Cervical Cancer & CTASC™:

Improving the Future of Women's Health Research

INSIGHTS FOR PROVIDERS, PATIENTS, AND CLINICAL TRIAL SPONSORS

By John Fitzgerald, DO, FACOG
Medical Director, Ancillare, LP

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January is Cervical Health Awareness Month. Dr. John Fitzgerald, Medical Director and Subject Matter Expert at Ancillare, shares insights from decades in the women's health field to raise awareness of cervical cancer and other conditions, discuss the importance of preventive services, and highlight the potential of Decentralized Trials to advance necessary research.

Background

In the United States, nearly half of all women do not receive the preventive services they require. COVID-19 has stressed this situation even more by adding to the challenges women already face, shifting their priorities for preventive services and medical visits. A larger share of women have gone without health care services during the pandemic compared to men, especially those in fair or poor health.

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Standards of Preventive Care

Recommendations for women's preventive health care services are developed and reviewed by the Women's Preventive Services Initiative (WPSI). The coalition was launched in 2016 by the American College of Obstetricians and Gynecologists (ACOG), engaging the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), 21 national health professional organizations and consumer and patient advocates with expertise in women's health across the lifespan.

Its task is to develop, review, update and disseminate evidence-based clinical data that helps to ensure that women receive preventive services without the use of co-pays, co-insurance or deductibles. The WPSI focuses both on benefits and harms of an intervention or service and assesses the balance between them. Cost is not part of this assessment because the focus is on clinical benefits and harms. Their motto is "When women are healthy, communities thrive."

The WSPI recommends the following preventive services:

- Well-Woman Visits
- Human Papillomavirus (HPV) DNA Testing
- Human Immunodeficiency (HIV) Screening and Counseling
- Breastfeeding Support, Supplies, and Counseling
- Gestational Diabetes Screening
- Sexually Transmitted Infection (STI) Counseling
- Contraception and Contraceptive Counseling
- Interpersonal and Domestic Violence Screening and Counseling

Screening for Cervical Cancer

The WPSI recommends cervical cancer screening for women aged 21-65 years who are of average risk as a preventive service. These women should not be screened more often than once every 3 years.

Women who have received the vaccine for human papillomavirus (HPV) should be screened with the same guidelines as those who have not received the vaccine.

These guidelines do not apply to high-risk women such as those infected with HIV, women who are immunocompromised, women exposed to DES in utero, or women treated for high-grade precancerous lesions within the last 20 years.

Cervical cancer screening is not recommended for women younger than 21 years or older than 65 years who have

had prior normal screening and are not at risk for cervical cancer. This designation requires documentation or report of a reliable patient, of three consecutive negative pap tests or two consecutive negative HPV tests within the previous 10 years with the most recent test within the past 5 years. Cervical screening is also not recommended in women who have had a hysterectomy with removal of the cervix and no history of a high-grade precancerous lesion or cervical cancer.

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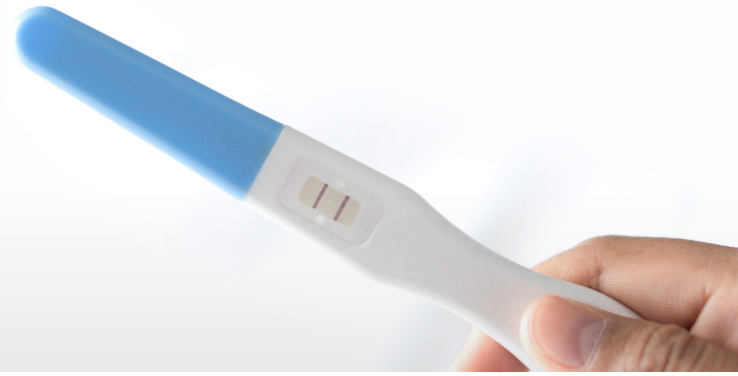
Patient-Centric Research Solutions

Women's health studies are often challenging to recruit for, due to time constraints, demands on women's schedules, underreporting, lack of treatment sought, and many other factors. Decentralized Trials have the potential to increase women's participation in clinical research and improve access to care by delivering needed supplies and IPs direct to the patients, allowing sponsors to increase recruitment numbers, test new technologies, and increase preventive services with fewer barriers.

Sponsors conducting Decentralized Trials must be able to count on their clinical supply vendors to coordinate necessary items, such as centrifuges and tubes, pipettes, cryogenic vials, and urine cups. The **Clinical Trial Ancillary Supply Chain (CTASC™)** model accounts for the specific configurations needed for the trial's protocol as early as possible so that supplies are sourced, produced, kitted, labeled, and shipped according to the trial's timeline. Single patient kits are assembled with precision and consistency for safety, compliance, and data quality.

For more information on Ancillare's Direct-to-Patient Kitting capabilities, reach out to our team at Ancillare.com/Contact.



John Fitzgerald, DO, FACOG
Medical Director

Dr. Fitzgerald has been a practicing obstetrician-gynecologist (OB-GYN) for over three decades. He completed his residency at Temple University Hospital and has since held roles and affiliations with a number of Philadelphia regional hospitals and networks, including Jefferson Health and Bryn Mawr Hospital. He currently serves as the Associate Director and Associate Professor for the Physician Assistant Program at Salus University. He has also contributed to a number of scholarly publications on a variety of women's health topics and was a lead investigator for the National HPV Study. Dr. Fitzgerald is a graduate of Philadelphia College of Osteopathic Medicine and is a Fellow of the American College of Obstetrics and Gynecology (ACOG).

References

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To learn more about Ancillare's industry-leading CTASC model, Subject Matter Experts, and therapeutic expertise, visit **Ancillare.com**.