF, are not available without money.

Procedures

In addition, providers may offer:

- **Basal Body Temperature** education using the Basal Body Temperature Chart, which is very similar to the Natural Family Planning section in the guidelines, and charting to confirm biphasic = ovulatory.
- **Semen Analysis** referral if indicated (no proven recent male fertility). Provide the client with the Semen Analysis Information Handout.

- **Postcoital Testing** is possible, which is essentially a wet mount test combined with a cervical mucous evaluation for estrogen effect done 2 days before anticipated ovulation date and within 9 to 12 hours after intercourse. The slide should then be evaluated for motile sperm. If at least one forward moving sperm is seen on the whole slide, they have a 50% chance of pregnancy over the coming year compared to only 15% if no sperm or only immotile sperm are found.
- Referral to HMC for hysterosalpingogram can be recommended, which can be done by referral.
- Strongly advise both partners to quit all tobacco use. Smoking not only leads to erectile dysfunction and poor sperm quality but also has been linked to female infertility and miscarriage (Lancet 2004; 363: 628).

A possible scenario would be a baseline evaluation to collect three months of basal body charts, refer for semen analysis if no prior fathered children, perform a postcoital test with the third cycle to document mid-cycle estrogen mucous and motile sperm, and then refer for hysterosalpingogram if no pregnancy after one year of unprotected intercourse and with biphasic temperatures on the basal body charts.

Menstrual Suppression or Withdrawal Bleeding Manipulation

Overview
Contraceptive hormones that block ovulation can also be used to suppress bleeding. DMPA with long-term use will result in amenorrhea in 90% of women by 2 years of use but during the first year only 50% have amenorrhea and women can have very heavy irregular bleeding. When women on DMPA are finally amenorrheric it is because of hypoestrogenism. Ovarian suppression without exogenous estrogen results in a low estrogen state consequently these women get amenorrhea but also have a loss of bone density. For this reason, if a woman is specifically requesting menstrual suppression the use of a combination product may be prudent, if estrogen can be used.

For **skipping a single period,** any OCP can be used simply by skipping the period week pills and going directly to another pill package, so a total of 6 weeks of the hormonal pills are taken followed by the usual pill free or period week. Advise women that spotting might happen but typically it is light and painless and it is important to keep taking the pill to maintain contraceptive efficacy. Multi-phasic pills are more likely to trigger bleeding and it is possible taking the second package backwards to create at least 2 weeks of the same dose pill might help although it is not proven. It might be best to advise women wishing to skip just one period to use a monophasic pill but if this is not practical even a multiphasic pill will work most times.

For **extended cycles** (skipping some periods), a monophasic 30 mcg EE_2 and norgestrel pill has been shown to be effective for skipping every other month period (42/7 cycle). Seasonale is a brand name for a pill (30 mcg EE_2 and 150 mcg Lng) taken for 84/7 days with a 7 day period or a 91 day cycle. There was a lot of irregular bleeding (not just spotting) even at the end of the year and a pulmonary embolus reported in 1 of the approximately 450 users. For this reason, women seriously interested in decreased periods should be encouraged to consider continuous use of lower estrogen dose pills instead of longer cycles for both safety (decreased dose exposure) and less irregular bleeding.

For **continuous active pill use**, a monophasic 20 mcg EE_2 and 100 mcg levonorgestrel pill, has been shown to be effective with 80% of women by 6 months only having rare bleeding. During the first 6 months irregular bleeding is very common and worse than with cyclic use. Missed or late pills can trigger the bleeding. If still bleeding at 3-6 months, consider a switch to NETA progestin pill but with only 20 mg EE_2 dose, without a period week.

Skipping the pill free week results in 7 more days each cycle of hormone pills and no week to allow the pill hormones to drop to zero. This prevents hormone withdrawal symptoms like bleeding, headaches, and mood changes. But it is also likely that there can be a small net increase in overall hormone exposure. A single study of only 30 women suggested the SHBG and HDL levels were slightly higher in women with extended 42 day cycles using a 30 mcg EE_2 pill. For this reason, extended cycles should be restricted to 30 mcg or less EE_2 dose and continuous or daily use to 20 mcg EE_2 formulations.

The patch delivers an estrogen dose equivalent to an oral 30-35 mcg EE_2 pill and should not be used until studied closely for daily use or no periods. It could possibly result in hyperplasia or excess estrogen effects. Phasic formulations increase the risk of irregular bleeding and are not appropriate for extended or continuous use. All sub 50 mcg extended OCP cycle literature has been

with gonane type progestin products and it is probable that for good endometrial stability a long half-life gonane type progestin is effective. However, norethindrone 20 mcg EE_2 products have a high rate of missed or silent menses with cyclic use and appears to work well especially in older women with less ovarian activity and perhaps the weaker progestin triggers less bleeding. Do not use desogestrel progestin products for continuous use, this progestin doubles the risk of blood clots in cyclic users and it is possible if this would increase with daily use (American Journal Obstet Gynecol 2004; 190:332-7).

Although, the CVR (vaginal ring) does contain a metabolite of this desogestrel progestin, the ethinyl estradiol serum levels are so low with the CVR it is likely the estrogen exposure would be lower than with 20 mcg oral pill use. Extended or continuous CVR use can suppress withdrawal bleeding. The levels of hormones released by the CVR stay high enough to block ovulation for up to 5 weeks (35 days) of use, but it is best to go no longer than 1 month of use per ring. Insert a new ring on a set day like the 1st of each month to take out old ring and insert a new ring. If the woman notices a lot of spotting at the end of each month, changing to a new ring sooner (by 4 weeks) may help. It is likely just as with continuous pill use irregular bleeding will be common in the first 6 months and it should decrease although there are no published studies.

For women wanting to do menstrual suppression or skip periods on the OCP or the CVR the following should be done:

1. Counsel and document the reason the woman is choosing this schedule (i.e. withdrawal symptoms, headaches, wants no period, wants better OC efficacy, etc.) and that she is aware this is not FDA approved. Long term studies have not been done but it is unlikely there would be any additional risk especially if doses used are less than cyclic OCs (cyclic 30 mcg EE_2 pills actually deliver more estrogen than daily 20 mcg EE_2 pills). Remember to discuss alternative choices like LngIUS or DMPA although the LngIUS does not suppress ovulation in at least half of women and DMPA can result in hypoestrogenism.

2. Write prescription for hormone pills only, skip spacer pills, #84 with 4 refills for 1 year. Give her a menstrual diary to record all bleeding and counsel carefully to expect irregular bleeding (can be 3 weeks of daily bleeding of 1 to 2 pads) and the relationship to pill taking compliance.

3. A year of continuous OCP prescription requires 18 pill packages. A year of extended or 42 day cycles requires 15 pill packages. It is best to only dispense 3 to 4 months prescription until well established use. Give the client a Menstrual Diary to record bleeding – sometimes by looking at the actual days it is reassuring and trends can then be seen.

4. The woman should be strongly counseled that irregular bleeding is common and to be expected in the first 6 months. Use the Continuous OC Handout.

5. See client at 2 to 3 months for blood pressure, menstrual diary and symptom review.

6. If at 6 months persistent irregular bleeding consider pregnancy testing, infection testing, referral for an ultrasound to rule out fibroids, and consult family planning medical director.

7. Offer HCG testing when amenorrhea if missed pills or concerns and prudent to do HCG testing at first revisit.

8. After 2 years of no bleeding, screen for polycythemia or hemochromatosis (a rare genetic disease causing excess iron absorption) by checking hemoglobin. If hemoglobin level is 15 or

greater, check a complete blood count, a fasting ferritin and transferrin saturation and if abnormal (ferritin >300ng/ml or transferrin saturation >45%) or if a family history then consult the Family Planning Medical Director before initiating or continuing suppression. Strongly consider referral to UW Iron Overload Clinic at 206-598-4886. The treatment for hemochromatosis is to avoid iron excess, which can lead to damaged organs (liver, brain) and while a woman could still choose menstrual suppression, she would need hematocrit monitoring and possibly phlebotomy with her primary provider. Polycythemia, excess red cell mass, can increase blood viscosity and the risk for thrombosis. Usually this happens because of renal or pulmonary disease or rarely a genetic condition (polycythemia vera) with abnormal myleoproliferation. These patients would need referral, probable phlebotomy, and menstrual suppression should only be done with very close monitoring.

Continuous Birth Control Pill Use

Taking an active, hormone containing, pill every day is designed to stop all bleeding after an initial period of irregular bleeding. This handout explains how and gives tips to decrease the irregular bleeding.

Why do the spacer pills cause the uterus to bleed?
"The Period Pills," "spacer," "or "sugar" pills contain no active or hormone medication. The reason you bleed when you take spacer pills is because your hormone levels drop. You bleed because you did not take a progestin hormone or "real" birth control pill. The lining of the uterus needs stable hormone levels to prevent bleeding. The best way to prevent any bleeding or spotting is to have constant levels of the estrogen and the progesterone hormones, because these hormones support and keep the blood lining of the uterus stabilized.

What do birth control pills do to the uterus?
Birth control pills work to shrink the blood lining of the uterus. Over time the lining is so thin, the chances of unexpected bleeding and spotting become very low. It is very, very unlikely something is building up inside your uterus when you are on the pill. As a matter of fact, the risk of endometrial cancer decreases by 80% in women using the birth control pill for five years.

Irregular Bleeding is common at first
Break-through bleeding, or bleeding when you are not scheduled to bleed, is very common in the first 6 months of continuous birth control pill use. Your body is getting used to the constant level of hormones. If you have been on a higher dose pill or injection contraceptives, it can take longer to stop irregular bleeding. Spotting is when the amount of blood is so tiny that no pad or tampon is needed. The longer you take the continuous pills the less bleeding and spotting will happen. You do not need to stop the pill to have a period because bleeding happens, instead try to figure out what caused the bleeding and keep taking the daily pill if you want to have no bleeding. Stopping the pill only begins the whole process again.

How can you help prevent a drop in the pill hormones and stop bleeding/spotting?
The most important thing is to take your pill as close as possible to the **same time every day.** Estrogen in the body begins to wear off, especially if you take your pill over 4 hours late.

Other suggestions if spotting continues:
All these suggestions and ideas listed below are to help you make it through the first six months of continuous pill use. Most women will have significantly less bleeding or spotting after six months. Keep a menstrual diary so you can learn what triggers a bleeding episode for you. Remember all women are individuals. You can learn about how you metabolize your pill and what works with your body.

- **Alcohol:** Drinking alcohol keeps your liver busy detoxifying the alcohol so your hormone levels, especially estrogen, can be higher for a few days. If you drink everyday, even a glass of wine, your body could be used to the alcohol, so if you stop drinking, your estrogen levels may drop and trigger spotting.

- **Tobacco:** Smoking can increase your metabolism of estrogen and result in lower levels of estrogen. If you smoke you now have another reason to quit or at least greatly reduce the amount you smoke.

- **Other medications:** Many medications, for example antibiotics, antifungals, anticonvulsants, and even herbal drugs like St. John's Wort, can change the amount of the pill hormones absorbed by the stomach and the metabolism of these hormones. It is very common to have some spotting with a new medication or a change in dose of medication. Sometimes these medications can actually decrease the pill hormones so much they become less effective at preventing pregnancy. Therefore, it is important to tell your provider about all the medications you are taking.

- **Time of day and stress** can affect your hormone levels. The progesterone receptors in the uterus look a little like cortisol receptors, so it might be possible that increased stress can trigger a change in progesterone activity. **Taking the pill at night**, before bed, could make the hormones peak when the cortisol levels are at nighttime levels and this could affect the activity of the hormones. Also, at night, the pill does not have to compete with food in you stomach to be absorbed. So, if you are having persistent spotting you could try switching the time of day you take your pill. However, you can expect some initial spotting with any change in the usual time you take your pill and it may take two weeks for your body to equilibrate to the new pill taking time.

- **Diarrhea or vomiting:** Anything that makes the pill go through your system too fast can make the pill not work as well because it was not absorbed or, worse, if it is lost in the vomit.

- **Altitude:** Some women report spotting when they take airplane trips or climb mountains. It could be the change in air pressure, just going to a new time zone, or even a change in your sleep patterns. If travelling in a different time zone, you should attempt to take your pill at the time based on your normal time zone.

- Non-steroidal anti-inflammatory medications, like **Naprosyn, Aspirin, or Ibuprofen** can decrease period bleeding and menstrual cramps, because they lessen the chemicals that cause period bleeding and decrease irritation in the lining of the uterus. Stop using them when your spotting stops. If your spotting continues after one week, you should call your provider, you may need a higher dose and your provider can give you a prescription. You should not use these drugs for more than 1-2 weeks or they could hurt your liver or kidneys.

- **Vitamin C**, 1000 mg, taken with your pill can help increase estrogen absorption for some women, so you should try this if the spotting has gone on for more than five days. However, you should stop taking the high dose of Vitamin C either when the spotting stops, or after a week if the spotting hasn't stopped. If you take it for too long, your body gets used to that large amount of Vitamin C, so that if you don't take it, you will then have a drop in estrogen levels and start spotting again!

- **Grapefruit juice** contains a chemical that slows estrogen metabolism if the pill is taken with a glass of juice. More estrogen may be available to your body to stop the spotting.

If you have any questions about any of these suggestions, please call your clinic. Often your provider can help and may even need to do an exam to find out why you are bleeding because there may be an infection or change in health that is causing the bleeding. ***Please call your clinic before you stop the birth control pill.*** *This handout is from the www.noperiod.com website and is used with permission.*

Cervical Cancer Screening

Overview

History:

Epidemiology:

Cancer Types:

Causative Agents:

Other Risks/Associated Factors:

Screening

Recommendations:

Supporting Rationale:

During Pregnancy:

Special Considerations

Clients using hormonal contraception but who are not sexually active:

Established clients wishing to delay their cervical cancer screening and exam:

New clients wishing to delay their cervical cancer screening and exam:

Spotting between menses or with intercourse:

Women with a history of exposure to DES:

Liquid Based Cytology:

The Procedure

When to Test:

How to Test:

Tracking Specimens:

Documentation of Cytology Results:

Interpreting Cytology Results

Definitions:

- Negative for Intraepithelial Lesion or Malignancy (NIL) Pap Test Result
- Unsatisfactory Pap Test Result
- Benign Cellular Changes (BCC) Pap Test Result
- Excessive Inflammation, Follicular Lymphocytic Cervicitis
- Candida, Yeast
- Cellular Changes Consistent With Bacterial Vaginosis
- Actinomyces
- Trichomonas
- Herpes Simplex Virus
- Parakeratosis, Hyperkeratosis, and Reactive
- Endometrial Cells present
- Endocervical Reserve Cell Hyperplasia
- Absence of Endocervical Cells

Abnormal Pap test Results Requiring Follow-Up

Atypical Squamous Cells of Undeterminant Significance (ASCUS) and Low Grade Squamous Intraepithelial Lesions (LSIL or CIN1)

High Grade Squamous Intraepithelial Lesions (HSIL or CIN II/III)
Or Carcinoma In-Situ (CIS) or Invasive Cervical Cancer Suspected
Atypical Squamous Cells Indeterminate for Dysplasia (ASCUS) High Grade also termed by the new Bethesda System as ASCUS cannot rule out HSIL

Abnormal Glandular Cells

- Atypical Glandular Cells of Undetermined Significance (AGCUS)
- Endocervical Dysplasia or Adenocarcinoma, Atypical Endometrial Cells or Adenocarcinoma

Other Indications for Referral for Colposcopic Evaluation

Colposcopy

Colposcopy Services for Minors

Post-Colposcopy Complications

Patient Education about Dysplasia and HPV

Testing for High Risk HPV

Follow-Up After Cervical Dysplasia Treatment

Follow-Up After Colposcopy When No Treatment Done

Low Income Colposcopy Referrals With No Insurance

Non-Title X Covered Services: Problem, Evaluation and Management

Cessation of screening:

History of hysterectomy:

Women who are postmenopausal with bleeding:

Endometrial Biopsy

Cervical Cancer Screening

Overview

History

Papanicolaou, "Pap" testing, microscopic examination of exfoliated cervical cells, began in 1943 as a method to detect pre-invasive cervical cancer. It is one of the best screening tests available in medicine and has in developed countries, greatly reduced cervical cancer incidence and mortality.

Epidemiology

Worldwide, cervical cancer is the second leading cause of female cancer mortality. Over 500,000 women are diagnosed each year. Almost 80% of cases occur in developing countries where the mortality rate approximates 50%. This is largely due to lack of screening programs and late detection.
http://www.who.int/vaccine_research/diseases/viral_cancers/en/index3.html

In the United States cervical cancers occur in less than 0.8% of women, 1 out of every 130. Over half of the women in the US diagnosed with cervical cancer have never had a Pap smear. About 25% of women with cervical cancer had an abnormal Pap smear but did not get proper follow up. The rest of women have had infrequent Pap screening, at least 5 years or more between Pap smears. Incidence rates among Hispanic, Vietnamese and Native-American women are higher nationally than among other groups. Age adjusted mortality rates among African American women are double those of white women. Women living in poverty and lacking medical insurance also experience much higher rates of cervical cancer.
http://seer.cancer.gov/statfacts/html/cervix.html?statfacts_page=cervix.html&x=14&y=20
http://planning.cancer.gov/disease/Cervical-Snapshot.pdf

In Washington State between the years of 1999 and 2002, age-adjusted incidence rates from invasive cervical cancer were higher among Asian, Pacific Islander and Hispanic women than among white and non-white women. Women living in poverty and in areas where there was overall less college education also experienced higher rates of invasive cervical cancer.
http://www.doh.wa.gov/HWS/CD2004.shtm

In King County between 1998 and 2002, 57 women were diagnosed with cervical cancer. Between 1999 and 2003, 15 women died as a result of cervical cancer. During this time, the age adjusted cervical cancer death rate per 100,000 women decreased from 2.6 to 1.0. Asian/Pacific Islanders and women living in poverty experience higher rates of cervical cancer than other women in the county. They are also less likely to receive Pap smear screening. In 2004, 83.2% of women over age 18 in King County had received a Pap smear in the last 3 years. Click here for the full report.

Cancer Types:

- Squamous cell carcinomas: Account for 85% of cervical cancers.
- Adenocarcinomas: Account for 10-15% of cervical cancers and tend to grow more rapidly. In one series, 20% of women found to have adenocarcinomas had a negative Pap smear within the last year.

Causative Agents:

Human Papilloma Virus, HPV, is the etiologic agent that begins the oncogenic changes that lead to most, almost 99% of squamous cell and adenocarcinomas. There are over 40 types that can affect the genital area. Some of those found to be oncogenic and identified as 'high risk' are, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 59, and 68.

Other Risks/Associated Factors:

- Absence of or infrequent screening with Pap smears: See section on epidemiology
- Cigarette use: Appears to be a dose related independent risk factor for increased rates of squamous cell dysplasia and cervical cancer in women.
- Early age, <18 years at first intercourse, high parity, multiple partners, high-risk partners, and a history of STIs: Increases exposure to and chance of becoming infected with HPV[1]
- Immune deficient states

- DES Exposure or other lower genital tract neoplasia
- Some epidemiologic studies of fair quality suggest prolonged, >5 yr use, of combined oral contraceptives as being a risk.
- Neither form of cervical cancer has been proven to "run in families" or to be hereditary

Screening

Recommendations:

While some minor variations as to intervals between tests and when to stop screening for cervical cancer exist across guidelines, recommendations are fairly consistent as to when to initiate screening. Recommendations for screening with liquid based cytology versus conventional testing and the use of HPV testing can also be found in the recommendations of these groups but as neither of these tests are recommended as routine for PHSKC clients, they are not included here. Separate sections addressing both tests, appear later in this section.

Cervical Cancer Screening Guidelines

Guideline	Screening Initiation	Screening Interval	Screening Cessation	Screening Pregnant Women	Screening Women Post-Hysterectomy	Screening HIV positive women
ACOG[2] 2003	21 years (or 3 years after 1st intercourse)	Annually for women < 30yrs Every 2-3 years for women > 30 yrs*	Not enough evidence to determine	No comment	Hysterectomy for benign causes: discontinue	Women should be screened twice in the first year after diagnosis and then annually
ACS[3] 2004	21 years (or 3 years after 1st intercourse)	Annually for women < 30yrs Every 2-3 years for women > 30 yrs*	70 years	No comment	Hysterectomy for benign causes: discontinue	Women should be screened more frequently
USPSTF[4] 2002	21 years (or 3 years after 1st intercourse)	At least every 3 years	65 years	No comment	Hysterectomy for benign causes: discontinue	No comment

*Provided the woman has had 3 consecutive normal annual Pap smears

Adapted from: McLachlin, VM, et. Al: Cervical Screening: A Clinical Practice Guideline. Cervical Screening Guidelines Development Committee of the Ontario Cervical Screening Program and the Gynecology Cancer Disease Site Group. Program in Evidence-based Care, Cancer Care Ontario,

May 2005.

Supporting Rationale:

Because cervical dysplasia and cancer risk are linked to sexual acquisition of HPV, annual Pap testing should begin 3 years after becoming sexually active or by the age of 21 and continue until age 30. [2,3] Acquisition of high risk HPV is the inciting event for cervical cancer but it takes time to develop and for this reason invasive cancer is virtually unheard of in adolescents. The published data on the natural history of HPV infection, and low-grade and high-grade precancerous lesions suggest there is little risk of missing an important cervical lesion within 3 years of the initial exposure to HPV. In young women aged 13 to 22, 70% of high-risk and over 90% of low-risk HPV infections regress within 3 years. Screening more frequently than every 3 years may lead to an over diagnosis of clinically insignificant lesions and unnecessary treatment[5]

Women who are low risk, only one lifetime sexual partner, or the same partner for enough years to insure no HPV infection, are not immunocompromised and never had any abnormal Pap tests can be screened less frequently. Because there is a false negative rate of 3 to 10% with smear cytology tests there should be three sequential annual tests to establish 100% normal cytology before reducing the frequency at age 30 at which time screening every 2-3 years is acceptable. While 3 sequential negative Pap smears are important in assuring a lesion is not missed, the risk of a Pap smear suggesting abnormalities when there are none, false positives, increases with the number done. It is therefore important to be thoughtful and judicious in screening at appropriate intervals.

Just because the decision to not provide cytology screening is made, ACOG consensus guidelines recommend annual GU and pelvic exams to screen for vulva, uterine, or other pelvic abnormalities. In women older than 25 years who require Pap smears only every 3 years, in the absence of other indications, a pelvic exam is not necessary in years not requiring a Pap. Women under the age of 25 should be screened annually for Chlamydia infection. If they do not require a Pap smear or evaluation for symptoms of an STI, a pelvic exam is not necessary to obtain a specimen. A vaginal swab or urine sample for NAAT (nucleic acid amplification test) is adequate for Chlamydia screening.

Title X requirements advise an external GU and pelvic exam for the initial physical exam, screening exams and STD exams. They are also advised for interval IUD exams or to check diaphragm placement, as well as prior to placing an IUD or fitting for a diaphragm.

During Pregnancy:

Though no specific recommendations are listed for the screening of pregnant women, standards of care dictate that if a woman is due for her annual Pap during pregnancy, it should be obtained in the usual manner.

Special Considerations:

Clients using hormonal contraception who are not sexually active:

All patients, even if not sexually active should be advised to begin cervical cytology screening at age 21. If she declines the exam and screening, she should be advised to review and sign the Birth Control Method Specific Informed Consent Form. The Delayed Pelvic Guidelines form should be used to document the reason for the exam refusal and her understanding that if she were to have early pre-cancer of the cervix, its early diagnosis is the best way to prevent hysterectomy and death. If the client continues not to be sexually active and wishes to decline the exam beyond six months, the case should be discussed with the Family Planning Medical Director. In addition, a note outlining the discussion and the patient's understanding of the risks and benefits of her decision should be documented and placed in the medical record.

Established clients wishing to delay their cervical cancer screening and exam:

Clients with a documented normal Pap from up to 12 months prior may delay their annual exams and Pap test up to 18 months from her last one, provided there are no concerns or problems and there is documentation as to why the client is choosing to delay her Pap test. This does not apply to women on a less than annual Pap smear schedule or to women who are initiating a birth control method for the first time. (In this case see the method specific new start guidelines.) After 18 months an established client who is on a schedule to receive annual Pap smears, can no longer be given hormonal contraceptives without an annual exam unless she signs the Birth Control Method Specific Informed Consent Form documenting she understands the risks and potential consequences of her decision.

New and transferring clients wishing to delay their cervical cancer screening and exam:

New clients may choose to delay their Pap test screening for six months and still receive hormonal contraceptives. A Delayed Pelvic Guidelines form should be completed.

If a client has transferred from another agency and reports having had a recent normal Pap smear, her Pap can be delayed for up to 18 months after her last one if she signs the Delayed Pelvic Guidelines form. Records from her prior provider should be requested and reviewed to confirm her report of a previous normal result.

Spotting between menses or with intercourse:

Premenopausal woman with these complaints need to have a normal pap test documented within the past year. Pregnancy and infection should be ruled out and treatment with COC pills or cyclic progesterone should be attempted to regulate the bleeding. If after 3 months the bleeding persists and if there is no other etiology (such as hormonal contraception or PID) for the complaint, she should be sent for colposcopic exam and/or endometrial biopsy, especially if over the age of 35.

Women with a history of exposure to DES:
DES (diethyl stillbesterone) was used to prevent miscarriage from 1943 until 1971 when the FDA banned it. DES is not a carcinogen but it is a teratogen and when taken while pregnant, can affect the developing genital tract of the female fetus. Structural changes caused by DES can include uterine and cervical malformations. It is estimated about 70% of women exposed to DES will have an abnormal hysterosalpingogram. All women presenting with a history of

exposure to DES should have the history confirmed if possible, a routine cervical Pap test sampling the visible squamocolumnar junction and a separate 4-quadrant vaginal cytologic smear obtained as they are at higher risk of developing adenocarcinoma. If the woman has not had a previous colposcopic exam, she should be referred for a DES specific, complete colposcopic exam of the cervix and vagina. If this exam is abnormal, the client may need treatment and annual colposcopic examination by the referral physician. If this exam and the cytology are normal, the client can be followed with yearly routine ectocervix pap tests and additional 4-quadrant vaginal smears. With the bimanual portion of the annual exam, careful palpation of the vaginal walls is done to make sure there is no nodularity, which could be indicative of early vaginal adenocarcinoma. In-utero under the influence of DES, islets of glandular tissue can be left in the vaginal wall and are usually below the surface epithelium. If they become malignant, the nodules can sometimes be palpated on exam. If nodules are present on exam (make sure the nodules are not rectal stool), refer the client to a gynecologist, as this will be a difficult evaluation. The risk of this type of vaginal adenocarcinoma is less than 1 in a thousand. Women can find more information on DES at www.cdc.gov/DES .

Liquid Based Cytology:

Two types of collection strategies exist for LBC. In the first, split sampling, a monolayer slide of cells from suspension is made from a conventional cytology collection. In the other, an independent sample, the collection device is inserted into fixative where the cells in suspension are then used to prep a slide. These slides can then be read manually or automatically. Proponents of liquid based testing have suggested its benefits include fewer numbers of unsatisfactory samples, the ability to perform reflex HPV testing and an improved sensitivity to detect abnormalities.

A recent systematic review evaluated primary studies comparing the accuracy and performance of conventional and liquid based cytology.[6] The authors applied strict methodological review criteria to the studies to evaluate the effect of the quality of the study on its results. Fifty-six trials were identified as appropriate for inclusion. Using the criteria of adequate blinding, the verification of abnormal results and the use of a reference standard, only 5 studies were categorized as high quality. Thirty-two were categorized as medium quality and 19 as low quality. Only 4 of the 5 high quality studies provided enough verified raw data to allow estimation of sensitivity, specificity and a comparison of accuracy between liquid based and conventional Pap testing.

When only the high quality studies were evaluated, no differences between conventional and liquid based cytology in rates of unsatisfactory slides or the ability to detect high-grade lesions were found. When medium and high quality studies results were combined, higher rates of ASCUS were seen in the liquid based cytology group. In low quality studies the opposite was found, higher rates of ASCUS were found in women undergoing conventional cytology testing. The findings of this systematic review suggest large randomized controlled trials are needed to determine the actual benefits of LBC and its role in cervical cancer screening.

Due to the higher cost and lack of clear benefit of liquid based cytology in terms of accuracy, PHSKC will continue to screen clients for cervical cancer and its precursors using conventional Pap testing. Liquid based cytology may be used if recommended as part of a client's post-colposcopy or treatment follow up.

When to Test:

The best cytologic specimen is obtained after a minimum of 4 weeks since the last cytology sample and 48 hours from intercourse, tampon use, vaginal medication use, or bleeding. If a client is diagnosed with vaginitis or cervicitis it may be best to defer the Pap test until these conditions are resolved. The Pap test result could be falsely abnormal due to inflammation. Cytology is best done at least 8 weeks after an abortion or pregnancy unless the woman needs screening. Pap testing is appropriate and should be done as needed in pregnancy with both the spatula and cytobrush.

How to Test:

Patients can be given a handout on Pap testing prior to tests called: Cervical Cancer Screening Patient Handout. A small amount of water-soluble lubricant gel can be placed on the outside inferior blade of the speculum to ease speculum insertion.[7] In this study the authors compared blinding reading of slides done with women who had lubrication used to assist in placement of the speculum to those who did not. Rates of unsatisfactory Pap smears were equal. Though not expected to change, rates of other findings, for example ASCUS, were not compared across the groups. Avoid sampling the lubricant for assessment of vaginal discharge or culture collection.

Use a large cotton swab to gently wipe away any excess cervical mucous or discharge, then use the spatula to scrape the ectocervix in a 360 degree arc, being sure to include the squamocolumnar junction in the portion sampled. Next use the cytobrush, insert into the cervical os, and sample with only a 180-degree arc to minimize bleeding. The cytobrush should be used for all Pap test collections, even in pregnancy. It is not contraindicated and if not used, the sample is frequently inadequate. Apply both specimens to the glass slide and IMMEDIATELY add alcohol fixative. Use either an alcohol pad or an alcohol spray bottle (which the cytology lab will provide free if requested). The PHSKC system uses smear cytology preparation rather than liquid cytology. If liquid cytology is used then testing intervals should be the same as with smear cytology. Offer the Pap Reminder Card to all women at the time of pap testing. A woman can refuse if she does not want mail sent to her address. If she agrees, on the day of the Pap test have the woman fill out the Pap Reminder Card so it can be sent to her in one year to remind her of her annual exam.

