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Contraception: Transdermal contraceptive patches

Author: Ronald T Burkman, MD
Section Editor: Courtney A Schreiber, MD, MPH
Deputy Editor: Kristen Eckler, MD, FACOG

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INTRODUCTION

The transdermal contraceptive patches are a highly effective form of estrogen-progestin contraception. Most individuals who desire a reversible, nonevent-based method of contraception and who have no contraindications to use of estrogens or progestins can safely use this method. As either patch type is applied weekly, it can offer a more convenient form of contraception that can also be used in an extended cycle manner.

This topic will review patient selection, counseling, and use of the estrogen-progestin transdermal contraceptive patches. Related topics on estrogen-progestin contraceptive pills, risks and benefits of estrogen-progestin contraceptives, and selection of contraception are presented separately.

- (See "Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use".)
- (See "Contraception: Counseling and selection".)
- (See "Combined estrogen-progestin contraception: Side effects and health concerns".)

DESCRIPTION AND STRUCTURE

Patch types — The patch structure and hormonal content vary based on the product.

- Ethinyl estradiol-norelgestromin **(EE/N) patch** – The EE/N transdermal contraceptive patch (commercial names Xulane and Zafemy, formerly Evra) is a matrix system composed of three layers: the outer layer is water-resistant and protects the underlying layer from the environment, the middle layer is medicated and adhesive, and the inner layer is a clear release liner that is removed before patch application [1]. The medicated layer contains two hormones, EE and norelgestromin, the primary active metabolite of norgestimate. Approximately 35 mcg of EE and 150 mcg norelgestromin are released daily, but the EE exposure to the patient is approximately 60 percent higher compared with oral contraceptive pills of a similar dose [1-3]. The patch covers 14 cm^2 and consists of three layers.
- Ethinyl estradiol-levonorgestrel **(EE/LNG) patch** – A patch releasing EE/LNG (commercial name Twirla) was approved by the US Food and Drug Administration in 2020 [4]. The patch will release approximately 30 mcg of EE and 120 mcg of LNG per day, which is similar to oral contraceptive pills of the same dose [3]. The patch covers 28 cm^2 and consists of five layers, with the innermost two layers containing the active ingredients.

Dose comparison with oral contraceptive pills — Based on studies of the EE/N patch, the average overall EE concentration ("area under the curve") in patch users following pharmacokinetic analyses of 21-day cycles is 60 percent higher than in individuals who use a 35 mcg EE pill. However, peak EE concentrations are 25 percent lower than in pill users because of the continuous release system [5,6]. For the EE/N patch, the area under the curve may be more comparable to that of a 50 mcg EE oral contraceptive pill. Other than increased risk of venous thromboembolic events, the clinical significance of the relatively higher average overall EE concentration in patch versus pill users is not fully known. The pharmacokinetic studies of the EE/LNG patch have been of week 1 and week 3 of the first two cycles of use without comparative data with an oral contraceptive. The clinical significance of the findings is unclear. (See 'Risk of venous thrombotic events' below.)

PATIENT SELECTION

Candidates — Individuals desiring a reversible, nonevent-based method of contraception who have no contraindications to use of estrogens or progestins constitute the initial population of potential users. Both the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have published comprehensive tables of medical conditions and personal characteristics that may affect contraceptive choice [7,8]. Summary tables can be found through the CDC's Summary Chart of US Medical Eligibility Criteria and the WHO's Medical Eligibility Criteria for Contraceptive Use. (See "Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use", section on 'Candidates'.)

Contraindications — Contraindications to contraceptive patch use are the same as those for other estrogen-progestin contraceptives (eg, history of thromboembolism, an estrogen-dependent tumor, abnormal liver function) [1]. Summary tables can be found through the CDC's Summary Chart of US Medical Eligibility Criteria and the WHO's Medical Eligibility Criteria for Contraceptive Use. In addition, both patches are contraindicated in patients with a body mass index ≥30 kg/m^2; the ethinyl estradiol and norelgestromin (EE/N) patch is contraindicated because of concern for increased risk of thromboembolism while the ethinyl estradiol and levonorgestrel (EE/LNG) patch has a lower efficacy in this population [2,4].

Neither patch should be used in patients being treated for hepatitis C with combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, or in individuals with skin hypersensitivity to any component of the transdermal systems [1,2,4]. Individuals with a history of sensitive skin or exfoliative dermatologic disorders may not be ideal candidates for using a transdermal system.

- (See 'Efficacy' below.)
- (See 'Risk of venous thrombotic events' below.)
- (See 'Special populations' below.)
- (See "Contraception: Counseling for females with obesity".)

Patch versus pill or vaginal ring — The benefits, risks, and contraindications of the transdermal contraceptive patches are generally similar to those of other combined hormonal contraceptives (oral pill and vaginal ring). All methods offer highly effective, reversible, noncoital-based contraception. (See "Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use" and "Contraception: Hormonal contraceptive vaginal rings".)

However, transdermal hormonal contraceptive systems offer several differences compared with oral estrogen-progestin pills and the contraceptive vaginal ring, which may influence method selection by the patient.

- **Comparison of patch versus pill**
  - Potential benefits of contraceptive patches:
    - Weekly rather than daily dosing, which appears to result in improved compliance [9,10].
    - The non-oral route of administration is useful for patients who have difficulty swallowing pills.
    - Therapeutic effects are achieved at lower peak doses since first-pass hepatic metabolism and enzymatic degradation in the gastrointestinal tract are avoided [1].
    - Sustained drug delivery results in relatively constant plasma hormone levels while the patch is worn (ie, peaks and troughs do not occur) [1,4].
  - Potential benefits of oral estrogen-progestin contraceptive pills:
    - Pills are more private than a visible patch.
    - Pills do not detach.

- Although data are limited, there is a possibility of an increased risk of venous thromboembolism in patch users compared with pill users. (See 'Risk of venous thrombotic events' below.)

- **Comparison of patches versus vaginal ring**
  - Both methods offer weekly dosing and non-oral administration (for individuals with difficulty swallowing pills).
  - Patches may appeal to individuals or their partners who find vaginal contraception unacceptable (eg, inserting the ring into the vagina, increased vaginal discharge, feeling the ring during intercourse).

