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July 15, 2008

TO: FAMILY PLANNING, ACCESS, CARE, AND TREATMENT  
(PACT) PROVIDERS

SUBJECT: FAMILY PACT PROGRAM LETTER 08-01, FAMILY PACT *CLINICAL PRACTICE ALERTS*:

- UPDATE: MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY
- CONTRACEPTION FOR WOMEN WITH CHRONIC MEDICAL CONDITIONS
- IMPLANON™ CONTRACEPTIVE IMPLANT

The Office of Family Planning issues *Clinical Practice Alerts* to provide guidance to Family PACT providers on current clinical and programmatic issues. The three enclosed *Clinical Practice Alerts* have been developed to provide state-of-the-art information on the following topics:

- Management of abnormal cervical cytology and biopsies, adapted from the Association for Colposcopy and Cervical Pathology (ASCCP) 2006 guidelines
- Contraceptive management of women with chronic medical conditions, based upon the 2004 “Medical Eligibility Criteria for Initiating Contraceptive Methods,” developed by the World Health Organization
- The newly added contraceptive implant benefit, Implanon™.

Also note that the first two *Clinical Practice Alerts* are appended with helpful tables that summarize recommended clinical management in an easily accessible format. You are encouraged to share this information with all of the clinicians in your practice that provide clinical care to Family PACT clients.

*Clinical Practice Alerts* provide an interpretation of the Family PACT Program Standards. Providers should refer to the *Policies, Procedures, and Billing Instructions* manual for the complete text of the standards, official administrative practices, and billing information. For the purposes of this and other *Clinical Practice Alerts*, the term “shall” indicates a program requirement while the term “should” is advisory and not required.

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Additional copies of these documents and resources such as the Family PACT Benefit Grid and Clinic Dispensed Drugs and Supply Update can be downloaded from our Web site at: [www.familypact.org](http://www.familypact.org). If you have questions or comments regarding these *Clinical Practice Alerts*, please contact Michael Policar M.D., M.P.H., Chair, Family PACT Clinical Practice Committee, at (916) 650-0424.

Thank you for participating in the Family PACT Program. We hope these *Clinical Practice Alerts* are useful to your practice.

Sincerely,

ORIGINAL SIGNED BY

Laurie Weaver, Chief  
Office of Family Planning

Enclosures

## UPDATE: MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY

Invasive cervical cancer is a preventable disease in large majority of women, as long as preinvasive cervical lesions are effectively detected and treated. The Family PACT Program has adopted the 2006 Consensus Guidelines of the American Society for Colposcopy and Cervical Pathology (ASCCP), which are included with this *Alert*.

### KEY POINTS

- The purpose of cervical cancer screening is the detection and treatment of high-grade squamous epithelial lesions (CIN 2, 3), adenocarcinoma precursors, and cervical cancers.
- Women with biopsy proven CIN 1 should be observed carefully and treated only if the lesion progresses to CIN 2, 3, is persistent for two years or more, or if the woman insists upon early treatment.
- An office-based tracking system should be used to ensure that women with abnormal cytology findings have been notified of their results and that those who are being followed are reminded of the need for return visits, tests, and procedures.
- The tables included in this *Alert* summarize the 2006 ASCCP Guidelines, but more comprehensive versions are listed as references. Since not all recommended interventions are Program benefits, please refer to the *Family PACT Policies, Procedures and Billing Instructions (PPBI)* for more information.

### QUESTIONS AND ANSWERS

#### What is the role of HPV-DNA testing in women under 21 years old?

The new guidelines emphasize that there is *no role* for HPV-DNA testing in women under 21 years old, since incident HPV infections are common and a positive test result would have no impact on client management. HPV infections in young women are likely to be transient and most will resolve quickly.

#### What is the preferred approach to managing ASC-US?

Adolescents with results of ASC-US or LSIL should have repeat cytology in one year, but not HPV testing or colposcopy. Consequently, in women under 21 years old, “reflex HPV tests for ASC-US” must **not** be ordered when submitting the Pap request to the laboratory. Women 21 years of age and older can be managed by either repeat cytology in six months, reflex HPV-DNA testing, or colposcopy.

#### Why aren't all women with CIN 1 treated with cryotherapy or LEEP?

Of women with CIN 1 lesions, fewer than 20 percent will develop a high grade lesion, with even lower progression rates in adolescents. For women 21 years and older, observation is recommended, with treatment only if the CIN 1 lesion progresses or persists for at least two years.

#### Should all women with CIN 2 or 3 be treated?

In general, the treatment for CIN 2 or 3 is cryotherapy or a LEEP procedure. However, the preferred treatment for adolescent and young women with CIN 2 and satisfactory colposcopy is observation, which consists of colposcopy plus cytology every six months for up to 24 months. If the colposcopic pattern worsens or a high grade lesion persists for more than 24 months from diagnosis, treatment is necessary.

#### What are the indications for colposcopy?

- Cytology result with ASC-H, HSIL, or suspicion of cancer
- Cytology with LSIL in a women  $\geq 21$  years old (unless pregnant or post-menopausal)
- Cytology with atypical glandular cells (AGC), unless AGC-atypical endometrial cells **and** positive endometrial sampling
- Cytology showing ASC-US in the following circumstances:
  - Women who are unwilling to return for frequent follow-up
  - Repeat cytology test with ASC-US or worse performed during observation period (except adolescents)
  - High-risk HPV-DNA present at initial or subsequent testing (except adolescents)
- Cervical leukoplakia (visible white lesion) or other unexplained cervical lesion regardless of cytology result
- Unexplained or persistent cervical bleeding regardless of cytology result

#### Why doesn't Family PACT pay for LEEP cone or “cold knife” cone biopsies?

Family PACT is a limited benefit family planning and sexually transmitted infection (STI) program. When a woman requires a medically necessary service and does not have other coverage, the California *Breast and Cervical Cancer Treatment Program (BCCTP)* may provide support. Family PACT providers can easily certify and enroll clients in the BCCTP via an internet application.

### PROGRAM POLICY

This Alert provides an interpretation of the Family PACT Standards for management of abnormal Cytology test results. Providers should refer to the Family PACT PPBI for the complete text of the Family PACT Standards, official administrative practices, and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term “shall” indicates a program requirement; the term “should” is advisory and not required.

## APPLICATION OF FAMILY PACT STANDARDS

### Application of Family PACT STANDARDS

Family PACT services include family planning methods, STI detection and management, and selected related reproductive health conditions. The detection and management of pre-cancerous and cancerous lesions of the cervix are considered to be part of the later category.

#### 1. Informed Consent

- Clients shall be advised of the availability of cervical cancer screening, diagnostic and limited management services.
- Clients should be informed of the recommended cervical cancer screening interval that applies to her individual circumstance.
- The consent process for cervical cancer screening, diagnostic, and treatment services shall be provided in a language understood by the client and supplemented with written materials.

