

Contraception for Adolescents: Focusing on Long-Acting Reversible Contraceptives (LARC) to Improve Reproductive Health Outcomes

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Abstract Adolescent pregnancy rates in the USA have reached an all-time low from their peak in the 1980s and 1990s. However, the USA maintains the highest rate of teenage pregnancy among developed nations. Adolescents experience higher typical use failure rates for user-dependent contraceptives compared to their adult counterparts. Long-acting reversible contraception (LARC), intrauterine devices (IUDs), and implants have failure rates that are both very low and independent of user age. In settings where the most effective methods are prioritized and access barriers are removed, the majority of adolescents initiate LARC. Use of LARC by adolescents significantly reduces rates of overall and repeat teen pregnancy. All methods of contraception are safe for use in teens, including IUDs and depot medroxyprogesterone acetate (DMPA). Dual use of LARC and barrier methods to reduce risk of sexually transmitted infection is the optimal contraceptive strategy for most adolescents. Adolescent access to evidence-based and confidential contraceptive services, provided in a manner that respects autonomy, is a vital public health goal.

Keywords Adolescent · Teen · IUD · Implant · LARC · Contraception · Birth control · Oral contraceptives · Injectable contraceptive · DMPA · Condoms · Barrier methods · Emergency contraception · Dual method · Pregnancy

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Introduction

The effectiveness of a contraceptive method is directly related to the effort needed to adhere to its perfect use. This is particularly true for adolescents who have more difficulty continuing and complying with methods that require daily adherence or use with each act of intercourse [1, 2]. Long-acting reversible contraceptive (LARC) methods, which include the intrauterine device (IUD) and the contraceptive implant, are highly effective because they require no action on the part of the user beyond insertion to remain highly effective [3]. Because of the safety and efficacy of LARC methods, the American Academy of Pediatricians (AAP) and the American Congress of Obstetricians and Gynecologists (ACOG) recommend IUDs and implants as first-line contraceptives for adolescents [4, 5].

Epidemiologic Trends

The teenage pregnancy rate in the USA has reached a historic low. Fewer teens are becoming pregnant, giving birth and having abortions. In 2010, the pregnancy rate among teens was 57.4 per 1000 women, the birth rate 34.4 per 1000 women, and abortion rate 14.7 per 1000 women. These rates have decreased substantially from highs in the 1980s and 1990s when the teenage pregnancy rate was 116.9 per 1000 women, the birth rate 61.8 per 1000 women, and the abortion rate 43.5 per 1000 women [6].

However, pregnancy in adolescents must be considered in a global context. The USA continues to have the highest teenage pregnancy rate among developed countries. Three in 10 teens will become pregnant before they turn 20, resulting in approximately 750,000 pregnancies each year, more than 80 % of which are unplanned [6]. In 2010, births among teens resulted in nearly 10 billion dollars in public assistance and

health care costs [7]. A woman who has a baby in her teens is significantly more likely to have lower educational and income attainment in adulthood compared to her non-childbearing peers [7].

Disparities in the rates of teenage pregnancy are dramatic and fall along racial and ethnic lines. Black teenagers have double the birth rate (51.4 per 1000 women) and quadruple the abortion rate (34.5 per 1000) of non-Hispanic white teenagers (birth rate 23.6 per 1000 women, abortion rate 8.5 per 1000) [6]. Hispanic teenagers have double the birth (55.6 per 1000) and abortion rate (15.3 per 1000 women) of non-Hispanic white teenagers [6].

The most rapid decline in the teenage pregnancy rate occurred between 2008 and 2010, when a decrease of 15 % was noted. Though the etiology of this decline has not been fully elucidated, increased use of long-acting reversible contraceptives (LARC) is a leading hypothesis [6]. Use of LARC methods increased from 1.4 % of current contraceptors age 15 to 19 between 2006 and 2008 to 4.4 % between 2008 and 2010. Though this increase seems modest, it represents a tripling in the rate of LARC use among teens [8•].