COUNSELING POINTS

Contraceptive mechanism — All combined estrogen-progestin contraceptives (pills, patches, rings) have a similar contraceptive mechanism. The most important mechanism for providing contraception is estrogen-progestin-induced inhibition of the midcycle surge of gonadotropin secretion so that ovulation does not occur. Another potential mechanism is suppression of gonadotropin secretion during the follicular phase of the cycle, thereby preventing follicular maturation. Progestin-related mechanisms also contribute to the contraceptive effect. These include changes in cervical mucus, fallopian tube motility, and endometrial receptivity that have unfavorable effects on fertilization and implantation. (See "Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use", section on 'Mechanisms of action'.)

Efficacy — Transdermal contraception is highly effective and as effective as oral combined hormonal contraceptives (figure 1) [11]. This was illustrated in three clinical trials that evaluated contraceptive efficacy in transdermal contraceptive patch users and oral contraceptive users.

- **Ethinyl estradiol and norelgestromin (EE/N) patch (commercial name Xulane)** – In three initial trials including over 3300 individuals followed over 12 months, the pregnancy rate in individuals aged 18 to 35 years was 1.07 (95% CI 0.60-1.76) per 100 woman-years [2]. Other clinical trials reported that both the typical-use and method-use (perfect compliance with the dosing schedule) pregnancy rates were less than one pregnancy per 100 woman-years (table 1) [12,13].

- **Ethinyl estradiol and** levonorgestrel **(EE/LNG) patch (commercial name Twirla)** – In the initial trial of over 1700 females, the unintended pregnancy rates were 3.5 (95% CI 1.8-5.2), 5.7 (95% CI 3.0-8.4), and 8.6 (95% CI 5.8-11.5) pregnancies per 100 woman-years of use for normal weight, overweight, and obese individuals, respectively, as defined by body mass index (BMI) [4]. As a result, obesity (BMI ≥30 kg/m^2) is considered a contraindication to EE/LNG patch use. (See 'Special populations' below.)

Based on the EE/N trials, the similarity between the typical and method patch use rates suggests that individuals in the trials were able to use the patch correctly without difficulty. This finding is supported by an analysis of self-reported rates of "perfect" compliance of patch users versus oral contraceptive users, which showed that users of the transdermal contraceptive patch achieved perfect compliance more often than oral contraceptive users (88 versus 78 percent of cycles) [14]. The rate of perfect compliance did not vary by age for patch users, while oral contraceptive users who were in younger age groups had lower perfect compliance rates.

Of note, the US Food and Drug Administration (FDA) has issued a warning to providers and consumers about online sales of counterfeit contraceptive patches, as well as other drugs, which may be less effective [15].

Side effects

Local — In general, transdermal patches cause few topical problems. In initial clinical trials, application site disorders were reported by approximately 17 percent of EE/N users and 3 percent of EE/LNG users [1,4].

Systemic — As with other combined estrogen-progestin contraceptives, the systemic side effects experienced by contraceptive patch users are generally well-tolerated and often improve within three to six months of use.

- **Irregular uterine bleeding** – Irregular uterine bleeding is common with initiation of use but generally improves with continued use of either product [2,4]. In the initial cycles of EE/N patch use, unscheduled bleeding and spotting are reported by up to 18 percent of users and then stabilize by approximately six months of use to 5 to 7 percent (table 2) [16]. For EE/LNG patch users, 50 to 60 percent reported unscheduled bleeding or spotting with the first two cycles, which dropped to 42 percent by

cycle 13. The mean number of bleeding days was 1.6 by cycle 13 [4]. Although there are insufficient data to fully evaluate the difference in the rate of irregular uterine bleeding between the two patches, particularly due to the lack of a head-to-head comparative trial, potential users should still be made aware of this difference during the counseling process. Of note, there are some data to indicate the pattern of breakthrough bleeding (bleeding requiring more than one pad or tampon daily) and spotting with the transdermal contraceptive patch is similar to that reported in oral contraceptive trials.

- **Weight gain** – Of note, weight gain is **not** a significant side effect for either patch. In initial trials of both patches, weight increase was reported by approximately 2.5 percent of patients [2,4]. A study comparing the EE/N patch with an oral triphasic pill reported, for both contraceptives, a mean increase in body weight of 0.3 kg over 13 treatment cycles and that 80 percent of users were within 5 percent of their starting weights by the end of nine months [17].

- **Mood disorders** – Neither patch formulation appears to significantly negatively impact mood or worsen existing mood disorders. The initial EE/N trials indicated that 6 percent of individuals reported psychiatric disorders, which represented a bundled group of related terms including mood, affect, and anxiety disorders [2]. Psychiatric disorders reported as part of postmarketing surveillance included anger, emotional disorders, frustration, and irritability, but the frequency is not known and causality has not been established. In the initial EE/LNG trials, less than 1 percent of individuals reported major depression or suicidal ideation [4].

- **Other symptoms** – Other symptoms reported by users are similar for the two patches, although somewhat less prevalent for users of the EE/LNG patch. It is not yet clear if these differences are real or related to the smaller size of the EE/LNG trials. Individuals in the initial EE/N patch trials most commonly reported breast symptoms (22 percent), headache (21 percent), nausea (17 percent), and dysmenorrhea (8 percent) [2]. In the initial trials of the EE/LNG patch, the most common other symptoms were nausea (4 percent), headache (4 percent), and dysmenorrhea (2 percent) [4].

- **Laboratory changes** – Based on studies of estrogen-progestin oral contraceptive pills, treatment with either patch may increase serum concentrations of thyroxine-binding globulin and cortisol-binding globulin [2,4]. Individuals taking thyroid or cortisol replacement therapy may need the dose increased. Studies of the EE/N patch indicate that increases in sex hormone-binding globulin are greater than those observed in pill users while the reduction in androgen levels is similar [6,18]. Thus, the patch may be useful in treating individuals with androgen excess (eg, acne, hirsutism).

Risk of method discontinuation — The initial EE/N trials reported the most common events leading to discontinuation included application site reactions, breast symptoms, nausea and/or vomiting, headache, and emotional lability [2]. A subsequent review of three studies reported discontinuation of EE/N patches related to adverse events was approximately 3 percent [9]. For EE/LNG patches, nearly 11 percent of individuals discontinued the method because of an adverse reaction, including application site disorder (3 percent) and any bleeding irregularities (2 percent) [4].

Risk of venous thrombotic events — Both oral and transdermal estrogen-containing contraceptives appear to adversely affect coagulation factors and thus place users at increased risk of venous thromboembolism (VTE), although the overall risk of VTE is low [19-21]. Based on the evidence described below, there may be a modest increased risk of VTE for patch users compared with users of low-dose (ie, less than 35 mcg of estrogen) combined oral contraceptives. In 2020, the FDA labeled the EE/N patch as contraindicated for individuals with a BMI of ≥30 kg/m^2 based on concern for elevated VTE risk in this population [2]. The rationale for the label change in the absence of new data was not provided.