#### 2. Access to Care

- Cervical cancer screening services shall be provided without cost to Family PACT clients at all clinical service sites.
- Diagnostic and limited treatment services for abnormal cytology are available under Family PACT, although each provider may determine whether these services will be provided on-site or by referral.
- Referral resources for medical and psychosocial services beyond the scope of Family PACT, including treatment for cervical conditions, shall be made available to clients. The BCCTP offers seamless service delivery to clients with high grade lesions and cervical cancer. Services not listed in the Family PACT PPBI are not reimbursable by the program.
- Family PACT providers that have completed a Medi-Cal POS Network/Internet agreement can access the BCCTP Enrollment Application at [www.medi-cal.ca.gov](http://www.medi-cal.ca.gov) and using the BCCTP link and their national provider identifier (NPI) and PIN to certify and enroll clients needing services beyond the scope of Family PACT.

#### 3. Availability of Covered Services

- Family PACT Program benefits include a routine cytologic screening as often as once a year, although clients may choose to have cytology tests less frequently once informed of the guideline.
- Screening for cervical abnormalities as listed in the PPBI shall be made available to clients as a condition of delivering services under Family PACT.
- Clients with cervical abnormalities may receive diagnostic and limited treatment services on-site or through referral as defined in the PPBI.

#### 4. Scope of Clinical and Preventive Services:

- Clinicians delivering services under Family PACT shall have professional knowledge and skills about medical practice standards pertaining to cervical cancer screening, management of abnormal results, and treatment.
- Cervical cancer screening is **NOT** required prior to the provision of contraception.
- The treatment of cervical cytologic abnormalities should be consistent with the *American Society for Colposcopy and Cervical Pathology, Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities*.
- Providers should have an office-based tracking system for all cytology tests, to insure that all results are evaluated, women with cytologic abnormalities are notified, and those who are observed are reminded of their need for follow-up.
- Documentation in medical record shall include clinical findings and justification for services.

#### 5. Education and Counseling Services

- Clients shall receive education on protecting their reproductive health and plans for future pregnancy.
- Individual education and counseling should be provided for all women to inform them of cytology periodicity and the significance and management of abnormal cytology results.

## RESOURCES FOR INFORMATION ON CERVICAL ABNORMALITIES

- Breast and Cervical Cancer Treatment Program (BCCTP), at [www.medi-cal.ca.gov](http://www.medi-cal.ca.gov) or call (800) 824-0088
  - Cancer Detection Services: Every Woman Counts (EWC), at [www.dhs.ca.gov/cancerdetection](http://www.dhs.ca.gov/cancerdetection) or call (800) 511-2300
- \* Women not at risk for pregnancy are ineligible for Family PACT but may be eligible for services through BCCTP or EWC.

## REFERENCES

1. Wright TC, Massad S, et al. 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ. *Am J Obstet Gynecol* 2007,197(4):340-345. Access at:
  - <http://www.asccp.org/consensus/histological.shtml>
  - <http://ajog.org/article/PIIS0002937807009337/fulltext>
2. Wright TC, Massad S, et al. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. *Am J Obstet Gynecol* 2007, 197(4):346-355. Access at:
  - <http://www.asccp.org/consensus/cytological.shtml>
  - <http://ajog.org/article/PIIS0002937807009301/fulltext>
3. Davey D, et al. Cervical cytology specimen adequacy: Patient management guidelines and optimizing specimen collections. *J Lower Genital Tract Disease* 2008; 12(2):71-83.

**Family PACT Abnormal Cytology Test Guidelines**

| <b>Cytology Finding</b>  | <b>Action</b>   |
|--|---|
| <b>Specimen adequacy</b>   |   |
| Unsatisfactory for evaluation <sup>3</sup>   | <ul style="list-style-type: none"> <li>Repeat cytology in two to four months.</li> </ul>  |
| Satisfactory, negative for SIL, but limited by...few (scant) endocervical cells <sup>3</sup> | <ul style="list-style-type: none"> <li>Repeat cytology at six months if unable to clearly visualize the cervix or sample the endocervical canal, previous Pap smear with glandular abnormality, similar obscuring factor in last Pap, a previously abnormal Pap without adequate follow up, a positive HPV-DNA test within the past year, or insufficient previous screening.               <ul style="list-style-type: none"> <li>Otherwise, repeat cytology in one year.</li> </ul> </li> <li>If practice-wide rate is <math>\geq 15</math> percent, discuss remediation with cytopathologist.</li> </ul>   |
| <b>Organisms</b>   |   |
| Trichomonas vaginalis  | <ul style="list-style-type: none"> <li>If recently treated, no further evaluation is necessary.               <ul style="list-style-type: none"> <li>If not, notify patient and offer <i>either</i> presumptive treatment or confirmatory testing.</li> </ul> </li> <li>Finding may indicate presence of other STIs, although long term colonization also is possible.</li> <li>Unless unsatisfactory, repeat cytology at scheduled screening interval.</li> </ul>  |
| Fungal organisms morphologically consistent with Candida spp                                 | <ul style="list-style-type: none"> <li>Usually due to asymptomatic Candidal colonization.</li> <li>No action is necessary; patient notification is optional.</li> <li>Unless unsatisfactory, repeat cytology at scheduled screening interval.</li> </ul>  |
| Shift in flora suggestive of bacterial vaginosis (BV)  | <ul style="list-style-type: none"> <li>Poor correlation with clinical diagnosis of BV.</li> <li>If recently treated, no further evaluation is necessary.               <ul style="list-style-type: none"> <li>If not, patient notification is optional. If notified, offer confirmatory evaluation</li> </ul> </li> <li>Repeat cytology at scheduled screening interval.</li> </ul>   |
| Bacteria consistent with Actinomyces   | <ul style="list-style-type: none"> <li>In IUC user, rarely associated with pelvic actinomycosis.</li> <li>To evaluate, perform pelvic exam or refer for gynecologic consultation.               <ul style="list-style-type: none"> <li>If negative pelvic exam, IUC removal is not required and there is no evidence of benefit of antibiotic therapy.</li> </ul> </li> </ul>   |
| Cellular changes consistent with herpes simplex virus  | <ul style="list-style-type: none"> <li>Strongly suggestive of herpes simplex viral shedding.</li> <li>If herpes diagnosis is in medical record, patient notification is optional.               <ul style="list-style-type: none"> <li>If not, notify patient of result. Direct tests for herpes virus (culture, DFA) are not indicated.</li> <li>If the patient requests confirmation, a positive HSV type-specific serology will confirm prior infection (not a Family PACT benefit).</li> </ul> </li> <li>Finding may indicate presence of other STIs, although long standing HSV infection also is possible.</li> <li>Repeat cytology at scheduled screening interval.</li> </ul> |
| <b>Other non-neoplastic findings</b>   |   |
| Reactive changes associated with (severe) inflammation <sup>3</sup>                          | <ul style="list-style-type: none"> <li>May be due to GC, Ct, trichomonas, viruses, irritants, (very rarely) cancer.</li> <li>If recent GC, Ct tests were negative, no further STI evaluation is necessary.               <ul style="list-style-type: none"> <li>If not recently screened, notify patient and offer GC, Ct testing.</li> <li>Do not presumptively treat with topical or oral antibiotics.</li> </ul> </li> <li>If unexplained inflammation, repeat cytology in 6-12 months.</li> <li>If <i>persistent unexplained</i> inflammation, consider colposcopic evaluation.</li> </ul>  |
| Reactive changes associated with intrauterine contraception                                  | <ul style="list-style-type: none"> <li>No action is necessary</li> <li>Patient notification is unnecessary</li> <li>Repeat cytology at scheduled screening interval</li> </ul>  |
| Atrophy  | <ul style="list-style-type: none"> <li>No action is necessary</li> <li>Patient notification is unnecessary</li> <li>Repeat cytology at scheduled screening interval</li> </ul>  |
| Benign endometrial cells (including stromal cells or histiocytes)                            | <ul style="list-style-type: none"> <li>For post-menopausal women, endometrial assessment is recommended (<i>not a Family PACT benefit</i>).</li> <li>For premenopausal women:               <ul style="list-style-type: none"> <li>No action is necessary</li> <li>Patient notification is unnecessary</li> </ul> </li> <li>Repeat cytology at scheduled screening interval</li> </ul>  |