Long-Acting Reversible Contraceptive Methods

Implants

The single-rod etonogestrel implant (Implanon®, Nexplanon®, Merck, Whitehouse Station, NJ) has perfect and typical use failure rates of five pregnancies per 10,000 women in 1 year [9]. It is FDA approved for use for 3 years, though ongoing studies are investigating whether it continues to prevent ovulation for a longer period of time. The implant must be inserted by a clinician who has completed specific insertion training. One study suggests that younger teens (14 to 17 year olds) tend to select the implant over the IUD while older teens (17–18 year olds) tend to select the IUD over the implant [10]. Continuation of contraceptive implants among adolescents is high. In a study of women younger than 20 years of age, the 1-year continuation for the contraceptive implant was 80 % [10].

Adolescents who use an etonogestrel implant will either experience amenorrhea or non-cyclic bleeding or spotting. While some will not find this bleeding pattern bothersome, others cite it as a reason for discontinuation. Adolescents who are concerned about weight gain can be reassured that the contraceptive implant has not been associated with weight gain. Only 2.3 % of women in clinical trials discontinued the contraceptive implant because of weight gain [11]. Though the implant results in a relatively hypo-estrogenic state for the user, the slight decrease in bone mineral density demonstrated in some studies is clinically insignificant [12, 13].

Intrauterine Devices

Three intrauterine devices (IUDs) are available in the USA, a copper IUD (T380A, Paragard, Teva North America, North Wales, PA) and two levonorgestrel (LNG) IUDs. The 5-year LNG20 IUD (Mirena, Bayer HealthCare Pharmaceuticals Inc., Wayne, NJ) initially releases 20 mcg of hormone per day which decreases to 10 to 14 mcg after 5 years. The smaller LNG14 IUD (Skyla, Bayer HealthCare Pharmaceuticals Inc., Wayne, NJ) initially releases 14 mcg of LNG per day decreasing to 5 mcg after its FDA-approved duration of use of 3 years. Typical and perfect use failure rates for the copper and LNG IUDs are approximately 0.2–0.6 % [9]. Continuation is high; the 12-month continuation rate for a large cohort of teens aged 14 to 19 years was 80.6 and 75.6 % for the LNG20 and copper IUD, respectively [14•].

IUDs do not cause tubal infertility and are safe to use in nulliparous adolescents [15, 16]. Contamination during the insertion process results in a slightly increased risk of upper genital tract infection for the first 21 days after insertion, after which time the risk of pelvic inflammatory disease is similar to non-IUD users [17–19]. The U.S. Selected Practice Recommendations for Contraceptive Use, 2013 recommend screening for sexually transmitted infections (STIs) in women prior to IUD insertion according to national screening guidelines [20]. Unless adolescents are known to have untreated gonorrhea or chlamydia, have symptoms of cervicitis or pelvic inflammatory disease (pain, purulent discharge), or are at very high individual risk for a STI (e.g., recent sex with an infected partner), IUD placement should not be delayed until the results of STI testing are available [20]. Even when subclinical cervicitis is present at the time of insertion, the risk of upper genital tract infection is between 0 and 5 % [19]. The U.S. Selected Practice Recommendations for Contraceptive Use recommend that adolescents who test positive for gonorrhea or chlamydia with an IUD in situ be treated with the IUD in situ [20].

Nulliparous women report more pain with IUD insertion than parous women [21]. However, administration of misoprostol 2 to 3 h prior to insertion is associated with more pain prior to insertion and does not improve the ease of insertion or decrease pain at the time of insertion [22–24]. The most effective pain control regimen for IUD insertion has not been established [25]. Randomized controlled trials demonstrate a paracervical block [26] decreases pain at the time of insertion, while vaginal nitroglycerin [27], self-administered vaginal 1 % or 2 % lidocaine gel [28, 29], and intrauterine lidocaine [30] do not decrease insertion-related pain.

IUD expulsion rates are generally reported to be 5 % or less [31•, 32]. However, a wide range of expulsion rates have been reported in the literature [33, 34•]. Data from a large prospective cohort suggested a 3-year cumulative expulsion rate of approximately 10 % for the LNG20 IUD and 8 % for the

copper IUD [33, 34•]. IUD expulsion may be higher in adolescents than adults. In a cohort of more than 5400 IUD users, the hazard ratio of expulsion for females age 14 to 19 was 2.26 (95 % CI 1.68–3.06) for the LNG 20 IUD and 3.06 (95 % CI 1.75–5.33) for the copper IUD compared to women 20 years and older [34•]. In contrast, nulliparity is associated with fewer IUD expulsions. Among nulliparous adolescents age 14 to 19, the 12-month expulsion rate was 9.8 % (95 % CI 7.1–13.5), compared to 11.9 % (95 % CI 7.7–18.3) among parous adolescents [34•]. A higher risk of expulsion should be discussed with adolescents considering an IUD. However, the higher incidence of expulsion should not discourage providers from recommending IUDs to adolescents given that the risk of expulsion is lower than the risk of discontinuation with shorter-acting methods such as oral contraceptive pills.