Tracking Specimens:

When completing the requisition, indicate to the lab if the client has a history of HPV, cervical dysplasia, or treatment, like LEEP. A detailed chronology of pap result history is unnecessary. The lab requisition form stickers can be placed on the Lab Test Tracking Log as a reference if the lab misplaces the specimen. Use the Lab Test Tracking Log to document the specimen has been sent and a result obtained. The tracking log should be used to verify that results for the test have been obtained in a timely fashion. The tracking log should be kept for three years and then shredded. When the reports are received they should be signed with a legal signature and dated as received of that date. Later in 2007, all clinics will be using the MediTracks i2i system to follow and manage clients' cytology specimens.

Definitions:

The laboratory should send a written report within 14 days. Read the Bethesda Diagnostic Descriptive Terms category carefully, to obtain the Pap test result. Use the Pap Diagnosis Name Comparison Chart, if needed. Do not use the outdated class system "Epithelial cell abnormality," as it is not the final diagnosis and one must look below to see what exactly the problem is. The new Bethesda System was introduced 9/01 updating the 1991 nomenclature and classification of cytology (www.bethesda2001.cancer.gov). If there are any conflicting or confusing statements on the Pap test report, consult with the Family Planning Medical Director before making a plan for follow-up with the client.

Use the following list of categories to help make follow-up, treatment, or referral plans for specific clients as discussed below.

- **Negative for Intraepithelial Lesion or Malignancy (NIL) Pap test Result**: This indicates the client has normal cervical cytology and the next Pap test is recommended in 12 months. If there have been 3 consecutive NIL results, if the client is >30 years of age, and has no risk factors, then cytology could be obtained every 2 – 3 years.

- **Unsatisfactory Pap test Result**: Repeat when practical, preferably within three months. Correct any identified cause of the unsatisfactory pap first. The clinic should carefully look at the 6-month statistics for their site to see that their unsatisfactory cytology specimen rate is not elevated. If greater than 1.5% of Pap tests need to be repeated because of unsatisfactory collection technique, the cytology lab should be contacted so the site can get a more detailed report of what and perhaps who is the source of the problem.

- **Benign Cellular Changes (BCC) Pap test Result**: This category is not part of the 2001 Bethesda System but if used it indicates normal cervical cytology and the epithelial cells are normal. However, the following are benign and/or mild inflammatory descriptors, which may necessitate some follow-up depending on the individual client's history. Since BCC is a normal result, the next Pap test is in one year.

- **Excessive Inflammation, Follicular Lymphocytic Cervicitis**: Many women can have cervical inflammation or ectopy without an infection and there is no reason to treat unless there is a documented infection to treat. At her next visit it may be prudent to evaluate her need for an infection check.

- **Candida, Yeast**: If not symptomatic, there is absolutely no indication to treat as yeast does not cause upper tract disease and is a common finding in the vagina of women especially if pregnant or on COC pills.

- **Cellular Changes Consistent with Bacterial Vaginosis**: Predominance of Coccobacilli Consistent with Shift in Vaginal Flora (A Sign Of Bacterial Vaginosis): Recommend treatment only if exam findings confirm the Pap test findings (sometimes pap is not accurate) and if the client is symptomatic, pregnant, planning an abortion, or an IUD insertion.

- **Actinomyces:** (IUD associated): Typically actinomyces is not seen until the IUD has been in place for over 6 years. Refer to the IUD guidelines.

- **Trichomonas**: Treat the woman and her contacts. If possible verify by pelvic exam because occasionally the cytology diagnosis is incorrect and what looked like a trichomonad was

actually a deformed white blood cell.

- **Herpes Simplex Virus**: Notify the woman if she has not already been diagnosed in the past. HSV epithelial changes seen on the Pap test are highly diagnostic and specific for HSV, however, it is also reasonable to consult the STD guidelines and provide culture and/or serology as indicated by those guidelines.

- **Parakeratosis, Hyperkeratosis, and Reactive squamous or endocervical cells**: are all benign changes. Unless nuclear atypia is described, which the lab should have signed out as "ASCUS" and not "BCC", the Pap test can be repeated in one year as with other normal Pap test results.

- **Endometrial Cells present:** If the client is still premenopausal then this is a normal finding. If the client is postmenopausal, then referral is indicated unless there is a documented normal endometrial biopsy in past year and she is on HRT.

- **Endocervical Reserve Cell Hyperplasia**: This is benign and no action is needed.

- **Absence of Endocervical Cells:** If the client has had no previous abnormal Paps and the report is otherwise satisfactory, repeat in one year. Many women using progestin containing hormonal contraceptives may have regression of ectopy and migration of the transformation zone up the endocervical canal. Lack of endocervical cells on the specimen should not be a cause for concern if indeed the cervical os was sampled well with the cytobrush. If the client has a history of high-grade dysplasia treatment and a current NIL result but without endocervical cells, repeat the Pap test within 3 months. If still no endocervical cells on repeat, discuss the case with the Family Planning Medical Director as the client may need referral for an endocervical curettage (ECC) particularly if there were positive margins or a positive ECC at the time of treatment. If ECC tissue results are normal, annual pap tests without endocervical cells are acceptable as long as the client has normal cytology and no symptoms like post-coital bleeding, bleeding between menses, or sign of new HPV infection. In postmenopausal women and even long term OCP or DMPA users, many cytology samples will lack endocervical cells and there is no need to do additional testing. Recent studies found that the absence of endocervical cells in untreated women undergoing routine screening was actually predictive of a normal colposcopy exam and the absence of high-grade dysplasia biopsy.

Atypical Squamous Cells of Undetermined Significance (ASCUS) and Low Grade Squamous Intraepithelial Lesions (LSIL or CIN1)

There are several appropriate strategies for women (**over age 25**) who present with ASCUS as their first abnormal pap smear.[2, 8]

1) Repeat the Pap smear in 6 months, if negative repeat again in 6 months. If repeat testing reveals ≥ ASCUS, the women should be referred to colposcopy. **This is the preferred strategy in women between the ages of 25-35.**

2) Referral for colposcopy, particularly if the cervix appeared abnormal at the time the Pap smear was collected. This holds true whether or not the Pap smear is normal.

3) For women over **35 years**, triage to colposcopy using a test for high risk HPV, HR-HPV. If liquid based cytology was not used for the initial Pap, which allows reflex HR- HPV, a second visit to collect the specimen will be needed. Due to the moderate cost of the test, its variable utility across age groups, and the increased expense associated with an additional visit, HR-HPV testing to help triage women with ASCUS pap smears is not recommended as a triage strategy for women under the age of 30. As women over 35 are more likely to have persistent HPV and be at higher risk of having CIN2/3, testing for HR- HPV or repeating the Pap test in 6 months are both acceptable triage strategies for women over the age of 35 with an ASCUS Pap.

If a patient has had an ASCUS pap smear and an HPV test elsewhere and comes to public health for follow-up, the following is recommended:
ASCUS and HPV + for high-risk types, refer for colposcopy
ASCUS and HPV - for high-risk types, repeat a Pap smear in 12 months

- If the patient is **under age 25** with no prior history of cervical dysplasia and has had normal cytology results in the prior 3 years or has only become sexually active in the prior 3 years then repeat her Pap test in 6 months. If the repeat Pap test is normal, then repeat a second Pap test in another 6 months and consider adjusting the annual exam also to be in 12 months. If either repeat Pap test is ASCUS or LGSIL, repeat the Pap again in 6 months with colposcopy referral only for atypia or LGSIL that persists for 12 months or more. A longitudinal study found 91% of LGSIL lesions regressed within 36 months in women under age 22 at diagnosis and only 3% progressed to HGSIL.[9] A large observational cohort study of the Kaiser population found the cytology rates for CIN II-III are more common in women 25 to 29 years of age and CIN I peaked at ages 20-24 years.[10] It is fairly well accepted that for women under age 22, observation or repeating an ASCUS or LGSIL cytology result is the preferable management thereby utilizing colposcopy only for persistent disease. Treatment should not be done for CIN I in this population. In fact, treatment for CIN I-II in young women may also be unnecessary given the high rates of spontaneous regression although concerns about compliance could change this risk-benefit assessment.[11] Excisional treatment or LEEP has been associated with an increase in preterm birth; consequently one must balance treatment of a precancerous lesion at a young age against reproductive outcomes.[12] Recent recommendations by ACOG for the management of cytological abnormalities in adolescents, women < 21 years old, support the above recommendations including the option of following young women with histologically proven CIN 2 if they are able to manage regular follow-up.[13]

- If the **client has not had a documented normal cytology result in the past 3 years** a colposcopy referral may be considered. Approximately 10% of ASCUS represents HGSIL although only 1% of all ASCUS are CIS; but these rates increase in women not getting regular screening.

- **If the last Pap test within the past 18 months was also abnormal**, obtain records to verify, and if no colposcopic examination has been performed during the past 18 months, referral for colposcopy may be indicated, especially if her age is greater than 25 and her Pap testing compliance has been erratic.

- **If the client has been treated for high-grade cervical dysplasia in the past** (cryocautery, LEEP, or cone biopsy), then referral for colposcopy evaluation is probably indicated and if

possible with the provider who performed the treatment in the past.

- **If an HPV test result is available** and the woman is negative for oncogenic HPV types then a Pap in 1 year is appropriate in most situations. If the woman was positive for oncogenic HPV then referral for colposcopy is indicated if abnormal cytology. A recent consensus panel concluded that woman with a normal cervical cytology result but positive for oncogenic HPV have a low risk of HGSIL and can be managed with repeat cytology in 6- 12 months.[14]

- **If a woman is HIV positive or immunosuppressed** she needs colposcopy to evaluate any abnormal cytology.

- Consult the Family Planning Medical Director if the decision is not clear as each patient's individual history may bear on the decision to refer for colposcopy.

High Grade Squamous Intraepithelial Lesions (HSIL or CIN II/III)
Or Carcinoma In-Situ (CIS) or Invasive Cervical Cancer Suspected
Atypical Squamous Cells of Undetermined Significance (ASCUS) High Grade also termed by the new Bethesda System, as ASCUS cannot rule out HSIL

These diagnoses require immediate referral for colposcopy and biopsy. Remember cytology specimens are only estimates of biopsy pathology and final diagnosis may be milder or more severe. CIS or carcinoma-in-situ is also called Severe Dysplasia or CIN III. CIS is not invasive cervical cancer, but it is associated with a high rate of progression (20% to 30% over 10 years) to invasion so it should be treated, however, CIN I or even CIN II can have a 60-80% spontaneous regression rate and are often not treated unless it persists for more than 2 years.

Abnormal Glandular Cells

Women with Pap test results in this category usually need endometrial biopsy, endocervical curettage and colposcopic examination. Most cervical cancers are of squamous cell origin, but 10-15% of cervical cancers originate from the glandular epithelium. Unfortunately, adenocarcinoma is more likely to be missed on routine Pap tests and has a more aggressive course.

Atypical Glandular Cells of Undetermined Significance (AGCUS)

Refer for ECC and colposcopy. There is a very high rate of severe dysplasia or even cancer with this cytology result and the client needs further evaluation.

Endocervical Dysplasia or Adenocarcinoma, Atypical Endometrial Cells or Adenocarcinoma

These women need immediate referral for endocervical curettage and colposcopy as they have a high likelihood of needing treatment. There is no longer a reactive atypia type of AGCUS with the new Bethesda System and any glandular atypia or dysplasia should be investigated.

Other Indications for Referral for Colposcopic Evaluation

Women with a visible or palpable lesion of concern to the provider should be referred for colposcopy.

Unexplained, persistent vaginal bleeding, especially postcoital bleeding can be a symptom of cervical cancer and may require colposcopy and ECC.

Colposcopy

Referral for colposcopy should be done using the consult and referral guidelines. You may use the Colposcopy Patient Handout. The PHSKC Family Planning Program may perform some of the colposcopy evaluations if the individual provider has been formally trained and works under the supervision of the Family Planning Medical Director. The procedure for colposcopy involves visualization of the cervix with the colposcope, application of 5% acetic acid solution, examination of the entire squamo-column junction, biopsy collection if indicated, silver nitrate application or Monsel's Solution for bleeding, and if necessary endocervical curettage (ECC). Use the Informed Consent for Colposcopy Form, Colposcopy Report, and the Colposcopy Log to document the consent, visit, and track the results and to review with the Family Planning Medical Director if a question.

There can be treatment of cervical dysplasia by cryotherapy by trained providers if the Family Planning Medical Director reviewed the case. Use the Cryotherapy Patient Handout.

Cryotherapy visits involve obtaining consent using the Informed Consent for Cryotherapy, and verifying pregnancy is absent. Use the cryoprobe with lubricating jelly adequate to cover the ectocervical lesion, turn on the refrigerant and perform two 3-minute freeze – thaw cycles or for a time needed to freeze 5 mm past the lesion. Women over the age of 35, or with a history of prior cervical dysplasia treatment, CIS or glandular dysplasia should obtain their colposcopy evaluations with providers that will be able to offer excisional treatment. When referring for colposcopy because of persistent ASCUS or LGSIL changes, make sure the cytology result is current. If it has been more than 16 weeks, the Pap test should be repeated, as these changes may have resolved or worsened. If the Pap is then normal, the client probably does not need colposcopy, but the case should be discussed with the Family Planning Medical Director.

Colposcopy Services for Minors

Since most practices in the county do not offer colposcopy to minors without parental consent or without the ability to pay, the PHSKC Family Planning Program may offer a limited service to minors as part of our contraception and STD services. For all of 1995, there was only one woman under 18 with a CIN III pap in the PHSKC program. For all the Planned Parenthood clinics in the USA over a 5-year period of time, there was a single invasive cervical cancer in a teenager, a 19 year old with abnormal cytology prior to diagnosis.

Post-Colposcopy Complications

Rarely a client will present after colposcopy with complaints of bleeding following the

cervical biopsy. Perform a speculum exam and if the biopsy site is actively bleeding, apply silver nitrate or Monsel's solution, along with pressure for 3 to 5 minutes. If the bleeding cannot be controlled, refer the client to an emergency room or gynecology clinic for electrocautery or suture. Clients are advised to avoid vaginal penetration for 3 to 7 days following cervical biopsy.

Patient Education about Dysplasia and HPV

While there is controversy, some studies have suggested that tobacco use promotes and/or prolongs the dysplastic effect of HPV on cervical epithelium. It is also unproven but believed by some, that women with high folate levels may have less cancer. Foods that contain high levels of folate are dark leafy greens, nuts, eggs, and meat. It is clear that dysplasia is caused by HPV infection and the best protection is no genital contact with an infected person. Patients may be given the Information About the HPV Infection Patient Handout. Among newly sexually active women, consistent condom use by their partners appears to reduce the risk of cervical and vulvovaginal HPV infection.[14] Also HPV infection detection by Pap test may be years after initial infection so it is usually impossible to pinpoint the source. In settings that perform liquid based cytology, HPV testing can be done reflexively. The ability to determine whether or not 'high risk' types of HPV are present allows the triage of women with ASCUS to immediate colposcopy or a repeat Pap smear reducing the number of unnecessary colposcopies. This type of triage is only sensible in women over 35 for they are more likely to have persistent HPV changes. Further cost utility studies will determine whether or not there are other benefits as well. Because HPV type testing has no other benefit at this time, we do not offer HPV testing as a routine triage strategy for women with ASCUS results. A woman can seek this FDA approved test (Hybrid Capture II) from other local providers. A recent consensus panel concluded that a woman with a normal cervical cytology result but positive for HR-HPV has a low risk of HGSIL and can be managed with repeat cytology in 6 -12 months.[15]

Testing for High Risk HPV

Testing for high risk HPV, (HR-HPV), should be reserved to help triage women over 35 who have an ASCUS cytology result. If a woman over 35 has an ASCUS result she should be tested for HR-HPV. If the test for HR-HPV is positive, she should be referred for colposcopy. If the HR-HPV test is negative, a repeat Pap in one year is adequate follow up.

Public Health uses the Digene™ kit for high risk HPV assessment. These can be ordered from the Dynacare supply center. To collect the sample, excess mucus should be removed from the cervix using a cotton or Dacron swab. Insert the brush, (which accompanies the kit) 1-1.5 cm into the cervical os or until the largest bristles of the brush touch the ectocervix. Rotate counterclockwise 3 times being careful not to insert the brush completely into the endocervical canal. Remove the brush and avoid touching any other object or surface before placing into the receptacle for transport. Labeling of the specimen should occur in the usual fashion. Samples may be shipped at room temperature. If a sample is collected on a Friday of either a typical or long weekend, it may safely be shipped the next business day.

Follow-Up after Cervical Dysplasia Treatment

If cryocautery, laser, LEEP, or surgical knife cone was performed, then confirm the tissue

diagnosis by obtaining the pathology and operative reports. This is to make sure there was no invasive cervical cancer. If there was evidence of invasive cancer then this client needs to be referred back for further treatment and/or cancer follow-up. Cancer follow-up is individualized and can involve multiple visits and imaging tests. If the pathology specimen confirms dysplasia only, then repeat the Pap test six months after the procedure and then every 6 months for two years from the date of the treatment. The Post Cervical Dysplasia Treatment Tracking Alert Slip can be used to flag the chart. If the Pap test shows evidence of dysplasia, refer back to the treating provider for colposcopy.

Follow-Up after Colposcopy When No Treatment was required

REMEMBER, CIN I is not treated and CIN II might not be treated, particularly in young women. A Pap test one year after the colposcopy is all that is needed. Refer back for colposcopy at that time, if the 12-month pap result is abnormal, even an ASCUS, because HGSIL may have developed and treatment may now be considered depending on the individual's history.

Low Income Colposcopy Referrals with No Insurance

- **Harborview Medical Center Women's Clinic** (206-731-3367, 325 Ninth Ave.) accepts all women, no pre-payment, and sliding scale for all costs for women who qualify as low income allowance. Payment plans possible. Every Thursday morning. See the Information About Referral to Harborview Medical Center handout for more information.

- **Swedish Family Medicine** (206-386-6111 (press 1), 1401 Madison) can see women every Thursday morning and Friday afternoon. This is Family Medicine not Gynecology consultation. The woman is responsible for costs of anesthesia and lab including the colposcopy biopsy costs of $200 to $300. They may be able to get it "written off" or forgiven but this requires "proof of income".

- **Community Health Care Clinics in Pierce County** (253-589-7030, 9112 Lakewood Dr. S.W., Tacoma) offers colposcopy, no client refused. All visits pay $10 and there is a sliding scale with proof of income. The most client ever pays is $80. They will directly schedule the colposcopy if the client brings her records.

- **Community Health Care Clinics in Pierce County** (253-597-3813, 1002 South "I" Street, corner of 11th and "I" in downtown Tacoma) does colposcopy every day. They require an initial visit to review records before the colposcopy visit. They also offer a sliding fee with proof of income.

Non-Title X Covered Services: Problem, Evaluation and Management

Cessation of screening:

If at age 65, the client has a documented history of repeated negative pap tests, including no

history of dysplasia then cytology testing may be discontinued. Consensus guidelines suggest an annual pelvic examination is still beneficial to evaluate the rest of the genital and pelvic anatomy.

History of hysterectomy

Confirm the client had a complete and not a supracervical hysterectomy. A supracervical hysterectomy leaves the cervix and requires ongoing cervical cancer screening.

A woman who required a hysterectomy for documented benign reasons (fibroids, bleeding, endometriosis, or pelvic pain for example) has almost no risk of cervical cancer and Pap smears may be discontinued.

If the women had a history of dysplasia, then Pap smears yearly for 3 years after the procedure to confirm resolution is adequate follow-up. If these are all negative then screening for cervical cancer may be stopped.

If the hysterectomy was done for cancer ongoing yearly evaluation is required. Consult with the Family Planning Medical Director as the client may need her follow up exams with a cancer specialist.

Following hysterectomy, if there are any abnormal cells, even just atypia, the client needs referral for colposcopy and evaluation.

Women who are postmenopausal with bleeding:

Women not on HRT (hormone replacement therapy) with spotting need gynecologic evaluation. If they are still receiving cervical cancer screening, a normal Pap smear within the last year should be documented and can be done by the referring provider or the primary care provider.

On HRT: Women with no bleeding for one year prior beginning on HRT can be expected to spot and do not need referral for endometrial biopsy unless still spotting at 6 months of HRT. Referral for endometrial biopsy would also be indicated if the medical history suggests risk factors for endometrial cancer or her prior menstrual history is unclear. Screening recommendations for cervical and breast cancer in women receiving HRT are the same as in women not receiving HRT.

Endometrial Biopsy

Endometrial biopsies, EMB, are not included in the scope of Title X family planning services. If a patient needs an endometrial biopsy, they should be referred to a Public Health Clinic that provides family health services or another community provider. If an EMB is done in a Public Health clinic, the EMB Procedure Form and EMB Consent Form should be used.

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Preconceptional Management

All women who can become pregnant and who present for continuing care in primary care settings, family planning clinics, and other women's health care settings are candidates for preconception care.

The period of embryogenesis and greatest risk to fetus starts before the missed menses and continue until the 4th or 5th month of pregnancy when most organ development is complete. Provision of preventive education and care can help increase the health of a pregnancy or future pregnancies. The Pregnancy Screening Form should be used if pregnancy testing is the main purpose of the visit. The Before You Get Pregnant: Planning is the Key handout can be provided to the patient. The following preconception assessment and counseling points should be offered as appropriate.

Risk Assessment

- Individual conditions - age less than 18 years or over 34 years, nutrition, exercise, education, stress level, partner support, support system.
- Social conditions - economic status, housing, social support, family violence.
- Adverse health behaviors - tobacco, alcohol, illicit drug abuse.
- Immunizations - rubella immunity, hepatitis risk
- Medical conditions - infections, prescription and OTC medications; or chronic medical conditions such as diabetes, epilepsy, hypertension, heart disease, renal disease, and autoimmune disease (lupus, rheumatoid arthritis).
- Gynecologic history - fertility problems, endometriosis, abnormal Pap smears, STD, sexual practices
- Prior obstetric history - recent delivery, infant weight over 9 pounds or under 5.5 pounds, five or more pregnancies, three or more miscarriages, two or more abortions after 14 weeks, or adverse outcome of pregnancy.
- Family history - Sickle cell or other hemoglobinopathies, Tay-Sachs disease, cystic fibrosis, mental retardation, seizure disorders, birth defects, diabetes, bleeding disorders.
- Environmental conditions - work place hazards, toxic chemicals, radiation.
- Barriers to family planning, prenatal care and primary health care.
- Neural tube defects -if at risk for this (sel f, prior history, family history, anti-seizure medication use, or any other low folate condition), they need to take 4 mg orally every day of folate, preferably beginning 3 months before conception and throughout the pregnancy. This dose is not available in a prenatal vitamin and needs to be supplied separately as an outside prescription.

Medical Evaluation

- Physical examination - Document weight and blood pressure.
- Laboratory testing - Do hematocrit or hemoglobin and Pap smear. If status is unknown recommend rubella immunization if known no pregnancy at time of vaccine and hepatitis B (HBsAg) testing or immunization.

- High-risk women should be screened for gonorrhea, chlamydia, syphilis serology, and HIV.
- Refer for genetics evaluation and counseling as appropriate.

Health Promotion

Promotion of healthy behaviors: Counsel about proper nutrition including vitamins, diet counseling, and food programs. Women should take 0.4mg (we prescribe 0.8mg as part of a prenatal vitamin) folic acid daily for three months before seeking pregnancy. An over the counter prenatal vitamin will have 0.4mg of folate. Stress avoidance of and treatment of smoking, alcohol, illicit drugs, and teratogens, and practice of "safer sex" with new or casual partners. If not already done, advise women to be immunized for rubella and hepatitis B. Counsel about availability of social, financial, and vocational assistant programs.

To avoid heavy metals like mercury, the US FDA is recommending that pregnant women, women who may become pregnant, and lactating women avoid shark, swordfish, king mackerel, and tilefish along with recommending these women eat less than 12 ounces a week of other fish and less than 6 ounces if the seafood or fish is caught locally by the woman or family. www.epa.gov/ost/fish

Pregnancy spacing should be at least two years and not more than 9 years between children. Advise women to continue family planning until a pregnancy is planned. When discontinuing hormone contraceptives, use barrier contraception for one cycle to avoid a theoretical but unproved risk of increased loss of implantation with atrophied endometrium. After DMPA use, expect a delay of six to eighteen months before conception. After IUD use, either copper or Lng IUS, use barrier contraception until after one menses. With barrier contraception there is no need to delay pregnancy. Menstrual calendar recording is important during the time from cessation of contraception until a pregnancy is diagnosed.

Counsel women about early prenatal care and high-risk programs if warranted. Advise women over age 34 of amniocentesis if birth is expected after age 35. Identify barriers to care and offer assistance to overcome them. Refer them to a primary care provider for treatment of medical conditions including changes in medication if appropriate and for good control of conditions that adversely affect pregnancy. Refer to high-risk pregnancy programs.

Reduce psychosocial risks by counseling or referral as appropriate to home health agencies, community mental health centers, safe shelters, medical assistance, housing assistance, or social support.

Advise women to return for pregnancy detection promptly for a delayed menses or for symptoms of pregnancy so that prenatal care can be started early in pregnancy.

Paternity testing is offered by a private company, DNA diagnostics Center at 1-800-DNA-Center (1-800-362-2368) but it can be very expensive (cash needed), invasive (requires amniocentesis while pregnant), and requires samples from the possible father.

Pregnancy Detection

Procedure
The Pregnancy Screening Form is used for history collection and visit documentation. The Pregnancy Screening Form Instructions for Completion are detailed instructions for RN/CSO staff. Complete initial/annual exam is encouraged and should be done when appropriate/possible.

Exam
A weight and blood pressure should be done. Pelvic examination and inspection for signs of cervicitis with GC culture, chlamydia culture and Pap smear as appropriate should be done for women who have a positive pregnancy test and:

- are less than age 24 or meet STD guidelines for CT screening
- are seeking abortion or are undecided regarding their decision
- have conflicting dates
- have symptoms of infection
- have history suggestive of ectopic pregnancy (pain, bleeding, etc.).

Also, on exam confirm uterine enlargement. The uterine size can correlate with EGA as follows (Obstet Gynecol 2001; 98: 341-4):

- 7 weeks = tangerine
- 8 weeks = juice orange
- 10 weeks = naval orange
- 12 weeks = grapefruit
- 20 weeks = to umbilicus

Lab
HCG (human choriogonadotropin) is made by the pituitary by all women and even men at very low levels but during pregnancy the trophoblast or placenta makes large amounts of HCG. A website detailing the history of pregnancy testing is located at http://www.history.nih.gov/exhibits/thinblueline/. A urine pregnancy test can be done for HCG to confirm pregnancy, unless pregnancy is detected by abdominal examination. A qualitative serum pregnancy test is rarely indicated but can be done in the clinic using the same pregnancy test kit as used for urine. The urine HCG may be a false negative if the urine is very dilute or if the HCG level is low. Rarely the urine test may turn faintly positive after the 3 minutes wait. If a test is negative but a pregnancy suspected, repeating the test after 48 hours may be advised or collecting a quantitative serum test to send to a lab.

There can also be a false positive serum HCG test with a negative urine test because the patient's serum, an antibody or protein, reacts with the test reagent but HCG is not present.(Am J Obstet Gynecol 2002; 187: 217-24). Both urine and serum HCG tests sensitive to 25 mIU remain positive for about six weeks after induced abortion. By contrast they are often negative at the time of a spontaneous abortion since the serum HCG levels can be so low with abnormal pregnancies. A serum HCG level of 1500mIU or greater

indicates the pregnancy should be visualized as intrauterine by vaginal ultrasound. Most normal pregnancies double their HCG level every 48 hours early in pregnancy (before 10 weeks). If there was a recent abortion or a reason to suspect the test is only positive because of a recently ended pregnancy then a consider quantitative test or a repeat test in 2 weeks to document a fall in the level to negative.

Management

If the pregnancy test is negative and the woman is seeking pregnancy:

- Consult with client regarding plans and options. Consult the Preconception guidelines. Repeat the test in two weeks if no menses still, then do a complete exam if not already done.
- Counsel or refer to infertility and preconception guidelines if the couple has been actively trying to achieve a pregnancy for over one year.

If the pregnancy test is negative and the woman is not seeking pregnancy:

- Provide interim contraception; consider Emergency Contraception if appropriate; consult regarding contraceptive choice and usage.
- Repeat test in two weeks if still no menses, and do a complete exam if not already done.

If the pregnancy test is positive and indicating on going pregnancy provide counseling regarding all options (provide the Pregnancy Options Handout and Abortion Facts Handout if needed) and refer as appropriate for:

- abortion
- adoption arrangements
- clinic prenatal care
- DSHS - complete referral if indicated
- maternity screening
- private physician prenatal care
- WIC

For all women, complete the pregnancy verification section of the Pregnancy Screening Form.

Tell the client to take the confirmation letter to the DSHS Community Service Office closest to her current mailing address and make an application for financial assistance. Give the client the instruction sheet on what information to take with her. Provide the additional copy of the form for her to give to her provider if appropriate.

When the client receives her medical coupons, ask that she bring a coupon to the Health Department. This coupon can be sent in or given to the family planning, family health, or adolescent clinic, a WIC visit, maternity screening appointment, or a prenatal visit within the Health Department.

Discuss screening for rubella serology, HIV, syphilis, and HBsAg as part of routine prenatal testing and encourage the client to obtain counseling and testing as soon as possible.

Discuss asymptomatic STDs, risks to the woman and fetus/neonate, and encourage clients not getting a pelvic exam to return to the clinic for screening or obtain screening from her prenatal provider as soon as possible.

Spontaneous Miscarriage

A spontaneous abortion (SAB) is an involuntary loss of an embryo or fetus before 20 weeks of pregnancy. Approximately 50 to 75% of all pregnancies end in spontaneous abortion, however, most occur at about the time of implantation and thus the menses is not significantly changed and the pregnancy and subsequent abortion are not recognized clinically. Hence, only 15 to 20% of clinically recognized pregnancies are lost. About 50% of SABs after six weeks are due to a chromosomal abnormality of the pregnancy. Serious illness, some viral infections, or toxic drugs in the mother may also be a cause. Women reporting 3 or more SABs should be referred to an obstetrical provider to be assessed for reasons for recurrent miscarriage like autoimmune disease, uterine anomaly, or genetic abnormality. If the client is a PHSKC obstetrical patient and presents with SAB, the obstetrical guidelines need to be consulted.

Diagnosis

The pregnancy test may be positive if the tissue passed recently and it is possible it can take up to 4 weeks to clear the HCG to a negative urine test. It is important to make sure the HCG levels do not persist as this could be a sign of gestational trophoblastic disease or another pregnancy. The uterus may be small for dates. Symptoms of pregnancy (breast tenderness, nausea) may have disappeared. Vaginal bleeding with or without cramps indicates that spontaneous abortion is possible, although 25% of pregnancies that go to term had some spotting during the pregnancy. Perform an exam to rule out infection or other cause of bleeding, to determine if the cervical os is dilated, and to date the gestation. Do a hematocrit or hemoglobin as appropriate. Refer for Rh typing if not known because Rhogam is indicated if the client is Rh negative. Referral will be needed to administer the Rhogam because the Family Planning program does not stock this. If a Doppler monitor is available you may try to listen for fetal heart sounds.