**Family PACT Abnormal Cytology Test Guidelines:** Adapted from: ASCCP 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests.

| Finding   | Initial Intervention  | Next step   | Following step  |
|---|---|---|---|
| <b>ASC-US</b><br>Women ≥21 years old<br><br>OR<br><br><b>LSIL</b><br><i>Post-menopausal</i><br>Women (not eligible for Family PACT) | <ul style="list-style-type: none"> <li>Repeat cytology @ 6 mos</li> </ul>   | <ul style="list-style-type: none"> <li>Negative: repeat cytology @ 6 mos - - →</li> <li>≥ASC: colposcopy</li> </ul>   | <ul style="list-style-type: none"> <li>Negative: routine screening</li> <li>≥ASC: colposcopy</li> </ul>   |
|   | OR<br><ul style="list-style-type: none"> <li>HPV DNA testing (reflex test)</li> </ul>   | <ul style="list-style-type: none"> <li>Negative: repeat cytology @ 12 mos - →</li> <li>Positive: colposcopy</li> </ul>  | <ul style="list-style-type: none"> <li>Negative: routine screening</li> <li>≥ASC: colposcopy</li> </ul>   |
|   | OR<br><ul style="list-style-type: none"> <li>Colposcopy (with ECS*)</li> </ul>  | <ul style="list-style-type: none"> <li>No CIN, HPV pos: cytology @ 6 &amp; 12 mos or HPV testing @ 12 mos - - - →</li> <li>No CIN, HPV unkn: cytology @ 12 mos →</li> <li>CIN: per ASCCP CIN guideline</li> </ul>   | <ul style="list-style-type: none"> <li>Negative: routine screening</li> <li>≥ASC or HPV (+): repeat colposcopy</li> </ul>   |
| <b>ASC-US</b><br>OR<br><b>LSIL</b><br><i>Adolescents</i><br>Women ≤20 years old   | <ul style="list-style-type: none"> <li>Repeat cytology @ 12 mos</li> </ul>  | <ul style="list-style-type: none"> <li>&lt;HSIL: repeat cytology @ 12 mos later →</li> <li>≥HSIL: colposcopy</li> </ul>   | <ul style="list-style-type: none"> <li>Negative: routine screening</li> <li>≥ASC: colposcopy</li> </ul>   |
| <b>ASC-H</b>  | <ul style="list-style-type: none"> <li>Colposcopy</li> </ul>  | <ul style="list-style-type: none"> <li>No CIN 2,3: cytology @ 6 &amp; 12 mos or HPV testing @ 12 mos - - - - →</li> <li>CIN 2,3: per ASCCP CIN guideline</li> </ul>   | <ul style="list-style-type: none"> <li>Negative: routine screening</li> <li>≥ASC or HPV (+): colposcopy</li> </ul>  |
| <b>LSIL</b><br>Women ≥21 years old, not pregnant  | <ul style="list-style-type: none"> <li>Colposcopy (with ECS*)</li> </ul>  | <ul style="list-style-type: none"> <li>No CIN: cytology @ 6 &amp; 12 mos or HPV testing @ 12 mos - - - - - →</li> <li>CIN/cancer: per ASCCP CIN guideline</li> </ul>  | <ul style="list-style-type: none"> <li>Negative: routine screening</li> <li>≥ASC or HPV (+): colposcopy</li> </ul>  |
| <b>LSIL</b><br><i>Pregnant women</i><br>(Not eligible for Family PACT)  | <ul style="list-style-type: none"> <li>Colposcopy</li> </ul> OR<br><ul style="list-style-type: none"> <li>Defer colposcopy ≥6 wks post-partum</li> </ul>  | <ul style="list-style-type: none"> <li>No CIN 2,3: post-partum follow-up</li> <li>CIN 2,3: per ASCCP CIN guideline</li> </ul>   |   |
| <b>HSIL</b><br>Women ≥21 years old  | <ul style="list-style-type: none"> <li>Immediate LEEP (if CIN 2, 3 likely)</li> </ul> OR<br><ul style="list-style-type: none"> <li>Colposcopy with ECS*</li> </ul> <p><b>NOTE:</b> <i>Immediate LEEP is not a Family PACT benefit</i></p>   | <ul style="list-style-type: none"> <li>No CIN 2,3</li> <li>Unsatisfactory: DEP**</li> <li>Satisfactory (either):                             <ul style="list-style-type: none"> <li>Colposcopy + cytology at 6 mo intervals for 1 yr - - - - - →</li> <li>Pathologist review</li> <li>DEP**</li> </ul> </li> <li>CIN 2,3: per ASCCP CIN guideline</li> </ul>  | <ul style="list-style-type: none"> <li>Negative cytology x2: routine screening</li> <li>HSIL: DEP**</li> <li>Other results: per ASCCP CIN guideline</li> </ul> <p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>If no cervical lesion, evaluate for VaIN with Lugol's solution</li> </ul> |
| <b>HSIL</b><br><i>Adolescents</i><br>Women ≤20 years old  | <ul style="list-style-type: none"> <li>Colposcopy</li> </ul> <p><b>Immediate LEEP is unacceptable in this age group</b></p>   | <ul style="list-style-type: none"> <li>CIN 2,3: per ASCCP CIN guideline</li> <li>No CIN 2,3: colposcopy + cytology @ 6 mo intervals for up to 2 yrs - - - →</li> </ul>  | <ul style="list-style-type: none"> <li>Two consecutive negative cytologies and no HG colposcopic abnormality: routine screening</li> <li>HSIL cytology persists for 1 yr: biopsy</li> <li>HSIL cytology persists for 2 yrs: DEP**</li> <li>Other: ASCCP CIN guideline</li> </ul>                    |
| <b>AGC: Atypical endometrial cells</b>  | <ul style="list-style-type: none"> <li>Endometrial biopsy + ECS* (in all cases)</li> </ul>  | No endometrial pathology: colposcopy  |   |
| <b>AGC: All other sub-categories</b>  | <ul style="list-style-type: none"> <li>Colposcopy + ECS*</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>HPV testing</li> </ul> <p><b>AND</b></p> <ul style="list-style-type: none"> <li>Endometrial sampling (if ≥35 yo or at risk for endometrial neoplasia)</li> </ul> | <ul style="list-style-type: none"> <li>Cytology = AGC-favor neoplasia or AIS: DEP**</li> <li>Cytology = AGC-not specified (NOS):                             <ul style="list-style-type: none"> <li>Bx = CIN or AIS: per ASCCP guideline</li> <li>No CIN and No AIS:                                     <ul style="list-style-type: none"> <li>HPV neg: cytology+HPV in 12 mos - - - - - →</li> <li>HPV pos: cytology+HPV in 6 mos →</li> <li>HPV status unknown: cytology @ 6 mo intervals 4 times - - - - - →</li> </ul> </li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>All tests negative: routine screening</li> <li>&gt;ASC or HPV pos: colposcopy</li> </ul>   |