The LNG14 IUD is smaller (28 mm wide, 30 mm long) than the LNG20 IUD (32 mm wide, 32 mm long) and has a minimally smaller inserter diameter (3.8 versus 4.8 mm). Whether expulsion is higher or lower in adolescents using the LNG20 versus LNG14 IUD is unknown, as women younger than 18 were excluded from comparative trials [32, 35]. A multicenter, single-arm study of the LNG14 IUD in adolescents found 1-year expulsion rate of 3.3 % [36]. Amenorrhea occurs in 13 % of adult women with the LNG14 IUD compared to 24 % of the women with the LNG20 IUD after 3 years [35]. In one study, insertion was reported to be “easy” in 90 % of both LNG20 and LNG14 IUD insertions [32], though clinicians reported insertion was “easy” more frequently with the LNG14 IUD in one comparative study (LNG14 IUD 94.0 % versus LNG20 IUD 68.2 %, $p < 0.001$) [35]. Though comparative studies did not include adolescents, amenorrhea is likely to be higher with the LNG20 IUD compared to the LNG14 IUD in adolescents. Similarly, based on data from adult women, insertion is likely to be “easy” more frequently with the LNG14 IUD in adolescents compared to the LNG20 IUD.

Decreased Unintended Pregnancy in Adolescent Cohorts Using LARC

The Contraceptive CHOICE project (<http://www.choiceproject.wustl.edu/>) is a longitudinal observational cohort study of women’s use and continuation of reversible contraception. The CHOICE project sought to decrease barriers to contraception by providing participants with evidence-based counseling and access to all contraceptive methods without a cost. More than 1400 females aged 14 to 19 years participated in the CHOICE project between 2008 and 2013. When provided with no-cost access to all contraceptive methods, 37.1 % selected the levonorgestrel IUD, 5.3 % selected the copper IUD, and 34.5 % selected the contraceptive implant, resulting in 71.5 % selecting a LARC method

[37]. Nearly all adolescents who participated in this study (99 %) were sexually active during the study period.

Overall, sexually active teens in the Contraceptive CHOICE cohort had a pregnancy rate of 34.0 per 1000, birth rate of 19.4 per 1000, and abortion rate of 9.7 per 1000 [37]. This is dramatically lower than rates reported for 2008 among sexually experienced teens in the USA who had a pregnancy rate of 158.5 per 1000, birth rate of 94 per 1000, and abortion rate of 41.5 per 1000. Unintended pregnancy among all participants (adults and teens) was 22 times higher among those using short-acting contraceptives (46 pregnancies per 1000 women-years) compared to LARC users (3 pregnancies per 1000 woman-years, adjusted HR 21.8, 95 % CI 13.7 to 34.9) [38•].

Dual Method: LARC Plus Condoms

The ideal contraceptive approach for sexually active adolescents is a LARC method along with latex or polyurethane condoms for STI protection. Condoms are commonly used in adolescents; 50 to 70 % of females and 75 to 80 % of males report use of condoms with their most recent penile-vaginal intercourse [39, 40]. The main disadvantage of condoms is that they must be used with every act of intercourse, which results in typical use failure rates of 18 % when used alone [41]. Benefits of condom use include accessibility without a visit to a health care provider and relative low cost.

Use of condoms along with a LARC method is challenging because it requires joint decision-making and an admission of STI risk by both partners. As perceived risk of STIs decreases, so does condom use. Consequently, longer relationship duration is predictive of lower condom use [42]. LARC users are less likely than users of short-acting hormonal contraceptives to also use condoms. Only 3.3 % of LARC users also use condoms, compared to 21.7 % of oral contraceptive pill users, 32.6 % of ring users, and 16.7 % of depot medroxyprogesterone acetate (DMPA) users [42]. Six months after LARC insertion, 33.7 % of 15 to 24 year olds reported decreased condom use with a new partner compared to 14.7 % of short-acting hormonal contraceptive users [43•]. By 12 months, 36.7 % of LARC and 34.3 % of short-acting hormonal contraceptive users reported decreased condom use with a new partner [43•]. Interventions to promote condoms in addition to LARC show higher rates of dual method use at 6 months, but these effects were not sustained by 12 months [44].