Ectopic gestation should always be suspected with pain, bleeding, and early pregnancy. One out every 50 pregnancies in the United States is an ectopic pregnancy. Prior history of ectopic pregnancy, PID, or current use of an IUD, sterilization, or contraceptive implant can all increase the risk of ectopic pregnancy. Refer emergently to a facility with diagnostic imaging and gynecology services if an ectopic pregnancy is suspected. Ectopic pregnancies can be treated medically if diagnosed early.

Management

If a nonviable pregnancy is suspected before the onset of bleeding and cramping, refer the client to her pregnancy care provider for management. The clinician managing the pregnancy may order serial quantitative serum pregnancy tests to determine if an abortion is inevitable or an ultrasound to identify gestational dating and viability.

There is no evidence that medical intervention can change the miscarriage process. Often gestations before 6 weeks or greater than 11 weeks will need a procedure to complete the abortion. Most abortions between 7 to 10 weeks pass without surgery. Discuss the possibility of a miscarriage. Advise resting, staying near home, use of NSAIDs, and avoiding sexual intercourse or anything in the vagina until the process has resolved. If bleeding and cramping occur or tissue passes, advise the client to see her primary care provider or go to an emergency room if the bleeding is greater than one pad an hour for over three hours. Often the bleeding and cramping

resolve after the tissue has passed. All clients with bleeding should be assessed and counseled regarding the possibilities of ectopic gestation. Consult the PHSKC Maternity Practice Guidelines for the management of threatened spontaneous abortion and suspected ectopic pregnancy.

Remember ovulation is not suppressed by HCG and can happen even with a positive urine HCG test as early as 10-14 days following a miscarriage, so women at risk for pregnancy need counseling and provision of contraception.

Termination of Pregnancy

Evaluation

Management after a spontaneous abortion or an induced abortion is similar. After a woman has had a termination of a pregnancy, a surgery like D&C, or a suction curettage for a spontaneous abortion, usually she should continue under the care of the physician or abortion provider until resolution of all problems has occurred. Bleeding with clots similar to or lighter than a normal menses is expected. If the woman did not have suction curettage after a spontaneous abortion, the bleeding may be heavier. Women frequently have some cramping or discomfort for several days. Breast tenderness and other symptoms of pregnancy may continue for a week or so.

The pregnancy test may remain positive for 4 weeks after an induced abortion because the HCG is a protein which can be at very high levels in the first trimester of pregnancy and although the level drops rapidly immediately after tissue is passed for from abortion, it can take weeks for complete renal clearance to a negative test level. It is important to remember that HCG does not block ovulation (at least at low levels) and women can ovulate even with a positive HCG test, hence women at risk for pregnancy still need access to ECP and contraception. If a patient has had unprotected intercourse and has a positive pregnancy test with a recent abortion, consider the possibility of a new pregnancy, gestational trophoblastic disease, or just normal decline of HCG levels by counseling the woman appropriately and have her sign the **Specific Informed Consent Form** to document she knows to get a repeat test.

Management

It is important to refer the woman to the abortion provider for complications as they may need to repeat the procedure and the follow-up is included in the cost of the abortion. If the procedure was done elsewhere or after a spontaneous abortion without medical intervention, a woman should be seen in the clinic for post-abortion care. Call and ask to speak to the abortion provider if necessary to arrange the referral.

For cramping and bleeding, suggest ibuprofen or similar medication. Rest, application of a heating pad to the abdomen, and massage of the abdomen may help. For heavy bleeding with pain, perform an exam and evaluate for infection and consider antiobiotics as for PID and/or methergine. If the infection is severe refer to emergency room for possible IV antiobiotics.

If there is active bleeding or cramping, the uterus is soft and enlarged, the cervix has dilated, or there is tissue visible in the cervical os, immediately refer the client to a physician or emergency room. Sometimes a suction dilatation and curettage is necessary to completely evacuate the uterus. Prompt management is needed if there is tachycardia or signs of hemorrhage or infection.

If tissue has passed, the bleeding and cramping have subsided, the uterus is contracted, firm and normal size, and the cervix is closed, the abortion is probably complete. The client may return home. She should avoid intercourse or anything in the vagina for about 10 to 14 days. Stress that if increased bleeding and cramping recur, she should immediately see a physician or go to an emergency room. Address contraception as indicated. Often the delay of a contraception method only exposes the woman to another pregnancy because ovulation can

occur as soon as two weeks after termination. About two weeks after an abortion the woman should be examined for evidence of infection or remaining products of conception. If the examination is normal, discuss future plans and provide contraception as appropriate. All hormonal contraceptive methods can be initiated on the day of the abortion and often this is advised. Any woman with a history of irregular bleeding following termination that persists beyond four weeks should be carefully evaluated to insure there is not retained tissue, persistent HCG indicative of a gestational troproblastic malignancy, infection, or other pathology.

Anemia

Who to Test
Recommend for all initial and revisit female examinations if history suggests excessive menstrual blood loss. A hematocrit or hemoglobin should be performed within 1 year of a copper IUD insertion. To roughly convert from hematocrit to hemoglobin divide by 3.

Normal Hemoglobin and Hematocrit Values (Harrison's Internal Medicine Textbook)

Age/Sex	Hemoglobin, g/L	Hematocrit, %
Adolescents	130	40
Adult men	160 (±20)	47 (±6)
Adult menstruating women	130 (±20)	40 (±6)
Adult non-menstruating women	140 (±20)	42 (±6)
Pregnancy (3rd trimester)	120 (±20)	37 (±6)

To convert Hgb g/l to mg/dL divide by 10, for example 130 g/l equals 13 mg/dL.

Evaluation
- Review nutrition and menstrual history.
- Check stool for occult blood (Hemoccult) on rectal exam at pelvic if no other etiology suggested by the history or age greater than 40.
- Inquire about other bleeding, bruising, GI problems, etc.
- Inquire if ethnic group or family history of sickle-cell or thalassemia.

Management
- If marginal anemia, give the **How We Get the Iron We Need Handout** and recommend a once-a-day vitamin with iron or a prenatal vitamin, perhaps consider a hormonal contraceptive to reduce menses.

- If known to be iron deficient and moderately anemic, prescribe ferrous gluconate or sulfate 320 mg (5 grains) three times daily after meals for three months. The stool should become dark colored as evidence she is taking the pills. Counsel the client that iron tablets are very dangerous if ingested by children, only 10-15 pills can kill a child. Repeat the test in one month. If improved, continue iron for three more months to replenish iron stores. If not improved, consider bone marrow suppression, inflammatory block, or hemoglobinopathy and refer to primary care provider for further evaluation.

- If ≥30% or ≤10 mg/dl, an anemia work-up is needed prior to iron prescription unless already done because iron tablets will interfere with the lab results and cause morbidity in some conditions like thalassemia. If it is not possible for the client to see another provider, order a CBC, ferritin and reticulocyte count, have the client return in one week for the results, and consult the Family Planning Medical Director. If the results are consistent with iron deficiency, prescribe therapeutic iron and retest in 1 month. If the test result has not improved, then referral for further work-up is mandated.

- **Iron should not be recommended for males or non-menstruating women** without consultation with a physician or primary care provider.

- If **an elevated Hgb** is detected referral is indicated. Hereditary hemochromatosis (excessive iron absorption) can cause cirrhosis, heart failure, and even death. Approximately 1 in 10 people carry one gene but only 1 in 200 to 400 have both genes. If it is diagnosed early before iron storage excess, it is easily treated with blood removal or phlebotomy. If this diagnosis is suspected because the Hgb can be normal, check a fasting ferritin and transferrin saturation too and if abnormal consult the Family Planning Medical Director.

Bone Health

Why is bone health important?
In the United States there are an estimated 1.3 million fractures from osteoporosis annually. Most fractures occur later in life and while low bone density is an important risk factor the propensity to fall is another important risk factor for fracture. About half of these fractures occur in vertebral bones and lead to a loss of stature or if severe, deformation of the spine. But it is hip fracture which leads to significant disability and mortality, with 2% of women dying during initial hospitalization and up to 10% within a year of the event (Endo 2005). Most of these fractures, 95%, are the result of a fall (Stevens 2000).

The lifetime risk for a hip fracture for the average white woman in the U.S. is estimated to be 17.5% at the age of 50, compared to only 5% for men (Surgeon General 2004). In women under age 35, only 2 per 100,000/yr will be hospitalized for hip fracture (Surgeon General 2004). Hip fracture risk increases rapidly with age to a worldwide rate of 6 per 1000 women at age 80 and about 15 per 1000 at age 90 (Melton 1993). These rates of fracture are thought to be increasing in the U.S. population as risk factors such as inactivity and age increase.

What is the structure of bone and how does it change with age?
There are two components to bone structure, cortical and trabecular. Cortical bone makes up 75% of the total bone mass and is the dense bone forming the outer shell of the long bones while trabecular bone accounts for less of the mass but most of the bone volume because it is the spongy interior structural portion of a bone. Bone is constantly remodeled and one can think of it as a balance between resorption and formation until the age of 30 when bone density peaks. After that time approximately 0.4% of bone mass is lost every year in both men and women.

Several factors contribute to women's higher risk for fractures. In general women with their smaller frames have lower bone densities compared to men, and women typically live longer and will have more time to continue to lose bone density and/or to experience a fall. In addition, women at menopause will have a rapid loss of approximately 6% of their total bone density within several years.

Definitions of abnormal bone density
Loss of bone density can result in a condition called ***osteopenia*** or low bone density which is typically not treated but can be a marker for the later development of osteoporosis. ***Osteoporosis*** is characterized by a further loss of density and a deterioration of microscopic architecture such that the bones become fragile and break easily. It has been estimated approximately 30% of American women over 50 have osteoporosis using the current WHO standards (Marshall 1996). By the age of 80, 90% of women have either osteopenia or osteoporosis although it may be the risk of falling that is the greatest risk factor for fracture at this point (Melton 1993).

How is bone density measured?
Bone density measurements can predict the risk of fracture but cannot identify individual people who will have a fracture (Marshall 1996). Bone density can be measured by the DEXA (dual energy x-ray absorptiometry) which involves radiation exposure similar to a mammogram and one tenth that of a chest x-ray. The DEXA scan takes approximately 20 minutes and involves positioning on a table in the supine and side position in a patient gown while the measurements are made and then later read by a specialist.

The heel ultrasound is another way to estimate bone density. It involves sound waves rather than radiation and is a tenth of the cost of a DEXA examination. However any peripheral (wrist or heel) measurement may not correlate to a central (spine or hip) measurement, especially if physical activity is either low or high. It is important to realize that DEXA and ultrasound machines themselves can vary, and follow up measurements should be conducted using the same machine if possible. In addition these individual measurements can vary such that it is not usually recommended to measure at intervals less than 2 years. These bone density measurements cannot assess bone quality and it is possible that the quality of the bone and the turnover rate may be as important as bone density for predicting who will sustain a fracture from a fall (Wilkin 1999). Urine or blood tests to measure metabolic markers for bone remodeling can be used to monitor the response to osteoporosis treatment.

How is a bone density reported?
The results of these tests are reported as bone density using a gram of bone per centimeter squared for units for the bone that was measured. The density of a bone can vary such that a wrist bone density (0.45 gm/cm^2) is not the same as the density of the hip or spine bone (1.3 gm/cm^2) in the same person. Age and gender are also very important when comparing bone density. A young woman might have a spine bone density of 1.045 gm/cm^2 and a hip density of 0.924 gm/cm^2 (Scholes 2002) while a post menopausal woman could have a spine density of 0.93 gm/cm^2 (McClung 1998) using similar DEXA machines. This means it would be difficult to know what bone density alone means.

What is usually reported is a comparison of the patient's bone density with the density found in a young normal population of the same gender; this is called a ***T score***. Think of the T score as a standard deviation which is arrived at by a comparison of an individual to the average value of the measured population. For example if the normal hip density for a 20-29 year old white female is 0.942±0.123 gm/cm^2 then if the density for an individual is 0.942 gm/cm^2 then she has a T score of 1.0 which is a very good score. But if she has a density of 0.696 gm/cm (which is the mean minus 0.246 gm/cm^2 or 2 standard deviations lower than the mean bone density for this population) this will correspond to a T score of -2.0 or two standard deviations below the mean value although this is still not osteoporosis as described below.

What is a normal bone density score?
A T score of -1.0 or greater is defined as normal. Osteopenia or low bone mass is present with a T score between -1 and -2.5 and osteoporosis if the T score is -2.5 or lower. There are a number of on-line calculators for estimating fracture risk using these scores and risk factors (iscd.org 2005 and Ott 2005).

As estrogen declines it will trigger bone loss
Any physiologic state which induces a decline in estrogen such as natural or surgical menopause will induce a decrease in bone resorption and an increase in bone turn over typically leading to a loss of bone density. During menopause women will usually lose up to 6%

of their bone density, although peri-menopausal women who had been using DMPA did not lose further bone density as they had already lost this estrogen sensitive component (WHO 2004). A 6% loss of bone density is similar to the loss seen with other hypoestrogenic states like lactation. The bone density loss with lactation occurs regardless of calcium intake (Kalkwarf 1997), is reversible, and a history of lactation is not associated with an increase in osteoporosis in cross-sectional studies (Polatti 1999 and Sinigaglia 1996).

With OC use the ovary diminishes estradiol production and the bones then rely on the ethinyl estradiol component of the OC. However, women using the OC typically have bone density measurements similar to women not using hormonal contraceptives (Berensen 2004). A population-based case control study in Sweden demonstrated a risk reduction of 25% for hip fracture with OC use after the age of 40 in healthy post-menopausal women even years from their OC use (Michaelsson 1999). It is possible that the lower OC or 20 mcg ethinyl estradiol dose OC formulations may not be as protective of bone density. It has also been suggested but unproven, that the progesterone component itself is important to bone growth (Prior 1990 and Gallagher 1990). For example, the use of the progesterone only OC during lactation ameliorated some loss in bone density (Caird 1994).

DMPA use and bone density measurement

After 2 years of DMPA use women will have lost up to 6% of their bone density (Scholes 2002 and 2005) and this bone loss can be reversed during DMPA use with estradiol supplementation (Cromer 2005). With DMPA use, loss of bone density of 6% or roughly 0.05 gm/cm^2 at the hip for example, translates to a half of a standard deviation and this degree of difference in a T score can increase the relative risk of fracture by 50%. Luckily during the use of DMPA this risk in women under 35 years of age is very small at 2 per 100,000 women per year so this increase to 3 per 100,000 is small and may only be measurable when combined with other risk factors such as extreme skeletal demands in young soldiers. In addition, just as with lactation, the bone density lost during DMPA use is typically regained within 3 years following cessation of DMPA exposure (Scholes 2002 and 2005). Post-menopausal women with a history of DMPA use have similar bone density compared to women never using DMPA (WHO 2004). It still remains a small possibility an adolescent with long-term DMPA use may not achieve the peak bone density she might have achieved if she had not been using DMPA (WHO 2004). Just as with any population there will be women in the lowest percentile for bone density and these women would be at the greatest risk from the additional loss of bone density with DMPA use.

Low bone density can predict fracture risk in post-menopausal women

In a cohort of women over age 65 volunteering for a bone density test, approximately 1 out of a 125 then experienced a hip fracture over the 1.8 years of observation and the risk for fracture doubled for each standard deviation of decrease in bone density measured at baseline (Cummings 1993). For example a woman with a hip bone density T score of -1.5 would have twice the risk of a hip fracture compared to a woman with a T score of -0.5. This risk also doubled for every increase of 10 years of age. The hip bone DEXA measurement was the best measurement to predict the risk of a hip fracture (Cummings 1993). These authors estimated if a 50 year old had a DEXA scan with a T score of -1.7 (in the lowest 10% for bone density) she then had a 25% risk of later hip fracture compared to another 50 year old in the top 90% for bone density who still had an 8% risk for hip fracture. Pointing out that bone density is not the only risk factor for fracture.

Problems with bone density measurements

Most of the literature about bone density has centered on older individuals since the preponderance of risk is in that population. In addition, while Asian populations may have less bone density this has not been associated with an increase in fracture risk uniformly and many of the "normal" populations may not be representative of ethnic or racial differences. It is not known exactly what heel density score in young women correlates with a hip bone density of less than 0.77 gm/cm^2 or a T-score of -1.7 which would correspond with the lowest 10th percentile for bone density.

A study correlating a bone density screening test result to clinical outcome has not been done in women using DMPA or the OC. It is not known if withholding DMPA from a woman with osteopenia would result in a reduction in fracture risk years later. It is difficult for young women to balance things like the risk of an unintended pregnancy or a blood clot if an estrogen containing contraceptive method is used against possibly increasing her later risk of fracture. Many of these hip fractures will not happen until 20 to 30 years after menopause and women identified at menopause to have osteopenia or osteoporosis can then undergo treatment at that time to increase their bone density and ameliorate this risk (McClung 1998).

Demographic and medical history risk factors for bone fracture

History of prior adult fracture from a fall or a fragility fracture (without trauma)*
Medical condition which would impair calcium or vitamin D absorption*
Medical condition with direct effects on bone metabolism such as hyperthyroidism*
Use of a medication known to have bone effects such as prednisone or anticonvulsants*
Early menopause (younger than 45) for any reason
History of prolonged amenorrhea due to hypoestrogenism of > 1year
Family history of osteoporosis especially hip fracture in a parent
Northern European race
Dementia, poor vision, or other conditions increasing the risk for falling
Low body weight (under 125 pounds or body mass index under 19
Poor nutrition such as low calcium intake
Smoking, alcoholism, and inadequate weight bearing activity

* these risk factors warrant bone density assessment and monitoring if DMPA were to be prescribed.

In summary
While it is now recognized to be important for women to have a bone density assessment at the age of 65 (ACOG 2004), it is unknown if there is any benefit to knowing sooner in an asymptomatic population without multiple risk factors. This is particularly unclear in pre-menopausal populations when bone loss from conditions like lactation or DMPA use are reversible and a treatment like bisphosphonates would not usually be recommended because of their teratogenicity.

It may make sense for a woman choosing to use DMPA to have a bone density assessment to see if she is in the lowest 10th percentile for bone density if that would change her decision to use an estrogen containing contraceptive method instead. Alternatively a woman without significant risk factors for osteoporosis who has decided that DMPA is the only method she can effectively use for contraception should not be denied access to DMPA just because she has not obtained a bone density assessment. It has not been determined that a single bone density assessment years before fracture risk is high will accurately predict risk or even if avoiding

DMPA can modify this risk for an individual woman. While it is generally accepted that adequate calcium and vitamin D intake, and weight bearing exercise are important for the development of strong healthy bones it is also true that the use of calcium supplementation has not been shown to prevent the bone loss measured with lactation (Kalkwarf 1997) and is unlikely to ameliorate the effects of DMPA.

All young women can benefit from screening for fracture risk factors, counseling about modifiable conditions, education about preventing falls, and advise that the use of DMPA and possibly low estrogen dose OC can decrease bone density, and referral for bone density screening if multiple risk factors and treatment such as a change in contraceptive method would be considered.

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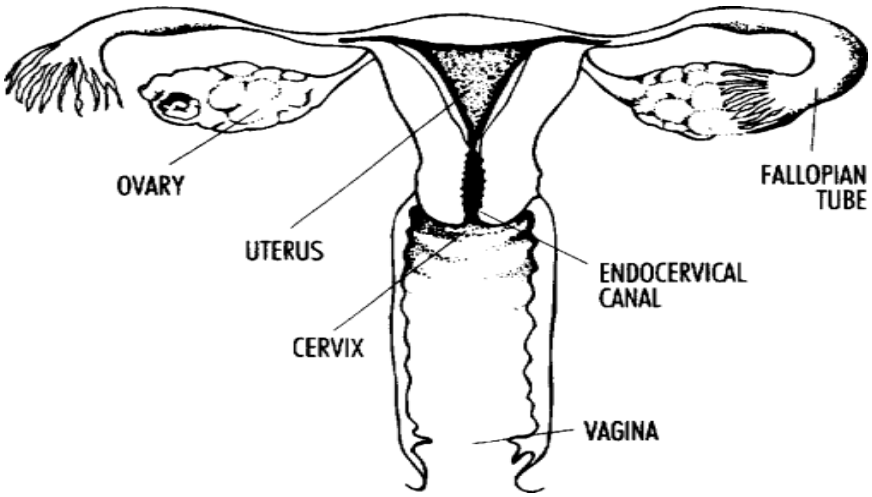
Cervical Cancer Handout

What is Cervical Cancer?
Cancer is a disease in which cells in the body grow out of control. When these abnormal cells are present in the cervix, it is called cervical cancer, or cancer of the cervix.

As the drawing shows, the cervix is the lower, narrower part of the uterus. The uterus is also known as the womb. The upper part of the uterus is where a baby grows when a woman is pregnant. The cervix connects the upper part of the uterus to the vagina (the birth canal).

Figure 1 – The Female Reproductive System



Important Facts About Cervical Cancer
- Cervical cancer can usually be prevented if women are screened regularly with a test called the Pap test.
- It is estimated that during 2003, about 12,200 women in the U.S. will be diagnosed with cervical cancer, and 4,100 will die of the disease.
- Any woman who has a cervix can get cervical cancer, especially if she or her sexual partner has had sex with several other partners.
- Most often, cervical cancer develops in women aged 40 or older.
- Abnormal cells in the cervix and cervical cancer don't always cause symptoms, especially at first. That's why getting tested for cervical cancer is important, even if there are no symptoms.
- When it is found early and treated, cervical cancer is highly curable.
- Most deaths from cervical cancer could be avoided if women had regular checkups with the Pap test.

Screening Prevents Cervical Cancer and Saves Lives
The Pap test can find abnormal cells in the cervix. These cells may, over time, turn into cancer. This could take several years to happen. If the results of a Pap test show there are abnormal cells that could become cancerous, a woman can be treated. In most cases, this treatment prevents cervical cancer from developing. When it is found early, the chance of being cured is very high. The most important thing you can do to avoid getting cervical cancer is to have regular Pap tests.

What is the Pap Test?
The Pap test, also called the Pap smear, is a cervical cancer screening test. It is not used to detect other kinds of cancer. It is done in a clinic. This test can find abnormal cells in the cervix that may turn into cancer if they're not treated.

During the test, the provider uses a plastic or metal instrument, called a speculum, to widen the vagina. This helps the provider examine the vagina and cervix, and collect a few cells and mucus from the cervix and the area around it. These cells are placed on a slide and sent to a laboratory to be checked for abnormal cells.

The provider also performs a pelvic exam, checking the uterus, ovaries and other organs to make sure there are no problems. There are times when a provider may perform a pelvic exam without giving you a Pap test. Ask your clinic provider which tests you're having, if you're unsure.

Who Should Have a Pap Test?
Providers recommend that women begin having regular Pap tests and pelvic exams at age 21, or within three years of the first time they have sexual intercourse – whichever happens first. It is recommended that after a woman over age 30 has a Pap test each year for three years in a row, and test results show there are no problems, she can then get the Pap test once every 2-3 years.

Who Does Not Need to be Tested?
The only women who do not need regular Pap tests are:
- Those over age 65 who have had regular Pap tests with normal results and have been told by their providers that they don't need to be tested anymore.
- Women who do not have a cervix. This includes women whose cervix was removed as part of an operation to remove the uterus. (The surgery is called a hysterectomy). However, a small number of women who have had this operation still have a cervix and should continue having regular Pap tests. If you're not sure whether you have a cervix, speak to your provider about it.

How Do I prepare for the Pap Test?
To prepare for the Pap test, providers recommend that for two days before the test you should avoid douching, using tampons, having sexual intercourse, and using vaginal medications or creams. Providers also recommend that you try to schedule your Pap test for at time when you are not having your menstrual period.

The Test Results
Most labs in the United States use the "Bethesda System" to describe Pap test results. This standard system helps plan treatment if needed. Under this system, your results will be placed in one of these categories:

- *Normal (negative):* Only normal cells are seen. There are no signs of cancer or precancer. Cells are called precancerous when there are changes in them they may, but do not always, become cancer.

- *Atypical squamous cells (ASC): Some* cells were seen that cannot be called normal, but do not meet the requirements to call them precancer. The abnormal cells may be caused by an infection, irritation, intercourse, or may be precancerous.

- *SIL (squamous intraepithelial lesion): Changes* were seen in the cells that may show signs of precancer. SIL can be low grade or high grade.
  - *Low-grade SIL (LSIL): Early*, mild changes were seen in the size or shape of cells.
  - *High-grade SIL (HSIL): Moderate* or severe cell changes are seen. HSIL changes on a Pap test suggest an increased risk of "precancer" being present than with LSIL changes.

- *Cancer:* Abnormal cells were seen to have spread deeper into the cervix or to other tissues. They have become a true cancer.

When Will I Get the Results?
It can take up to three weeks to receive Pap test results. Most results are normal. But if your test shows something may be abnormal, the provider or nurse will contact you and probably want to do more tests. There are many reasons that Pap test results can be abnormal, and usually it does not mean you have cancer.

Handout adapted from CDC Publication #99-6949. October 2003

Cholesterol Screening

The following section applies only to women obtaining their medical care through the Family Planning Program. These do not replace primary care guidelines or dictate management for primary care patients.

Lipid Panel Testing

Indications

In premenopausal women without a hereditary, hyperlipidemia family history (in which case earlier and more frequent lipid testing is advised), beginning at age 20 obtaining a lipid profile every 5 years is an adequate screening recommendation according to the National Cholesterol Education Program (JAMA 2001; 285: 2486-2500).

Education

All clients should be encouraged to maintain a normal weight, exercise regularly - especially aerobic activities, eat a low fat diet, and not use tobacco. Preventing obesity will decrease the risk of diabetes and cardiovascular disease.

Who to Test

- A fasting HDL, triglyceride, and LDL level (lipid panel) should be offered to women 21 years of age or older, with **no prior lipid testing,** and a first degree relative with a history of a stroke under age 50, MI, angina, coronary bypass or other evidence of coronary atherosclerosis under age 65 for female relatives or 55 for male relatives.
- Women over the age of 45 may especially benefit from lipid testing to help them make decisions about their risk for CVD as they approach menopause.

Preparation for Lipid Testing

- Fasting for 12 hours. Water is permitted.
- Avoid testing during pregnancy and for at least nine months afterwards.

What Test?

Use venous blood and order the contracted lipid panel test (total cholesterol, HDL, LDL, triglycerides).

Results

Remember that there is a wide laboratory variation in cholesterol test results. A variation of 5% is expected and a variation of 10% is frequent. Thus a cholesterol level of 200 mg/dL is really somewhere between 180 and 220 mg/dL. This is important in comparing results of repeat tests.

Management

- Discuss lipid panel results with client. The client can be provided with the Lipid Profile Results Handout.

- Discuss additional cardiovascular risk factors present that client can modify and change. If client has two or more of the below risk factors, their risk for CVD is increased:
  - Cigarette smoking
  - Family history of definite myocardial infarction or sudden death in a first degree relative before age 55 years if male or before age 65 years if female.
  - Hypertension (persistent blood pressure over 140/90 or using antihypertensive medication)
  - Diabetes mellitus
  - If HDL greater than 60 then this helps protect against CVD and the woman can subtract one risk factor.
  - Age greater than 55 in women.

- **Adult Lipid Panel Result Classification** According to JAMA article (JAMA 2001; 285:2487).

LDL cholesterol	
<100	Optimal
100-129	Near or above optimal
130-159	Borderline high
160-189	High
≥190	Very high
Total cholesterol	
<200	Desirable
200-239	Borderline high
≥240	High
HDL cholesterol	
<40	Low
≥60	High

- **Referral** for possible treatment if fasting lipid results are any of the following:
  - **Fasting Triglycerides over 250**.
  - **LDL over 160 mg/dL**
  - **HDL Cholesterol below 30 mg/dL in women**

- Repeat Lipid panel testing every 5 years if the client chooses. There is no reason to repeat sooner because asymptomatic premenopausal women rarely require aggressive lipid lowering treatment. If the client was referred for evaluation, then the follow-up lipid testing needs to be done at the referral site and not through the family planning program.

- Rarely will the lipid test results change a contraceptive method choice since current low dose COC pills do not change lipids significantly.
- Remember if low HDL (less than 40), DMPA users need to sign the Birth Control Method Specific Informed Consent Form because DMPA use can effect HDL levels in some women.
- Clients can be given the Preventative Health Documentation Card to track their results and to encourage attention to their health.

Northwest Lipid Clinic Referrals
This clinic often conducts studies and can provide counseling and testing for individuals with grossly abnormal lipid values. The clinic number is 206-341-4400. They are located at Harborview but do not provide free care unless it is within a study.

Colon Cancer Screening

Colon Cancer Overview

Colorectal cancer develops in the lining of the large intestine. At the present time, colon cancer is the second most common cause of a cancer related death in the United States with approximately 57,000 Americans dying each year (NEJM 2002;346:40-44 and Ann Intern Med 2002;137:96-104). Approximately 155,000 new cases of colon cancer are diagnosed annually and the survival rate is only slightly higher than 50%.

If colon cancer is detected early, it can be cured. If pre-malignant polyps are removed, up to 80% of colon cancer deaths can be prevented. It is thus cost effective to perform colon cancer screening at the age of 50 in individuals with average risk for colon cancer. Colon cancer increases with age and men and women have equal chances of getting it.

Risk Factors

The average individual's lifetime risk of developing colorectal cancer is only about 2%. An individual with a first degree relative diagnosed with colorectal cancer has a 6% chance of developing colon cancer in their lifetime. And if the first degree relative developed cancer before the age 45 the risk for the relative increases to 10%. In these families with a history of colon, breast, or ovarian cancers or abnormalities like multiple polyps of the colon; referral to primary care for earlier and more intensive screening should be recommended. Most, 85%, of individuals diagnosed with colon cancer do not have a family history or an inherited genetic defect.

All patients should be aware that risk factors for colon cancer include the following: age, obesity, sedentary life style, smoking, and excessive alcohol or red meat consumption. Deoxycholic acid, found in bile, appears to have carcinogenic properties and possibly is one mechanism. At 50, 1 in 2,000 people per year will develop this cancer. After age 65 it increases to 3 in 1,000. Polyps on the colon and rectum are fairly common in people over 50. African Americans are at higher risk of colon cancer and increased mortality when diagnosed. The highest risks are for men of African descent. Women with a history of cancer of the ovary, uterus or breast have a slight increase of developing colorectal cancer. Smoking may also increase the risk, and drinking alcohol regularly seems to have an additive effect. However, nonsmokers who drink and have diets high in fruits and vegetables do not seem to be at increased risk. Crohns disease and ulcerative colitis have been linked to an increase risk for colorectal cancer. Patients with either one of these illnesses who have a family history of colorectal cancer are at a 5-fold increased risk.