A detailed discussion of VTE risk for estrogen-progestin oral contraceptives is presented elsewhere. (See "Combined estrogen-progestin contraception: Side effects and health concerns", section on 'Venous thromboembolism'.)

Mechanism — The increased VTE risk has been attributed to the observation that the average overall EE concentration ("area under the curve") in EE/N patch users is 60 percent higher than in individuals who use a 35 mcg EE pill, although peak EE concentrations are 25 percent lower than in oral pill users [5,6]. However, the exact mechanism is not understood.

Studies have attempted to determine whether the contraceptive patch and oral contraceptives have different effects on serum/plasma markers of thrombosis. Two randomized trials reported that both the EE/N contraceptive patch and various oral contraceptives produced similar prothrombotic changes in several putative markers [19,20], while one small trial reported that the EE/N contraceptive patch and contraceptive vaginal ring produced more adverse changes on levels of protein C than did an oral

contraceptive [22]. It should be noted that differences in the effects on prothrombotic markers do not necessarily predict differences in risk of clinical thrombotic events in populations.

Comparison of risk — The potential risk of VTE with the patch should be balanced against the benefits of this method for preventing pregnancy in individuals who may not be able to use other methods successfully, against the absolute risk of symptomatic VTE in pregnancy and the postpartum period, and against the risk of VTE compared with other combined hormonal contraceptive methods for patients who can use them (figure 2). The risks of VTE in pregnancy and the postpartum period are estimated to be 20 to 30 and 40 to 65 per 10,000 woman-years, respectively [23,24]. For comparison, the baseline of risk of VTE among nonpregnant individuals of reproductive age is approximately one to five cases per 10,000 woman-years, and the risk among users of LNG-containing combined oral contraceptives is approximately seven per 10,000 woman-years [24-29]. The absolute risk of death from pulmonary embolism in contraceptive users has been estimated to be 10.5 per one million woman-years (95% CI 6.2-16.6 per one million woman-years) [30]. The impact of estrogen dose and progestin type on risk of VTE is discussed in detail separately. (See "Combined estrogen-progestin contraception: Side effects and health concerns", section on 'Thrombophilia and thrombosis'.)

Summary of data from epidemiologic studies — Epidemiologic studies have evaluated the risk of VTE, myocardial infarction, and stroke in EE/N contraceptive patch users compared with individuals using a norgestimate-containing 35 mcg EE oral contraceptive, but definitive conclusions have not been reached because of conflicting data.

A systematic review in 2017 included seven analyses from six studies that examined the risk of VTE among EE/N patch users compared with users of a combined oral contraceptive containing either LNG or norgestimate [31]. Two studies found a significantly increased risk among patch users: risk estimates of 2.2 and 2.3 [32,33]. A subanalysis in one study of only new users of either the patch or a combined oral contraceptive found an elevated risk of 2.0, which was not statistically significant [32]. Four studies did not demonstrate an increased risk for patch users compared with users of an oral contraceptive [34-37]. Two studies did not find an increased risk of arterial thromboembolism for patch users compared with users of a norgestimate-containing oral contraceptive [32,38]. Limitations of the various studies reviewed included the use of insurance databases without medical record verification [34-36,38], lack of adjustment for confounders [35,38], small numbers of VTE cases in comparative studies leading to lower precision, and studies that did not include only new users of oral contraceptives in their analysis since risk of VTE may be higher in new users [32,38]. Despite these concerns, the authors of this review determined that the studies still provided good to fair evidence on the risk of thromboembolism in users of the EE/N patch. They concluded that the results of these studies demonstrated conflicting evidence as to whether users of the EE/N patch are at higher risk for VTE compared with users of combined oral contraceptives. The authors also concluded that any potential elevated risk likely represents a small number of events on a population level. There were four cases of VTE in the initial clinical studies of the EE/LNG patch; all involved women who had a BMI >30 kg/m^2 [4]. However, the prescribing information for the EE/LNG patch, as well as the EE/N patch, lists BMI ≥30 kg/m^2 as a contraindication to patch use.

Noncontraceptive benefits — Although there are few data on potential noncontraceptive benefits of the transdermal contraceptive patch, users are likely to accrue the same benefits achieved by users of other types of estrogen-progestin contraceptives (eg, reductions in dysmenorrhea, iron deficiency anemia, and ovarian and endometrial cancer). (See "Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use", section on 'Noncontraceptive uses'.)

Risk of STI acquisition — The contraceptive patch does not protect the patient from acquisition of sexually transmitted infections (STIs), nor does it make STI infection more likely. All individuals at risk for STI acquisition are counseled regarding concomitant condom use. (See "External (formerly male) condoms", section on 'Protection from STIs'.)

ADMINISTRATION

Screening requirements — The screening requirements for either patch are the same as for other estrogen-progestin hormonal contraceptives. Hormonal contraception can be safely provided after obtaining a thorough medical history and a blood pressure measurement [39]. While breast examinations and screening for sexually transmitted infections and cervical cancer are important, these procedures are not necessary before a first prescription for hormonal contraceptives (table 3). (See "Combined estrogen-progestin oral contraceptives: Patient selection, counseling, and use", section on 'Screening requirements'.)

Initiation — The manufacturers advise starting the patch on either the first day of menses (first day start, both patch types) or the Sunday following the start of menses (Sunday start, ethinyl estradiol and norelgestromin [EE/N] patch) [2,4]. However, starting the

patch at the time of the initial office visit (quick start) is reasonable and may reduce the risk of unintended pregnancy (algorithm 1) [40] as long as pregnancy is reasonably excluded (table 4). Patient preference should guide the method of initiation. If the patch is initiated more than five days from onset of menses, abstinence or back-up contraception (eg, condom, vaginal spermicide) should be used through the first seven days of use [39].

Neither patch should be initiated earlier than four weeks postpartum. Postabortion initiation depends on gestation at the time of termination or pregnancy loss. Postpartum and postabortion initiation of combined hormonal contraceptive methods are discussed separately.

- (See "Postpartum contraception: Counseling and methods", section on 'Short-acting hormonal contraception'.)
- (See "Contraception: Postabortion", section on 'Combined estrogen-progestin contraceptives'.)