Condoms should be recommended to all adolescents regardless of their primary contraceptive method. Concerns about decreased condom use over time should not deter health care providers from recommending LARC methods. Additionally, IUDs should not be withheld from asymptomatic adolescents due to concerns about undiagnosed STIs

ascending into the uterine cavity at the time of insertion [20]. Those who have not been screened according to current guidelines should be screened at the time of insertion [20]. Those who have already been screened according to CDC guidelines do not require rescreening [20]. The levonorgestrel IUD may actually lower the risk of PID through cervical mucus thickening [18, 45]. The absolute risk of pelvic infection in the early months following IUD insertion is low at approximately 1 per 1000 [46].

Postpregnancy LARC Insertion

Rapid repeat pregnancy, defined as pregnancy that occurs within 2 years of a previous pregnancy, happens for more than a third of recently pregnant adolescents [47]. One in five births that occurs in an adolescent is a repeat birth [47]. Adolescents who have two children within 5 years are significantly more likely to forgo education and be affected by poverty [48].

ACOG, the U.S. Centers for Disease Control and Prevention (CDC), and the AAP recommend contraceptive implants and IUDs be discussed with pregnant adolescents and offered in the immediate postpartum period [4, 5, 49]. Insertion of the IUD shortly after delivery of the placenta, and insertion of the implant while the adolescent is still in the hospital, are given Category 1 and 2 (1=No restriction, method can be used, 2=advantages generally outweigh theoretical or proven risks) ratings by the US Medical Eligibility Criteria for Contraceptive Use [49].

Several studies have reported high satisfaction and continuation of the copper IUD when it is inserted in the immediate postpartum setting in adults and adolescents [50]. Fewer studies have investigated immediate postpartum insertion of the LNG IUD. A pilot study by Hayes et al., and a randomized controlled study by Chen et al., did not include women under the age of 18 [51, 52]. A third study by Dahlke et al. does not mention the age range of participants, but reported a mean age of 24.8 years [53]. Continuation of the LNG20 IUD following immediate postpartum insertion was high despite an increased rate of expulsion [53].

Placement of a postpartum contraceptive implant prior to discharge from the hospital significantly decreases the risk of repeat pregnancy within 1 year in adolescents. Only 2.6 % of teens in Colorado who received a contraceptive implant prior to hospital discharge became pregnant within a year, compared to 18.6 % of adolescents who did not receive an implant ($p < 0.001$) [54].

If a LARC method is not started prior to discharge from the hospital, adolescents who intend to use an implant are more likely to have it placed than those who intend to use an IUD. In a descriptive study of teens on Colorado, 37 % of teens who planned to use an implant had it inserted by 6 weeks postpartum. By 14 weeks, 68.4 % of those who intended to use the

implant had it inserted, with only 2.6 % resuming intercourse prior to insertion. Of teens who intended to use the IUD, none had it inserted by 6 weeks postpartum. Forty-three percent had an IUD inserted by 14 weeks postpartum, with 56.3 % resuming intercourse prior to insertion [54].

Increasing LARC Use Among Adolescents

Provider Knowledge

Though most family planning providers consider IUDs to be safe, many restrict their use to certain groups of women [55]. A 2011 survey of family planning providers in California found that more than 20 % considered the IUD inappropriate for nulliparous women. Seven percent thought the contraceptive implant should not be used in adolescents. More than 20 % thought the IUD should not be used in adolescents [56]. Other surveys have noted similar findings. A 2010 survey of obstetrician gynecologists found 38 % considered the IUD unsafe for nulliparous women [57]. A 2012 survey of family planning providers found 80 % rarely or never placed copper IUDs in nulliparous women and 67 % said they rarely or never placed LNG IUDs in nulliparous women [58]. Provider concern about IUD use in nulliparous women and adolescents stems primarily from misinformation regarding the risk of PID with IUD use and ineligibility among non-monogamous women and those with a history of an STI based on this risk [55–57]. Hesitancy in recommending the contraceptive implant to adolescents stems from a general lack of knowledge about this relatively new method. Approximately 20 % of family planning providers indicated they had “no opinion” regarding the implant’s safety, insertion timing, whether insertion was painful, and whether a follow-up visit was necessary, suggesting some providers do not know enough about the method to recommend it [56].

