Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Quality Care for Women's Health

ICYMI*

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Most of us have been awash in information regarding the pandemic and the impact of the SARS CoV-2 virus (COVID 19) on humans—and rightly so. As a result, I am sharing some important recent developments in women's health research and contraception that may have been lost in the information avalanche. The first item relates to the participation of women in clinical trials. Women have historically been underrepresented in clinical trials. The rationale for reluctance to enroll women is based on concerns for inadvertently giving an agent that has not been fully tested to a pregnant person. The persistence of the unfounded belief that results of trials conducted with young, healthy, male animals and humans would apply to women also contributes to the lack of recruitment of women participants. In 1993, the US National Institutes of Health introduced a mandate to include women in drug and device trials unless there was some compelling, evidence-based reason to exclude them. In their metanalysis of 5,493 research articles published from 2018 to 2019, Zucker and Prendergrast[1] determined that the National Institutes of Health mandate has thus far failed to meaningfully impact inclusion of women. Only 26% of the studies included outcomes data by sex or included sex as a covariate. Excluding women increases risk for sex-specific adverse events and side effects. That risk is borne out by the fact that women experience adverse drug reactions at twice the rate of men. The increase in adverse drug reactions is related to sex-based differences in all phases of the pharmacokinetic process that affect what women's bodies do to the drugs. In addition, women are more likely to use 2 or more agents simultaneously, thereby increasing the likelihood of drug—drug interactions. Lastly, women on average have lower body and organ weight and a higher percentage of body fat compared with men, which all determine pharmacodynamics of drugs. In an effort to reduce fears or misconceptions about clinical trial participation and increase willingness to enroll, the US Food and Drug Administration has prepared consumer-focused fact sheets for clinicians. The documents are available in English and Spanish and can be accessed at https://www.fda.gov/consumers/womens-health-topics/women-clinical-trials.

Most clinicians who screen and provide treatment for sexually transmitted infections (STI) follow the guidelines updated and published by the US Centers for Disease Control and Prevention (CDC). Although the current recommendations are titled "2015 STD Treatment Guidelines," the latest update was completed in December 2020. The incidence of STIs has continued to increase despite efforts to effectively screen for and treat the conditions. To improve detection and treatment and ensure that the guidelines are informed by the latest evidence, the CDC has completed a thorough review of their recommendations. The result of their work is the "CDC 2021 Sexually Transmitted Infection Treatment Guidelines," available in Summer 2021. There is a free app for the current guidelines for both Apple and Android devices available on the CDC website: https://www.cdc.gov/std/tg2015/default.htm.

In the ongoing effort to provide an oral contraceptive with high efficacy and user satisfaction and a more favorable safety profile, a new combined oral contraceptive product (COCP) that contains a known progesterone-like agent, drospirenone, and estetrol (E4), an estrogen not previously used in COCPs, received approval from the US Food and Drug Administration in spring 2021.[2] E4 was identified in 1965 and is an estrogen that is produced by the fetal liver. The COCP (Nextstellis) contains 14.2 mg of E4 synthesized from plant estrone and 3 mg of drospirenone, a synthetic progestin. COCPs have been established for decades as highly effective in preventing pregnancy due to the multiple mechanisms of action of 2 hormonal agents. However, it is the estrogen that is believed to be responsible for the increased risk of deep vein thrombosis and other side effects. The cohorts for 2 Phase III clinical trials had participants from the United States and Canada who were racially diverse, aged 16–50 years; the trials also included people whose body mass index was as high as 35 kg/m^2. The aim of the research was to develop a product that would retain favorable ovulation suppression while significantly reducing the incidence of deep vein thrombosis, breakthrough ovulation, and side effects such as unscheduled bleeding and breast tenderness.[2] The COCP is expected to be available as of June 2021.

Contraception strategy in the past decade has increasingly focused on encouraging people to consider family planning methods that require minimal effort on the part of the users and that do not require making a daily or in-the-moment choice to use an agent to prevent pregnancy. Although the increase in the use of long-acting reversible contraception has been associated with significant reduction in unintended pregnancy, it is believed that it is the lack of control on the part of the user rather than the intrinsic efficacy of the method itself that is responsible for the change. On the other hand, people express discomfort with having to rely on a

* In Case You Missed It.

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third party (a clinician) to obtain, administer, or remove the method. A person-controlled long-acting reversible contraception using drugs that are familiar to the public has been on the market for about 1 year. The contraceptive is a silicone vaginal ring containing both segesterone acetate (a progestin) and ethynyl estradiol (estrogen), marketed under the name Annovera.[3] The ring is effective for 1 year (13 cycles) of regular use. It can only be obtained by prescription, so the need for clinician involvement remains, but after that, the person can place and remove the device themselves. The method works by suppressing ovulation and changing the uterine environment in the same manner as oral agents; it is as effective as COCP and has the same consumer precautions and advisements as other hormonal methods. Nonetheless, it fills a niche for person-controlled and effective long-acting contraception. I hope that you find these resources helpful in your clinical practice and efforts to provide high-quality and accessible health care to your clients.

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