\* ECS = endocervical sampling in non-pregnant women, either with endocervical curettage or cervical brush  
 \*\* DEP = diagnostic excisional procedure, e.g., LEEP cone or cold-knife cone biopsy (*not Family PACT benefits*)

**Family PACT Abnormal Cervical Histology Guidelines:** Adapted from: ASCCP 2006 consensus guidelines for the management of women with cervical intraepithelial neoplasia or adenocarcinoma in situ.

| Biopsy Finding   | Initial Intervention   | Next step  | Following step  |
|--|--|--|---|
| <b>CIN 1</b><br><i>Preceded by ASC-US, ASC-H, or LSIL cytology</i> | Follow-up without treatment:<br><ul style="list-style-type: none"> <li>• Cytology every 6 mos twice - - - - - →</li> </ul> OR<br><ul style="list-style-type: none"> <li>• HPV-DNA test @ 1 yr - - - - - →</li> </ul>   | <ul style="list-style-type: none"> <li>• Negative: routine screening</li> <li>• ≥ASC: colposcopy - - - - - →</li> </ul><br><ul style="list-style-type: none"> <li>• Negative: routine screening</li> <li>• Positive: colposcopy</li> </ul>   | <ul style="list-style-type: none"> <li>• No CIN or CIN 2,3: per ASCCP guideline</li> <li>• CIN 1 persists <i>for at least 2 yrs</i>: follow-up or treatment</li> </ul>  |
| <b>CIN 1</b><br><i>Preceded by HSIL or AGC-NOS cytology</i>        | <ul style="list-style-type: none"> <li>• DEP**</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Review findings with pathologist</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Observation with colposcopy + cytology @ 6 mos twice - - - - - →</li> </ul>      | <ul style="list-style-type: none"> <li>• 2x negative results: routine screening</li> <li>• HSIL: DEP**</li> </ul>  |   |
| <b>CIN 1</b><br><i>Adolescent women ≤20 years old</i>              | <ul style="list-style-type: none"> <li>• Repeat cytology @ 12 mos</li> </ul>   | <ul style="list-style-type: none"> <li>• &lt;HSIL: repeat cytology @ 12 mos - - - - - →</li> <li>• ≥HSIL: colposcopy</li> </ul>  | <ul style="list-style-type: none"> <li>• Negative: routine screening</li> <li>• ≥ASC: colposcopy</li> </ul>   |
| <b>CIN 2,3</b>   | <ul style="list-style-type: none"> <li>• Unsatisfactory colposcopy or recurrent CIN 2,3: DEP**</li> <li>• Satisfactory colposcopy: ablate or excise T-zone</li> </ul>  | <p><b>Follow up all clients with either:</b></p> <ul style="list-style-type: none"> <li>• HPV DNA @ 6-12 mos after treatment - - - - - →</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Cytology @ 6 mo intervals →</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Cytology + colposcopy @ 6 mo intervals - - - - - →</li> </ul> | <ul style="list-style-type: none"> <li>• HPV negative: routine screening for ≥20 yrs</li> <li>• HPV positive: colposcopy with ECS*</li> </ul><br><ul style="list-style-type: none"> <li>• 2x negative results: routine screening for ≥20 yrs</li> <li>• ≥ASC: Colposcopy with ECS*</li> </ul> |
| <b>CIN 2,3</b><br><i>Adolescent and young women</i>                | <ul style="list-style-type: none"> <li>• Ablate or excise T-zone (preferred for CIN 3 or unsatisfactory colposcopy)</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Observation with colposcopy + cytology every 6 mos for up to 24 mos (preferred for CIN2 ) →</li> </ul> | <ul style="list-style-type: none"> <li>• 2x negative results and normal colposcopy: routine screening</li> <li>• Colposcopy worsens or, HG cytology, or CIN 2,3 persists &gt;1 yr: repeat biopsy - - - - - →</li> </ul>  | <ul style="list-style-type: none"> <li>• CIN 3 or CIN 2,3 that persists &gt;24 mos since initial diagnosis: treat</li> </ul>  |
| <b>Adenocarcinoma-in-situ (AIS)</b>                                | <ul style="list-style-type: none"> <li>• Hysterectomy preferred</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Conservative management if fertility desired - - - - - →</li> </ul>  | <ul style="list-style-type: none"> <li>• Margins involved or ECC positive: re-excision (recommended)</li> </ul> OR<br><ul style="list-style-type: none"> <li>• Re-evaluate at 6 mos (acceptable)</li> <li>• Margins negative: long term follow-up</li> </ul>   |   |

\* ECS = endocervical sampling in non-pregnant women, either with endocervical curettage or cervical brush  
 \*\* DEP = diagnostic excisional procedure, e.g., LEEP cone or cold-knife cone biopsy (*not Family PACT benefits*)

## CONTRACEPTION FOR WOMEN WITH CHRONIC MEDICAL CONDITIONS

The Family PACT Program encourages the use of the World Health Organization (WHO) *Medical Eligibility Criteria for Initiating Contraceptive Methods*, an evidence-based guideline that offers recommendations for four risk levels, based upon a matrix of 34 medical conditions and six types of contraceptive methods (attached). The risk levels are defined as:

