New developments in long-acting reversible contraception: the promise of intrauterine devices and implants to improve family planning services

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After decades of having the developed world's highest rates of unintended pregnancy, the United States finally shows signs of improvement. This progress is likely due in large part to increased use of highly effective long-acting reversible methods of contraception. These methods can be placed and do not require any maintenance to provide years of contraception as effective as sterilization. Upon removal, fertility returns to baseline rates. This article addresses advances in both software—improved use and elimination of barriers to provide these methods; and hardware—novel delivery systems and devices. (Fertil Steril® 2016;■:■–■. ©2016 by American Society for Reproductive Medicine.)

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The United States has the highest rates of unintended pregnancy and abortion in the developed world, resulting in an imperative to improve these public health measures. Fortunately we are beginning to see declining rates at urban region, state, and national levels associated with removal of access barriers to long-acting reversible contraception (LARC), including intrauterine devices (IUDs) and contraceptive implants. Methods of LARC share the following attributes: they function for an extended period of time (at least 1 year), do not require any user action to maintain efficacy, and are as effective as sterilization (pregnancy rates are less than 1 per 100 women years), but unlike sterilization, they are completely reversible.

Significant advances in LARC service delivery over the past decade and new and future LARC methods will continue to favorably change the contraceptive landscape. Paul Blumenthal, M.D., M.P.H., at Stanford University refers to these two different forms of contraceptive developments as improvements in software (programmatic approaches and service delivery) and hardware (new methods) (1). This article will follow this approach in addressing both forms of LARC improvements.

LARC SOFTWARE ADVANCES

The central theme in recent and future LARC software developments is increasing access by breaking down initiation barriers. Barriers may include cost, clinical care access restrictions, unwarranted safety concerns, or expansion to previously restricted populations. Ongoing, multi-pronged software development will set the stage for future hardware successes.

LARC Promotion Reduces Unintended Pregnancies

Several studies promoting LARC devices documented declines in unintended pregnancy and abortion rates, fueling an intense interest in broadening LARC access and use. These studies featuring LARC methods have

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two important issues in common: [1] removing cost barriers to IUDs and implants; and [2] counseling patients on the superior efficacy and satisfaction associated with these devices. However, to avoid possible coercion while providing easy access to LARC devices, care must include the full range of contraceptive options (2, 3).

At the urban region level, the CHOICE project in St. Louis enrolled 9,256 women, offering no-cost access to their desired contraception for 3 years, and 75% chose LARC methods. Contraceptive pill, patch, or ring users were more than 20 times more likely to have an unintended pregnancy than LARC users (4). Moreover, teenage study participants had pregnancy and abortion rates less than half the rates St. Louis residents and the nation (5). At the state level in Iowa and Colorado, similar experiments showed remarkable decreases in teen pregnancies, unintended pregnancies, abortions, and preterm births (6–8).

Nationally, among women using contraception, a significant rise in the use of LARC devices from 2.4% in 2002 to 11.6% in 2012 occurred (9). Over this period, rates of unintended pregnancies and abortions declined (10). These successes may have contributed to the foundation for evidenced-based, professional organization guidelines to support increasing availability of LARC methods to all women (11, 12). More recently, counseling and clinic service provision focused on LARC methods demonstrated reductions in unintended pregnancy rates (13).

LARC Expansion in Clinical Care

In all settings where same-day LARC is provided, women are more likely to initiate the device than if a return visit is required. This increased uptake was demonstrated in postabortion (14, 15) as well as postpartum settings (16–18). In a clinical setting requiring an initial visit to complete an order form and second visit IUD placement, only half (54%) actually returned for the device (19). More importantly, women who receive same-day IUD or implant insertions have lower short-term pregnancy rates than those with delayed insertions (14, 20, 21).

The most rigorous evidence supporting immediate first-trimester post-abortion IUD placement comes from a randomized, controlled trial (RCT) of 575 women (14). All of the women randomized to immediate postprocedure insertion received their IUD, compared with 71% randomized to delayed insertion. Within 6 months there were no pregnancies in the immediate insertion group, compared with five in the delayed insertion participants, none of whom received their IUD (14).

Evidence documenting the benefits of LARC use in the postpartum period is abundant. An assessment of 2006–2010 National Survey of Family Growth data found that 13% of postpartum women using short-acting hormonal contraception had a pregnancy within 18 months, compared with 0.5% of LARC users (adjusted hazard ratio 21.2, 95% confidence interval [CI] 6.2–72.8) (22). During the in-hospital postpartum period, the IUD expulsion rate is lowest with an immediate post-placental insertion (within 10 minutes) (23, 24). Expulsion rates among women obtaining immediate post-placental hormonal IUDs seem to be higher than for those receiving copper IUDs (25). Future research initiatives investigating optimal insertion approaches will address postpartum LARC delivery software adjustments to decrease expulsion rates.

Another area where LARC methods can greatly benefit women at high risk of unintended pregnancy is among emergency contraception (EC) users. The copper T380 IUD is the most effective method of EC (0.1% risk of pregnancy) (26), while providing ongoing contraception, regardless of insertion timing in the menstrual cycle or days since unprotected intercourse (27). One barrier to IUD insertion for EC is the preference by many women for a hormonal IUD, such as the 20-μg levonorgestrel (LNG20) IUD, over the copper T380 IUD (28). A recent study found a low risk of pregnancy when the LNG20 IUD was placed with use of oral LNG for EC (28). To further break down obstacles to the LNG20 IUD, data are needed to assess the risk of pregnancy when LNG20 IUDs are inserted alone for EC.

Data are amassing supporting extending the use of IUDs and implants beyond their US Food and Drug Administration (FDA) approval. Prospective monitoring of CHOICE study participants identified one pregnancy among 108 LNG IUD users beyond 5 years of use and no pregnancies in 123 contraceptive implant users reaching 4 years of use (29, 30). These data add to a large LNG 52 mg IUD study reporting no pregnancies among women followed from 5 to 7 years after insertion (30). Additional data are forthcoming on use of an LNG 52 mg IUD through 7 years from the ACCESS intrauterine system (IUS) phase 3 FDA study (31).

Dispelling Concerns over IUD Infection Risk

Concerns for upper genital tract infection and subsequent infertility have limited the widespread use of IUDs in the United States. Historically, the inappropriate selection of a comparison group, the overdiagnosis of pelvic inflammatory disease in IUD users, and the failure to control for confounding sexual behavior effects contributed to the misunderstanding of evidence and overestimation of infection risk (32). This misperception of increased risk is outdated, not well-supported by evidence, and should not be a barrier to utilization. The American College of Obstetricians and Gynecologists supports IUD placement and supports routine screening for sexually transmitted infections (STIs) but does not require screening before IUD insertion (11, 33, 34).

The safety of a single visit IUD insertion with simultaneous STI testing is demonstrated by an evaluation of 57,728 Kaiser Permanente Northern California patients (35). The overall rate of pelvic inflammatory disease in this study was 0.5%. There were no differences in infection rates between those receiving same-day STI testing, those screened within 3 months, or women without screening.

Other recent large, prospective studies also demonstrate pelvic infection rates of 0.5% with IUD use (36) and low infection rates for all women, including those at a high risk for STIs (37). An evidence-based approach to STI screening at the time of IUD insertion should follow current guidelines (38, 39) and should not delay or interfere with LARC initiation (40). Wide