Colon Cancer Prevention
Diet may play a role in preventing colon cancer. Many of the comments listed below are not widely proven or accepted as causative but for patients making dietary choices it may be prudent to recommend the following advice.

Diets high in fruits and vegetables and low in meat are thought to be protective against many cancers. Phytochemicals such as careotenoids or organosulfur compounds in vegetables and fruits may have cancer fighting properties. They are typically found in foods that are dark-green, red, yellow-orange and blue in color (cabbage, carrots, or garlic and onions). Contrary to belief, fiber has not been found to have a protective effect on preventing colon cancer. Fats found in animal fat may increase the risk for colon cancer. Olive oil, may reduce levels of deoxycholic acid, and therefore, may be protective. Grilled or fried foods, particularly fats can increase risk. Fermented milk, which contains acidophilus may help protect against colon cancer.

The higher the intake of sugar and calories the greater the risk for developing colon cancer. Some studies have found that drinking 4 or more cups of coffee per day is associated with a lower risk for developing colorectal cancer. Green tea may have some benefit. Selenium is a trace element in meat, whole grains, egg yolks, fish and Brazil nuts and may reduce risk. The use of aspirin or other NSAIDS has been associated with reduced risk and hormone replacement therapy (HRT) continues to show that estrogen protects against colon cancer. Birth control pills are being investigated to see if they reduce a woman's risk of developing colorectal cancer. And last but not least, regular to moderate exercise (30 minute daily jog or 60 minute daily walk) reduces the risk of many chronic diseases and colon cancer as well.

Colon Cancer Symptoms
It is known as a "silent" disease because many people do not develop symptoms until the cancer is difficult to cure.

The following are some of the symptoms that may occur:
- Diarrhea, constipation, or feeling that the bowel does not empty completely.
- Blood in the stools
- Stools that are narrower than usual
- General abdominal discomfort (increase gas pains, bloating, fullness and/or cramps.
- Weight loss with no known reason
- Anemia
- Constant tiredness
- Vomiting

Colon Cancer Screening
1. Start screening at age 50 if there are no other risk factors. This has been shown to be more cost effective than not providing screening. Although exactly what test or combinations of tests for what duration is not known.

2. Fecal Occult Blood Testing (FOBT) of three stool samples should be done yearly at a minimum beginning at age 50. In addition a flexible sigmoid done every 5 years may provide additional benefit although this is controversial and was not the

recommendation by the US Preventative Services Task Force in 1996 but was recommended by the American Cancer Society and the American College of Gastroenterology. Because the flexible sigmoid only visualizes the left colon and will miss half of the polyps any negative study with positive stool blood or abnormal result should be followed with colonoscopy. Colonoscopy is more sensitive for detecting colon cancer but has a higher rate of complications and cost. But it is now being recommended for any high-risk and older patients.

3. Individuals with risk factors (personal or first degree relative history of colon cancer or adenomators polyps, a polyposis syndrome, or chronic inflammatory bowel syndrome) should be referred to primary care to make appropriate screening recommendations.

Fecal Occult Blood Testing

A test for fecal occult blood should be done annually on three serially obtained samples of stool. The testing cards are sent home with the patient and one card is used each day. Do not collect the samples when on menses or if any active rectal or vaginal bleeding three days prior to or during testing. The stool should be sampled from the center of the stool mass using a clean collection device to smear a small sample on the card. There are two spots on the card so two entirely different areas of the stool can be sampled, preferably one from the beginning and one from the end of the stool. These cards are then returned to the clinic for rehydration or testing with the test reagent. It is advised, to decrease false positive results that patients avoid consuming red meat, horseradish, certain raw vegetables (broccoli, turnips, cabbage, cauliflower, or radishes), aspirin, any NSAIDS, and any vitamin C 2 weeks before and during stool collection. If any one of the tests is positive for occult blood then the patient should be referred for evaluation because the chance of an adenoma or cancer is 17 % to 46%. The need for a digital anal exam has not been proven as necessary for colon cancer screening but would be a part of any evaluation or work up of rectal bleeding, suspicious symptom (such as change in stool caliber) or a positive fecal occult blood test.

Diabetes Screening

The following section applies only to women obtaining their medical care through the Family Planning Program. These do not replace primary care guidelines or dictate management for primary care patients. These recommendations are taken from the American Diabetes Association and the entire text can be viewed at: http://journal.diabetes.org.

Fasting Glucose Testing

Indications

The prevalence of diabetes in the US is thought to be about 12%. Unfortunately, many people go undiagnosed until late with almost ½ not diagnosed until 10 years from the onset of the disease. Early diagnosis of diabetes can decrease the damage to end organs like the kidney and eyes so it is important to offer fasting glucose testing for certain clients. The Diabetes Screening Handout can be given to clients to provide more information about diabetes and diabetes testing.

The following women should be offered testing every 3 years according to the American Diabetes Association. Testing is done by fingerstick or venous blood draws for fasting glucose testing using an on-site glucose meter.

- Age 45 or older
- Obesity – BMI ≥ 30 at any age increases the risk for diabetes
- Hypertensive
- Has documented low HDL (less than 40) or triglycerides greater than 250.
- Known PCOS or androgen disorder
- Women with a history of gestational diabetes need screening with a fasting blood sugar one year after the pregnancy has ended. If they have a normal result, they will then need to be tested every three years. The women should also be strongly advised to have a normal body weight, perform aerobic exercise, and prevent future pregnancies, as pregnancy greatly increases her risk of progressing into true diabetes.

Also every 3 years IF AGE GREATER THAN 30 and has one of the following:

- Overweight (BMI greater than 26)
- First degree relative with diabetes
- Ethnicity with increased diabetes risk: African American, Asian American/Pacific Islander, Latino, or Native American.
- Gave birth to a baby weighing 9 or more pounds

According to the American Diabetes Association, a fasting venous blood sugar over 125 mg/dL or a non-fasting random blood sugar > 200 mg/dL in a patient with symptoms of diabetes (polyuria, polydipsia and unexplained weight loss) meet the criteria for a diagnosis of diabetes. Anyone with readings above these levels should be referred to their primary care provider for further evaluation.

Anyone with a fasting venous blood sugar over 110 mg/dL on a prior screening test who has not been further evaluated for diabetes should have a repeat fasting glucose test within six months. This can be done with a fingerstick or capillary blood test in the Family Planning Program as we are only performing a screening test.

Capillary glucose results are 15% lower than venous fasting blood glucose (FBG)
If capillary or fingerstick is used for the blood glucose test, then the glucose results are 10-15% lower than a venous puncture for the glucose test. So, if the result is marginal or abnormal, one can multiply the result by 0.15 to add 15% to increase the value.

Summary of Fasting Capillary Glucose (FBG) Test Results

- A result of less than 100 (<110 mg/dL if venous) is normal.
- 100-109 (≥ 110 and < 126 mg/dL if venous) is impaired and should be repeated in 6 months.
- 110 (≥ 126 mg/dL if venous) and was fasting necessitates referral to primary care provider for possible diabetes.
- If result is 140 or above an immediate referral is indicated.
- If result is non-fasting and over 175 than an immediate referral is indicated.

Hypertension Screening

Who to Test
Blood pressure should be assessed a minimum of once a year for all women. Pregnant women should have a blood pressure measurement with every visit. Women just beginning estrogen-containing methods should have a blood pressure evaluation after 3 months of use because there are rare individuals who are sensitive to estrogen and with estrogen use became hypertensive.

Definitions
Normal blood pressure is under 120/80mm mercury pressure. **Mild** hypertension is defined as three or more readings on separate occasions over a 4 to 8 week period of time of a diastolic blood pressure between 90 and 99 mm. **Moderate** hypertension is when the diastolic blood pressure continues between 100 and 109 mm. **Severe** hypertension is sustained diastolic blood pressure greater than or equal to 110 mm.

Classification of Blood Pressure for Adults Age 18 and Older*
(Reprinted from the 7th report of the National Committee on Prevention, Detection, and Treatment of High Blood Pressure, JAMA 2003; 289:2560)

Category	Systolic (mm Hg)		Diastolic (mm Hg)
Optimal†	<120	and	<80
Prehypertension	<120-138	and	<80-89
Hypertension‡			
Stage 1	140-159	or	90-99
Stage 2	≥160	or	≥100

*Not taking antihypertensive drugs or acutely ill. When systolic and diastolic blood pressure fall into different categories, the higher category should be selected to classify the individual's blood pressure status. In addition to classifying stages of hypertension on the basis of average blood pressure levels, clinicians should specify presence or absence of target organ disease and additional risk factors. This specificity is important for risk classification and treatment.
† Optimal blood pressure with respect to cardiovascular risk is below 120/80 mm Hg. However, unusually low readings should be evaluated for clinical significance.
‡ Based on the average of two or more readings taken at each of two or more visits after initial screening.

Elevated Blood Pressure
Blood pressure may be temporarily elevated by many factors. It is essential that BP be repeated under conditions free of these factors before referral to a physician or taking the client off estrogen methods.

Blood pressure may be temporarily elevated (especially systolic) by:

- Exercise
- Pain
- Emotion
- Disease - endocrine disease, CNS disease, etc.
- Drugs - pressor agents, asthma medications, nose or eye drops, cold or sinus pills, diet pills, caffeine, hormones, etc.
- Smoking
- Alcohol
- Noisy or crowded environments
- Recent food consumption
- Full bladder

How to Take a Blood Pressure

The direct method to measure arterial pressure involves placing a catheter directly into an artery. This is not usually done. The indirect method is when external pressure is applied to the overlying tissue using a sphygmomanometer and the compression necessary to occlude the artery is assumed to be equal to the intra-arterial pressure. The arm cuff should be at least 10 cm wide and if the arm is large a wider cuff is needed or the pressure readings will be falsely elevated. A rubber pump is used to inflate the cuff and a manometer is used to measure the applied air pressure in mm of mercury. The client should be sitting, preferably after a period of rest. Bare the arm and affix the cuff snugly and smoothly so the distal margin of the cuff is at least 3 cm proximal to the antecubital fossa. Then rest the supinated arm on the table with the antecubital fossa at the approximate level of the heart. Palpate for the location of the brachial arterial pulse; it is usually medial to the insertion of the biceps tendon. Inflate the cuff to the pressure of 30 mm above the point where the palpable pulse disappears. Open the valve slowly so the pressure drops gradually. From this point on the use of the stethoscope to auscultate and to hear the return of the pulse. Press the bell of the stethoscope lightly over the brachial artery and note the pressure reading at which sounds first become audible: this is the systolic pressure. As deflation of the cuff proceeds, the sounds become louder and then become muffled; take a reading at the point of muffling and again at the point when the sounds disappear. The pressure at which the sounds disappear is the accepted definition of the diastolic pressure. It is often advised to repeat the entire procedure a second time particularly when learning and being careful to completely deflate the cuff between measurements.

Management

- If blood pressure is below 80 mm diastolic, no further action is required.
- If diastolic blood pressure is elevated (85 mm or above), have the client rest in the clinic for 10 to 20 minutes. Repeat blood pressure in both arms, using correct technique and appropriate cuff size. Document the measurements taken in the progress notes. If blood pressure persists ≥ 80 mm diastolic, give advice about low sodium diets, relaxation, stress management, medications (diet drugs), smoking, and low-calorie diets if appropriate. Advise the client to visit the local fire station or pharmacy to have her blood pressure checked 1 to 2 times a week for the next month and to return with the Preventative Health Documentation Card documenting her blood pressure. If sustained diastolic pressures of 80 or above are recorded, refer the client to her primary care provider because early treatment of hypertension is important and it can help prevent cardiopulmonary disease like heart failure.
- If blood pressure is ≥ 100 mm diastolic or over 160 mm systolic, refer that week for primary care appointment and treatment. If this same client has a headache, visual changes, or this is a substantial increase over past blood pressure readings, then refer emergently as this may be an impending stroke or other serious condition.
- If blood pressure is ≥ 110 diastolic or ≥ 180 systolic, refer emergently to avoid a stroke.
- If client is diagnosed with hypertension and she is taking an estrogen-containing pill, she needs to be counseled about the possibility of the estrogen worsening her hypertension. If her blood pressure stabilizes and she wishes to continue on the COC pill, she needs to sign the Birth Control Method Specific Informed Consent Form and be switched to the lowest estrogen dose pill possible. If her blood pressure continues to be elevated due to no treatment or in spite of treatment, then estrogen-containing methods are contraindicated.

Hypothyroid Screening

The following section applies only to women obtaining their medical care through the Family Planning Program. These do not replace primary care guidelines or dictate management for primary care patients.

Hypothyroid Screening

Who to Test?

- Hypothyroidism, especially in the early stages can present with nonspecific symptoms and can include the following: cold intolerance, weight gain, hair loss, or dry skin. Refer or possibly send the TSH, but even if normal result, consider referral to primary care provider or an endocrine clinic. Even if a woman is hypothyroid evidenced by an elevated TSH, she may receive hormonal contraceptives.
- Clients with amenorrhea greater than 6 months with no etiology known.

Send only the TSH test and not the entire thyroid panel. The entire thyroid panel is for evaluating hyperthyroidism. A primary care or endocrine provider should do that evaluation. Women to consider referral for hyperthyroidism include women with a goiter, or women with symptoms of hot flashes, weight loss, and a pulse greater than a 100 should be present in clinically significant hyperthyroidism. Refer patients that need thyroid testing during pregnancy or patients already taking thyroid medications.

Obesity

Americans have an increasing problem with obesity. In 1980, only 16% of women had a BMI ≥ 30, and in 1994 this increased to 24.9% of US women. It is estimated ¼ of Americans are obese and obesity can be directly responsible for many serious chronic diseases like hypertension, diabetes, osteoarthritis, sleep apnea, and anovulation infertility. Clinical obesity can reduce one's life expectancy by 5 to 13 years *(JAMA 2003; 289:187-93)*.

Healthy Weight Table from US FDA & DHHS (not as accurate as BMI described at end of this section) These guidelines make allowances for expected weight gain as people grow older. Both sexes are combined on one table. The higher weights generally apply to men with the lower applying especially to women. Distribution of weight is important since lower (hips) body fat is less harmful than central (belly) body fat.

HEIGHT	19 TO 34 YEARS	35 OR MORE YEARS
5' 0"	97 TO 128 #	108 TO 138 #
5' 1"	101 TO 132 #	111 TO 143 #
5' 2"	104 TO 137 #	115 TO 148 #
5' 3"	107 TO 141 #	119 TO 152 #
5' 4"	111 TO 141 #	122 TO 157 #
5' 5"	114 TO 150 #	126 TO 162 #
5' 6"	118 TO 155 #	130 TO 167 #
5' 7"	121 TO 160 #	134 TO 172 #
5' 8"	125 TO 164 #	138 TO 178 #
5' 9"	129 TO 169 #	142 TO 183 #
5' 10"	132 TO 174 #	146 TO 188 #
5' 11"	136 TO 179 #	151 TO 194 #
6' 0"	140 TO 184 #	155 TO 199 #
6' 1"	144 TO 189 #	159 TO 205 #
6' 2"	148 TO 195 #	164 TO 210 #
6' 3"	152 TO 200 #	168 TO 216 #
6' 4"	156 TO 205 #	173 TO 222 #

Evaluation

Assess motivation for weight loss or change. Does the client perceive the weight as a problem? Evaluate the medical history for special problems that might be exacerbated by weight such as heart disease, hypertension, or diabetes. Take a diet history, including 24-hour recall. Ask about use of diet drugs, as these can be harmful and can cause hypertension. Evaluate the level of physical activity and exercise. Ask about vomiting, purging, diuretics, or unusual food habits.

Determine if the weight is outside the normal range on the weight table. Weight reduction may be encouraged for anyone over healthy weight. Discourage weight loss if client is at the low end of the range or below healthy weight.

Management

- Provide supportive counseling and introductory information.
- Provide the client with information on weight control including: four food groups, dietician and other referral sources, low fat diet information, self-help groups, and medical referral if morbidly obese because if insured, may be able to pay for obesity treatment.
- Encourage regular aerobic exercise 30 to 45 minutes daily. No longer is 3 times a week enough to gain maximal benefit.
- Refer persons significantly below the weight range for possible anorexia evaluation and treatment. Persons who induce vomiting or have evidence of bulimia need referral and treatment.
- Calculate BMI or read off the **Body Mass Index (BMI) Chart** (also attached below) for the client if possible. BMI = weight in kg divided by the height in meters which is squared, kg/m^2.
- Persons who have a BMI of 26 to 29 are considered overweight and if greater than 29 are considered obese and need treatment.
- If BMI is greater than 26 and the client is over age 35, they should have blood pressure testing at every visit and a fasting glucose every 3 years by fingerstick because the risk for diabetes increases with obesity.
- The **Preventative Health Documentation Card** can be given to clients to monitor their weight, blood pressure, and cholesterol levels.

Body Mass Index (BMI) Table

Body mass index is weight (in kilograms) divided by height (in meters) squared. Locate the height along the left-hand column. Then slide your finger to the right along that row until you come to the number closes to the weight. At the top of that column is the BMI. For instance, if you are 5'5" and 140 pounds, your BMI is 23. If you are 6' tall and 210 pounds, your BMI is 29.

If the height or weight isn't listed, or it you want to compute the exact BMI, here's a shortcut: Multiply the weight (in pounds) by 703 and then divide it by the height (in inches) squared.

		19	20	21	22	23	24	25	26	27	28	29	30	35	40
							WEIGHT (pounds)								
	4'10"	91	96	100	105	110	115	119	124	129	134	138	143	167	191
	4'11"	94	99	104	109	114	119	124	128	133	138	143	148	173	198
	5'0"	97	102	107	112	118	123	128	133	138	143	148	153	179	204
	5'1"	100	106	111	116	122	127	132	137	143	148	153	158	185	211
	5'2"	104	109	115	120	126	131	136	142	147	153	158	164	191	218
H	5'3"	107	113	118	124	130	135	141	146	152	158	163	169	197	225
E	5'4"	110	116	122	128	134	140	145	151	157	163	169	174	204	232
I	5'5"	114	120	126	132	138	144	150	156	162	168	174	180	210	240
G	5'6"	118	124	130	136	142	148	155	161	167	173	179	186	216	247
H	5'7"	121	127	134	140	146	153	159	166	172	178	185	191	223	255
T	5'8"	125	131	138	144	151	158	164	171	177	184	190	197	230	262
	5'9"	128	135	142	149	155	162	169	176	182	189	196	203	236	270
	5'10"	132	139	146	153	160	167	174	181	188	195	202	207	243	278
	5'11"	136	143	150	157	165	172	179	186	193	200	208	215	250	286
	6'0"	140	147	154	162	169	177	184	191	199	206	213	221	258	294
	6'1"	144	151	159	166	174	182	189	197	204	212	219	227	265	302
	6'2"	148	155	163	171	179	186	194	202	210	218	225	233	272	311
	6'3"	152	160	168	176	184	192	200	208	216	224	232	240	279	319
	6'4"	156	164	172	180	189	197	205	213	221	230	238	246	287	328

ABORTION FACTS

If you are pregnant, you may feel afraid or confused. These feelings are normal for most women with an unintended pregnancy. This handout explains some of the facts about abortion.

Be Sure You Are Pregnant
First, you need to be sure you are pregnant. Get a pregnancy test if your period is late and you have recently engaged in sexual intercourse. Other early pregnancy signs are breast soreness, frequent urination, or nausea. Some women may spot or have a very light flow in the first months of pregnancy, so even if it seems that you have had a period, you may want to be tested. A health care provider can confirm the stage of pregnancy.

When Is It the Best Time?
The easiest and safest abortions are done during the first 3 months. Most abortions before the 12th week are done in a clinic and take about 5 minutes for the surgery, but the visit is for 3 to 4 hours. Abortions done in the second trimester (12 to 24 weeks) require a more complicated and expensive procedure. Several visits to the clinic or an overnight stay in a nearby hospital may be necessary. Abortions are very rarely preformed after the fifth month, and are only done for serious medical reasons. These abortions require hospitalization.

Surgical Abortion Procedures
Before 6 Weeks
Surgical abortions before 6 weeks are rarely done because the pregnancy is so small it can be missed and the uterus is difficult to open for the surgery.

6 to 12 Weeks
For abortions from 6 to 12 weeks, a procedure called vacuum aspiration is done.

After a pelvic exam, the doctor will numb your cervix. Another instrument will be used to hold your cervix. Your cervix will then be slowly opened with a series of small rods, each one getting bigger. The biggest rod is about the size of a pencil. Some women feel cramping during this, but it only last a few minutes. A small tube is placed into the uterus and the pregnancy is removed by a small vacuum type machine attached to the tube. This takes about 2 minutes. At first, you may have more cramping, but this will go away in about 20 to 30 minutes. The abortion is done now, and you will rest for about 15 to 30 minutes in the clinic.

12 to 22 Weeks: Dilation and Evacuation (D&E)
When a pregnancy has been continued past the first trimester, a different method of abortion is used. This method is called dilation and evacuation, or D&E. D&E is more complicated than early abortion, so the risks are slightly higher. It is important that the doctor know how far along the pregnancy is, so a pelvic exam will be done. Often an ultrasound test is done to tell the exact length of pregnancy.

Ultrasound involves sending sound waves through the skin to determine the size of the uterus. This procedure is completely painless and harmless, but very accurate.

Your cervix is then opened with laminaria. This is a spongy material that slowly swells in the cervix. The laminaria are usually left in overnight and removed the next day by the doctor. Then, the pregnancy is removed by a small suction machine and sometimes forceps. Your uterus is checked with a spoon-shaped instrument to be sure the abortion is complete. When the abortion is done you will rest in the clinic for 30 to 60 minutes.

Past 5 Months
Rarely are abortions performed past five months. If they are done, it is usually for serious medical reasons and the mother may be in danger. The procedure for a late abortion can use medications to make the uterus contract and labor to expel the fetus out of the vagina. This method takes 1 to 3 days, require hospitalization, and has a higher risk of complications than an earlier abortion.

Medical Abortion
If your pregnancy is before 9 weeks you may be able to get the abortion pill or injection to induce a miscarriage. You may be given pills to take by mouth or in your vagina to produce uterine contractions. These medications cause you to have a miscarriage and you often have cramping and bleeding usually heavier than a period, to expel the pregnancy. You will still need 2 to 3 visits to the clinic and 1 in 10 women may still need a surgical procedure to complete the abortion. These medications can cause birth defects so it is very important to finish the abortion.

Follow-Up Care
To recover as quickly as possible, follow these aftercare instructions. Call a doctor if you have a fever, increasing pain, or unusual bleeding. Take your medication if the doctor prescribes any. Use pads instead of tampons for vaginal bleeding. Do not have vaginal intercourse until the bleeding stops (about two weeks). Use an effective method of birth control. You may begin your hormonal birth control method (pill, shot, or IUD) on the day of the abortion. Return for your check up two to three weeks later.

Possible Risks
Abortion before 12 weeks is safer than a shot of penicillin or delivery of a baby. But like any other surgery, abortion has some possible risks. These risks increase as you wait longer to get an abortion. Sometimes problems happen during the abortion such as tearing the cervical opening (requiring a few stitches) or poking through the uterus (very rare).

Sometimes problems arise after the abortion. Excessive bleeding, upset stomach, and cramping may occur. These symptoms usually disappear before you leave the clinic. Antibiotics are used to control any infections after the abortion. Problems are usually rare and most women do not report having any at all. Call the doctor or clinic if any problems occur.

Where Do You Get an Abortion?
Your health care provider can give you the names of several qualified doctors in the area.

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ACNE

WHAT IS ACNE?

Acne, or pimples, starts with blockage of the skin glands with a thick secretion called sebum. This forms a whitehead. If it gets exposed to the air, then sebum turns dark, forming a blackhead. If skin bacteria, for example, Corynebacterium acnes, feed on the sebum it will cause redness and inflammation.

WHY DOES ACNE OCCUR?

Acne occurs in most people during the teens. Sometimes it clears up by the time we are in our 20's, but it may persist for years. In some women, it gets worse before menses. Diet doesn't seem to make much difference but if certain foods cause a flare-up, it is best to avoid them. Oily soaps and cosmetics may make acne worse. Avoid picking at or rubbing your face. Use an unscented mild soap, or just warm water and a wash cloth once to twice a day. Avoid lotions and creams. If you must use make-up, use only water based cosmetics and always remove them before sleep.

WHAT CAN BE DONE ABOUT ACNE?

Benzoyl Peroxide Gel 5% is available without a prescription and can be helpful in treatment of acne. Apply it every night at bedtime after scrubbing with soap and water. If there is no irritation, it may be used 2 or 3 times daily. Your skin will probably look worse for awhile after you start using it. This is because many pimples have started weeks before they are visible and the medication peels off the surface and makes the pimples mature. Expect your face to get a little red at first. If it becomes very irritated, use the gel less often for a while. If the pimples are severe, medication such as Retin A, a vitamin A preparation applied to the skin or antibiotics may be prescribed by your provider.

If you are able to take birth control pills these can reduce the hormones that promote skin oils and acne. All birth control pills can reduce acne. Probably the best pills are monophasic meaning each pill is the same color, so every day you get the same dose of hormones. Pills with a higher estrogen dose and a lower and weaker progestin could also be tried. Any pill brand should be used for 3 months before switching to a new one. Changing your birth control method or going on and off the pill can make acne worse because then your hormone levels are going up and down.

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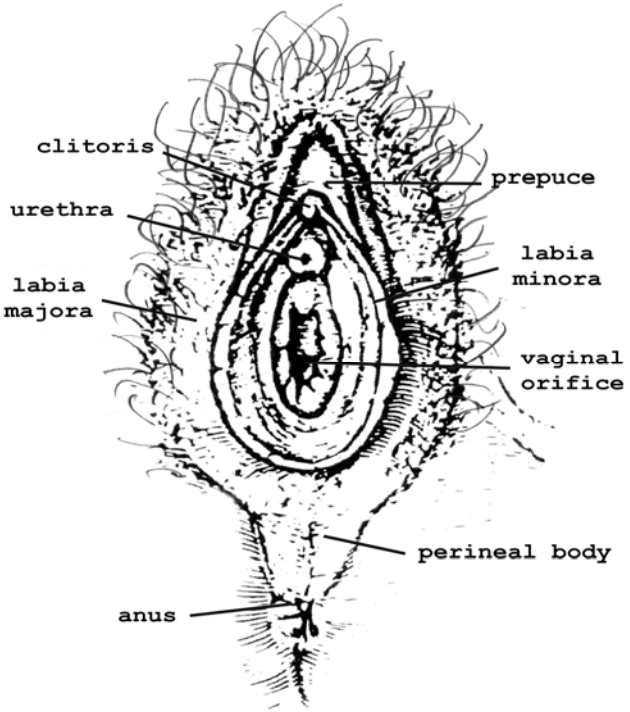
Female Anatomy

Vulva:
The vulva is the outside of a woman's genitals and reproductive system. It includes the labia majora where hair grows, the labia minora tissue or lips, and the vaginal opening called the introitus. The urethra is the opening to the bladder for urine passage. The clitoris, similar to the male penis, is very sensitive and gets firmer and larger with arousal and is important for sexual pleasure. Notice the anus is close to a woman's vulva and it is important to avoid touching the anus and then touching the vulva or vagina to prevent irritation.



These are the parts of a woman's body that enable her to become pregnant and carry a baby.

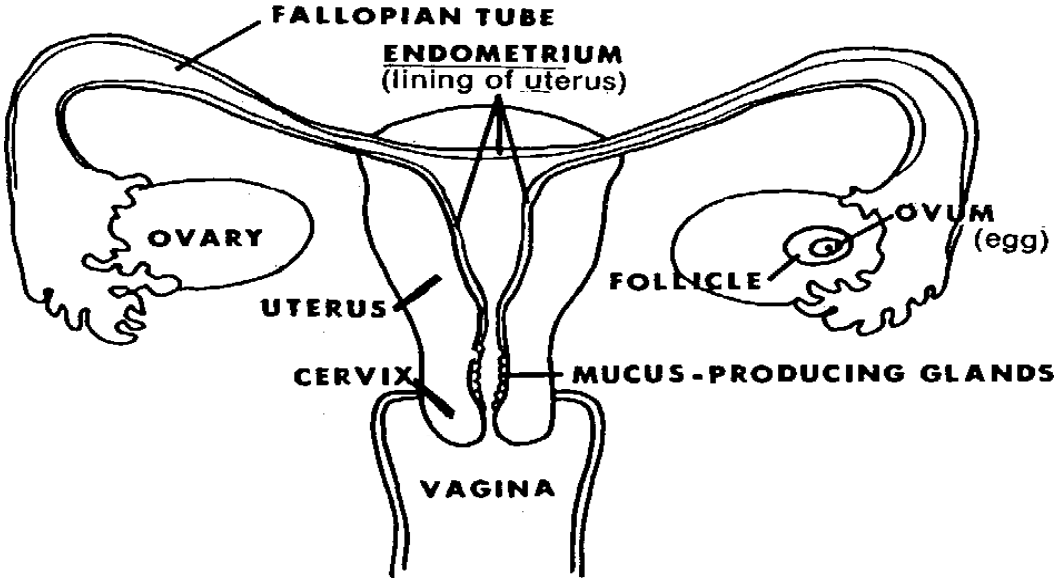
- **Vagina**: tube leading from the uterus to the outside of the body. Allows for the passage of blood, or a baby during childbirth, and receives the penis during sexual intercourse.

- **Uterus or "womb":** pear-shaped muscular organ, normally about the size of a fist, where the fetus develops when a woman is pregnant.

- **Cervix:** bottom part of the uterus, which can expand to allow for the passage of a baby during childbirth. Inside the cervix there are glands that produce mucus that changes in response to hormones during the woman's menstrual cycle.

- **Ovaries:** two almond-shaped organs, which lie on each side of the uterus. These are the female sex organs which produce hormones that control the menstrual cycle, and also release the egg, or ovum. The release of the egg is called ovulation.

- **Fallopian tubes:** delicate tubes, which pick up the egg when the woman ovulates. If a woman becomes pregnant, the egg meets with the sperm (or is fertilized) in the outer part of the tube. The fertilized egg will travel through the tube into the uterus, where it will burrow into the lining of the uterus for nourishment for the next nine months.