Individuals switching from a hormonal pill (estrogen-progestin or progestin-only), vaginal contraceptive ring, or alternate patch are advised to complete the existing cycle and then start the desired patch on the first day of the next cycle (and stop the prior method) [2,4]. For individuals using depot medroxyprogesterone acetate (commercial name Depo-Provera), the patch is started when the next injection should occur. Either patch can be initiated on the same day that an intrauterine device or contraceptive implant is removed.

Patch management

Applying and changing the patch — Both patches can be applied to the buttock, abdomen, or upper torso (but not the breast as it might cause breast tenderness due to high local estrogen concentration) [2,4]. The EE/N patch can also be applied to the upper outer arm [2]. A different site is used each time a new patch is applied, and only one patch is worn at a time. Lotions and occlusive dressings should not be used at patch application sites.

The patch is changed once per week for three weeks (21 total days) followed by one patch-free week (7 days) [2,4]. To maintain contraceptive efficacy, there should never be more than a seven-day patch-free interval. The patch should always be changed/applied on the same day of the week (eg, Sundays for Sunday start). Reminder systems are useful to ensure appropriate weekly changes. If a patient wants to switch to a new patch change day, the switch should be made during the last week of the cycle (ie, the patch-free week).

Delayed patch changes — The consequences of failing to change the transdermal contraceptive patch at the appropriate time should be addressed with patients. The clinician should discuss various strategies to help users adhere to a schedule and thus avoid an unplanned pregnancy. As an example, smartphone apps can provide the patient with calendar reminders. For individuals with delays in initiating the patch, we take the following approaches (figure 3) [2,4,39]:

- **Delay in beginning the first patch in a cycle** – When a new patch cycle is delayed beyond the scheduled start day, users are instructed to apply a patch as soon as they remember and use back-up contraception (or avoid sex) for at least one week. The day they apply the new patch becomes the new patch change day.
- **Delay in beginning the second or third patch in a cycle** – There is a two-day (48 hours) period of continued release of adequate contraceptive steroid levels when the patch is left on for two extra days. If users change the patch within this window, the patch change day remains the same, and there is no need for back-up contraception.

  After this two-day (48 hours) time period, failure to replace the second or third patch in a cycle increases the risk for contraceptive failure. Therefore, users will need to use back-up contraception (or avoid sex) for seven days and, in some instances, use emergency contraception if this occurs. The day the patient remembers to apply the patch becomes the new patch change day.
- **Delay in removing the third patch in a cycle** – Forgetting to remove the third patch on time carries less risk than forgetting to remove the first or second patch. The user is instructed to remove the patch when she remembers and start the new patch on the usual start day. The patch change day is not altered.

Detached patch — If a patch becomes partially or completely detached for less than 24 hours, it should be reapplied at the same location (if it has not lost its stickiness, ancillary adhesives or tape should **not** be used) or replaced with a new patch immediately (figure 3) [2,4]. If detachment lasts longer than 24 hours, a new patch should be applied, and this day of the week becomes the

new patch change day. An additional method of contraception (eg, condoms, spermicides) should be used for the first seven days of this cycle, or the patient should avoid sex.

In various trials of the EE/N patch, approximately 2 percent of transdermal patches required replacement for complete detachment, and 3 percent became partially detached [41]. Living in a warm, humid climate did not increase the risk of detachment. Skin adherence is also not adversely affected by a vigorous, athletic lifestyle or swimming. In a study in which 30 EE/N patch users were subjected to various conditions (normal activity, use of a sauna, immersion in a whirlpool bath, use of a treadmill followed by showering, cool water immersion, and a combination of these activities) over several seven-day time periods during EE/N patch use, only one patch became detached during the 87 cycles that were evaluated [41].

Extended cycle use — The patch may be administered for extended cycles (an "off-label" use), although we avoid this practice given the controversy about thrombosis risk in patch users. (See 'Risk of venous thrombotic events' above.)

In the only study evaluating extended use of the EE/N system, 239 women were randomly assigned in a 2:1 ratio to an extended or standard (cyclic) regimen [42]. The extended regimen was a weekly application of the patch for 12 consecutive weeks followed by 1 patch-free week. After the patch-free week, users completed three additional consecutive weekly applications. Compared with cyclic use, the extended regimen group had significantly fewer median bleeding days (14 versus 6), fewer bleeding episodes (1 versus 3), and fewer bleeding or spotting episodes (3 versus 2). However, the median numbers of bleeding or spotting days were similar for both groups (16 versus 14). In the extended use group, there was a significantly delayed median time to first bleeding (54 versus 25 days) and higher amenorrhea rates (12 versus 1 percent). Both regimens were associated with high user satisfaction rates (88.6 versus 86.3 percent), although there were more reports of headache, nausea, and breast discomfort in the extended regimen group.

Prescribing information — In general, we provide a three-month supply of medication (nine patches) and enough refills (three) to cover a calendar year. Where allowed, dispensing a 12-month supply at one time may be advantageous [43]. The patch is applied and changed as above. (See 'Applying and changing the patch' above.)

Return of fertility — Upon removing the patch, serum levels of both hormones reach very low to nonmeasurable levels within three days [1,2,4]. Individuals who desire to conceive may attempt to do so as soon as they are ready after patch discontinuation.

DRUG INTERACTIONS

Since patch use avoids intestinal absorption and the first-pass effect through the liver, the patch is unlikely to impair the efficacy of other drugs (eg, some anticonvulsants and antibiotics), and its own efficacy is unlikely to be affected by administration of other drugs given concomitantly. Support for this theory was provided by a study that reported serum levels of ethinyl estradiol and norelgestromin (EE/N) were not affected when tetracycline was administered to users [44].

However, the US Food and Drug Administration manufacturer package inserts and the Centers for Disease Control and Prevention US Medical Eligibility Criteria for Contraceptive Use warn of potential drug interactions based on data from estrogen-progestin oral contraceptive pill studies. Specifically, there is concern that the plasma levels of estrogen and progestin, and ultimately efficacy, of the transdermal contraceptive patches may be lowered by concomitant use of enzyme-inducing medications (eg, cytochrome P450 3A4), including HIV protease inhibitors (eg, fosamprenavir), some hepatitis C virus protease inhibitors (eg, boceprevir and telaprevir), some non-nucleoside reverse transcriptase inhibitors (eg, nevirapine), and anticonvulsants, although the data are mainly based on studies of combined oral contraceptive pills [1,2,7]. Package labeling also warns against concomitant use of the contraceptive patch and combination therapy for hepatitis C virus (specifically drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir) because of the potential for elevated liver enzymes [1,2]. For individuals who require fosamprenavir or anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, and lamotrigine), we counsel on the potential risk of reduced efficacy and liver enzyme changes and suggest that other methods (eg, intrauterine device) may be better contraceptive options. However, for individuals taking these medications who wish to use the contraceptive patch and are adequately counseled, the effects of concomitant antiretrovirals and anticonvulsants are of less concern compared with users of lower dose methods because the patch provides relatively higher concentrations of EE and the progestin is not associated with antiretroviral interactions related to contraceptive failure. (See 'Description and structure' above.)