Patient Knowledge

Adolescents in the USA have only a modest awareness of LARC methods. In two studies among women younger than 25, only half had ever heard of an IUD [59, 60]. In a racially diverse group of adolescents age 14 to 19, only 21.1 % had ever heard of the IUD, despite being at high risk for unintended pregnancy, given that 76.4 % were sexually active and 56.6 % reported a history of pregnancy [61].

For adolescents, the two major sources of contraceptive information are the media and personal sources, such as family and friends. As part of a national campaign to decrease teen pregnancy, Kaye et al. surveyed young adults and found that 52 % first went to the media to get information about birth control [62]. About one third reported that they use a personal source, such as family or friends, to get information about

birth control. The potential for misinformation is high, given that the media tends to over-emphasize the risks of contraceptives [63]. Counseling by a health care professional is critical in increasing the use of LARC. In the survey by Kaye et al., 85 % of teens said the source they trusted most for contraceptive information was their doctor or other health care professional [62].

When adolescents participate in contraceptive counseling, discussion of the most effective, first-line methods should be prioritized [5]. The contraceptive conversation should begin with IUDs and the contraceptive implant. In the Contraceptive CHOICE Project, evidence-based counseling, in which the most effective methods were discussed first, resulted in 72 % of adolescents selecting a LARC method [37].

Confidentiality and Autonomy

Confidentiality is of particular importance to furthering access to LARC. Laws regarding the rights of adolescents to confidential contraceptive services without parental consent vary by state. Even in states where adolescents have reproductive autonomy, insurance billing practices may disclose personal health information to parents. Adolescents who usually use a parent's health insurance may not want to use drug benefits because of confidentiality concerns. Without insurance coverage, the high up-front cost of LARC is entirely prohibitive to most adolescents. In this instance, the federally funded Title X Program, which is charged with providing low- and no-cost contraception, may serve as a resource.

Although adolescents should have confidential access to top tier contraceptives, the rights of adolescents to decline and discontinue LARC methods without barriers must be supported. Adolescents represent a group that are particularly vulnerable to reproductive coercion as they may not be used to having autonomy and confidentiality in health care decisions. Furthermore, pregnancy intention and ambivalence is a complex issue even among adolescents.

Other Methods

Depot Medroxyprogesterone Acetate

Depot medroxyprogesterone acetate (DMPA, Depo-Provera, Pfizer, New York, NY) is an injectable progestin that can be given every 11 to 15 weeks. Two formulations are available, a 150-mg intramuscular injection and a 104-mg subcutaneous injection. Both formulations have similar side effects and efficacy. The overall typical use 1-year failure rate is approximately 6 % [64] though a 1-year pregnancy rate of 16.1 % has been reported in an adolescent population [2]. In a large cohort of adults and adolescents where methods could be obtained

without any cost at multiple sites, failure rates for DMPA were 0.1 % at 1 year, 0.7 % at 2 years, and 0.7 % at 3 years, respectively [38•]. Younger age is significantly associated with method discontinuation [2]. Only 12 % of adolescents were still using DMPA after 12 months, with half of those who continued to use the method reporting they “took a break” from the method for a period of time [2].

In 2004, the FDA issued a black-box warning about decreased bone mineral density among DMPA users. Studies demonstrate the decrease in bone mineral density with DMPA use is small, does not have clinical consequences (i.e., increased risk of fracture), and recovers after discontinuation [13]. ACOG states that DMPA can be used in adolescents without a limit to the duration of use. Routine monitoring of bone mineral density is not recommended, although weight-bearing exercise, smoking cessation, and age-appropriate intake of calcium and vitamin D should be encouraged for all women [65]. Adolescents may be a particularly vulnerable group to weight gain with DMPA. Weight gain in the first 6 months of use appears to be a predictor of excessive weight gain in both adolescents and adults [66–68].