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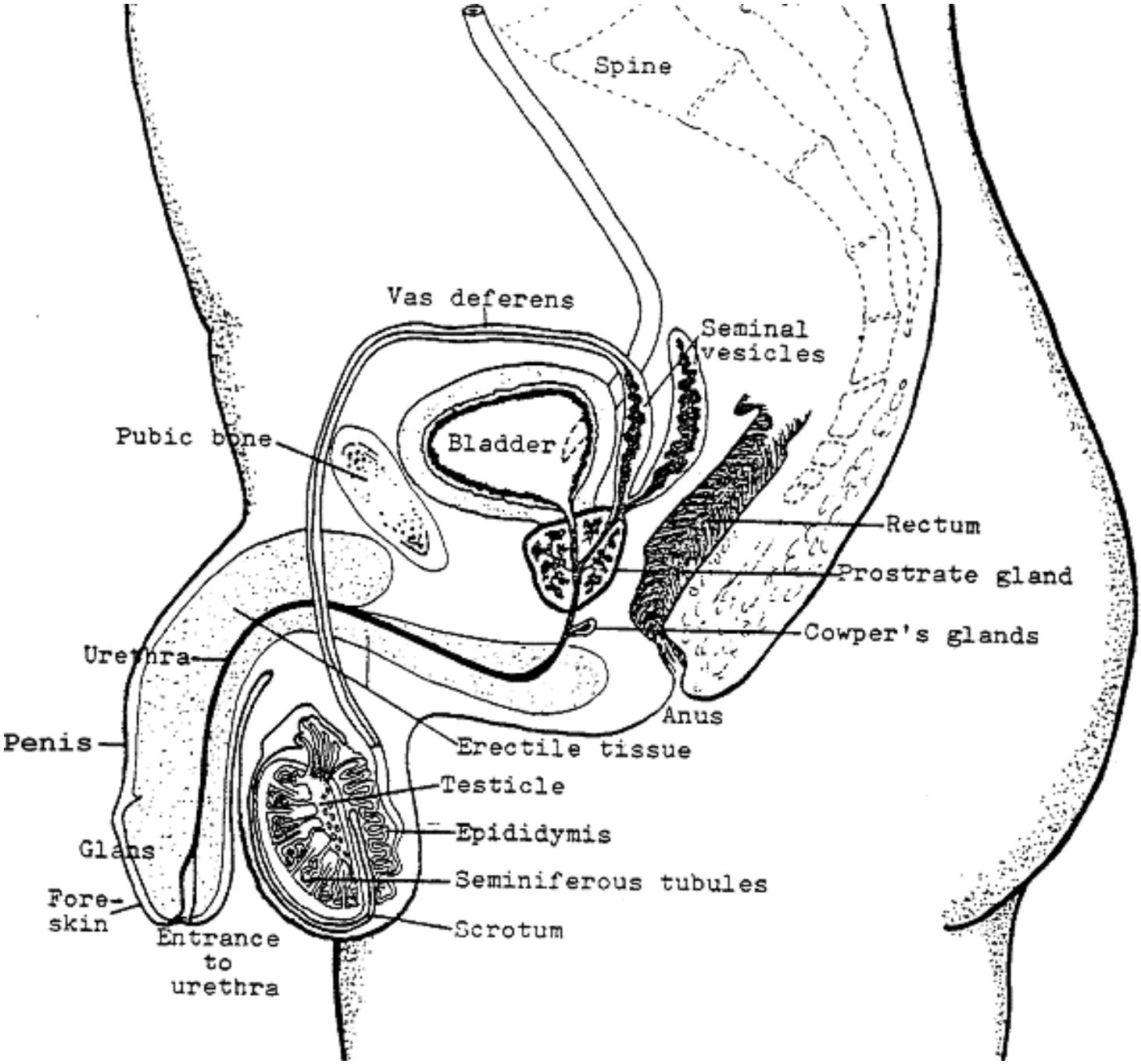
Male Anatomy



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Last updated: 05/23/03

Antibiotic Use and Hormonal Contraceptives

Antibiotics known to cause birth control pill failure:

- Rifampin
- Griseofulvin

Antibiotics with a very small possibility of birth control pill failure and pregnancy:

- Ampicillin
- Amoxicillin
- Itraconazole
- Doxycycline
- Metronidazole
- Tetracycline
- Ketoconazole
- Fluconazole

Antibiotics with an even smaller possibility of failure:

- Ciprofloxacin
- Trimethoprim
- Isoniazid
- Ofloxacin
- Clindamycin
- Cephalexin
- Erythromycin

Oral contraceptives have a failure rate of less than 1% a year in healthy women who take their pills every day within 2 to 4 hours of the same time every day. Typical users of birth control pills do occasionally miss a pill or take a pill late so usually 5% of pill users get pregnant every year. Over 10 million women in America take birth control pills and millions of women take antibiotics so it is not surprising a woman may become pregnant while on the pill when taking an antibiotic. The risk is increased with high doses or multiple antibiotics taken. Daily low dose antibiotics to prevent acne has been proven to be safe for most women on the birth control pill. The contraceptive patch and vaginal ring do not rely on the intestines for absorption and may have less of an effect on the liver, which is the organ that changes drugs so they can be gotten rid of by your body. But these are also very new methods and we do not yet know if they are not changed by antibiotic use for all women. It is known that most of the time the use of antibiotics will not make a hormonal method like the pill fail (get pregnant) for most women but there are rare women who can be affected by the use of antibiotics and perhaps by following the below advise we can help prevent method failure *(Obstet Gynecol 2001; 98: 853-60).*

SOME ADVICE FOR WOMEN TAKING BIRTH CONTROL PILLS AND ANTIBIOTICS:

1. If you are really worried about a pregnancy use a back up method (no sex or condoms for example) while taking the antibiotics and for 7 days after stopping the antibiotics.

2. If you get diarrhea or have spotting, then you may not have absorbed as much of the birth control pill hormones and you should use a back up method.

3. No matter what, TAKE your birth control pills every day on time, which means within 2 to 4 hours of the same time every day! Missing or taking a pill late will make the birth control pill hormones less and will increases your risk of getting pregnant.

4. Remember birth control pills are not perfect and even women not taking antibiotics can get pregnant on birth control pills.

5. If you are going to take antibiotics every day for more than 2 weeks you should consider a different birth control method unless your provider said it is okay.

BACTERIAL VAGINOSIS

WHAT IS BACTERIAL VAGINOSIS?

Bacterial vaginosis is a common vaginal infection in women. It is normal and healthy for certain bacteria to grow in a woman's vagina. Bacterial vaginosis is an overgrowth of some of these bacteria. It is not a bacteria spread by sex, but sex can increase the chances of getting an imbalance in the vaginal pH (acid-base) and this can make the bacterial overgrowth happen. Treating your sexual partner does not prevent bacterial vaginosis. Bacterial vaginosis may increase the risk of pelvic infection and could increase the chance of premature delivery of babies.

SYMPTOMS

Women may complain of too much discharge or have a gray-white discharge from the inside of the vagina, which can smell like fish. There is usually no itching or burning around the vagina. Men do not get bacterial vaginosis and do not get symptoms from being with women who have bacterial vaginosis.

DIAGNOSIS AND TREATMENT

Your health care provider can tell if you have an infection by examining a sample of the discharge. If you have bacterial vaginosis, you will be given some pills, usually metronidazole (Flagyl). It is best to take metronidazole with food. Do not drink alcoholic beverages while taking this medicine and for 1 day after you finish the last pill. The combination of alcohol and metronidazole may make you vomit. If the pills seem to cause a problem or make you sick, call the clinic. If the infection is not gone after you finish the medicine, call the clinic.

PREVENTION OF BACTERIAL VAGINOSIS

Because bacterial vaginosis is an imbalance in the vagina, you should avoid douches, feminine hygiene wipes or feminine sprays, or any chemicals in the vaginal or vulvar area. It is also possible oral sex which puts mouth bacteria into the genital area could lead to bacterial vaginosis. Ejaculate or semen from intercourse changes the vaginal pH and this could promote an overgrowth of the bacteria found in bacterial vaginosis. Sleeping in your underwear or wearing nylons or tight pants have also been associated with bacterial vaginosis.

PREVENTION OF SEXUALLY TRANSMITTED INFECTIONS

The only sure way to avoid sexually transmitted diseases (STDs) is to not have sex. Alcohol and drug use can decrease your ability to make clear decisions about you sexual behavior. If you decide to have sex, you can reduce your risk by having sex with one person who has sex with only you. You can use a condom (rubber) to protect against infections. Always look at your partner's genitals before you have sex. If you see any sores, rashes, or discharge, talk to your partner. Do not have sex until he/she has been examined and treated. Have regular check-ups. Ask for STD tests.

Before You Get Pregnant: Planning is the Key

The best start for your future baby begins right now, before you are pregnant. There are many things you and your partner can do to give your baby the best possible start.

Did You Know…
All of your baby's important organs form very early. Birth defects may happen before a woman has missed a period and knows she is pregnant. The first 3 months are extremely important. You can lower the risk of birth defects and pregnancy problems by making good health choices before and during your pregnancy.

Getting Pregnant
An average woman can get pregnant during a short time about 2 weeks before her next period. However, some women can get pregnant at very different times in their menstrual cycles. Talk to your health care provider or clinic about when you are most likely to get pregnant.

Time: Choosing When You Get Pregnant is Important

- Family Planning : Planning your future is important. Family Planning lets you decide if you want a child, when that will happen, and helps you have a healthy baby. If you are having sex, it is important to use a method of birth control until you are ready to have a baby.
- Age: Women under 18 and over 34 who have babies are more likely to have problems with pregnancy or have small babies.
- Before You Stop Your Birth Control: Go to a clinic or health care provider for a physical exam and counseling. Go in for this visit at least three months before you want to become pregnant. Ask your clinic or doctor about taking vitamins like folic acid.

Habits: Habits Before You Get Pregnant May Be Good Or Bad

- Folic Acid: Take a vitamin with 400 mcg of folic acid for 3 months before getting pregnant. This will help prevent neural tube defects.
- Eating: Eat healthy food and regular meals. It is important for you and your baby. Dieting may be harmful. Use less caffeine.
- Exercise: Regular exercise will help you feel better and get your body ready for pregnancy.
- Smoking: Smoking or being around others' smoke can cause your baby to be born too small or too soon to be healthy. Smoking marijuana can cause these problems, too.

- Drugs and Medicines: Using illegal drugs or even some medicines (prescribed or bought over-the-counter) can cause miscarriage, brain damage, addiction, and/or death to your baby.
- Alcohol: Drinking alcohol (beer, wine, wine coolers, hard liquor, and even cough and cold medicines) can cause birth defects, mental retardation and even death to your baby.
- Other Hazards: Working with certain metals and chemicals such as lead, paint, oven cleaners, bug killers, gasoline, and car exhaust can cause pregnancy problems. They also could harm your baby. Other hazards include eating raw meats, handling cat litter, or being around animals or people with certain diseases.

Health: Before You Get Pregnant, Talk to Your Health Care Provider or Clinic About:

- Medical Conditions: Medical problems (such as diabetes, epilepsy, high blood pressure, heart or kidney disease, infections, hepatitis, or anemia) need to be treated before pregnancy.
- Immunizations: Make sure your immunizations are up to date. They can prevent some diseases like German Measles (rubella) which can cause serious birth defects.
- Family Health: Does anyone in your family have a birth defect, inherited disease, or mental retardation? Some disease and birth problems can run in families.
- STD: You or your partner may have a sexually transmitted infection (STD) that you do not know about. All STDs (such as chlamydia, gonorrhea, syphillis, and HIV/AIDS) can cause serious problems.
- Emotional Health: Get help if you have violence or abuse in your life, high levels of stress, or not enough personal support. Pregnancy can cause money problems or interfere with school or work.
- Get a Pregnancy Test: If you think you are pregnant or if you miss your period, ask your health care provider for a pregnancy test. Usual signs of pregnancy include sore or enlarged breasts, urinating more often, nausea, and tiredness. It is important to get care as early as possible when you are pregnant.

Plan Ahead

There are many things you need to think about before you get pregnant. What will you need to know, and do, to plan for your pregnancy and parenthood? You may find it useful to get more information from:

- Family planning services
- Pre-pregnancy books at your local library, bookstore, or clinic
- Exercise classes
- Stop smoking programs
- Food programs
- Counseling and mental health centers
- Religious leaders
- School counselors and nurses
- Alcohol/drug treatment programs
- Medical insurance plans
- Social services
- Health departments
- Health care providers – doctors, nurses, clinics, and hospitals

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Birth Control Pills ("The Pill")

What are birth control pills?
Birth control pills are pills that women take daily to prevent pregnancy. Some women take them for other reasons, such as helping painful periods or improving acne. They are also called "oral contraceptives" and "the pill." Most women can safely take them.

How do birth control pills work?
The pill prevents pregnancy by keeping the ovary from releasing an egg every month. The pill contains two hormones, estrogen and progesterone, that are normally present in women's bodies. (Hormones are natural chemicals in our bodies that tell different organs what to do. In this case, for example, they tell the body not to release an egg.)

How effective are birth control pills?
Birth control pills are very effective if they are taken correctly. If 100 women took the pill perfectly for a year, only 1 of them (at most) would get pregnant. Like other types of medication, taking the pill incorrectly makes them less effective.

What are the benefits of taking the birth control pills?
Research has shown many benefits of taking the pill:

- Shorter and lighter periods
- Less cramping with periods
- Less acne
- Stronger bones
- Less chance of getting cancer of the ovaries or uterus
- Less chance of getting breast lumps
- Less chance of getting cysts in the ovary

Who can take birth control pills?
Most women can take the pill. They are very safe. Your nurse or doctor will ask questions about your medical history and take your blood pressure to make sure it is safe for you to take the pill.

Who cannot take birth control pills?
Some women can't take the pill because they have certain health problems. A woman should not take the pill if she has ever had a heart attack, stroke, blood clots in the legs or lungs, breast cancer, cancer of the uterus, or severe liver disease. Also, women who are pregnant should not take the pill.

Do birth control pills cause any serious complications?

- Serious problems are very rare. However, women who smoke cigarettes every day, especially if they're over age 35, have an increased risk of getting a blood clotting problem on the pill.
- Women should contact their doctor, family planning clinic or emergency room if they have any of the following problems: severe pain in their abdomen, severe chest pain or shortness of breath, severe leg pain or swelling, severe headaches, or eye problems, such as blurry vision, flashing lights or blindness.

Commonly Asked Questions

Does the pill prevent STDs or HIV?
No, it is best to use condoms with the pill to protect yourself against STDs and HIV.

Does severe vomiting and diarrhea affect the pill (such as when you have the flu)?

- Yes, your body may not have absorbed all the hormones so there is a chance you could become pregnant.
- Use a back-up method of birth control, such as condoms, or don't have sex, while you finish taking the pack of pills.
- If you miss your period, call the clinic.

Is there anything I can do to skip my period on purpose?
Yes, ask your provider for instructions. They can help you skip one or more of your periods.

What should I do if I'm having bothersome side effects?

- Call the clinic before you stop taking the pill.
- Many women experience minor side effects, such as nausea, weight gain or loss, fluid retention, breast tenderness, tension headaches, tiredness, spotting between periods and others.
- Many side effects go away after you body adjusts to the pill.
- If the side effects do not go away on their own, sometimes changing to a different type of pill will help. There are over 40 different brands of pills available. Each kind may contain different types and amounts of hormones so your provider can prescribe the pills that best fit your body.

If I go to another doctor, will they be able to tell I am on the pill?
No, not unless you tell them. If you are admitted to the hospital or go to another clinic, be sure to tell them you are taking birth control pills.

Should I stop taking the pill if I break-up with my partner or stop having sex?

- It is best to continue.
- There are fewer side effects the longer the pill is taken.
- Stopping and starting the pill can increase irregular bleeding and other side effects.
- Remember, the pill also protects you from cancer, anemia, acne, and painful periods. Many women take the pill for these positive effects on their health.

What should I do if I want to get pregnant soon?

- Stop taking your pill and use another birth control method, such as condoms, until you have had 2 periods.
- All women, whether or not they are on the pill, should start taking vitamins with folic acid before they get pregnant to help prevent birth defects.

Instructions for Use

How do I take the pill?

- Start taking the pill on the first day of your period – the day the bleeding starts.
- Swallow one pill every day, around the same time each day.
- During your first two weeks on the pill, you are not fully protected against pregnancy. Use a second method of birth control, such as condoms, or don not have sex.
- When you finish a pack of pills, begin the next pack. (For example, if you take your last pill on Saturday, start your next pack on Sunday.)
- Try to develop a routine that will remind you to take one pill every day. For example, take it when you go to sleep or when you brush your teeth.

What should I do if I forget to take a pill?

If you're ever unsure about what to do . . .

- ✓ Call your clinic for instructions. The clinic staff will be happy to help you. Making up missed pills can be confusing.

If you miss only 1 pill . . .

- ✓ Take it as soon you remember.
- ✓ Then, continue taking 1 pill a day on your regular schedule.

If you miss 2 pills in a row during the 1st or 2nd week of your pill pack . . .

- ✓ Take 2 pills as soon as you remember and 2 pills the next day.
- ✓ Then, continue taking 1 pill a day on your regular schedule.
- ✓ Use condoms or do not have sex for the rest of your pill pack.

If you miss 2 pills in a row during the 3rd week of your pill pack . . .

- ✓ Take 1 pill a day and skip the "spacer" pills (the 4th week of pills) for that pack.
- ✓ Then, continue taking 1 pill a day on your regular schedule.
- ✓ Use condoms or do not have sex for one month.

If you miss more than 2 pills in a row . . .

- ✓ Take 1 pill a day and skip the "spacer" pills (the 4th week of pills) for that pack.
- ✓ Then, continue taking 1 pill a day on your regular schedule.
- ✓ Use condoms or do not have sex for one month.

What if I miss a period?

If you forgot to take one or more pills . . .

- ✓ Call the clinic to schedule a pregnancy test.

If you took every pill on time . . .

- ✓ Continue to take your pills as scheduled.
  - ✓ If you miss a second period, call the clinic. Birth control pills may cause some women to miss a period.

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Bladder Health Handout

- Use the toilet regularly. Make toilet facilities convenient. Do not hold urine until painful.
- Wear clothes that are easy to remove when it is time to use the toilet.
- Train your bladder. Use a clock to schedule times to the toilet. Every hour, then every one and a half-hours, etc., until you achieve a satisfactory schedule. Avoid frequent trips to the toiled "just in case."
- Remain at the toilet until you feel your bladder is empty. Don't rush. If you feel there is still some urine in the bladder, move around or stand up. If you were sitting, sit back down, and lean forward slightly over the knees.
- Empty your bladder before you start on a trip of an hour or more. Don't try and wait until you get home or until it's more convenient.
- Learn to squeeze before you sneeze or try crossing your legs to get control of your bladder before you cough, laugh, get out of a chair, or pick up something heavy.
- Establish regular bowel habits. Constipation makes bladder control worse.
- Watch your weight. Obesity makes bladder control more difficult. Ask your provider about a sensible diet if you are overweight.
- Stop smoking. Smoking is irritating to the bladder, and a smoker's cough may cause bladder discomfort or leakage.
- Consider avoiding foods that are known to effect the bladder, such as tomatoes, chocolate, spicy foods, and beverages, including alcohol and those containing caffeine. These make the bladder more irritable, and therefore increase incontinence.

Dietary Irritants to the Urinary Tract

Acidic foods to be avoided, as these can cause bladder spasm and irritation:

All alcoholic beverages	Coffee	Cranberries
Apples	Tea	Grapes
Apple juice	Vinegar	Lemon juice
Carbonated drinks	Peaches	Tomatoes
Chilies/spicy food	Pineapple	Onions
Citrus foods/juices	Plums	Vitamin B Complex
Chocolate		

If bladder symptoms are related to dietary factors, strict adherence to a diet which eliminates the above food products should bring significant relief in 2 weeks. Once you are feeling better, you can begin to add these items back into your diet, one thing at a time. This way, if something does cause you symptoms, you will be able to identify what it is. When you do began to add foods back into your diet, it is crucial that you MAINTAIN A SIGNIFICANT WATER INTAKE. Water should be the majority of what you drink every day (approximately 1-2 quarts a day).

Bone Health/Calcium/Osteoporosis Handout

Osteoporosis means porous or bones with holes. It is a bone-loss disease resulting in an increased risk of fractures. Osteoporosis is a silent disease that can begin early in life. It progresses slowly over the years and often with no symptoms. With osteoporosis, all bones may become fragile, but hip, spine, and wrist fractures are the most common of all. Osteoporosis causes more than fractures. As the spinal bones or back bones collapse, some people can no longer stand straight and tall. They develop a curved and hunched-over appearance.

As a woman, you are at greater risk than a man. Your bones are lighter and smaller. You will lose bone density faster at menopause when your estrogen levels decrease. Women typically consume less calcium-rich foods and often they eat less to control their weight. Osteoporosis is preventable, yet one in two women is at risk of developing fractures caused by osteoporosis.

For Bone Health and To Prevent Osteoporosis:

1. Get enough calcium. See the below advice on recommended daily allowances. Include a good intake of vitamin D, 400 i.u. daily, the amount found in most multivitamins. Vitamin D helps the body absorb and use calcium.
2. Quit smoking and avoid excess alcohol; both can cause calcium loss.
3. Do weight-bearing exercise (e.g., walking, jogging, dancing) for 30 minutes at least 3 times a week. This will strengthen bones and keep muscles strong to prevent falls.
4. Look around your home to make sure there are no loose rugs, or other things which can make you trip and fall.
5. Discuss the effects of other medications you take with your provider because some medications can increase your risk of osteoporosis or bone calcium loss.
6. If menopausal, consider hormone replacement therapy (HRT) which can slow bone loss.

Bones and Age

- **During adolescence:** Nearly half of all the bone mass is formed during the teen years.
- **If you are still in your 20's:** You are still in the prime bone-building years. You can continue to add bone tissue to make them denser and stronger by vigorous exercise.
- **If you are approaching 30:** Your window of opportunity is still open. You can make up for scarce calcium years by boosting your daily deposits before peak bone mass is reached, which is the maximum amount of bone that you will ever have.
- **If you are 35 to 45:** You have reached your peak bone density and now you need to preserve it with exercise and calcium intake. Both activities will help you maintain your bone density.
- **If you are over 45:** You need to start thinking about options to protect your bones and to slow bone loss. There is a sharp decline in the production of estrogen. This female hormone plays a role in preserving a positive calcium balance in our bones.

Where do you stand with your calcium balance?

Count you daily calcium intake:

1. Take credit for calcium in your diet's every day basic foods …… 172 mg
2. Take extra credit for calcium-rich food you eat every day:

Milk, whole - 1 cup	291 mg	____
Milk, low-fat - 1 cup	297 mg	____
Milk, chocolate - 1 cup	280 mg	____
Milk, half & half - 1 cup	254 mg	____
Milk, evaporated canned - 1 cup	675 mg	____
Egg nog, commercial - 1 cup	330 mg	____
Yogurt (depending on flavor) - 1 cup	343-415 mg	____
Cheddar cheese - 1 ounce	204 mg	____
Parmesan cheese - 1 ounce	390 mg	____
Provolone cheese - 1 ounce	214 mg	____
Swiss cheese - 1 ounce	272 mg	____
Almonds - 1 cup	304 mg	____
Hazelnuts - 1 cup	240 mg	____
Kale - 1 cup	206 mg	____
Collards - 1 cup	357 mg	____
Sardines, canned - 3 ounces	372 mg	____
Blue cheese - 1 ounce	150 mg	____
Cottage cheese- 1 cup	130 mg	____
Mozzarella cheese, whole milk - 1 ounce	163 mg	____
Mozzarella cheese, part skim milk - 1 oz	207 mg	____
American cheese - 1 ounce	174 mg	____
Broccoli - 1 stalk	158 mg	____
Spinach - 1 cup	167 mg	____
Ice cream, regular - 1 cup	176 mg	____
Ice cream, soft - 1 cup	237 mg	____
Egg - 1 egg	28 mg	____
Cabbage - 1 cup	44 mg	____
Cream cheese - 1 ounce	23 mg	____
Beef, pork, poultry - 3 ounces	10 mg	____
Apples, bananas - 1 medium piece	10 mg	____
Grapefruit - 1 medium piece	20 mg	____
Potatoes - 1 medium piece	14 mg	____
Carrots - 1 medium piece	27 mg	____
Lettuce - 1/2 head	27 mg	____

YOUR TOTAL _____

Add 1 and 2 to figure your daily calcium intake. If your calcium intake is over 1000 mg daily, congratulations! If it is under 1000 mg, you run the risk of putting your body in negative calcium balance.

To correct, either change your diet to include more calcium-rich foods or take a calcium supplement.

Recommended Daily Allowance for Calcium in Women

Ages 1 through 8	800 mg
Ages 9 through 18	1,300 mg
Ages 19 through 50	1,000 mg
Ages 51 through 64	1,200 mg
Ages 50 through 64 if not taking estrogen or over age 64	1,500 mg
Pregnant and lactating women	1,500 mg

Calcium Supplements

You can also buy calcium supplements, like Tums, which have 200 to 600 mg of calcium.

Calcium Carbonate	mg of calcium
Generic chewables	200 to 600
Caltrate 600	600
Equilet, chewable	200
OsCal 500, chewable	500
Titralac Chewable	168
Titralac Extra Strength	300
Tums:	
Regular Chewable	200
E-X Chewable	300
Ultra 500	500

Calcium Citrate	mg of calcium
Citracal 950	200
Liquitab	500
Nutravescent	500

Note: Calcium is best absorbed in divided doses with food.

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Bowel Program

The goal is to produce a soft formed stool every day about the same time of day.

1. Choose the best time of day for you to have a bowel movement. A good time is after breakfast. For some people, after lunch works better. These times are best because the gastrocolic reflex, when the colon muscles push stool towards the rectum, occurs only 2-3 times a day, often after eating will help to produce a stool.

2. When you feel the urge to go, **GO,** it is important to listen to your body's need to empty the rectum. Stool that stays in the rectum dries out and is difficult to push out.

3. Eat all your meals at about the same time each day. The bowel works better when food is introduced at the regular times.

4. The amount of food eaten for each meal – breakfast, lunch, or dinner – should be about the same each day. The bowel works best when food is predictable same amounts at the same time. It is okay to have a small breakfast and a large lunch, or vice versa – just be consistent.

5. At each meal eat fruit and/or vegetables and at least one serving of a complex carbohydrate (a whole grain product such as whole-grain cereal, brown rice, bran, whole wheat or rye bread, or oatmeal). A bowl of bran cereal (buy the 10 grams of fiber per bowl type of cereal) in the morning and two raw carrots at night is an affordable, easy way to add 15 grams of fiber to your day. Every day you need 20 grams of fiber to produce a good stool. Fiber provides soft bulk for the bowel. This stimulates bowel function and helps make a comfortable bowel movement.

6. Water, water, and more water! To make a soft stool the bowel needs 8 to 10 glasses of water, juice, or herbal tea every day.

7. Until regular bowel movements are established at a desired time every day, take 2-3 dried prunes (or 1/4 – 1/3 cup of prune juice) each night, to stimulate bowel function in the morning.

8. Exercise daily. This should be aerobic exercise. For example, 15 to 30 minutes swimming or a brisk walk. If the exercise is at the same time the exercise may trigger the gastrocolic reflex and could help produce regular bowel movements

9. If the stool is hard or firm and you cannot change your diet, Metamucil (1–3 tablespoons) or other fiber medication taken with breakfast can help. But these

medications can cause gas so fiber in your food is much better. If stool becomes too loose, you could try avoiding fruit juices and dairy products.

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Cervical Cap Handout

What is the cervical cap?
The cervical cap is a dome-shaped device that covers the opening of the cervix to keep sperm from getting into the uterus. Suction keeps the cap and spermicide in place. There are two types of caps available. One, the Femcap is made of vinyl and comes in 3 sizes. The other, the Prentif cap is made of latex and comes in 4 sizes. They both need spermicide to prevent pregnancy.

How does the cap work?
Like the diaphragm, the cap is a barrier that blocks sperm from entering the uterus and prevents fertilization of the egg. The cap is used with a spermicide (a detergent like chemical) that kills sperm.

How effective is the cap?
For those women who have not been pregnant and who use the cap correctly and every time, the cap can be up to 90% effective. This means over the first 6 months of use, 1 out of 10 women using the cap perfectly will still get pregnant. However, the typical woman does not use it perfectly and the cap is only about 80% effective for women who have had one or more vaginal deliveries. Remember both the IUD and the birth control pill can be 99% effective.

How do I get a cap?
To be fitted for a cap, you have to see a health care provider who is trained to fit them. The effectiveness of the cap can depend on the fit and a woman's cervix can be shaped a little differently, especially if she has had a pregnancy.

What are the advantages of the cap?
- Can be left in up to 48 hours allowing spontaneous protected sex for 42 hours
- Uses less spermicide than the diaphragm and is smaller and may be less noticeable to partner
- Easy to carry around, comfortable
- No hormones and does not alter the menstrual cycle

What are the disadvantages of the cervical cap?
- Requires a fitting in a clinic
- Some women cannot be fitted
- Can be dislodged during intercourse
- Can sometimes be felt during sex or by your partner
- Can be difficult to insert or remove
- Doesn't protect as well as a condom against sexually transmitted infections. But the cap can be used with a male condom.

Who should not use the cervical cap?
Women who should not use the cervical cap include those with:

- An unusually long or short or asymmetrical cervix
- Abnormal pap test or genital infection
- Latex or spermicide allergy
- History of toxic shock syndrome

Directions for use of the cervical cap

1. Fill the Prentif cap dome one-third full with spermicide or if using the FemCap place a teaspoon of spermicide inside the domed cap and on the reverse side put more spermicide in the groove made for this.
2. Squeeze the rim together with thumb and forefinger and insert into vagina.
3. Push cap deep into the vagina.
4. Use a finger to push the cap over your cervix.
5. Check that the cap is covering the cervix by running your finger around the rim.
6. Check the fit by tugging gently on the dome. If you can feel your cervix being pulled and the cap remains in place, it is correctly placed.
7. Leave the cap in at least 6 hours after intercourse.
8. Remove by squeezing the dome of the cap to break the seal and then tilt the cap to the side then hook your finger under the rim and pull down, off the cervix and out of the vagina.

Care of the cervical cap

1. After the cervical cap is removed from the vagina, wash it with a mild soap and warm water.
2. Rinse the cap thoroughly in clean water.
3. Dry the cap well.
4. Store the cap in its original or other suitable clean container between uses. Store in a place where the device will not be exposed to extreme heat, bright light, petroleum products, newspaper, or any chemicals as they may cause it to deteriorate.
5. Get a new cap at least every two years. Bring it to your annual exam to get the fit checked.

CAUTIONS:

- Do not take off sooner than 6 hours.
- If you have sex a second time keep the cap in place but add some more spermicide to your vagina using an inserter or consider removal and reinsertion prior to intercourse.
- Do not overfill with spermicide; it will cause loss of suction. (The cap will not maintain the seal.)
- Do not wear for more than 48 hours.
- Be careful of use during menses, as that is when toxic shock syndrome is more likely to occur. Remove the cap immediately and see a clinic if you develop a fever with a rash.
- If you have a pregnancy or gain more than 20 pounds get your cap fit checked as your shape may have changed.
- Use a back-up method during the first month of cap use. If it dislodges more than once, call and report it to the practitioner who fit your cap.
- If the cap slips or you are worried you did not use it correctly (or neglected to use it) remember you can always get emergency contraceptive pills within 5 days of the unprotected sex to help prevent pregnancy.