- WHO-1.** A condition for which there is no restriction for the use of the contraceptive method. *Use the method in any circumstances.*
- WHO-2.** A condition where the advantages of using the method generally outweigh the theoretical or proven risks. *Generally use the method.*
- WHO-3.** A condition where the theoretical or proven risks usually outweigh the advantages of using the method. *Use of the method is usually not recommended unless other more appropriate methods are not available or not acceptable.*
- WHO-4.** A condition which represents an unacceptable health risk if the contraceptive method is used. *The method is not to be used.*

### KEY POINTS

- In women with chronic medical conditions, the medical risks of pregnancy almost always outweigh the risks of contraceptive use.
- Women who use estrogen-containing combined hormonal contraceptives (oral contraceptives [OCs], Patch, Ring) and who have underlying cardiovascular disease (CVD) have an increased risk of heart attack and stroke. The development of CVD is multifactorial, and a woman's risk of CVD increases with a greater number of risk factors and an increasing severity of each risk factor. CVD risk factors include increasing age (especially over 35 years old), cigarette smoking, hypertension, diabetes, and abnormal lipid levels (increased triglycerides and low-density lipoprotein [LDL] cholesterol and decreased high-density lipoprotein [HDL] cholesterol).

## QUESTIONS AND ANSWERS

### Are any routine screening tests recommended before the initiation of hormonal contraceptives?

- According to WHO guidelines (and Family PACT Standards), a blood pressure check is the only routine screening test necessary for a woman initiating a hormonal contraceptive method. If the method is continued, Family PACT Standards also require a blood pressure measurement at least every two years thereafter.
- Women aged 40 years old or older or those with mild hypertension (see KEY POINTS, above) also should be evaluated for type 2 diabetes (with a fasting plasma glucose test) and hyperlipidemia (with a total cholesterol level or lipid profile).

### Can a combined hormonal contraceptive be used in women with a history of deep vein thrombosis or pulmonary embolism (venous thromboembolic events [VTE])?

In addition to estrogen-induced thrombosis, risk factors for VTE include obesity, advanced age, prolonged immobilization, and inherited coagulopathy, such as the Factor V Leiden mutation.

- Women with a known inherited coagulopathy or a personal history of an idiopathic or post-partum VTE must not use a combined hormonal contraceptive (WHO-4). Both intrauterine contraception (IUC) devices and progestin-only methods are safe.
- Women with a first degree family member with a history of VTE or a known inherited coagulopathy (e.g., Factor V Leiden, Protein S, Protein C deficiency) should be advised to undergo hematologic evaluation for inherited coagulopathy.
- Women with varicose veins or a history of superficial thrombophlebitis may use all hormonal methods.

### If a patient requires anticoagulation after a previous VTE, what methods of contraception can she use?

- If lab studies document that she is adequately treated with the anticoagulant drug being used, she can use any hormonal contraceptive method.
- Both the IUCs are acceptable methods, but the Levonorgestrel IUC is preferred due to the potential for increased bleeding with Copper IUC (Cu-IUC).

### Can a woman with treated hypertension use combined hormonal contraceptives?

- Women with controlled hypertension (systolic <159 / diastolic <99 ) without vascular disease or other CVD risk factors may be offered combined hormonal contraceptives (WHO-3), but blood pressure must be followed closely after method initiation. Hypertensive smokers, those with vascular disease, or women with poorly controlled hypertension (systolic >160 / diastolic >100) are considered to be WHO-4 in regard to combined hormonal contraceptives.

### Can I give combined hormonal contraception to a woman with a history of gestational hypertension? If starting pills, how often does she need follow-up?

- When current blood pressure is normal, combined hormonal methods are WHO-2. A follow-up blood pressure check in two months is recommended to ensure that hypertension does not develop as a result of method initiation.

### What methods can be used for women with type 2 diabetes or those with a history of gestational diabetes (GDM)?

- In diabetic women *WITH* vascular disease (i.e., retinopathy, nephropathy, peripheral vascular disease, heart disease) or diabetes >20 years duration, IUCs or progestin-only methods are preferred, while combined hormonal contraceptives are WHO-3.
- In diabetics *WITHOUT* vascular disease, all methods are considered to be safe whether or not the woman uses insulin.
- In women with a history of GDM, all methods are WHO-1. All women with gestational diabetes should be screened at six weeks postpartum with a 75gm, two-hour post-glucose load test to evaluate her for type 2 diabetes; if normal, repeat every two years.

## QUESTIONS AND ANSWERS (CONTINUED)

### Which methods are best in women who have a seizure disorder?

- DepoProvera (DMPA) is an ideal choice because of its low failure rate, lack of interaction with **any** anti-seizure medication, and because using DMPA may reduce the number of seizure episodes. Either of the IUCs also are excellent choices as they would not be expected to interact with anti-seizure drugs.
- Women who use a combination of certain enzyme inducing anti-seizure drugs and some hormonal contraceptives may have a significant reduction in blood level of progestin (and, in some cases, estrogen), enough to allow follicle development and ovulation. Drugs in this category include phenobarbital, phenytoin (Dilantin<sup>®</sup>), carbamazepine (Tegretol<sup>®</sup>), felbamate (Felbatol<sup>®</sup>), lamotrigine (Lamictal<sup>®</sup>), oxcarbazine (Trileptal<sup>®</sup>), and topiramate (Topamax<sup>®</sup>). Combined hormonal contraceptives, progestin-only pills, and progestin implants (Implanon<sup>®</sup>) are all categorized as WHO-3 in women who use these anticonvulsant drugs.
- If a woman who uses a listed anti-seizure medication insists upon using OCs, prescribe a product with a relatively higher progestin dose and at least 35mcg of ethinyl estradiol, cycled as an extended regimen with a short (three to four day) hormone free interval.

### Can women with migraine headaches use combined hormonal contraceptives?

- A critical issue is whether the woman experiences an *aura* before the onset of her headache. Pre-migraine auras begin within 60 minutes of headache onset and can consist of a flickering zigzag lines that moves toward periphery of the visual field, scotomata (blind spots) or intermittent loss of vision.
- All forms of contraception are acceptable in clients with any headache type, including simple migraine, EXCEPT those with aura or who are over 35 years old. In women who have migraines with aura, regardless of age, combined hormonal contraceptives are WHO-4.
- If a woman is older than 35 and has migraines without aura, all methods are acceptable *except* combined hormonal contraceptives, which are WHO-3.

### What methods can be used in women with a past history of breast cancer?

- For patients with a history of breast cancer treatment within five years, the Cu-IUC is WHO-1, but all other reversible methods are WHO-4.
- For patients with a history breast cancer and who have no evidence of recurrent breast cancer for more than five years, the Cu-IUC is WHO-1 and all other methods are a WHO-3.
- Key point: If a patient declines Cu-IUC or condoms, the levels of estrogen and progesterone from pregnancy would be much higher than the levels from all hormonal methods that are WHO-3.

### Can women with benign breast conditions (such as a fibroadenoma or fibrocystic change) or a family history of breast cancer use combined hormonal birth control?