Short-Acting Reversible Hormonal Contraceptives

Combined oral contraceptive pills continue to be the most commonly used reversible method in the USA [69]. The typical use failure rate for the combined oral contraceptive pill, which is 9 % in adult women, is likely to be higher in adolescents [2, 41]. In the Contraceptive CHOICE Project, women younger than 21 using short-acting hormonal contraceptives had twice the pregnancy rate as women older than 21 using the same method. This is in contrast to failure rates among LARC and DMPA users which did not differ by age [38•].

Discontinuation of short-acting hormonal methods is higher in adolescents than adult women. In the Contraceptive CHOICE Project, 12-month discontinuation rates were 1.47 (95 % CI 1.31–1.66) times higher in 14 to 19 year olds, compared to those 20 years and older [1•]. Continuation of short-acting hormonal contraceptives was 48.8 % at 1 year and 36.6 % at 2 years among 14 to 19 year olds [1•].

Discontinuation and pregnancy rates among adolescents and young adults using the ring and patch are higher than among those using the combined oral contraceptive pill. In an observational study of more than 1300 adolescents and young adults (age 15 to 24), approximately half of those who initiated the patch had discontinued by 2 months. Half of participants discontinued the ring and combined oral contraceptive pill by 5 months. One-year continuation of the patch was 10.9 %. One-year continuation of the ring was 29.4 and 32.7 % for the combined oral contraceptive pill [2]. Approximately half of users reported “taking a break” from their method for periods of time during the year. The pregnancy rate for the oral contraceptive pill was 16.1 % over a year

compared to 30.1 for the patch and 30.5 for the ring ($p < 0.001$) [2].

Progestin-only pills provide a contraceptive pill option to the small percentage of adolescents who have contraindications to estrogen, such as those with a known thrombophilia, history of venous thromboembolism, or migraines with aura [49]. Use of progestin-only pills in adolescents should be a rare occurrence, as they are less effective than combined oral contraceptive pills and require strict adherence to maintain efficacy. Pills must be taken at the same time every day, as differences of only 3 h are equivalent to a missed combined oral contraceptive pill [70].

Barrier Methods, Fertility Awareness Methods, Withdrawal

Methods like the female condom, periodic abstinence (fertility awareness, “the rhythm method”), spermicides, the cervical cap, and the diaphragm are not commonly used by adolescents. These methods require use with each act of intercourse, resulting in typical use failure rates above 20 % [41]. Withdrawal (coitus interruptus) is commonly used by adolescents, with 57 % reporting that they have used this method [39]. A high typical use failure rate of 22 % and the exposure of the user to STIs make it a problematic method for adolescents [41].

Emergency Contraceptives

All emergency contraceptives (EC) methods including the copper IUD, ulipristal acetate, LNG EC, and the Yuzpe method (combined oral contraceptive pills) should be made available to adolescents. The copper IUD is a highly effective EC which can be inserted within 120 h of unprotected sex. Branded and generic versions of LNG EC are safe to use regardless of age or comorbidities. Plan B One Step (Teva Women’s Health) is FDA approved for over-the-counter use in all age groups and should be readily available to male and female adolescents without a prescription. Cost, misinformation on over-the-counter age restrictions, and unwillingness of some pharmacists to facilitate ECP use by adolescents all serve as barriers. Informing adolescents about EC and giving them a prescription for an appropriate oral form of EC in advance can decrease barriers and increase the likelihood that it will be used when it is needed [71].

Conclusions

The current era is marked by historically low rates of teen pregnancy and modest, though significant, increases in LARC use among adolescents. Cohorts of adolescents who benefited from improved LARC access, including no-cost

contraception, postpregnancy insertion, and evidence-based counseling practices, demonstrate high use and continuation rates of LARC and low unintended pregnancy rates [54, 72].

Outside of these research cohorts, adolescents rarely select the most effective methods. The current charge is to extrapolate findings from the scientific literature and apply it to adolescents throughout the USA. A patient brings her own preferences to a health care encounter which stem from past contraceptive experiences, perceived risks of pregnancy and STIs, exposure to the media, and advice from family, partners, and friends. The role of the family planning provider is to provide the adolescent with evidence-based information regarding the most effective methods, while addressing her individual concerns so she can make a contraceptive choice consistent with her reproductive plans.

Compliance with Ethics Guidelines

Conflict of Interest Bliss Kaneshiro reports royalties for commissioned articles from Uptodate. Jennifer Salcedo declares that she has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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