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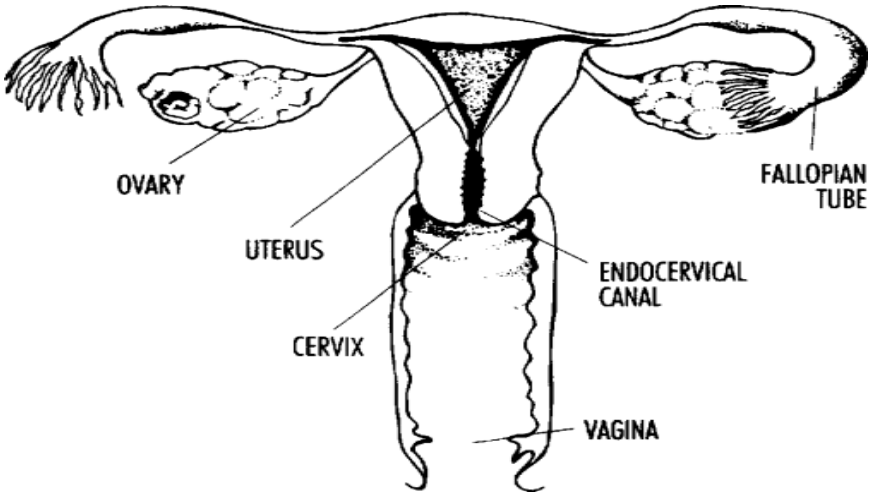
COLPOSCOPY: EXAMINING THE CERVIX

Colposcopy, Biopsy, Endocervical Curettage

Colposcopy is looking at the cervix with a microscope. It is done to study the abnormal cells found on your Pap test. Once found, the abnormal cells can be treated. This prevents the abnormal cells from possibly changing into cancer of the cervix.

The colposcope is like a microscope with lights in it. It enlarges about 8 -10 times the details seen with just normal vision. The health care provider can then see any abnormal areas on your cervix and find the area where the abnormal cells come from. If necessary, the provider then takes a sample of the cells. This is called taking a biopsy. The provider may also take samples from inside the cervix in the endocervical canal. This is called endocervical curettage. These tissue samples are sent to the laboratory for a more exact diagnosis than is possible from the Pap test.

Figure 1 – The Female Reproductive System



Preparing for Colposcopy

Do not douche, have vaginal intercourse, use a tampon or put anything in your vagina for at least 24-48 hours before your colposcopy. This helps prevent infection and makes your test more accurate. If you think or know you are pregnant it is important to tell the provider because it will change the procedure.

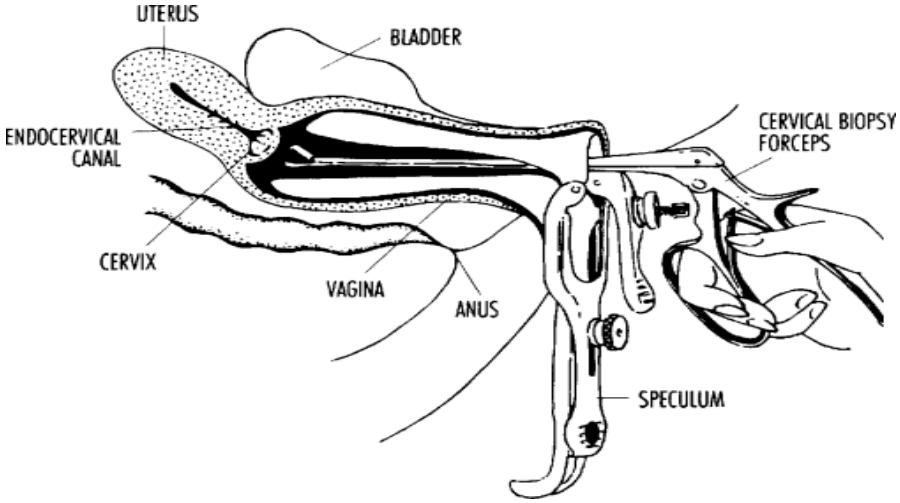
Women have different amounts of feeling on their cervix and can handle different amounts of pain. Some women do not need any pain medicine, but some do. You can take two or three ibuprofen tablets just before your appointment or we can give you some in the clinic. Let the health care provider know what you decide to do.

What to Expect

Colposcopy: First you lie on the examination table just like you do for any pelvic examination. The provider puts a speculum in your vagina to gently hold it open to see your cervix. A dilute acetic acid (vinegar) solution is then put on the cervix to look for abnormal cells with the colposcope. This usually takes 5-10 minutes and it does not usually hurt.

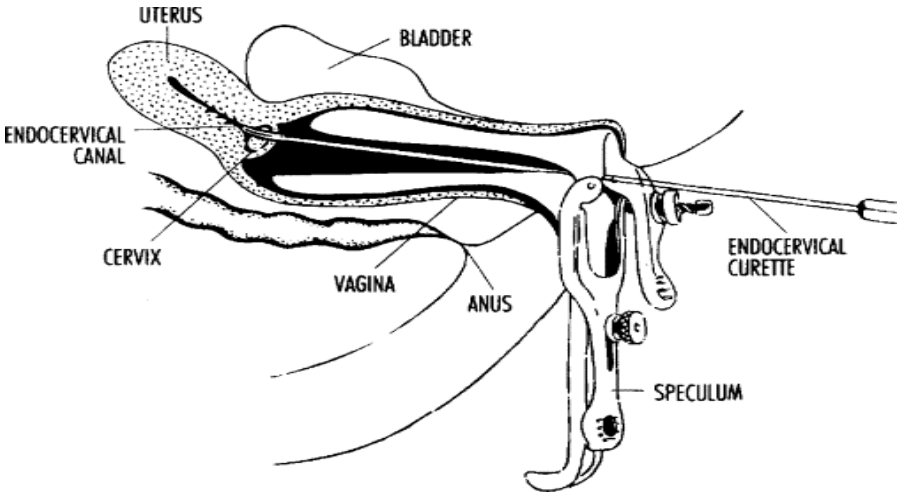
Biopsy: If abnormal cells are seen, a biopsy is done. The provider uses an instrument to take a very small piece of tissue from the cervix for further testing at the laboratory (see Figure 2). A biopsy usually feels like a pinch or a mild cramp.

Figure 2 – Taking a Biopsy



Endocervical Curettage: The inside of the cervix may be scraped with a tiny spoon-like instrument (see Figure 3). This is called endocervical curettage. It is done to check for abnormal cells inside the opening of the cervix, where we cannot see. This usually feels like a menstrual cramp and takes 1 to 2 minutes. The tissue sample is sent to the laboratory for examination.

Figure 3 – Endocervical Curettage



After the Procedure

After the procedure, you rest for a short time in the clinic. Some women feel dizzy if they get up too soon. When you go home, you may spot or bleed a little. **DO NOT** have vaginal intercourse, wear tampons, douche, or put anything in your vagina for a week until it heals. After healing, the cervix usually looks normal and has no visible scar tissue.

What to Watch for – Risks

Let us know if you have any heavy bleeding, pain in the lower abdomen (belly) or a fever. Bleeding or infection is a very rare problem, but prompt treatment may be necessary. You will need an appointment in 2 weeks to discuss the laboratory report if a biopsy was done to see if any further treatment is needed. It is very important to keep this appointment. If no biopsy was done you may be told to get another cytology (pap) test in 6-12 months.

Continuous Birth Control Pill Use

Taking an active, hormone containing, pill every day is designed to stop all bleeding after an initial period of irregular bleeding. This handout explains how and gives tips to decrease the irregular bleeding.

Why do the spacer pills cause the uterus to bleed?
"The Period Pills," "spacer," "or "sugar" pills contain no active or hormone medication. The reason you bleed when you take spacer pills is because your hormone levels drop. You bleed because you did not take a progestin hormone or "real" birth control pill. The lining of the uterus needs stable hormone levels to prevent bleeding. The best way to prevent any bleeding or spotting is to have constant levels of the estrogen and the progesterone hormones, because these hormones support and keep the blood lining of the uterus stabilized.

What do birth control pills do to the uterus?
Birth control pills work to shrink the blood lining of the uterus. Over time the lining is so thin, the chances of unexpected bleeding and spotting become very low. It is very, very unlikely something is building up inside your uterus when you are on the pill. As a matter of fact, the risk of endometrial cancer decreases by 80% in women using the birth control pill for five years.

Irregular Bleeding is common at first
Break-through bleeding, or bleeding when you are not scheduled to bleed, is very common in the first 6 months of continuous birth control pill use. Your body is getting used to the constant level of hormones. If you have been on a higher dose pill or injection contraceptive, it can take longer to stop irregular bleeding. Spotting is when the amount of blood is so tiny that no pad or tampon is needed. The longer you take the continuous pills the less bleeding and spotting will happen. You do not need to stop the pill to have a period because bleeding happens, instead try to figure out what caused the bleeding and keep taking the daily pill if you want to have no bleeding. Stopping the pill only begins the whole process again.

How can you help prevent a drop in the pill hormones and stop bleeding/spotting?
The most important thing is to take your pill as close as possible to the **same time every day.** Estrogen in the body begins to wear off, especially if you take your pill over 4 hours late.

Other suggestions if spotting continues:
All these suggestions and ideas listed below are to help you make it through the first six months of continuous pill use. Most women will have significantly less bleeding or spotting after six months. Keep a menstrual diary so you can learn what triggers a bleeding episode for you. Remember all women are individuals. You can learn about how you metabolize your pill and what works with your body.

- **Alcohol:** Drinking alcohol keeps your liver busy detoxifying the alcohol so your hormone levels, especially estrogen, can be higher for a few days. If you drink everyday, even a glass of wine, your body could be used to the alcohol, so if you stop drinking, your estrogen levels may drop and trigger spotting.

- **Tobacco:** Smoking can increase your metabolism of estrogen and result in lower levels of estrogen. If you smoke you now have another reason to quit or at least greatly reduce the amount you smoke.

- **Other medications:** Many medications, for example antibiotics, antifungals, anticonvulsants, and even herbal drugs like St. John's Wort, can change the amount of the pill hormones absorbed by the stomach and the metabolism of these hormones. It is very common to have some spotting with a new medication or a change in dose of medication. Sometimes these medications can actually decrease the pill hormones so much they become less effective at preventing pregnancy. Therefore, it is important to tell your provider about all the medications you are taking.

- **Time of day and stress** can affect your hormone levels. The progesterone receptors in the uterus look a little like cortisol receptors, so it might be possible that increased stress can trigger a change in progesterone activity. **Taking the pill at night**, before bed, could make the hormones peak when the cortisol levels are at nighttime levels and this could affect the activity of the hormones. Also, at night, the pill does not have to compete with food in you stomach to be absorbed. So, if you are having persistent spotting you could try switching the time of day you take your pill. However, you can expect some initial spotting with any change in the usual time you take your pill and it may take two weeks for your body to equilibrate to the new pill taking time.

- **Diarrhea or vomiting:** Anything that makes the pill go through your system too fast can make the pill not work as well because it was not absorbed or, worse, if it is lost in the vomit.

- **Altitude:** Some women report spotting when they take airplane trips or climb mountains. It could be the change in air pressure, just going to a new time zone, or even a change in your sleep patterns. If travelling in a different time zone, you should attempt to take your pill at the time based on your normal time zone.

- Non-steroidal anti-inflammatory medications, like **Naprosyn, Aspirin, or Ibuprofen** can decrease period bleeding and menstrual cramps, because they lessen the chemicals that cause period bleeding and decrease irritation in the lining of the uterus. Stop using them when your spotting stops. If your spotting continues after one week, you should call your provider, you may need a higher dose and your provider can give you a prescription. You should not use these drugs for more than 1-2 weeks or they could hurt your liver or kidneys.

- **Vitamin C**, 1000 mg, taken with your pill can help increase estrogen absorption for some women, so you should try this if the spotting has gone on for more than five days. However, you should stop taking the high dose of Vitamin C either when the spotting stops, or after a week if the spotting hasn't stopped. If you take it for too long, your body gets used to that large amount of Vitamin C, so that if you don't take it, you will then have a drop in estrogen levels and start spotting again!

- **Grapefruit juice** contains a chemical that slows estrogen metabolism if the pill is taken with a glass of juice. More estrogen may be available to your body to stop the spotting.

If you have any questions about any of these suggestions, please call your clinic. Often your provider can help and may even need to do an exam to find out why you are bleeding because there may be an infection or change in health that is causing the bleeding. ***Please call your clinic before you stop the birth control pill.*** *This handout is from the www.noperiod.com website and is used with permission.*

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Contraceptive Implant Patient Education Form

What are implants?

Implants are plastic tubes about the size of a match stick. They are put just under the skin on the inside of a woman's upper arm. The tubes release a progestin, which is one of the hormones in the birth control pill. The progestin medication is released slowly from the device directly to the blood stream. Implants prevent pregnancy by stopping ovulation and sperm passage through cervical mucus. The only implant currently available in the US is Implanon®. It uses a single rod to release the progestin medication, etonorgestrol. It lasts 3 years.

Who can use implants?

Implants are best for women who want long lasting, continuous birth control. It is also a good method for those who want birth control that is private, does not need to be remembered every day, or used for each act of intercourse. Women who may want a child in the next year may wish to consider another type of birth control. Some women cannot use implants because of certain medical problems like breast cancer. That is why a complete medical history and exam are done before implants are put in.

Advantages of Implants

Once the implants are put in, a woman does not need to do anything else to prevent pregnancy. It is private and does not interrupt love making. Implants are very effective and long lasting, but can be removed at any time.

Because implants release progestin steadily, 24 hours a day, a smaller amount is needed than with the birth control pill. Implants also do not use estrogen, the other medicine found in most birth control pills, so implants have no estrogen-related side effects. This makes implant systems very safe for most women.

What are possible problems with implants?

1. Many women have changes in their periods – irregular bleeding, spotting, or no periods. Some women can spot or bleed every day for weeks, especially in the first year of use. But the amount of blood lost is actually very little and women do not get anemic.
2. Some women wonder about pregnancy because they have irregular periods or no periods. A pregnancy test can be done, even though there is little chance of a pregnancy occurring. However, if your periods are regular on the implants and suddenly stop, it is important to get a pregnancy test.
3. Some women find the implant is slightly visible under the skin. Others may have a change in weight, acne (pimples), or hair loss. These problems usually go away and are not very common.
4. There is a slight chance of infection (heat, redness, pus) of the skin when implants are put in or removed.
5. For those who need to pay for the implant, the cost is higher at first than other methods. Plus, it has to put in and taken out by a trained health care provider.

How are implants put in?
It takes about 5 minutes to put the implant system in. First, you lie down on an exam table. Then the health care provider gives you a shot on the inside of your upper arm so the area feels numb. A special insertion device is then gently inserted under the skin. It is similar to a needle. The implant is put in the insertion device and placed under the skin. After the insertion, the area is covered with a band-aid and your arm is wrapped in a bandage.

This should not be painful. Let your health care provider know if you feel pain during or afterwards or develop a fever or redness at the opening in the skin. Keep the implant area covered and dry for a few days. Be careful not to bump the area. Call the clinic for any questions or if you notice any problems. Pregnancy protection does not begin until 7 days after insertion unless the implants were put in during the first 5 days of your period.

How are the implants removed?
This usually takes less than 5 minutes. The provider feels for the location of the implant. Then a shot is given to numb your upper arm around the implant. The shot may sting, but it should not hurt after the area is numb. A small cut is made (less than ¼ inch). The provider gently pushes the implant toward the opening and removes any scar tissue to then remove the implant. If you want a new implant put in that day, the same skin opening can be used.

Important Facts About the Implants

1. Implant systems are the most effective (over 99%) form of reversible birth control.
2. Remember to replace the Implanon® system implant at 3 years.
3. **Implants do not protect you from STIs** (sexually transmitted infections**)**. Use condoms to lower the risk of getting an STI.
4. Fertility and the ability to get pregnant can return right after the implant is removed.
5. See your health care provider to have implants removed if you wish to get pregnant before the 3 years is up.

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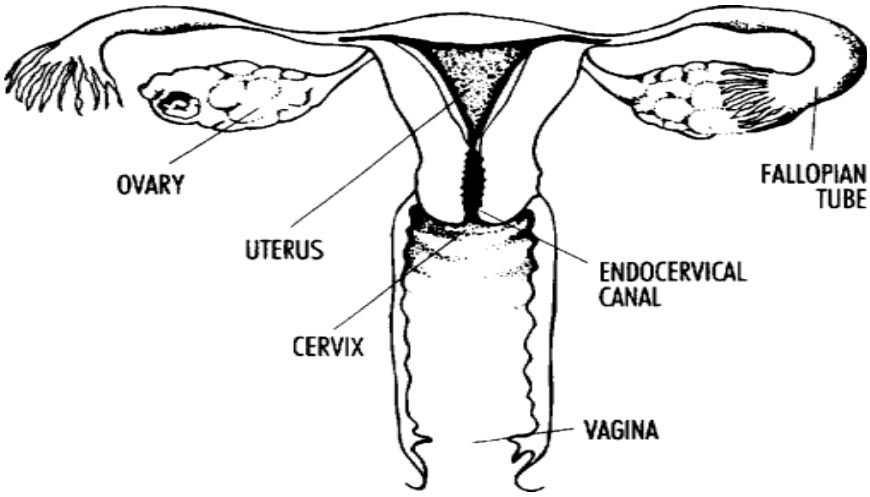
TREATING CERVICAL DYSPLASIA WITH CRYOTHERAPY

What Is It?

Cryocautery is freezing abnormal precancerous (dysplastic) cells on the surface of the cervix. This freezes the unhealthy cells and makes them peel off so new healthy cells grow in their place. Cryocautery cures the problem in 80% to 90% of all women with abnormal cells on their cervix. Some women may need to have further treatment like LEEP (Loop Electrical Excision Procedure) or a knife cone biopsy done at a hospital.

If the abnormal cells are not treated women could develop cancer of the cervix. Frequent Pap tests should be done after the freezing to make sure the abnormal cells are gone and do not return.

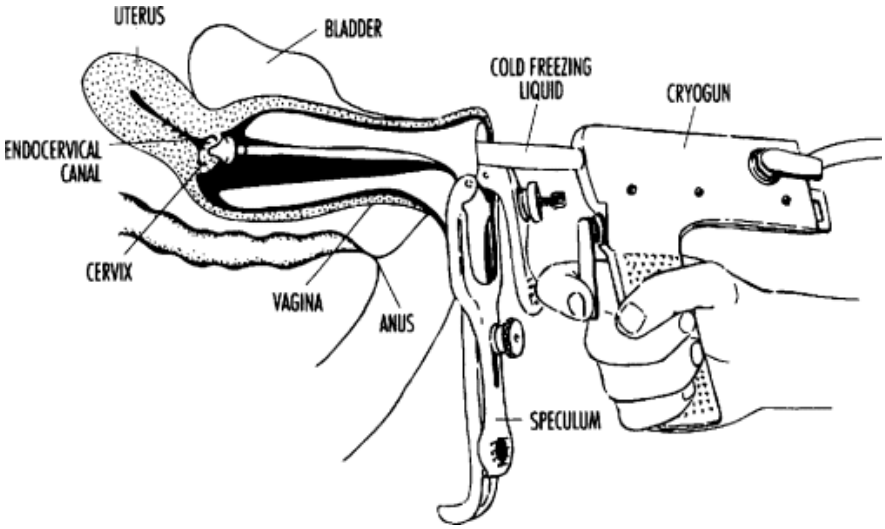
Figure 1 – The Female Reproductive System



What to Expect

It is important you are not pregnant at the time of the procedure and do not have it done if you think your are pregnant. First you lie on the examination table just like a regular pelvic examination. The provider puts a speculum inside your vagina to gently hold it open. Then an instrument with very cold liquid inside is put on your cervix (see Figure 2). It usually feels very cold. Some women have mild cramps. Deep, slow breathing helps you relax. The procedure takes about 10 minutes. Women have different amounts of feeling on their cervix and can handle different amount of pain. Some women do not need any pain medicine, but some do. You can take two or three ibuprofen tablets just before your appointment.

Figure 2 – Cryotherapy



After the Procedure

After the procedure, you rest for a short time in the clinic. Some women feel dizzy if they get up too soon. When you go home, you may have a lot of watery discharge for about two weeks. The freezing burns the cervix and this makes a blister which is the source of the discharge.Sometimes there is a little bleeding and the discharge may have an unpleasant odor. This is normal.

DO NOT have vaginal intercourse, wear tampons, douche, or put anything in your vagina for at least two weeks or until the discharge is gone. Wear a sanitary pad to absorb the flow.

What to Watch for – Risks

If you have a fever, chills, pain in your lower abdomen (belly), heavy vaginal bleeding (like an abnormal period), foul discharge or other problems, call the clinic. If the clinic is closed, call the emergency room.

Follow-Up

Since cryocautery does not always cure the problem, it is very important that you come back for repeat pap tests, especially by six months. You will then need pap tests every six months for two years. If any of these tests is abnormal you may need additional treatment to prevent cancer.

Reason for cryosurgery (biopsy results): _____

Date of cryosurgery:_____

Your next pap test should be done:_____

You should then have yearly pap tests for the rest of your life. If you go to another clinic for these tests, take this information sheet with you and share it with your health care provider.

Depo Provera ("The Shot")

What is Depo-Provera?
Depo-Provera is a shot that women get every 12 weeks (4 times a year) to prevent pregnancy. It is also called "the shot." Most women can safely use it.

How does Depo-Provera work?
Depo-Provera contains a female hormone, called progesterone, that is normally present in women's bodies. It prevents pregnancy by keeping the ovary from releasing an egg every month, blocking sperm from passing through the cervix, and changing the lining of the uterus.

How effective is Depo-Provera?
The shot is very effective if it is used correctly. If 200 women took their shot on time for a year, only 1 of them (at most) would get pregnant. Like other types of medication, the shot is less effective if it is not gotten on time.

What are the benefits of using Depo-Provera?

- Effective and long lasting
- Private
- Only needed 4 times a year
- Lighter periods, and in many cases, no periods
- Less anemia (low blood iron)
- Less cramping with periods
- Safe for women who are breast feeding
- Safe for women who cannot take estrogen

Who can use Depo-Provera?
Most women can use the shot. It is very safe. For over 30 years, millions of women around the world have used Depo-Provera.

Who cannot use Depo-Provera?
Some women should not use Depo-Provera because they have certain health problems. A woman should not use the shot if she has any of the following conditions: unexplained bleeding from her vagina, pregnancy, osteoporosis (thinning of the bones) or other bone diseases, older women wanting to get pregnant soon, breast cancer, or severe depression.

What affect does Depo-Provera have on menstrual periods?
Many women have a change in their periods when they're on the shot. This is normal and safe.

- **First 12 months:** Women may have irregular bleeding, spotting, heavy bleeding, or no bleeding.
- **After 6 to 12 months:** Women may skip a period or stop having periods completely.
- **After stopping the shot:** Women's periods may take one year to return to their normal pattern.

Commonly Asked Questions

Does the shot prevent STDs or HIV?
No, it is best to use condoms with the shot to protect yourself against STDs and HIV.

Will my periods stop on the shot?
Many women skip or miss a period after 6-12 months, but not everyone. Over half of the women who use the shot for a year have no menstrual bleeding. The ovaries are in a resting state and are not releasing an egg each month. As a result, the body does not have to shed the lining of the uterus each month, and there is no period.

What should I do if I have irregular spotting or bleeding on the shot?
Irregular spotting or bleeding on the shot is normal and safe. However, if you find it annoying, call the clinic to make an appointment. They may be able to help you reduce these side effects.

What should I do if I'm having bothersome side effects?
Many women experience minor side effects, such as weight gain or loss, mood changes, and changes in their periods. Your provider may be able to help you reduce these side effects or help you find a different method of birth control that suits you better.

How does the shot affect bone strength?
In some women, the shot may cause their bones to become thinner. Once they stop the shot, their bone strength (also called "bone density") usually returns. In some women, however, there could be an increased risk of breaking bones more easily later in life. To help prevent bone thinning, women who are on the shot for more than 2 years are recommended to not smoke, take calcium and get regular exercise. Women who already have osteoporosis (low bone density) may take the shot if they sign a form stating that they understand the risks.

How does the shot affect depression?
Progesterone, the female hormone in the shot, can have an effect on moods. This doesn't mean that all women who use the shot will get depressed; in fact, most do not. But, if a woman <u>already</u> suffers from depression, and it gets worse on the shot, she might not get relief until the shot wears off.

How does the shot affect body weight?
Many women gain weight using the shot, and others gain none. Progesterone, the female hormone in the shot, can increase a woman's appetite and cause tiredness. If this is a concern, a good diet, regular exercise, and healthy lifestyle can help.

If I go to another doctor, will they be able to tell I'm on the shot?
No, not unless you tell them. If you're admitted to the hospital or go to another clinic, be sure to tell them you're using the shot.

Will I be able to get pregnant after I stop taking the shot?
Yes, the ability to get pregnant usually begins 3 months after the last shot, but sometimes it takes longer - 6 to 18 months after the last shot. Therefore, women who want to get pregnant in the next 3 months should not use the shot. Women who are 33 or older may not want to use Depo-Provera because they are already less likely to get pregnant than women in their 20's. All women, whether or not they are using the shot, should start taking vitamins with folic acid before they get pregnant to help prevent birth defects.

Instructions for Use

How do I use the shot?

- The shot is given in the arm or buttock once every 12 weeks.
- Only a trained health provider can give the injection.
- During your first 2 weeks on the shot, you may not be fully protected against pregnancy.
- Use condoms, another birth control method, or don't have sex during this time.
- Call the clinic to make an appointment 1 – 2 weeks before your next shot is due.

Can I get the shot early (before the 12 weeks is up)?
Yes, the shot can be given early.

What happens if I'm late getting my shot (after 12 weeks have already passed)?

- There's a risk of getting pregnant if you're more than one week late.
- Make an appointment to get your shot as soon as possible. The clinic staff will give you a pregnancy test first. If you're not pregnant, another shot will be given.
- If you get your shot late, use condoms, or don't have sex, for 2 weeks because it will take 2 weeks for the shot to prevent pregnancy again.
- In some cases, they will ask you to return to the clinic in 4 weeks for another pregnancy test, just to be sure.

What if I miss my period on the shot?

If you got your shot late . . .

- ✓ Call the clinic to schedule a pregnancy test.

If you got your shot on time . . .

- ✓ There is almost no chance of pregnancy occurring.
- ✓ Many women skip their periods when they're on the shot for more than a year. This is normal and safe.
- ✓ However, you should schedule a pregnancy test whenever you're concerned about pregnancy.

Other Information
You can get an email reminding you when to get your next shot by visiting the Depo Provera website to sign up for their email reminder program: http://www.depo-provera.com/reminder/index.htm.

Diabetes Screening

Why is it important?

Diabetes can cause damage to blood vessels and lead to heart disease, kidney disease, blindness, amputations, and even death before a person even knows they have it. Over 5 million people in the U.S. have diabetes. Diabetes is the fourth-leading cause of death by disease in the United States. If the early signs of a tendency to develop diabetes can be discovered, it is much easier to prevent full-blown diabetes. It is much easier for a young person to make diet and exercise changes which could actually stop progression to full-blown diabetes.

Diabetes is more common in African Americans, Asian American/Pacific Islander, Latinos, and Native Americans.

Some people with diabetes have symptoms. Do you have any of the following symptoms?

- Extreme thirst
- Blurry vision from time to time
- Frequent urination
- Unusual tiredness or drowsiness
- Unexplained weight loss

Myths and Facts about Diabetes

Myth: Borderline diabetes is not serious
Fact: There is no such kind of diabetes as 'borderline.' You either have diabetes or you do not.

Myth: Diabetes is caused by eating too much sugar.
Fact: Sugar does not cause diabetes, but maintaining proper blood sugar levels is critical to controlling the disease. Scientific evidence points to obesity and heredity as causes of diabetes.

Myth: All people with diabetes must take insulin shots.
Fact: The vast majority, 90% of those with diabetes, control the disease with diet, exercise, and oral medication. Only 10% depend on insulin shots.

Myth: Insulin cures diabetes.
Fact: Insulin, along with diet and exercise, controls diabetes, but there is no cure for diabetes.

Myth: All people with diabetes develop heart disease, kidney disease, and blindness.

Fact: Controlling diabetes can help prevent these complications from occurring and enables people with diabetes to live normal and productive lives.

How can I be tested for diabetes?

We offer a simple "finger-stick" blood test to evaluate your blood sugar. The test is BEST DONE after "fasting" (no food or drink for 8 to 10 hours).

Women who should be tested:

1) If you have had any history of gestational diabetes (treated with diet only or Insulin that went away after delivery) OR a history of a baby over 9 pounds.
2) If you are over 35 years old and you are overweight.
3) If you have a family history of diabetes (mother, father, sibling or child has diabetes)
4) If you are of a certain ethnic group in which diabetes is more common (African American, Asian American/Pacific Islander, Latino, or Native American).
5) If you are a woman over the age of 45, even without the above risk factors.
6) If you have hypertension or abnormal cholesterol/blood lipid levels.

Results of fingerstick glucose test:

If 99 or less:	Normal, re-test every three years.
If 100-109:	Re-test in 6 months and begin to change your diet and exercise patterns.
If 110 or above:	You will be referred for further testing. You may have diabetes.

For more information on diabetes, call the American Diabetes Association at 1-800-DIABETES (1-800-342-2383) or visit the American Diabetes Association at website http://www.diabetes.org.

DIAPHRAGMS

What is a diaphragm?
A diaphragm is a soft, thin, dome-shaped rubber cup with a spring around the rim. It is used with a contraceptive jelly or cream which kills sperm. The diaphragm prevents pregnancy by covering the cervix and holding the contraceptive jelly or cream next to the cervix. Diaphragms come in different sizes. A trained health care provider must fit each woman individually.

How effective is the diaphragm?
The diaphragm is 82 to 96% effective. The main reason for the range of effectiveness is that the diaphragm is not used every time the couple has sexual intercourse. When the diaphragm is used correctly every time, it is a very effective method for preventing pregnancies.

Below is a table showing the percentage of women experiencing an unintended pregnancy within the first year of typical use of each of the listed contraceptives, the first year of perfect use, and the percentage of women continuing to use that form of contraceptive at the end of the first year.