SPECIAL POPULATIONS

The World Health Organization and the Centers for Disease Control and Prevention have published medical eligibility criteria for use of hormonal contraceptives, including transdermal contraception, in individuals with special clinical considerations or illnesses, including prior or active cancer [7].

- **Adolescents** – Use of the contraceptive patch is appropriate once menarche has occurred. The weekly dosing schedule may help improve compliance. A discussion of contraceptive use in adolescent patients is presented in detail separately. (See "Contraception: Issues specific to adolescents".)

- **Diabetes** – As diabetic individuals appear to be at increased risk of venous thromboembolism (VTE) with patch use, neither patch should be used in patients with diabetes with vascular disease or end-organ damage (eg, nephropathy, retinopathy, neuropathy) [2,4]. Although presence of uncomplicated diabetes is not a contraindication to use of the patch [39], given the availability of other lower risk combined hormonal contraceptives, progestin-only contraceptives, and intrauterine devices, we prefer to avoid use of the contraceptive patch in individuals with diabetes who can use other methods. In a database study of over 36,000 women with either type 1 or type 2 diabetes who were continuously prescribed contraceptives, the VTE rate for users of estrogen-progestin oral pills, vaginal rings, and patches, after controlling for other potential risk factors, was 10.3, 13.5, and 16.4 per 1000 woman-years, respectively [45].

- **Postabortion or miscarriage** – Either contraceptive patch can be started immediately following a first- or second-trimester miscarriage or abortion [7]. Although the package insert advises individuals who have experienced a second-trimester miscarriage or abortion to wait four weeks to initiate the patch because of theoretical concerns for increased risk of VTE events, there are no specific studies involving the patch to support this recommendation [1,2,4].

  Individuals who start the patch immediately following miscarriage or abortion do not need to use a back-up method of contraception (eg, condoms). Those who wish to start the patch more than five days after miscarriage or abortion follow the same instructions as first-time users. (See 'Administration' above.)

- **Postpartum and lactating** – Individuals who are at least 30 days postpartum and do not have additional risk factors for thromboembolic events can reasonably begin estrogen-progestin contraceptives, including either patch [2,4,7]. Issues specific to contraception use in postpartum and lactating individuals are discussed in detail separately. (See "Postpartum contraception: Counseling and methods".)

- **HIV** – The contraceptive patch does not appear to impact the risk of HIV acquisition. (See "HIV and women", section on 'Risk associated with contraception'.)

  For individuals living with HIV infection, the use of fosamprenavir is considered a relative contraindication to use of the transdermal patch, although the data are extrapolated from studies of combined oral contraceptive pills. (See 'Drug interactions' above.)

- **Intellectual or physical disability** – The weekly dosing schedule and non-oral route can be helpful for individuals with physical or intellectual disabilities who desire a combined hormonal contraceptive. For individuals with limited mobility, the convenience of the patch must be balanced against the potential increased risk of VTE with exogenous estrogen use. We do not advise extended cycle use of the patch, such as for menstrual suppression. (See 'Extended cycle use' above.)

- **Obesity** – Use of either patch type is contraindicated for individuals with a body mass index ≥30 kg/m^2. The ethinyl estradiol and levonorgestrel (EE/LNG) patch is contraindicated because of increased risk of unintended pregnancy while use of the ethinyl estradiol and norelgestromin (EE/N) patch is contraindicated because of increased risk of VTE [2,4]. Given the availability of other lower risk combined hormonal contraceptives, progestin-only contraceptives, and intrauterine devices, we avoid use of the contraceptive patch in individuals with obesity. (See "Contraception: Counseling for females with obesity".)

- **Perimenopause** – Use of combined hormonal contraception is generally safe for healthy nonsmoking individuals age 40 or older [7]. However, given the possible increased risk of VTE specific to either patch and the availability of other contraceptive options, we prefer to avoid the patch in individuals age 40 and older unless no other method is acceptable.

RESOURCES FOR PATIENTS AND CLINICIANS

- Bedsider – A free website developed by the National Campaign to Prevent Teen and Unplanned Pregnancy (a private nonprofit group).
- CHOICE Project – A free website sponsored by the Washington University School of Medicine in St. Louis that provides resources on contraceptive options and training resources for clinicians.
- Center for Young Women's Health – A free website run by Boston Children's Hospital that addresses reproductive health needs of teens and young adults.
- Beyond the Pill – A free website run by the University of California San Francisco.
- Sex and U – An educational site run by the Society of Obstetricians and Gynaecologists of Canada that includes descriptions of various methods and a tool to help with selection of birth control.
- Planned Parenthood – A nonprofit organization dedicated to reproductive health with resources for patients and clinicians.
- Association of Reproductive Health Professionals – A nonprofit organization that provides resources for patients, including an interactive tool to compare birth control methods.
- ACOG Contraceptive FAQs – The American College of Obstetricians and Gynecologists (ACOG) addresses frequently asked questions about contraception.
- Centers for Disease Control and Prevention (CDC) Medical Eligibility Criteria for Contraceptive Use
- Centers for Disease Control and Prevention (CDC) Selected Practice Recommendations for Contraceptive Use
- World Health Organization Medical Eligibility Criteria for Contraceptive Use

SOCIETY GUIDELINE LINKS

Links to society and government-sponsored guidelines from selected countries and regions around the world are provided separately. (See "Society guideline links: Contraception".)

INFORMATION FOR PATIENTS

UpToDate offers two types of patient education materials, "The Basics" and "Beyond the Basics." The Basics patient education pieces are written in plain language, at the 5th to 6th grade reading level, and they answer the four or five key questions a patient might have about a given condition. These articles are best for patients who want a general overview and who prefer short, easy-to-read materials. Beyond the Basics patient education pieces are longer, more sophisticated, and more detailed. These articles are written at the 10th to 12th grade reading level and are best for patients who want in-depth information and are comfortable with some medical jargon.

Here are the patient education articles that are relevant to this topic. We encourage you to print or e-mail these topics to your patients. (You can also locate patient education articles on a variety of subjects by searching on "patient info" and the keyword(s) of interest.)