- All methods are WHO-1. A woman with an undiagnosed breast mass may remain on any hormonal method during her medical evaluation (all are WHO-2), as the risk of pregnancy outweighs the risk of hormones should breast cancer be confirmed.

### What is the best contraceptive method for a woman with sickle cell anemia?

- While all methods are considered to be safe (WHO-1 or -2), DMPA may be the best choice, as it may decrease the likelihood of painful sickle cell crises.

### Can a woman with fibroids use a hormonal method of contraception?

- All hormonal methods of contraception are categorized as WHO-1 in women with fibroids. In women with distortion of the uterine cavity, use of both IUCs are classified as WHO-4.

### When is liver disease a problem?

- In a woman who is an asymptomatic hepatitis virus carrier, all methods are WHO-1.
- If she has severe cirrhosis, active hepatitis, a history of a benign liver tumor (adenoma) or a malignant liver tumor (hepatoma), or a history of cholestatic jaundice in pregnancy, combined hormonal contraceptives are classified as WHO-4, the Cu-IUC is considered to be WHO-1, and all other methods are classified as WHO-3.

## PROGRAM POLICY

This Alert provides an interpretation of the Family PACT Standards regarding care of adolescent clients: Providers should refer to the Family PACT *Policies, Procedures, and Billing Instructions* for the complete text of the Family PACT Standards, official administrative practices, and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term "shall" indicates a program requirement; the term "should" is advisory and not required.

## RESOURCES FOR MORE INFORMATION

- World Health Organization (WHO) Medical Eligibility Criteria for Contraceptive Use, 3rd Edition, 2004 downloaded from: <http://www.who.int/reproductive-health/publications/mec/>.
- The attached table summarizing the WHO Medical Eligibility Criteria can be downloaded in multiple formats at: [http://reproductiveaccess.org/contraception/WHO\\_chart.htm](http://reproductiveaccess.org/contraception/WHO_chart.htm).
- Thorneycroft I, Klein P, Simon J. The impact of antiepileptic drug therapy on steroidal contraceptive efficacy. *Epilepsy & Behavior* 2006;9(1):31-39.
- ACOG Committee on Practice Bulletins- Gynecology. ACOG practice bulletin. No. 73: Use of hormonal contraception in women with coexisting medical conditions. *Obstet Gynecol.* 2006 Jun;107(6):1453.
- Gittes EB, Strickland JL. Contraceptive choices for chronically ill adolescents. *Adolesc Med Clin.* 2005 Oct;16(3):635.

# Medical Eligibility for Initiating Contraception: Absolute and Relative Contraindications

| Risk Level |   |
|------------|---|
| 1          | Method can be used without restriction  |
| 2          | Advantages generally outweigh theoretical or proven risks   |
| 3          | Method not usually recommended unless other, more appropriate methods are not available or not acceptable |
| 4          | Method not to be used   |

These contraceptive methods do not protect against sexually transmitted infections (STIs). Condoms should be used to protect against STIs.

For more information, see [www.who.int/reproductive-health/publications/mec/mec.pdf](http://www.who.int/reproductive-health/publications/mec/mec.pdf)

| Condition                      | Qualifier for condition                         | Estrogen/<br>progestin:<br>pill, patch,<br>ring | Progestin-<br>only: pill | Progestin-<br>only: injection | Progestin-<br>only:<br>implant | Progestin<br>IUD | Copper<br>IUD |
|--------------------------------|---|---|--------------------------|-------------------------------|--------------------------------|------------------|---------------|
| <b>Anemia</b>                  | Thalassemia                                     | 1   | 1                        | 1                             | 1                              | 1                | 2             |
|                                | Sickle cell disease                             | 2   | 1                        | 1                             | 1                              | 1                | 2             |
|                                | Iron-deficiency anemia                          | 1   | 1                        | 1                             | 1                              | 1                | 2             |
| <b>Breast cancer</b>           | Family history of cancer                        | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|                                | Current   | 4   | 4                        | 4                             | 4                              | 4                | 1             |
|                                | In past, no evidence of disease for > 5 years   | 3   | 3                        | 3                             | 3                              | 3                | 1             |
| <b>Breast problems, benign</b> | Undiagnosed mass                                | 2   | 2                        | 2                             | 2                              | 2                | 1             |
|                                | Benign breast disease                           | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Cervical cancer</b>         | Cervical intraepithelial neoplasia              | 2   | 1                        | 2                             | 2                              | 2                | 1             |
|                                | Awaiting treatment                              | 2   | 1                        | 2                             | 2                              | 4                | 4             |
| <b>Cervical ectropion</b>      |   | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Depression</b>              |   | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Diabetes mellitus (DM)</b>  | History of gestational DM only                  | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|                                | DM without vascular disease                     | 2   | 2                        | 2                             | 2                              | 2                | 1             |
|                                | DM with end-organ damage or > 20 years duration | 3   | 2                        | 3                             | 2                              | 2                | 1             |
| <b>Drug interactions</b>       | Antiretrovirals                                 | 2   | 2                        | 2                             | 2                              | 2                | 2             |
|                                | Certain anticonvulsants                         | 3   | 3                        | 2                             | 3                              | 1                | 1             |
|                                | Griseofulvin                                    | 2   | 2                        | 1                             | 2                              | 1                | 1             |
|                                | Rifampin  | 3   | 3                        | 2                             | 3                              | 1                | 1             |
|                                | ALL OTHER ANTIBIOTICS                           | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Endometrial cancer</b>      |   | 1   | 1                        | 1                             | 1                              | 4                | 4             |
| <b>Endometriosis</b>           |   | 1   | 1                        | 1                             | 1                              | 1                | 2             |
| <b>Gallbladder disease</b>     | Asymptomatic gallstones                         | 2   | 2                        | 2                             | 2                              | 2                | 1             |
|                                | Symptomatic gallstones, without cholecystectomy | 3   | 2                        | 2                             | 2                              | 2                | 1             |
|                                | Gallstones treated with cholecystectomy         | 2   | 2                        | 2                             | 2                              | 2                | 1             |
|                                | Pregnancy-related cholestasis in past           | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|                                | Hormone-related cholestasis in past             | 3   | 2                        | 2                             | 2                              | 2                | 1             |
| <b>Headaches</b>               | Non-migranous                                   | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Headaches: migraines</b>    | Without aura, age < 35                          | 2   | 1                        | 2                             | 2                              | 2                | 1             |
|                                | Without aura, age > 35                          | 3   | 1                        | 2                             | 2                              | 2                | 1             |
|                                | With aura, any age                              | 4   | 2                        | 2                             | 2                              | 2                | 1             |
| <b>HIV infection</b>           | High risk                                       | 1   | 1                        | 1                             | 1                              | 2                | 2             |
|                                | HIV infected                                    | 1   | 1                        | 1                             | 1                              | 2                | 2             |
|                                | AIDS (without drug interactions)                | 1   | 1                        | 1                             | 1                              | 3                | 3             |