Important Facts About Diaphragms

- You or your partner can put in the diaphragm as part of love making. If you want your partner to insert the diaphragm, have him come to the clinic to learn how.
- The diaphragm can be inserted up to six hours before having sex. If it has been in for more than two hours, put in a full applicator of contraceptive jelly or cream just before having sex. Do not remove the diaphragm, but use the plastic applicator to insert jelly or cream outside of the diaphragm in the vagina.
- Do not douche after intercourse. Recent studies have shown that douching may be related to pelvic inflammatory disease.
- The diaphragm does not need to be removed after 6 hours. Some women prefer to leave it in for as much as 16 hours. Additional jelly or cream must be used before each act of intercourse.
- The diaphragm may be more easily moved out of position in the woman is on top during sex or if the man inserts his penis into the vagina from behind.
- You can walk about, take a bath, or use the toilet with the diaphragm in place. It will not fall out or get lost in your body. If you have a bowel movement while the diaphragm is in, check afterwards to make sure that it is still in the proper position.
- If a lubricant is needed to aid the penis in entering the vagina, use the contraceptive jelly or cream. Do not use foam or Vaseline, as these will damage the rubber.

Advantages of the Diaphragm
The diaphragm has other benefits in addition to contraception. The chemical in the jelly or cream that kills sperm has also been found to kill the organisms that cause several sexually transmitted disease, including chlamydia, gonorrhea, and trichomonas. Therefore, women who use diaphragms are less likely to catch these diseases or get pelvic inflammatory disease.

Problems from Diaphragms

- Women who use diaphragms may have an increased risk of urinary tract and vaginal infections. You could ask about using a flat spring diaphragm to decrease the pressure on your urethra. You may also want to consider using another method.
- Men or women may be allergic to the rubber in the diaphragm, the jelly, or the cream. This is very rare, however.
- Women may get a bad smelling discharge if the diaphragm is left in too long.
- There is a slight risk of toxic shock syndrome with use of the diaphragm. If you use it during menstruation, DO NOT leave it in for more than 4 hours.
- Never leave the diaphragm in for more than 24 hours. Watch for the following signs of toxic shock syndrome:
    - Fever (over 101F)
    - Muscle aches
    - Rash (like a sunburn)
    - Diarrhea
    - Vomiting

How to Put in the Diaphragm

1. Empty your bladder. A full bladder makes it harder to fit the diaphragm.
2. Hold the diaphragm with the dome down (like a cup). Place one heaping teaspoon or two strips an inch long of contraceptive jelly or cream into the diaphragm. Spread it around the inside of the diaphragm and on the rim.
3. Stand with one foot propped up, squat, or lie down to put in the diaphragm.
4. Spread the skin folds around the vagina with one hand. With the other hand, put the diaphragm into the vagina by pressing the opposite sides of the rim together so the diaphragm folds. Make sure the contraceptive jelly or cream remains inside. Push the diaphragm in as far back as it will go. Then tuck the front rim tightly behind and against the pubic bone. This is the bone you can feel in the front of your vagina.
5. Check to see if you can feel the tip of the cervix through the rubber cup. The cervix feels like the tip of your nose – round and firm. The contraceptive jelly or cream should be next to your cervix. You may not be able to feel the back rim. Make sure the front rim is behind your pubic bone.
6. If you have sex a second time, leave the diaphragm in place and insert a full applicator of contraceptive jelly or cream outside the diaphragm in the vagina.
7. Wait 6 to 8 hours after ejaculation (release of sperm) before taking the diaphragm out.

How to Remove the Diaphragm

1. Put your finger behind the rim of the diaphragm. Pull down and out. Be careful not to make a hole in the diaphragm with your fingernail.
2. If you find it hard to hook your finger behind the diaphragm, try squatting and push downward with your stomach muscles (as though you were having a bowel

movement). You can also put a finger between the diaphragm and the pubic bone to break the suction of the diaphragm.

How to Care for Your Diaphragm

- After each use, wash the diaphragm with mild soap and water, and rinse it in clean water.
- Dry it thoroughly, especially around the rim.
- Look for holes by holding it up to the light and carefully stretching the rubber with your fingers. If a hole develops, the diaphragm will not protect you.
- Dust the diaphragm with cornstarch to help preserve the rubber. Never use talcum powder or baby powder since these contain oil and will cause the diaphragm to fall apart. If you have problems with yeast infections, rinse the cornstarch off before insertion.
- Place the diaphragm in a dry container away from heat so it will not fall apart.

When to Check Your Diaphragm Size

Have your diaphragm fit checked if:

- You lose or gain more than 10 to 20 pounds
- The diaphragm causes discomfort or pain
- You have a pregnancy (an abortion or full-term pregnancy)
- You have any kind of pelvic surgery

DRUG REACTIONS

ALLERGIC REACTIONS:

The following side effects are dangerous allergic reactions. They can happen right away, within 15 minutes of taking certain medicines. They are rare but they ARE emergencies. You should call 911 if the following danger signs occur:

- Difficulty breathing - You may also feel anxious or agitated
- Itching or swelling in your throat

Less serious side effects can also occur. Call your health care provider if:

- Hives (red blotches) or a rash breaks out anywhere on your body

OTHER POSSIBLE SIDE EFFECTS FROM COMMON MEDICATIONS:

∂ **AZITHROMYCIN:** This antibiotic is often given in one dose. Side effects are rare. If side effects are present, they are usually mixed and can include diarrhea and nausea.

∂ **CEFIXIME:** There are usually no side effects from this antibiotic. If side effects are present, they are usually mild and can include diarrhea, abdominal cramps, and gas.

∂ **CEFTRIAXONE:** This is an antibiotic to treat infection. It is given be a shot. There are usually no side effects other than soreness where the shot was given.

∂ **DOXYCYCLINE:** This antibiotic is used to treat or prevent infections. **Do not take it if you are allergic to tetracycline or if you are pregnant or breastfeeding.** While taking this drug, you are more sensitive to the sun. **Avoid being out in direct sun or using tanning booths while taking this drug.** The most common side effects from this drug are upset stomach, vomiting, and diarrhea. Take the medication with food or immediately after a meal.

- **IBUPROFEN OR NAPROXEN:** This drug decreases the chemicals of inflammation and can decrease period bleeding or cramps. It is related to aspirin. It is common to experience some nausea or upset stomach especially if taken on an empty stomach.

- **METRONIDAZOLE:** This antibiotic is used to treat infections. The most common side effects while taking this drug are nausea, loss of appetite, vomiting, diarrhea, headache, and a metallic taste in the mouth. This drug can interact with alcohol and cause severe nausea and vomiting. **Do not drink alcohol while taking this drug.**

TRIMETHOPRIM/SULFAMETHOXAZOLE, DOUBLE STRENGTH (TMS/DS): This drug (antibiotic) is used to treat infections. **It should not be taken by anyone allergic to sulfa drugs, or if you have liver or kidney disease or severe asthma. It should not be taken in the first three months or last few weeks of pregnancy or during the first two months of breastfeeding.** Drink 1 to 2 full glasses of water each time you take a tablet. Dangerous side effects to this drug are rare. Stop taking this medicine and call the clinic if you get a rash, joint pains, severe headache, or dizziness. This drug can cause nausea, vomiting, diarrhea. Take it with food or immediately after a meal.

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FEMININE HYGIENE

Vaginal Discharge and Odor

The vagina is like the mouth, it is supposed to be moist and lubricated. The vagina produces a small amount (1/2 to 1 tablespoon) of fluid each day. This fluid keeps the vagina healthy. It can increase during ovulation when estrogen is high and the egg cell is released. The week before your period the discharge may be more noticeable. The color can be white and sticky, thicker, and sometimes appear light yellow on your underwear.

If you place a clean finger in your vagina, you can smell the discharge or vaginal fluid. It has a faint sweet smell; after sex, semen can temporarily change the odor to fishy, but a persistent bad or fishy odor inside the vagina or of the vaginal discharge is abnormal. The vulva, the outside part of the genitals, has sweat glands which make sweat and odor similar to the armpit.

Keeping Clean

Do not douche. Douching is when liquids are washed into the vagina. The vagina makes fluid or discharge to protect itself naturally, and douching can kill good bacteria and lead to vaginal infection. Douche often contains chemicals that are bad for the vagina. Even water and vinegar can wash out good bacteria or introduce bad bacteria.

Avoid using feminine hygiene sprays, wipes, or powders. These chemicals can cause irritation and burning. They do not keep you any cleaner or fresher. For the same reason, avoid scented tampons, sanitary napkins, and panty liners. Powders are unnecessary, but if you must use one, cornstarch may be the least irritating.

Always wipe gently from the front to the back of the genitals after passing urine, bowel movements, sex, or during your period bleeding. This helps prevent spreading bacteria from the anus to the vagina or urethra. Use unscented toilet paper because the chemicals used for color and scent can be irritating to the skin. Sometimes even toilet paper can hurt and instead sit on the toilet and use a cup of water and your hand to gently wash (no soap is needed for the vulva) your genitals, dry with a soft cloth and then wash your hands with soap.

If your genital area is sensitive to cleansing products like soap of bubble bath, you could try a baby shampoo (Tearless), or use only water. Taking showers instead of baths may help because you are nor sitting in soapy water. When you bathe, rinse off the genital area with fresh water.

There are risks to cutting genital hairs short or shaving the genital area. Shaving can cause ingrown hairs, rashes, irritation, nicks to the skin that can increase the risk of infection, and itching. Hair that has been cut or shaved can be like bristles or stubble like and cause itching and rashes. If you must remove your genital hair, waxing is less likely to result in infections,

cuts, and bristles. Some cultures and religions require the shaving of genital hair, but throughout most of the world and history, genital hair has been allowed to grow and genital hair is a sign of sexual maturity.

Clothing

After bathing, make sure your skin is dry before dressing. Moisture can increase discomfort and irritation. Wear loose, 100% cotton underwear. Wear loose clothing and avoid nylons, synthetic, or tight clothing that trap moisture around the vulva. This creates an ideal situation for irritation and yeast or bacterial growth. Tight pants often have seams that rub and irritate the genital area. Loose clothing allows air to get to the vulva. Do not wear underwear for sleeping. Underwear prevents fresh air, blocks the vaginal opening, and has been associated with bacterial vaginosis (a common cause of abnormal vaginal discharge). For centuries, and even now all around the world, many women often wear skirts with very loose undergarments like bloomers, a type of loose short, and many may wear no underwear. In the U.S., underwear was only invented in the last 100 years to hold menstrual pads in place.

Sexual Activity

The vagina gets wet and more relaxed with excitation or foreplay. This is an indication that you are ready for sex, similar to a man's erection. With arousal, the vaginal tissues get engorged and more sensitive because of extra blood flow to the area. If you need extra lubrication during sexual intercourse, use an unscented water-based lubricant. Avoid lubricant with scents, antibacterial agents, or detergents. If you use silicone sex toys, avoid using lubricants that contain silicone, as these can damage the toy. Some lubricants are specifically made for intercourse like Slippery Stuff® or Replens®. Do not use oil-based lubricants, such as Vaseline® or petroleum jelly if you are using latex products like condoms and diaphragms. Sometimes a vegetable oil can be the best lubricant for sex (but you can not use this with a latex condom or it will break the condom).

Anal intercourse can traumatize the anus and introduce stool bacteria to the genital area. Do not put the penis in the vagina after anal sex unless it is washed with soap and water first. Sometimes even oral-genital sex can be irritating. Avoid oral-genital sex it you or your partner has a cold sores on the lip. You can get genital herpes from a cold sore. Urinating after sex helps flush out any bacteria that might have gotten into the urethra and can prevent bladder infections. Semen has a high pH (like a chemical) and it can be irritating to some women. Rinsing out the semen from the vagina with water using your fingers after sex may help prevent irritation.

Problems

Sometimes the vulva can feel irritated. Do not scratch. Fingernails cause injury to the delicate skin and can make the problems worse. Some women scratch at night when they are sleeping. Cut your fingernails short or wear socks on your hands when sleeping to prevent scratching. You could take an antihistamine pill (Benadryl® 25 to 50 mg) at night to help you sleep deeper and prevent itching. If you feel a desperate need to scratch, you could try an ice cube to numb the area briefly, a lukewarm bath, or a cold moist washcloth. Anhydrous lanolin, A and D®, or Desitin® ointment for a day or two can be soothing to the area and because it is very sticky, prevent further rubbing and scratching. If you have persistent itching, odor, pain, frequent or painful urination, sores, or unusual discharge around the vulva, call your health care provider for an appointment. There are many things that can cause these problems. You will usually need an examination and lab test to find the cause and best treatment.

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ARE YOU GETTING ENOUGH FIBER?

Usually, ingredients in foods that are good for you are absorbed and used by your body to function properly and keep you healthy. Fiber, an important part of a healthy diet, is different. Although fiber is not absorbed and passes through the digestive system largely intact, it is a very important part of good digestive health and protects against other serious diseases, such as heart disease and cancer. Fiber is found only in plant foods, such as whole grains, fruits, vegetables, beans, nuts, and seeds.

What is fiber?
Fiber is the component of plants (such as fruits, vegetables, and grains) that the body does not digest. There are 2 types of dietary fiber - **soluble**, which forms a gel when mixed with liquid, and **insoluble**, which does not. Foods high in soluble fiber include oat bran, oatmeal, beans, peas, rice bran, barley, and citrus fruits. Foods high in insoluble fiber include whole-wheat breads, wheat cereals, wheat bran, rye, whole-grain rice, barley, cabbage, carrots, and Brussels sprouts.

How to eat more fiber:

- To get adequate fiber in your diet, follow the U.S. Department of Agriculture's Food Guide Pyramid, which recommends eating 2 to 4 servings of fruit, 3 to 5 servings of vegetables, and 6 to 11 servings of cereal and grain foods every day!
- Begin your day by eating a whole-grain cereal that contains at least 5 grams of fiber per serving.
- Try to eat vegetables raw as much as possible because cooking may reduce fiber content.
- Try not to peel fruits (such as apples and pears) and vegetables (such as carrots or cucumbers), because much of the fiber is found in the skin.
- Add beans to soups, stews and salads.
- Eat fresh and dried fruits as snacks.
- Read food labels for fiber content.
- **Summary:** 2 to 4 servings of fruits
  3 to 5 servings of vegetables

6 to 11 servings of cereal and grain foods.

How much do you need?
The recommended daily intake of fiber is 20 to 35 grams each day. For example, a 1/2 - cup serving of bran flake cereal has 5.5 grams and an unpeeled pear has 4.5 grams of fiber. This amount of daily fiber intake should come from foods high in fiber, rather than diet supplements.

What does it do?
Both soluble and insoluble fibers are an important part of a healthy diet because they help normal bowel function and maintain regularity. In addition, soluble fiber, when part of a diet low in saturated fat and cholesterol, has been associated with a reduced risk of certain cancers, diabetes, digestive disorders, and heart disease.

For more information:

- American Dietetic Association Consumer Nutrition Hot Line 800/366-1655 or www.eatright.org
- American Heart Association 800/AHA-USA1 or www.americanheart.org
- U.S. Department of Agriculture Center for Nutrition Policy and Promotion *Food Guide Pyramid* 800/687-2258 or www.usda.gov/cnpp

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Getting Fit

1. Deciding you want to get fit and believing you can reach this goal is the first step.

2. Accept that it will take time, maybe years, but it will be worth it.

3. Diets alone don't work because they limit your caloric intake, which results in starvation and you could lose muscle, and actually store additional fat. Instead, consider these tips:
   - Use smaller plates to eat smaller portions.
   - When you eat, sit down. Eat slowly, this allows time for the food to get to the intestines and to signal properly when you are full. If you eat too fast your body does not have a chance to tell you that it has already had enough.
   - Eat only at meals – if you do not have 4-6 hours between meals your body will not burn fat.
   - Do not snack.
   - If you must snack, eat foods like carrots, celery, fruit, nuts, or other healthy foods.
   - Do not drink soda pop or sweet drinks; one can of soda a day can give you 15 pounds a year of calories. Drink water!
   - Eat what satisfies your hunger.
   - If eating an egg, bacon, and fruit at breakfast then allows you to go until lunch without eating. then that is better than a high carbohydrate meal.
   - Starchy and sugary foods can drive your blood sugar up, it then falls, and you are so hungry you then snack or you eat too much at the next meal.
   - Alcohol has no nutrition and drinking too much can keep you from losing weight.

4. Activity is the key to long-term health and fitness.
   - Aerobic exercise builds strength, burns calories, and replaces fat with lean muscle which burns calories even when you sleep. Watching TV has been associated with obesity.
   - Do exercise every day for a minimum of 30 minutes. A brisk walk counts! Get outside.
   - Getting enough sleep prevents stress which can trigger carbohydrate craving and overeating.

5. If you have a medical diagnosis such as hypertension or diabetes as well as obesity (means you are>100 pounds over ideal body weight), you may qualify for a medical dietary consult at a clinic.

6. Support programs which may be able to help are:
   - **Weight Watchers**
     1-800-562-6962
   - **Overeaters Anonymous**
     24-hour help/information line: 206-264-5045

7. Also, here are two helpful books to read:
   - **The New Fit or Fat**
     By Covert Bailey
     Houghton Mifflin, Boston 1991
   - **Stop the Insanity**
     By Susan Powter
     Simon & Schuster 1995

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Information about the HPV Infection and Your Pap

What is HPV?

HPV (human papillomavirus) or the "wart virus" is a virus that infects skin cells. There are many different types of HPV. Some types cause warts in the genital region, and some types cause warts on other parts of the body, such as the fingers. Many people infected with HPV do not know they have it because often there are no visible signs of HPV infection

There are many types of HPV or "wart virus" that cause genital infection. HPV found on the genitals usually does not infect other parts of the body. You can become infected with more than one type of HPV and having one type of HPV will not protect you against other types of HPV in the future.

How do I get it?

Between 40 and 80% of sexually active adults have been infected with a genital type of HPV. People usually get exposed to the virus through skin to skin contact during sexual activity and that includes intercourse or even just touching the genitals. In rare instances, transmission of the virus may occur from nonsexual contact.

HPV is the most common STD in the United States. HPV is easily transmitted because most people who are infected with it do not know they have it.

How long will I have it?

We know HPV may be found by DNA tests beginning as early as a month after a person has caught the virus from someone. The virus may then continue to shed by the genital skin for 1 to 2 years. Often the virus then "disappears" and may not be detectable on subsequent DNA testing. However, it is possible that the virus will remain present forever in the genital skin at very low levels.

How about my partner?

Persons with HPV infection are potentially infectious to their sex partners. HPV has been linked to certain health problems in men like cancer of the penis. The risk of this is very small, much smaller than the risk of cancer of the cervix in women. If your partner does not have any genital symptoms or warts, usually there is no need for him to see a health care provider. Many men and women have HPV infection and most do not know they have it. It is usually not possible to determine who caught the virus from whom.

Risk of Cervical Cancer

Certain HPV types have been linked to abnormal Pap tests and can increase the risk of developing cervical cancer later in life. Other HPV types cause genital warts and may cause abnormal Pap tests, but are not associated with the development of cervical cancer later in life.

The HPV types that are associated with the highest risk of developing cancer later in life are HPV type 16 and HPV type 18. Other types, specifically HPV type 6 and type 11, are not associated with the later development of cervical cancer. Still others, like HPV type 31, cause a small but definite increased risk for developing cervical cancer later in life. Even in women with a high risk HPV type however, only a small percent will progress to cervical cancer. Presently there is no way of predicting whether certain individuals with HPV infection will develop cancer later.

Follow-up

There is no effective treatment against the virus at this time. In most cases the infection goes away on its own. There is some evidence that quitting the use of tobacco products can help your immune system to get rid of the virus.

Even though someone may have an infection with an HPV type that may increase the risk of cancer, it is important to remember that very few women actually develop serious abnormal cervical cells from HPV. Regular cervical cytology (the Pap Test) can detect early signs of abnormal cells and early treatment will prevent later development of actual cancer.

Regular pap test are important to any women's health. Pap testing should be every year beginning at age 21 or earlier if sexual activity is begun earlier. It is important to begin to get pap tests by 3 years after starting sexual activity. If a woman knows she was infected with certain high risk HPV types (for example, types 16, 18, or 31) or has a history of cervical precancer or treatment then she needs pap testing every year, at least.

Prevention

In general, we recommend that condoms be used with all new sexual partners, especially casual sexual partners. Condom use can greatly reduce the spread of genital bacterial infections like chlamydia and gonorrhea but they are less effective in preventing HPV infection. This is probably because the condom does not cover all the genital skin and often during foreplay there can be touching of the genitals. Someday there will be a vaccine to prevent HPV infection.

Do I need treatment?

Not unless you have precancer of the cervix that needs treatment or external genital warts that are causing you discomfort.

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Family Planning Program
How We Get the Iron We Need

- Iron is found in many foods, but in small amounts. It can be hard for some people to get enough iron from the foods they like to eat. Eating **iron-rich foods** and **vitamin C foods** in the same meal helps the body absorb the iron.
- Eating iron rich food **everyday** can help prevent iron deficiency anemia.
- Cooking food in a **cast iron pot or pan** is a safe, easy way to add iron to your diet.
- Get more iron from greens such as spinach, kale and collard greens by eating the liquid you cook them in.
- Tea, coffee and soft drinks reduce the amount of iron you get from food. Drink less of them with meals.
- Babies get the iron they need from breast milk or iron fortified formula. Cow's milk is not a good source of iron.

The two most important things that the body needs to make blood are protein and iron. Vitamin C helps the body use iron. At the same time, the body needs protein for other reasons: building muscles and repairing old and injured parts of the body. Vitamin C has several important functions in the body, such as helping to form bones and teeth and healthy skin and tissue. Vitamin C also plays a significant role in wound healing and maintaining strong blood vessels.

Since our bodies do not make Vitamin C, we must eat foods, which provide us with it. It's a good idea to eat foods with Vitamin C every day.

Iron Rich Foods

Foods from animals:	**Foods from plants**
• Liver: beef, pork, lamb, chicken • Meat: beef, pork, lamb, veal, chicken, turkey, fish • Eggs	• Grains: iron-enriched baby cereals, iron-enriched breakfast cereals, enriched bread, whole wheat bread • Dark green leafy vegetables: spinach, chard, collards, kale, turnip greens, mustard greens, beet greens, broccoli • Dried fruits: apricot, prunes, raisins • Dried beans: lima beans, navy beans, red beans, white beans, kidney beans and other dried beans • Dried peas: split peas, cowpeas, black-eyed peas, green peas, lentils and other dried peas • Nuts: almonds, Brazil nuts, cashews, walnuts, peanuts and peanut butter • Molasses

Vitamin C Rich Foods (*Indicates a very good source)

asparagus	greens (collard, kale)	*pineapple
avocado	beets, mustard	*potatoes
*broccoli	lemon or lemon juice	spinach
*brussels spouts	lima beans	squash
*cabbage, raw	mangos	*strawberries
*cantaloupe	*orange or orange juice	*tomato or tomato juice
*cauliflower	*papaya	turnips
*grapefruit or grapefruit juice	peas	
*green pepper		

Intrauterine Device (IUD)

What is an IUD?
An IUD (Intrauterine Device) is a small piece of plastic, with copper or progestin added to make it more effective. It is put inside the uterus to prevent pregnancy. Only a trained health care provider can insert it. The IUD plastic is flexible and T-shaped, about one inch tall and one inch wide. The copper IUD provides birth control protection for up to 10 years and progestin IUD provides birth control for up to 5 years. In order to have an IUD inserted, you will need to read and sign a special consent form.

How effective is the IUD?
The IUD is over 99% effective if it is in place. The IUD releases copper or progestin, which interferes with sperm entry to the uterus, transport, and fertilization. Unlike the birth control pill, IUDs do not prevent ovulation although in some women the progestin IUD can decrease ovulation.

Who can use an IUD?
The IUD is best for women who have had children. Women who have not had children can have a higher risk for pelvic inflammatory disease (PID). Women get PID from sexually transmitted infectious like chlamydia. PID can scar the fallopian tubes and make some women infertile (unable to have babies).

Some women cannot use an IUD because of certain medical conditions. That is why a complete medical history is taken and a pelvic exam is done before you have an IUD put in. If you have any of the following conditions, you should not use an IUD:

- Current pregnancy
- Current infection in the uterus, tubes, and/or ovaries
- Abnormal size or shape to your uterus (measured by the health care provider)
- Cancer of the uterus
- An allergy to copper or you cannot use the progestin hormone levonorgestrel

Advantages of the IUD
With an IUD there is nothing you have to do except check your string at least once a month to make sure it is in place. It is as effective as sterilization, but is reversible.

Problems
There are some serious problems, which are rare, but important to know about. You can get a serious infection in your uterus, or the procedure to put in the IUD could put a hole in your uterus. If you have any of the following danger signs, call the clinic right away:

- Abdominal pain – deep pain when having sex or abnormal cramps
- Increased temperature, fever, chills, feel ill
- Not normal, bad smelling discharge from your vagina
- Spotting or bleeding between periods, heavy periods, blood clots, or any change in the period

Any of the above symptoms may mean that you are developing a serious problem. Do not ignore these symptoms or wait to see if they go away. If the clinic is closed and you think you might have a serious infection or problem, go to the closest emergency room.

Period Changes
When you first get your IUD, you may have spotting for a month after it is put in. The copper IUD (T380A) can increase the amount and days of bleeding during your periods. The progestin IUD (Mirena) will cause irregular bleeding and spotting the first 6 months and then this will gradually decrease by one year and 20% of women (one in five) may have no period and many may have only 1 to 2 days of a light period bleeding by one year of use. You can use tampons with an IUD.

How is an IUD put in?
The IUD can be put into your uterus anytime when you are sure you are not pregnant. First, the provider examines and measures your uterus. Then the IUD is put inside a thin plastic applicator tube. The tube is put through your cervical opening and into your uterus. The tube is removed and the arms of the IUD unfold inside the uterus. The strings attached to the IUD are cut short. The applicator tube and extra string are removed.

Most women feel discomfort or cramping when they get an IUD put in. It is possible you might even have heavy cramping or feel nauseated. Be sure and eat before your visit and you could take some aspirin or ibuprofen before the procedure. Taking deep breaths to help yourself relax will relieve some of the discomfort. If you feel very uncomfortable after the IUD is put in, tell your provider before you leave the clinic.

What if I get pregnant with an IUD in place?
If you become pregnant while using an IUD, you should have it taken out. There is risk that removing the IUD will cause a miscarriage. If the IUD is left in, you have greater risk of miscarriage and you may also develop a serious infection in your uterus which could cause premature birth and problems for the baby.

If you miss a menstrual period with the copper IUD or feel pregnant while using the IUD, call the clinic right away to get a pregnancy test. If you get pregnant with an IUD in place, there is a 30 to 60% risk the pregnancy is ectopic (in the tubes) and this is a serious problem which could need emergency surgery or treatment.

You can reduce your risk of getting pregnant while using an IUD. Check for the strings at least once a month to make sure the IUD is in place. Because 2 to 5% of IUDs can be expelled or lost especially in the first year of use, call your clinic if you experience pain, a change in bleeding, or you cannot feel the strings or you think the strings have changed.

How do I check my strings?
Your provider will help you learn how to feel for your strings at the time of insertion. The strings can only be felt by putting your finger into your vagina, they are usually about 1 inch long and come out of your cervix, brush your finger against them but do not pull on them. For the first few months you should check your strings every week. Later you should check them at least once a month.

If you cannot feel your strings, or they feel shorter or longer, or you feel the plastic frame, call the clinic to make an appointment to be checked. Do not pull on the strings. If you think your strings are too long or if they bother your partner during sex, ask the clinic provider to cut the strings shorter.

What if I want to stop using the IUD?
Removal of the IUD is usually very simple. During a pelvic exam, your provider pulls the IUD out by the strings using an instrument. Your fertility returns immediately and unless you want to be pregnant, you should use another contraceptive method. If you want to get pregnant, it is advised that you wait

one menstrual cycle. At age 6 or at menopause, it is recommended that the IUD be removed unless you are choosing to use the progestin IUD as part of menopausal hormone replacement.

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LIPID PROFILE RESULTS: WHAT DO THEY MEAN?

Listed below are the results for your lipid test. The purpose of lipid screening is to evaluate your risk for cardiovascular disease and to provide you with useful information.

CHOLESTEROL
Total Cholesterol Level:_ HDL_ DL_ Triglycerides:_

	Total Cholesterol	HDL	DL_	Triglycerides
Optimal	Under 180	Above 60	Under 100	Under 200
Desirable	Under 200	---	Under 130	Under 300
Borderline	200-239	---	130-159	300-400
Needs Improvement	Over 240	Below 40	Over 160	400

What Your Score Means
Optimal: Exceeds the 'desirable' or recommended range. If you currently exercise 3 to 5 days per week and maintain a low fat diet – Congratulations! Keep up the good work. If you do not, keep in mind that there a variety of benefits to regular exercise and a low fat diet.

Desirable: Maintain a low fat diet and a regular exercise routine. Have your cholesterol checked again in another 5 years.

Borderline: Assess your current diet and exercise plan for improvements, if you have not been doing so already. Consider any other risk factors for heart disease, such as: high blood pressure, smoking, diabetes, obesity, and family history.

Needs Improvement: See you health care provider to determine if you need medications to lower your cholesterol and if you have any other heart disease risk factors.

What Is Cholesterol?
Cholesterol is a fatty, waxy substance found in foods of animal origin, including meat, poultry, eggs, and dairy products. We acquire cholesterol from food and through our body's natural production. It is used to make cell walls, bile acids, and some hormones.

What Are Triglycerides?
Triglycerides are lipids (fats) that are normally present in the blood and are used in producing energy for the body. Excess triglycerides are stored in fat. Calories ingested in a meal, and not used immediately by tissues, are converted to triglycerides and transported to fat cells to be stored.

How to Lower Total Cholesterol & Increase HDL Cholesterol

Limit your dietary fats. Avoid saturated fats (solid at room temperature and come from animal sources). Include more water-soluble fiber in your diet (oat bran, vegetables, fruits, legumes, and soy beans). Decrease your alcohol consumption. Get regular exercise (3 to 5 days per week such as walking, swimming, biking, jogging, etc.). If you are overweight, work to achieve and maintain a healthy weight. If you smoke, QUIT.

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LUNELLE

What exactly is Lunelle?
The Lunelle Monthly Contraceptive Injection contains a medroxyprogesterone acetate and estradiol cypionate injectable suspension. Lunelle is given as an injection in your arm, thigh, or buttock once a month by your health care professional.

How effective is Lunelle?
Lunelle is as effective as the Pill. When you receive your injection each month on time, Lunelle gives you over 99% protection against pregnancy, which means if 100 women use Lunelle, only one woman will become pregnant in the first year of use. You are protected the moment you get your first injection – if you get it within the first 5 days of your period.