- Basic topic (see "Patient education: Choosing birth control (The Basics)")
- Beyond the Basics topics (see "Patient education: Hormonal methods of birth control (Beyond the Basics)" and "Patient education: Birth control; which method is right for me? (Beyond the Basics)")

SUMMARY AND RECOMMENDATIONS

- There are two transdermal contraceptive patch systems; each is a matrix system composed of multiple layers. The ethinyl estradiol and norelgestromin patch (EE/N, commercial name Xulane) releases approximately 35 mcg of EE and 150 mcg norelgestromin daily. The ethinyl estradiol and levonorgestrel patch (EE/LNG, commercial name Twirla) will release approximately 30 mcg of EE and 125 mcg of LNG per day; this patch is approved but not yet commercially available. (See 'Patch types' above.)

- Potential candidates include individuals desiring a reversible, nonevent-based method of contraception who have no contraindications to use of estrogens or progestins. Summary tables of medical conditions and personal characteristics that impact patch use can be found through the Centers for Disease and Control Prevention's Summary Chart of US Medical Eligibility Criteria and the World Health Organization's Medical Eligibility Criteria for Contraceptive Use. Contraindications to contraceptive patch use are the same as those for other estrogen-progestin contraceptives (eg, history of thromboembolism, an estrogen-dependent tumor, abnormal liver function). In addition, individuals with a body mass index ≥30 kg/m^2 should not use the EE/LNG patch. (See 'Patient selection' above.)

- Transdermal contraception is highly effective and as effective as oral combined hormonal contraceptives (figure 1). For both patches, efficacy appears to be reduced in individuals with higher body weight. (See 'Efficacy' above.)

- The most common side effects associated with either patch are unscheduled bleeding in the first few cycles, breast tenderness, and application site reactions. Weight gain and mood disorders are **not** significant side effects for either patch. As with other combined estrogen-progestin contraceptives, the systemic side effects experienced by contraceptive patch users are generally well-tolerated and often improve within three to six months of use. (See 'Side effects' above.)

- Both oral and transdermal estrogen-containing contraceptives appear to adversely affect coagulation factors and thus place users at increased risk of venous thromboembolism (VTE), although the overall risk of VTE is low, especially when compared with the VTE risk of pregnancy (figure 2). There may be a modest increased risk of VTE for patch users compared with users of current combined oral contraceptives. (See 'Risk of venous thrombotic events' above.)

- Both patch products are applied weekly for three consecutive weeks followed by a patch-free week. Either patch can be applied to the buttock, abdomen, or upper torso (chest wall, not breasts). The EE/N patch can also be applied to the upper arm. A different site should be used each time a new patch is applied. (See 'Patch management' above.)

- If a patch is not changed at the appropriate time, back-up contraception may be needed (figure 3). (See 'Delayed patch changes' above.)

- If a patch is detached for less than 24 hours, it can be reapplied at the same location or replaced with a new patch immediately (figure 3). If detachment lasts longer than 24 hours, a new patch should be applied. (See 'Detached patch' above.)

- Since patch use avoids intestinal absorption and the first-pass effect through the liver, the patch is unlikely to impair the efficacy of other drugs (eg, some anticonvulsants and antibiotics), and its own efficacy is unlikely to be affected by administration of other drugs given concomitantly. However, supporting studies are limited, and data are mainly extrapolated from studies of estrogen-progestin oral contraceptives. Despite these limitations, it is reasonable to discuss drug interaction warnings with patients. (See 'Drug interactions' above.)

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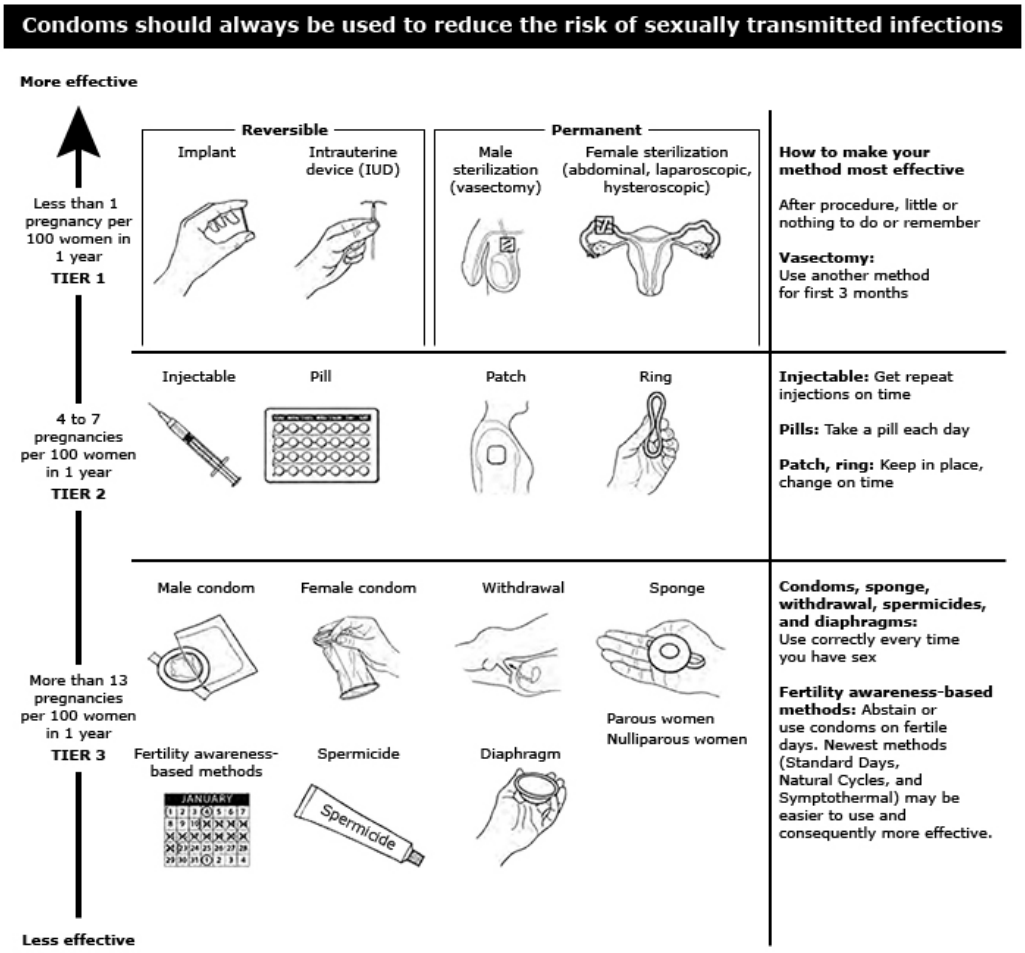
Topic 5425 Version 50.0

GRAPHICS

Comparison of effectiveness of contraceptive methods



Other methods of contraception:

- Lactational amenorrhea method – LAM is a highly effective, **temporary** method of contraception
- Emergency contraception – Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy

LNG: levonorgestrel.