| Condition                              | Qualifier for condition                        | Estrogen/<br>progestin:<br>pill, patch,<br>ring | Progestin-<br>only: pill | Progestin-<br>only: injection | Progestin-<br>only:<br>implant | Progestin<br>IUD | Copper<br>IUD |
|--|--|---|--------------------------|-------------------------------|--------------------------------|------------------|---------------|
| <b>Hypertension</b>                    | During prior pregnancy only – now resolved     | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Well controlled                                | 3   | 1                        | 2                             | 1                              | 1                | 1             |
|  | Systolic 140-159 or diastolic 90-99            | 3   | 1                        | 2                             | 1                              | 1                | 1             |
|  | Systolic > 160 or diastolic > 100              | 4   | 2                        | 3                             | 2                              | 2                | 1             |
|  | With vascular disease                          | 4   | 2                        | 3                             | 2                              | 2                | 1             |
| <b>Ischemic heart disease</b>          | Past or current                                | 4   | 2                        | 3                             | 2                              | 2                | 1             |
| <b>Liver Disease</b>                   | Cirrhosis–mild                                 | 3   | 2                        | 2                             | 2                              | 2                | 1             |
|  | Cirrhosis–severe                               | 4   | 3                        | 3                             | 3                              | 3                | 1             |
|  | Tumors–benign                                  | 4   | 3                        | 3                             | 3                              | 3                | 1             |
|  | Tumors–malignant                               | 4   | 3                        | 3                             | 3                              | 3                | 1             |
|  | Viral hepatitis–carrier                        | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Viral hepatitis–active                         | 4   | 3                        | 3                             | 3                              | 3                | 1             |
| <b>Obesity</b>                         | BMI > 30 kg/meter squared                      | 2   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Ovarian cancer</b>                  |  | 1   | 1                        | 1                             | 1                              | 3                | 3             |
| <b>Ovarian cysts</b>                   | & benign tumors                                | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Pelvic inflammatory disease</b>     | Past, with subsequent pregnancy                | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Past, without subsequent pregnancy             | 1   | 1                        | 1                             | 1                              | 2                | 2             |
|  | Current  | 1   | 1                        | 1                             | 1                              | 4                | 4             |
| <b>Postpartum, not breastfeeding</b>   | < 48 hours                                     | 3   | 1                        | 1                             | 1                              | 3                | 2             |
|  | 2-21 days                                      | 3   | 1                        | 1                             | 1                              | 3                | 3             |
|  | 3-4 weeks                                      | 1   | 1                        | 1                             | 1                              | 3                | 3             |
|  | > 4 weeks                                      | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Postpartum, &amp; breastfeeding</b> | < 6 weeks postpartum                           | 4   | 3                        | 3                             | 3                              | See above        | See above     |
|  | 6 weeks – 6 months postpartum                  | 3   | 1                        | 1                             | 1                              | 1                | 1             |
|  | > 6 months postpartum                          | 2   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Post-abortion</b>                   | First trimester                                | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Second trimester                               | 1   | 1                        | 1                             | 1                              | 2                | 2             |
|  | Immediately after septic abortion              | 1   | 1                        | 1                             | 1                              | 4                | 4             |
| <b>Sexually Transmitted Infections</b> | Vaginitis                                      | 1   | 1                        | 1                             | 1                              | 2                | 2             |
|  | High risk                                      | 1   | 1                        | 1                             | 1                              | 3                | 3             |
|  | Current GC/Chlamydia/<br>Purulent cervicitis   | 1   | 1                        | 1                             | 1                              | 4                | 4             |
| <b>Smoking</b>                         | Age < 35                                       | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Age > 35, < 15 cigarettes/day                  | 3   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Age > 35, > 15 cigarettes/day                  | 4   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Seizure disorder</b>                | Without drug interactions                      | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Stroke</b>                          |  | 4   | 2                        | 3                             | 2                              | 2                | 1             |
| <b>Surgery</b>                         | Minor, without prolonged immobilization        | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Major, without prolonged immobilization        | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Major, with prolonged immobilization           | 4   | 2                        | 2                             | 2                              | 2                | 1             |
| <b>Thyroid disorders</b>               | Simple goiter, hyperthyroidism, hypothyroidism | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Uterine fibroids</b>                | Without distortion of uterine cavity           | 1   | 1                        | 1                             | 1                              | 1                | 1             |
|  | With distortion of uterine cavity              | 1   | 1                        | 1                             | 1                              | 4                | 4             |
| <b>Valvular heart disease</b>          | Uncomplicated                                  | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Complicated                                    | 4   | 1                        | 1                             | 1                              | 2                | 2             |
| <b>Varicose veins</b>                  |  | 1   | 1                        | 1                             | 1                              | 1                | 1             |
| <b>Venous thrombosis</b>               | Family history (1st-degree relatives)          | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Superficial thrombophlebitis                   | 2   | 1                        | 1                             | 1                              | 1                | 1             |
|  | Past DVT                                       | 4   | 2                        | 2                             | 2                              | 2                | 1             |
|  | Current DVT                                    | 4   | 3                        | 3                             | 3                              | 3                | 1             |

## IMPLANON™ CONTRACEPTIVE IMPLANT

Implanon™ is a progestin-only (etonogestrel) single rod contraceptive system, inserted under the skin between biceps and triceps, that is effective for up to three years.

### KEY POINTS

- **Attributes of Implanon™ include extremely high efficacy, rapid reversibility, steady hormone release, and a discreet placement site.**
- **Implanon™ use will cause changes in menstrual bleeding patterns such that predictable monthly periods will cease and all bleeding will be unscheduled. Potential Implanon™ users must be counseled regarding characteristic bleeding patterns and be willing to accept these changes before Implanon™ insertion is performed.**
- **Implanon™ must be inserted and removed only by clinicians who have completed a company-sponsored training program.**
- **All Implanon™ devices purchased for use in Family PACT clients must be obtained from the single source supplier and labeled for use in the United States (U.S.). Providers must maintain invoices for Implanon™ units billed to Family PACT for at least three years in accordance with Title 22, California Code of Regulations (CCR), Code 51476(a).**

## QUESTIONS AND ANSWERS

### How effective is Implanon™?

Implanon™ is one of the most effective contraceptives available. International studies showed no pregnancies in over 73,000 cycles of use. In later studies performed in the U.S., the failure rate was 0.4 failures per 100 couples per year. No ectopic pregnancies were reported in either study. There are no clinical studies of Implanon™ efficacy in women whose weight is more than 130 percent of ideal body weight. However, in one study, etonogestrel levels were sufficient to prevent ovulation even in women weighing 90 kg or more.