If Lunelle is monthly, do I have to get it exactly the same day each month?
As long as you get your injection is within 28 to 30 days of your last injection, and no later than 33 days after your last injection, you will be protected from pregnancy for the entire month. It may be helpful to remember if you make your shot appointment on the same day of every month.

Who should not take Lunelle?
Pregnant women, women who think they may be pregnant, or women with blood clots, chest pains, certain cancers, unexplained vaginal bleeding, or a history of liver disease, stroke, or heart attacks should not take Lunelle. Women over 35 who smoke 15 or more cigarettes a day should also not take Lunelle.

Are there any risks involved in taking hormonal contraceptives?
The use of any hormonal birth control containing estrogen can increase the risk of serious side effects that can be life threatening including blood clots, stroke, and heart attack. Smoking increases these risks, especially if you are over 35 and smoke 15 or more cigarettes a day.

Does Lunelle protect against STDs?
Just like all hormonal contraceptives, Lunelle does not protect against HIV/AIDS and other sexually transmitted diseases. Only latex condoms can help protect you.

What about side effects?
During the first few months of taking Lunelle, most women will have a change in their periods, which may include no bleeding, irregular bleeding, or spotting. If this continues or is serious, discuss it with your clinic. For most women, a monthly period will return. Many women may gain weight while taking Lunelle. In clinical studies, women generally gained an average of 4

pounds during the first year. Generally, most side effects are not serious. It is important, though, to talk with you clinic if the side effects bother you.

What about when I want to get pregnant?
Upon stopping Lunelle shots, most women start ovulating (making an egg or having regular periods) 2 to 3 months after their last injection. Some women start ovulating with the very next cycle. It varies from woman to woman, so you need to be prepared immediately for the possibility of pregnancy.

Other information
You can sign up for a monthly email reminder by visiting the Lunelle website at http//eminder.lunelle.com .

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Menstrual Products

Pads are worn on the outside of your genitals to collect menstrual blood. The pad is usually attached to underwear with tape or a belt is worn.

Tampons are inserted inside the vagina to collect menstrual blood. Tampons will not break your hymen or take away virginity. Tampons can be more comfortable than a pad. Avoid using tampons or pads for only light spotting. They can be irritating and a dry tampon can be very painful to pull out of the vagina. Sometimes after childbirth, the opening to the uterus (cervix) is lower in the vagina and if the tampon does not collect menstrual blood as well, a menstrual cup device might work better.

How to use tampons:

- Wash your hands with soap and water before inserting a tampon.
- Push the tampon towards the small of your back as far as it will go comfortably.
- Be careful when you wipe after using the bathroom to avoid getting the string of the tampon near your anus.
- Avoid using tampons when your flow is very light. Removing a dry tampon can irritate or damage your vagina.
- If your flow is heavy, you can use more than one tampon at a time. Insert the first one part way, then insert another alongside it, then push both in fully.

To reduce your risk for toxic shock syndrome:

- Use the lowest absorbency tampon needed to manage your flow
- Change your tampon at least every 8 hours
- Discontinue tampon use and go to the hospital if you develop a high fever, vomiting, diarrhea, smelly or yellow, and/or rash that looks like a sunburn

The **Menstrual Cup Device, Instead®**. Menstrual blood collection devices like Instead® or cups are inserted into your vagina to cover the cervix where the blood comes from and can be used for 12 hours to collect the blood. Be careful when removing the device as the blood can spill. The blood collects in the soft vinyl cup and then you remove it at least once a day. It is best to use a new cup each time and dispose of the old one in the trash not the toilet. Some women reuse these cups and if this is done it is important to wash cup with soap and water.

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The Contraceptive Patch

What exactly is the Patch?
The Patch (OrthoEvra) is a transdermal contraceptive system or more simply a 2-inch by 2-inch plastic patch that sticks to your skin. The Patch releases a progestin (norelgestromin) and an estrogen like a pill. The Patch is worn for 7 days and then changed for a new Patch. After 3 weeks (3 patches) you then have a patch free week to have a period.

How effective is the Patch?
The Patch is as effective as the Pill. The Patch prevents the release of an egg and makes it hard for sperm to enter the uterus. When you wear your Patch each week, with a new one used every 7 days, then the Patch gives you over 99% protection against pregnancy. You are protected the moment you put on your Patch – if you put it on the first day of your period. Otherwise, use protection for the first 7 days. Women weighing 198 pounds or more have a much higher risk of pregnancy (8%) with the Patch and should choose another method.

If the Patch is weekly, do I have to put it on exactly the same day each week?
Yes, this is the best habit. But if you are 1 to 2 days late you are still protected as long as you put the new Patch on right away and wear the new one for the full 7 days. Never go more than 7 days without a patch.

How is the Patch used?
The Patch can be put on the upper arm torso (back), buttock or lower abdomen (never the breasts). Make sure the skin is clean and dry to the touch and avoid any oil or lotion in that area or the Patch won't stick. Press the patch to the skin firmly for 10 seconds. Do not write on or color the patch it might make it less effective. Wear the Patch for 7 days. After removing the Patch you can clean off the adhesive with mineral oil if you wish. Fold the old Patch in half (sticky side stuck to sticky side) and throw in the trash not into the water system or toilet. Put the new Patch on a different place on your skin. If you notice a rash or skin irritation you might have to stop using the Patch and should consult your clinic. Bathing, showering, swimming, exercise, or humid weather should not affect the Patch.

What happens if the Patch comes off or gets loose?
The Patch must be completely stuck on your skin for it to work and if even an edge is loose it must be replaced with a new Patch within 1 to 2 days. Check your patch every day to make sure it is firmly attached.

Who should not use the Patch?
Women who think they may be pregnant, or women with blood clots, chest pains, certain cancers, unexplained vaginal bleeding, or a history of liver disease, stroke, or heart attacks should not use the Patch. Women weighing 198 pounds have a much higher risk of pregnancy (8%) with the Patch and should choose another method. If a woman wants to skip her periods then the Patch should not be chosen because you only get 3 patches a month and the amount of estrogen is too high for daily or continuous use. Just like all hormonal contraceptives, the Patch does not protect against HIV/AIDS and other sexually transmitted diseases. Only abstinence, female condom, or the male condom can help protect you.

What about side effects?
During the first few months of using the Patch, most women will have a change in their periods, which may include no bleeding, irregular bleeding, or spotting. If this continues or is serious, discuss it with your clinic. Many women reported breast tenderness or nausea with the Patch, sometimes worse than with the pill, but usually these problems get better after 3 months. It is important to call or see your clinic before stopping the Patch, they might be able to help make it better.

What about when I want to get pregnant?

Upon stopping the Patch, most women start ovulating (making an egg or having regular periods) soon after stopping the Patch. Some women start ovulating with the very next cycle before even having a period, so you need to be prepared immediately for the possibility of pregnancy.

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Post Implant Insertion or Removal Patient Handout

TO AFTER IMPLANT SYSTEM INSERTION/REMOVAL:

- Keep the pressure bandage dry and on your arm for 24 hours. You may take a tub bath but keep the bandage dry.
- Avoid trauma to your arm, strenuous arm exercise, and lifting more than 10 pounds.
- When the anesthetic wears off in 2-3 hours, your arm will ache like a muscle bruise or cramp. Tylenol, aspirin, or ibuprofen can help. A ice pack will also reduce swelling. Make sure the ice is wrapped so the bandage stays dry.

WHAT TO EXPECT AFTER INSERTION:

- Swelling, aching, soreness and bruising are all normal after the procedure.
- Discoloration may last up to ten days. Soreness is common for two weeks so you should be careful when you use that arm.
- Expect tenderness with motion or pressure for 10 to 30 days.
- Expect skin sensitivity to touch or clothing for up to six weeks.

CARE OF IMPLANT SYSTEM INSERTION REMOVAL SITE:

After taking the pressure bandage off in 24 hours, you will see the tapes to hold the skin closed (steri-strips). These should stay on for 3-5 days. You may shower and gently wash that arm but try not to rub the steri-strips off. When you get out of the shower blot them dry so they stay in place. The steri-strips should fall off by themselves. If they do not, you should remove them after a week. Usually the steri-strips fall off when the skin has healed. If there is still a scab, you might want to put a clean bandaid on every day if the area is sensitive to touch. Usually, however, the scab heals quicker if left open to air.

COMMON SIDE EFFECTS

It is common to experience irregular menstrual bleeding. This may improve with time although your periods may remain light but irregular. One in 5 women may skip their period bleeding while using an implant. The risk of pregnancy is 1 in 500 with implants but if you think you are pregnant get a pregnancy test.

REMEMBER: If you have been advised to use another method of birth control for the first 7 days after the implant has been inserted, it is very important that you do so. This will prevent getting pregnant before the implant hormones are fully working.

WARNING SIGNS:

If you experience any of the following, call your clinic. If the situation is getting worse, then go to a nearby emergency room.

- Increased swelling, redness, fever, or pain in the arm.
- Pus coming from the insertion or removal site.
- Implant coming out of the insertion site (expulsion)

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PREGNANCY OPTIONS

Do you think you might be pregnant? Have you had sexual intercourse since your last period? Have you missed your period, been experiencing nausea or vomiting, or felt dizzy or tired? You may also be spotting or urinating more than usual. These can all be early signs of pregnancy. If you are having any of these symptoms you may want to get a pregnancy test. Even if it is the first time you had sex, you can still get pregnant. You can even get pregnant if you haven't had your very first period.

Get the Test

If you think you might be pregnant, you should get a pregnancy test. There are three ways to get a pregnancy test.

1. A lab test done by a health care provider to check for the pregnancy hormone in your urine or blood
2. A pelvic exam by a health care provider to check for any changes in the size of your uterus or changes in the color or softness of your cervix.
3. A home pregnancy test purchased in your local drug store. These tests are fairly good and are easy to use, but you should have a health care provider confirm your pregnancy just to be sure.

Don't wait to find out it you are pregnant. Early detection will offer you the time to make the decisions that are best for you.

Your Choices

If You Decide to Keep the Baby

Good care for yourself and the developing fetus is important soon after conception. Avoid using any drugs, alcohol, and smoking cigarettes because they can be harmful to the developing fetus. Prescription drugs and ones you can buy at the drugstore should be checked by a health care provider to see if they will harm the fetus. Even aspirin can be harmful.

If you are under 16 or over 40 years old, or have health problems like diabetes, kidney disease, or high blood pressure, pregnancy could put you at risk. You may need special care.

Your relationship with the father, your health, and your emotional and financial resources are all affected by having a child. Decisions about these concerns and getting married or single parenthood are important. There are resources for financial, medical, and counseling assistance. Call the Community Information Line (206-461-

320) Community Obstetric Referral Line (206-452-3820), Public Health of Seattle-King County (206-296-4600), or Planned Parenthood (206-328-7700). These are just a few of the many resources available to you.

Adoption
A woman may choose to continue the pregnancy and place the child for adoption. There are many couples looking for a baby to adopt. Adoption agencies are available in King County. Look under 'Adoption' in your local phone book or 'Family Planning Services' for more information. Some agencies provide financial and medical assistance during pregnancy and birth.

In King County, both birth parents of the newborn have the same rights and they both need to sign papers for consent of the adoption. In some cases, the father is not known and a special legal procedure is required to cover for the father's signature. This procedure is not common. Also, open adoption where you can select the adoptive family is possible.

Abortion
You may choose to end the pregnancy with an abortion. Abortion is much easier and safer if done early in the pregnancy (7 to 11 weeks). An early abortion is done in a clinic or doctor's office. It takes about a half hour, with about one hour of recovery time. Abortion requires minor surgery, so there is a slight chance of a problem. But it is safer than getting a shot of penicillin or continuing the pregnancy.

Information about abortion services is available from your health care provider. The price and procedure of the abortion will depend on the stage of the pregnancy.

Cost
In Washington State, medical coupons pay for abortion as well as prenatal care. In adoption, costs are often covered by the adoptive parents.

If the Test Is Positive
Do you want to be pregnant? Depending on your situation, you may want to be pregnant, or you may be faced with an unintended pregnancy.

You may have mixed feeling about being pregnant. Parenthood is a big responsibility. Discussing it with someone you trust can help you sort out your feelings. You might want to share your thoughts and feelings with your partner, parents, close relatives, or a good friend. There are also family agencies, health organizations, social workers, and community counselors available for you to call. They can help you understand all of your choices. If you need special care, they can direct you to the best place for you. Don't panic and take immediate action before exploring all of your choices, but also don't ignore the fact that you are pregnant.

If the Test Is Negative
If you are not pregnant but had a close call, don't risk another pregnancy until you are ready to be a parent. It is your choice whether or not to have sexual intercourse. If you decide to have sex again, use a good method of birth control. Most places that give pregnancy tests also have information about different types of birth control like the pill,

condom, IUD, injection, implants, diaphragm, foam, and fertility awareness. If your birth control method failed, consider changing to another method. Information on new methods and possibly more effective methods are also available.

If you feel that you are having trouble becoming pregnant, ask your health care provider for information about infertility services (testing, treatment, referral).

Public Health Seattle & King County
Family Planning Program

Semen Analysis Instructions, Directions and Costs

What should I do before the test?
The first thing you should do is call the Urology Male Fertility Laboratory at the University of Washington Medical Center at 206-543-4767, to make an appointment with the laboratory. Abstain (do not have intercourse or masturbate) for at least two days before the test but for no more than five days, as this may change your results. Prolonged fever or hot tub use should be reported to the lab, as these may affect your sperm.

Where is the testing done?
For the best and most accurate results, you will be given a specimen cup when you arrive for your appointment at the laboratory, and the cup will collected as soon as you have given a sample. Your wife or partner is welcome to accompany you to the laboratory's collecting room as long as the sample is only obtained by manual friction and the following guidelines are observed:

- Do not use a condom
- Do not use lubricants (including saliva)
- Do not collect specimen with the aid of a partner as vaginal fluid changes test results

If you cannot give a sample at the lab, you MUST follow these steps:

- Use a sterile urine specimen cup that has been approved by the lab for specimen collection.
- It is IMPERATIVE that the sample arrives at the lab no later than 30 minutes since you gave the sample.
- If you lost much of your sample, it may be necessary to reschedule your appointment.

What should I bring with me to the laboratory?
Bring the following information with you to your appointment:

- Hospital ID number (if University Hospital patient)
- Provider's name and address for results
- Number of days since abstinence
- Medications taken (if any) and number of days since your last fever or hot tub use

- Your billing address

When can I get my results?
Your provider will be mailed the results about two weeks after the exam. You will need to talk with her or him about your results.

How will I be billed?
Your bill will be sent to you by the Community Services of University of Washington Laboratory Medicine, not the hospital itself, and will be mailed to your billing address approximately three weeks after the exam.

DIRECTIONS TO THE LABORATORY
AND COMMON TEST COSTS ARE ON THE BACK

Direction to the University of Washington Medical Center

Male Fertility Laboratory
UW Department of Urology
1959 NE Pacific Avenue
Seattle, WA 98195

From I-5 heading North or South
Take the 45th/50th Street exit (#169)
Turn east on 45th Street
Drive approximately 8 blocks to 15th Ave., then take a right
Drive approximately 6 blocks to Pacific Ave.
Turn left. The hospital is approx. 3 blocks down the road on your right (see below for parking)

Parking at University Hospital
Parking is available at the Triangle Parking Garage
After taking a left onto Pacific Ave. as mentioned above, stay in the left-hand lane of traffic.
At the next intersection, take the left turn (towards the stadium)
Just past the bus stop, turn right into the garage.

Using Public Transportation
Take either bus #44 or #48
Both of these drop you off in front of the hospital (on Pacific Ave.)

Directions to the Urology Laboratory
From in front of the hospital (on Pacific) go up the stairs west (right side) of the bus stop.
Follow the sidewalk under the red brick arch to the doors.
Go to the BB elevators just inside the doors. Go up to the 11th floor.
The room number is BB1112
The lab is the third door on the left.

Test Costs

General Andrology Analysis	2001
Semen Analysis (including Morphology)	$9.00
Computerized Sperm Motility Enhancement	$40.00
Cervical Mucous Penetration Test	$6.00
Sperm Morphology	$3.00
Sperm Live/Dead Stain	$10.00
Sperm Antibody Test	$12.00
Sperm Penetration Assay	$300.00-$65.00
Insemination Preparation of Sperm	$5.00-$8.00
Post-vasectomy Check	$9.00

Sperm Freezing	
Cryopreservation of Semen plus 1 year of storage	$55.00
Storage of Cryopreserved Sperm (annual)	$12.00

Sleeping Advice

Over the past century, Americans have reduced their average nightly time for sleeping by more than 2%. Approximately 100 million individuals routinely fail to get enough sleep. Many Americans are severely sleep deprived and dangerously sleepy during the day. Insomnia tends to occur more frequently in women than in men and often worsens with age. With increasing age, women may report more difficulty falling asleep as well lighter sleep and with more frequent awakenings.

Sleep hygiene Sleep hygiene is a term used to describe recommendations to help individuals enhance their sleep environment and to facilitate sleepiness. These suggestions include:

- Avoid clock watching – put your alarm clock where you can hear the alarm but not see the clock. If you awaken at night, dont look at the clock.
- Dont "try" to sleep – the harder you try the more awake youll become.
- Re-evaluate your work schedule. Avoid nightshift work if possible.
- http://www.sleepnet.com is a good resource.
- Control your sleep environment – design your bedroom for sleeping, regulate the room temperature to keep the room cool and make it a quiet and dark place.
- Establish a consistent sleep schedule – going to bed and getting up at the same time, regardless of nocturnal awakenings – even on weekends.
- Eliminate daytime naps – or at least limit them to no more than an hour.
- Reserve the bed for sleeping and sex – activities such as reading, eating, watching television, paying bills, etc., can be stimulating and lead to an association of wakefulness with the bedroom.
- Limit or give up foods or liquids that can interfere with sleep – as few as two cups of coffee per day can be stimulating, and can make it difficult to fall asleep. Large quantities of liquids ingested at bedtime can increase nocturnal urine output and cause awakening.
- Avoid or limit alcohol – while alcohol may initially be relaxing, it can result in fragmented sleep. Elderly patients are particularly sensitive to the effects of alcohol wakefulness a few hours later and it can result in an increase in snoring and, in some cases, sleep apnea.
- Exercise regularly – Done at the right time, exercise can relieve tension. Exercising too late in the day can over-stimulate the body, raise the body temperature and make it difficult to fall asleep.
- Establish a relaxing before-bed ritual – winding down with relaxing activities such as reading, taking a warm bath, or listening to music can create a transition for mind and body; such activities serve to transfer the individual from the stimulations of the day into a state of sleep readiness.

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TESTICULAR SELF-EXAMINATION

Testicular cancer is the most common type of cancer in men ages 20 to 35. Yet, because it accounts for only about 1 percent of all cancers in men, many people have never heard of this type of cancer.

Testicular cancer is of special concern to young men. It can occur anytime after age 15. It is less common in middle-aged and older men. White men are four times more likely to develop testicular cancer than black men. The rate among Hispanic men is between that of blacks and whites.

Two groups of men have a greater risk of developing testicular cancer - those whose testicles have not descended into the scrotum and those whose testicles descended after age 6. Testicular cancer is 3 to 17 times more likely to develop in these men.

Testicles are male reproductive organs. They produce and store sperm. They also produce testosterone, a hormone that causes such male traits as facial hair and lower voice pitch. Testicles are, oval-shaped, and somewhat firm to the touch. They are below the penis in a sac of skin called the scrotum. The testicles normally descend into the scrotum before birth. Parents should have their infant sons examined by a provider to be sure that the testicles have properly descended. If they have not, this can be easily corrected with surgery.

Years ago, testicular cancer was often fatal because it spread quickly to vital organs such as the lungs. Today, due to advances in treatment, testicular cancer is one of the most curable cancers, especially if detected and treated promptly.

SYMPTOMS

The most common symptom of testicular cancer is a small, painless lump in a testicle or a slightly enlarged testicle. It is important for men to become familiar with the size and feeling of their normal testicles, so that they can detect changes if they occur.

Other possible symptoms include a feeling of heaviness in the scrotum, a dull ache in the lower stomach or groin, a change in the way a testicle feels, or a sudden accumulation of blood or fluid in the scrotum. These symptoms can also be caused by infections or other conditions that are not cancer. A provider can tell you if you have cancer and what the proper treatment should be.

HOW TO DO TESTICULAR SELF-EXAMINATION

A simple procedure called testicular self-exam (TSE) can increase the chances of finding a tumor early.

Men should perform TSE once a month – after a warm bath or shower. The heat causes the scrotal skin to relax, making it easier to find anything unusual. TSE is simple and only takes a few minutes:

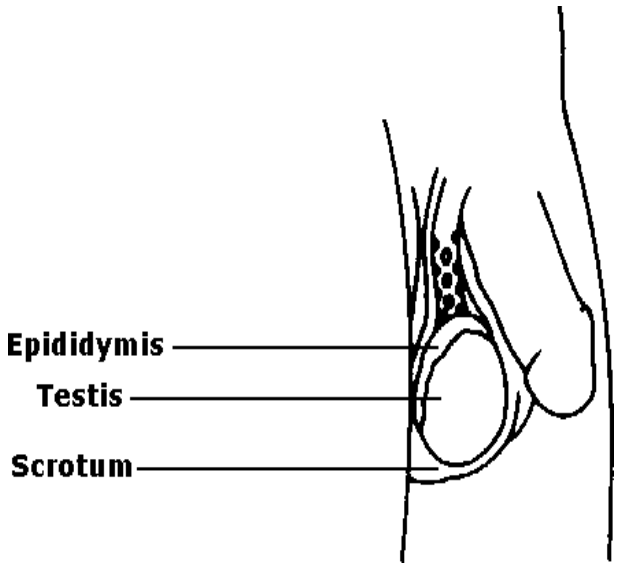
- Examine each testicle gently with both hands. The index and middle fingers should be placed underneath the testicle while the thumbs are placed on the top. Roll the testicle gently between the thumbs and fingers. One testicle may be larger than the other. This is normal.

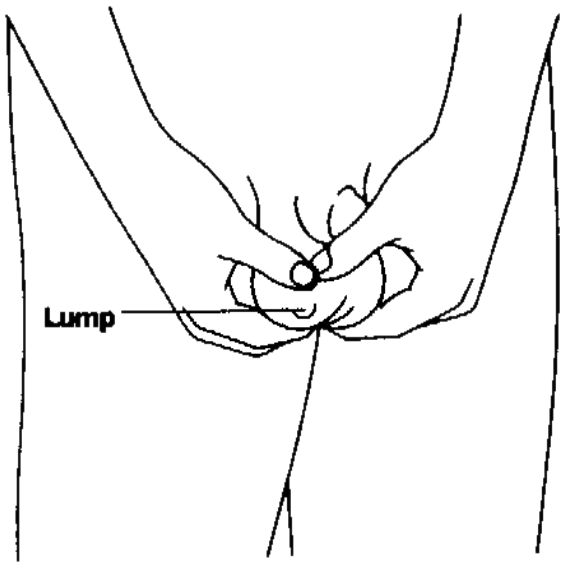
- The epididymis is a cord-like structure on the top and back of the testicle that stores and transports the sperm. Do not confuse the epididymis with an abnormal lump.

- Feel for any abnormal lumps – about the size of a pea – on the front or the side of the testicle. These lumps are usually painless.

If you do find a lump, you should contact your provider right away. The lump may be due to an infection, and your provider can decide the proper treatment. If the lump is not an infection, it is likely to be cancer. Remember that testicular cancer is highly curable, especially when detected and treated early. Testicular cancer almost always occurs in only one testicle, and the other testicle is all that is needed for full sexual function.

Routine testicular self-exams are important, but they cannot substitute for a doctor's examination. Your provider should examine your testicles when you have a physical exam. You also can ask your provider to check the way you do TSE.





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Trichomonas

What Is It?

Trichomonas is a small organism (protozoan) that can cause an infection of the vagina or male urethra (the passage for urine through the penis). Symptoms usually start about 7 days after having sex with an infected person. Both men and women can have trichomonas, but it is only diagnosed in women. It usually does not affect the uterus or fallopian tubes.

Symptoms

Women may often have a discharge from the vagina, which may smell fishy or different. They may also have burning, itching, or soreness around the vagina. Some women have no symptoms. Men usually have no symptoms. If they do, it is usually a slight discharge from the penis or mild pain when passing urine.

Diagnosis & Treatment

Your health care provider usually can tell if you have a trichomonas infection by examining a sample of the discharge from your vagina under a microscope. If you have a trichomonas infection you will be given a medicine called metronidazole (Flagyl) to take at the clinic. Do not drink any alcoholic beverages for 24 hours before or after taking the medicine because the mixture of alcohol and metronidazole may make you sick.

Talking With Your Partner

Be sure anyone you had sex with in the past month is examined and treated.

Some people feel embarrassed, scared or angry when they or their partner has a sexually transmitted disease (STD). This is common and is OK. Do not let these feelings stop you from getting medical help or telling your partner. Remember anyone who is sexually active can get an infection. Talk with your partner as soon as possible. If left untreated an infection could get worse and can be spread to anyone who you or your partner has sex with. Tell your partner or past sexual contacts to see their health care provider because they need to be treated.

Follow-Up

Do not have sex until you and your partner have been treated. If you continue to have symptoms after the treatment is finished, call your health care provider.

Prevention

The only sure way to avoid getting trichomonas or other infections is to not have sex. If you decide to have sex, you can reduce your risk.

- Have sex with one person who has sex only with you.
- Use a male condom (rubber) or a female condom when you have sex.
- Look at your partner's genitals before you have sex. If you see any sores, rashes, or discharge, talk to your partner. Do not have sex until he/she has been examined and treated.
- Alcohol and drugs decrease your ability to make clear decisions about your sexual behavior.

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The Contraceptive Vaginal Ring

What exactly is the Ring?

The Ring (NuvaRing) is a flexible, 2 inch diameter and 1/8 inch in thickness plastic ring that goes into your vagina. The Ring releases a progestin (etonogestrel) and an estrogen like the birth control pill. The Ring is left in the vagina for 21 days and then removed and disposed of, you then have a ring free week to have a period.

How effective is the Ring?

The Ring is as effective as the Pill. The Ring prevents the release of an egg and makes it hard for sperm to enter the uterus. When you wear your Ring 24 hours a day then the Ring gives you over 99% protection against pregnancy. Start the Ring on day 5 of your period because sometimes changing a tampon can accidentally pull out the Ring. The Ring still works with a tampon. You will not be protected from pregnancy until the Ring has been in place for 7 days that first month.

If the Ring is monthly, do I have to put it in on exactly the same day?

Yes, this is the best habit. But if you are 1 week late you are still protected as long as you put the new Ring in right away and wear the new Ring for a full 7 days. Never go more than 7 days without putting a Ring in your vagina. Putting a sticker on the calendar can help you remember when the 21 days are up. To help remember the day, some women may decide to put the new Ring in on day 1 of every month, remove it on day 21 of every month for a period time, and then place a new Ring on the 1st of the month.

How is the Ring used?

Place the Ring in the vagina. As long as it is in the vagina it is in the right place. If you can feel it, then it has slipped down and just push back in with a finger. Wear the Ring for 21 days and then remove it. Place the used Ring in to the foil packet it came in, seal it up, and then throw in the trash and not into the water system or toilet. Put a new Ring in after a Ring free week of no more than 7 days. Put the new Ring in even if you are still having your period bleeding.

What happens if the Ring falls out or I want to take it out?

The Ring must be in your vagina for it to work and if it has been out for more than 3 hours then use a backup method of contraception like condoms for 7 days. You can gently wash the Ring with soap and warm water but never freezing, boiling, or hot water as these extreme temperatures could ruin the ring.

Who should not use the Ring?

Women who think they may be pregnant, or women with blood clots, chest pains, certain cancers, unexplained vaginal bleeding, or a history of liver disease, stroke, or heart attacks should not use the Ring. If a woman wants to skip her periods then the Ring can be worn all month with a new Ring placed every month with no Ring free week. Skipping periods is not approved and has not been studied with the Ring but it is likely it would work although irregular bleeding might happen at first. Just like all hormonal contraceptives, the Ring does not protect against HIV and other sexually transmitted diseases. Only abstinence, the female condom, or the male condom can help protect you.

What about side effects?

During the first few months of using the Ring, most women will have a change in their periods, which may include no bleeding, irregular bleeding, or spotting. Sometimes women can have more vaginal wetness while wearing the Ring. Women may also have breast tenderness or nausea with the Ring, but usually this get better after 3 months. It is important to call or see your clinic before stopping the Ring; they might be able to help make your problem better.

What about when I want to get pregnant?

Upon stopping the Ring, most women start ovulating (making an egg or having regular periods) soon after stopping the Ring. Some women start ovulating with the very next cycle before even having a period, so you need to be prepared immediately for the possibility of pregnancy.

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Yeast Infection

What Is It?

Yeast is a fungus that is commonly present in the vagina in small quantities. This is not the same kind of yeast used in cooking. Yeast causes problems only when the number of organisms increase above normal amounts. This can happen when a woman takes antibiotics, gets pregnant, or has diabetes. Using perfume or too much soap on the genital area or excessive moisture from nylons, bathing suit, or tight clothing can all also increase the chance of yeast infection. The infection does not affect the uterus and fallopian tubes or hurt your ability to become pregnant. Yeast is usually not passed by sex.

Symptoms

Women may have itching, redness, and irritation around the vagina and vulva, and sometimes a thick curd-like white discharge. Men occasionally may have a rash or irritation on the penis when their partner has yeast in the vagina.

Diagnosis & Treatment

Your health care provider can tell if you have a yeast infection by doing a genital exam and looking at a sample under a microscope. Getting an exam to find out what is wrong is very important because other infections like herpes can have the same symptoms as a yeast infection. You may need other tests to make sure the symptoms are from yeast and not something else.

If you have a yeast infection, you will be given a medicine to put in your vagina and on the rash. You can also buy these medicated creams from the grocery store or pharmacy. Clotrimazole, miconazole, and butaconazole can all kill or reduce the number of yeast organisms. Use the medicine at bedtime after lying down if you use the inserter for your vagina or you can just apply the cream to where it feels sore. Be sure to use the medicine until it is either all gone or the symptoms are gone. If the medication causes severe burning or discomfort or do not get better after 3 to 5 days, call the clinic. Sometimes a pill called fluconazole or diflucan is given that is taken orally to treat a yeast infection. You may wish to stop having sexual intercourse, for your own comfort, until the symptoms have gone away.

Follow-up

If you still have symptoms after finishing the treatment, call the clinic. You may need another exam to make sure you have yeast and not a different problem. If you have diabetes in your family and you have a lot of problems with yeast infections, you should have a test for diabetes.

Prevention

To help prevent new yeast infections, wear loose clothing and cotton underwear to stay dry, do not sleep in your underwear, and avoid too much soap or chemicals on your vulva.