Adapted from: U.S. Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. MMWR Morb Mortal Wkly Rep 2013; 62:1.
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Graphic 57795 Version 9.0

Efficacy of the transdermal contraceptive patch*

Study	Cycles	Pregnancies	Perfect use ¶	Typical use Δ
Noncomparative trial	10,994	6	0.59	0.71
Oral contraceptive, comparative trial	5921	4	0.66	0.88
Oral contraceptive, comparative trial	5240	5	0.99	1.24
Combined total	**22,155**	**15**	**0.7**	**0.88**

* Pregnancies per 100 woman-years.
¶ Failure (pregnancy) when taking correctly.
Δ Perfect use failure plus user failure.

Adapted with permission from: Burkman RT. The transdermal contraceptive patch: a new approach to hormonal contraception. Int J Fertil Womens Med. 2002; 47(2): 69-76. Copyright ©2002 MSP International, Inc.

Graphic 77359 Version 4.0

Breakthrough bleeding and breakthrough bleeding/spotting by cycle for the ethinyl estradiol and norelgestromin contraceptive patch

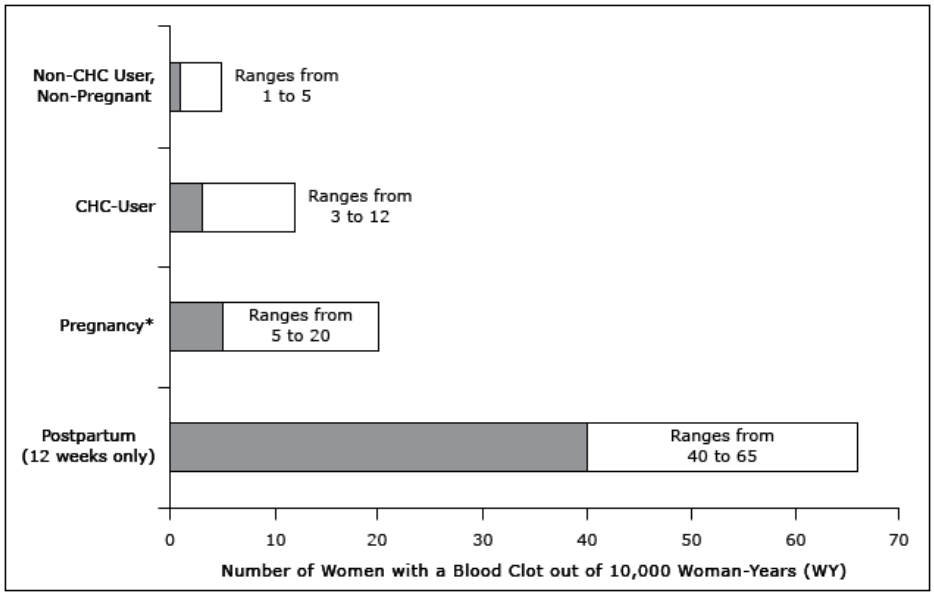
	Noncomparative trial	Comparative trial	
	Patch* (n = 1664), percent	Patch* (n = 812), percent	OC ¶ (n = 605), percent
Breakthrough bleeding			
Cycle 1	3.7	3.7	4.2
Cycle 3	3.7	2.9	4.5
Cycle 6	2.5	2.7	3.0
Cycle 9	1.5	1.3	3.1
Cycle 13	1.7	0	2.4
Breakthrough bleeding and/or spotting			
Cycle 1	17.5	18.3	11.4
Cycle 3	11.1	10.0	8.8
Cycle 6	7.3	9.5	7.1
Cycle 9	6.5	6.7	4.6
Cycle 13	9.2	5.5	7.1

OC: oral contraceptive.
* Patch: Ethinyl estradiol and norelgestromin transdermal contraceptive patch.
¶ OC: Triphasic preparation with levonorgestrel as progestin.

Adapted with permission from: Burkman RT. The transdermal contraceptive patch: a new approach to hormonal contraception. Int J Fertil Womens Med. 2002; 47(2): 69-76. Copyright © 2002 MSP International, Inc.

Graphic 64067 Version 6.0

Likelihood of developing a VTE within one year among pregnant and non-pregnant individuals



VTE: venous thromboembolism; CHC: combined hormonal contraception; WY: woman-years.
* Pregnancy data based on actual duration of pregnancy in the reference studies. Based on a model assumption that pregnancy duration is 9 months, the rate is 7 to 27 per 10,000 WY.

Reproduced with permission from: TWIRLA (levonorgestrel and ethinyl estradiol) transdermal system. Copyright © 2020 Agile Therapeutics. All rights reserved.