### What is the mechanism of action of Implanon™?

The major mechanism of action of Implanon™ is by inhibiting ovulation. A large clinical trial showed that no women ovulated in the first 30 months of use and six percent ovulated in the last six months of use, although no pregnancies resulted. In addition, the progestin in Implanon™ causes thickening of cervical mucus, which contributes to contraceptive efficacy.

### Are there any contraindications to Implanon™ insertion?

As a progestin-only method, Implanon™ has few contraindications. According to the 2004 World Health Organization (WHO) Medical Eligibility Criteria, current breast cancer is the only WHO-4 condition (an unacceptable health risk if the contraceptive is used). WHO-3 conditions (risks usually outweigh advantages of using the method) include past breast cancer (>five years ago and no recurrence), current deep vein thrombosis, active liver disease or history of liver tumors, and being less than three weeks post-partum.

### What should the client expect in regard to menstrual patterns?

The menstrual bleeding pattern of women who use Implanon™ is unpredictable and all bleeding is unscheduled. Studies show that there are no predictable trends in bleeding patterns over time. Counsel the client that she will have fewer bleeding episodes and the same or fewer bleeding days, but that her bleeding days and episodes will be unpredictable and she may have more spotting days than before.

### How should this bleeding pattern be managed?

Pre-insertion counseling regarding the nature of the expected bleeding pattern is an important step in improving method acceptability. When unpredictable bleeding occurs after insertion, reassure the client that this is an expected consequence of the method.

In addition, based on experience with treating irregular bleeding in women who use other progestin-only methods, the following interventions have been effective:

- Estradiol 1-2mg orally once a day for 10-14 days; or
- Oral contraceptives, given for two or three cycles; or
- Ibuprofen 800mg three times a day for seven days.

Since continuous progestin *prevents* endometrial hyperplasia; endometrial biopsy is rarely necessary.

### Is this a good method for adolescents?

While Implanon™ is as safe and efficacious in adolescents as in older women, some will not be able to tolerate the unpredictable bleeding pattern induced by the method. Clear and direct post-insertion counseling that is easily accessible to the client will improve continuation rates.

### What can clinicians do to be trained in Implanon™ insertion?

Only providers that have completed the company-sponsored three-hour training course will be permitted to purchase Implanon™. See Resources below for Organon's Web site to request training. Physicians and non-physician medical practitioners (nurse practitioners, CNMs, and physician assistants) can perform Implanon™ insertions and removals.

### How will my practice be reimbursed for Implanon™?

Family PACT will reimburse providers for both the insertion kit (purchased from CuraScript Specialty Pharmacy, the single-source supplier) and for the insertion (and removal) procedures. Limited to one per client, any provider, per 34 months. While the duration of action of Implanon™ is 36 months, the 34-month limit will permit early removal and insertion of a new implant if necessary for scheduling purposes.

## QUESTIONS AND ANSWERS (CONTINUED)

### Can Implanon™ be used in women using rifampin (for tuberculosis or methicillin-resistant *Staphylococcus aureus* [MRSA] infections) or enzyme-inducing anti-seizure drugs?

Although there are no published studies on drug interactions with Implanon™, this method is not recommended for women who require chronic use of enzyme-inducing drugs, as contraceptive efficacy probably will be reduced. A backup method should be used by women using rifampin for a limited period of time.

### When is the recommended time to insert Implanon™?

Implanon™ package labeling includes the following guidelines. If inserted as recommended, backup contraception is not necessary.

- Standard start-up: insert within five days of initiation of menses.
- Switching from combined hormonal methods: insert within seven days of last active dose.
- Switching from progestin-only method: insert any day when progestin only-pills are used or before due date of next DepoProvera injection.
- After first trimester abortion: insert within five days of procedure.
- After second trimester abortion or postpartum, but not exclusively breast feeding insert between 21 to 28 days after pregnancy has ended.
- If exclusively breast feeding, insert Implanon™ after the fourth postpartum week.

If an "off cycle" insertion is performed, pregnancy should be excluded and the client should use a non-hormonal method of birth control during the first seven days after the insertion. In addition, emergency contraception should be offered if there has been unprotected intercourse during the five days before the insertion.

## APPLICATION OF FAMILY PACT STANDARDS

### 1. Informed Consent

- All clients shall be advised of the availability of Implanon™ and offered this option in a non-coercive manner.
- Consent shall be voluntary and the client may withdraw this consent at any time.
- Parental consent is not required for provision of an Implanon™ to a minor.
- The consent process shall be provided verbally in language understood by the client and supplemented with written materials.
- The client must sign a written consent for Implanon™ insertion and removal. The consent form provided by the Implanon™ manufacturer with the insertion kit is recommended but another with equivalent content may be used.

### 2. Confidentiality

- A confidential contact address should be obtained from the client so that she can be notified in the event of a product recall or other Implanon™-related safety considerations.

### 3. Access to Care

- Implanon™ insertion, follow-up visits, and removal shall be provided without cost to all Family PACT clients, either onsite or by referral.

### 4. Availability of Covered Services

- Implanon™ services may be provided onsite or by referral. The enrolled provider shall have an established referral arrangement with the other provider(s) when making referrals for these procedures.
- The management of certain Implanon™ complications is a benefit of Family PACT, as specified in the *Policies, Procedures, and Billing Instructions* (PPBI). These services must be requested and authorized by the use of a Treatment Authorization Request.
- To facilitate client contact in the case of a product recall, providers must keep a written log or electronic record of all Implanon™ inserted for at least three years from the insertion date. The log must include the client's name, record number, Health Access Program (HAP) identification number, date of insertion, and the lot number of the Implanon™ used.
- All Implanon™ inserted through the Family PACT program must be Food and Drug Administration-approved, labeled for use in the U.S., and obtained from the single source distributor. Providers must maintain invoices for insertion kits billed to Family PACT for at least three years from the date of insertion.

### 5. Scope of Clinical and Preventive Services

- Follow-up care for complications associated with a client's contraceptive method at no cost to the client.
- Medical record documentation shall support services claimed for reimbursement.

### 6. Education and Counseling Services

- All staff performing education and counseling services shall be knowledgeable about Implanon™ and the policies for use under the Family PACT Program.
- Specific instructions for the use of Implanon™ should be provided both verbally and in written form. Clients should be given the opportunity to ask questions and discuss personal concerns about Implanon™.

## PROGRAM POLICY

This Alert provides an interpretation of the Family PACT Standards regarding care of adolescent clients: Providers should refer to the Family PACT PPBI for the complete text of the Family PACT Standards, official administrative practices, and billing information. For the purposes of this and other Family PACT Clinical Practice Alerts, the term "shall" indicates a program requirement; the term "should" is advisory and not required.

## RESOURCES FOR INFORMATION ON IMPLANON™

- Implanon™ consumer Web site: <http://www.implanon-usa.com/>.
- Implanon™ provider Web site: <http://www.implanon-usa.com/hcp/?OrgDom=www.implanonusa.com>.
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