Graphic 127232 Version 1.0

How to start contraception

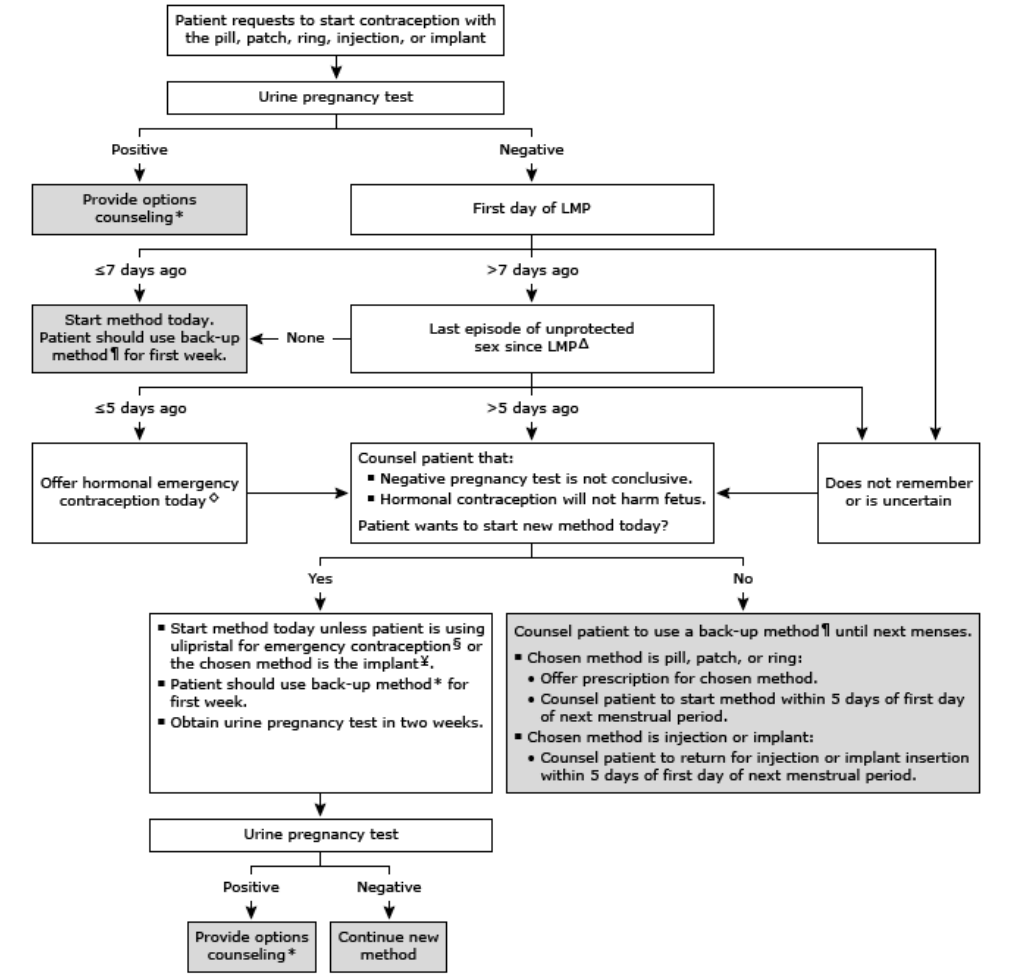
Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (ie, back-up) needed	Examinations or tests needed before initiation*
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection ¶
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days	Bimanual examination and cervical inspection ¶
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days	None

IUD: intrauterine device; BMI: body mass index; STD: sexually transmitted disease; CDC: Centers for Disease Control and Prevention.
* Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception, because all methods can be used (United States Medical Eligibility Criteria for Contraceptive Use 2010, US MEC 1) or generally can be used (US MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m^2]) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.
¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (US MEC 4). Women who have a very high individual likelihood of STD exposure (eg, those with a currently infected partner) generally should not undergo IUD insertion (US MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Reproduced from: US Selected Practice Recommendations for Contraceptive Use, 2013: Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd ed. MMWR Morb Mortal Wkly Rep 2013; 62:1.

Graphic 89825 Version 7.0

Quick-start (same-day start) approach to initiation of new birth control method: Pill, patch, ring, DMPA injection, implant



DMPA: depot medroxyprogesterone acetate; LMP: last menstrual period.

* Refer to UpToDate content on early pregnancy and pregnancy termination.

¶ Patient should use a barrier back-up method such as condoms for the first week after starting a new method.

Δ Unprotected sex includes episodes of sex in which a method of contraception was used but may not have been effective (eg, breakage of condom, multiple skipped pills).

◊ Refer to UpToDate content on emergency contraception.

§ For women using ulipristal for emergency contraception, progestin-containing contraception (ie, the pill, patch, ring, injection, and implant) should not be used for 5 days following ulipristal. For women taking levonorgestrel or combined estrogen-progestin emergency contraception, the new contraceptive method can be started after the emergency contraception. ◊

¥ If the patient would like the contraceptive implant, some providers prefer to offer a single injection of DMPA today and ask the patient to return for the implant within 5 days of the first day of her next menstrual period (to avoid the need for implant removal if the repeat urine pregnancy test is positive).

Adapted from: Quick Start Algorithm for Hormonal Contraception. RHEDI/The Center for Reproductive Health Education In Family Medicine, Montefiore Medical Center (Accessed on July 7, 2016).

Graphic 56863 Version 11.0

Checklist used to assess the possibility of pregnancy

The provider can be reasonably certain that the patient is not pregnant if the patient has no symptoms or signs of pregnancy and meets ANY of the following criteria:
☐ The patient has not had intercourse since last normal menses.
☐ The patient has been correctly and consistently using a reliable method of contraception.
☐ The patient is within 7 days from the first day of menstrual bleeding.
☐ The patient is within 4 weeks postpartum (for nonlactating patients).
☐ The patient is within the first 7 days postabortion or miscarriage.
☐ The patient is fully or nearly fully breastfeeding, amenorrheic, and less than 6 months postpartum.

A systematic review of studies evaluating the performance of a pregnancy checklist compared with urine pregnancy test to rule out pregnancy concluded the negative predictive value of a checklist similar to the one above was 99 to 100%.

Data from:

1. *Tepper NK, Marchbanks PA, Curtis KM. Use of a checklist to rule out pregnancy: A systematic review. Contraception 2013; 87:661.*
2. *Curtis KM, Tepper NK, Jatlaoui TC, et al. United States Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR Recomm Rep 2016; 65:1.*

Graphic 67567 Version 19.0

Managing partial or complete detachments and late/missed applications of the contraceptive transdermal system (ie, patch)

Scenario	Results in New TDS-Change Day	Starts New Cycle	Back-up Contraception Required (7 Days)
Did not apply TDS on scheduled Day 1/Week 1 of new cycle (late TDS-on day)	Yes	Yes	Yes
TDS detached for < 24 hours	No	No	No
TDS detached for ≥ 24 hours, or unsure duration	Yes	Yes	Yes
< 48 hours late for Patch Change Day (Day 8 or 15)	No	No	No
≥ 48 hours late for Patch Change Day (Day 8 or 15)	Yes	Yes	Yes
Forgets to remove last TDS on Day 22	No	No	No

TDS: transdermal system (ie, patch).

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Graphic 127233 Version 1.0

Contributor Disclosures

Ronald T Burkman, MD Nothing to disclose **Courtney A Schreiber, MD, MPH** Patent holder: Penn, Saul [Medical management of nonviable pregnancy]. Grant/Research/Clinical Trial Support: Bayer [Contraception]; Medicines360 [Contraception]; VeraCept [Contraception]. Consultant/Advisory Boards: Danco Pharmaceuticals [Early pregnancy loss]; Medicines360 [Consultant]. Other Financial Interest: American Board of Obstetrics and Gynecology. **Kristen Eckler, MD, FACOG** Nothing to disclose

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Conflict of interest policy

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