Ovarian Cancer: A Policy Perspective on an Orphan Disease
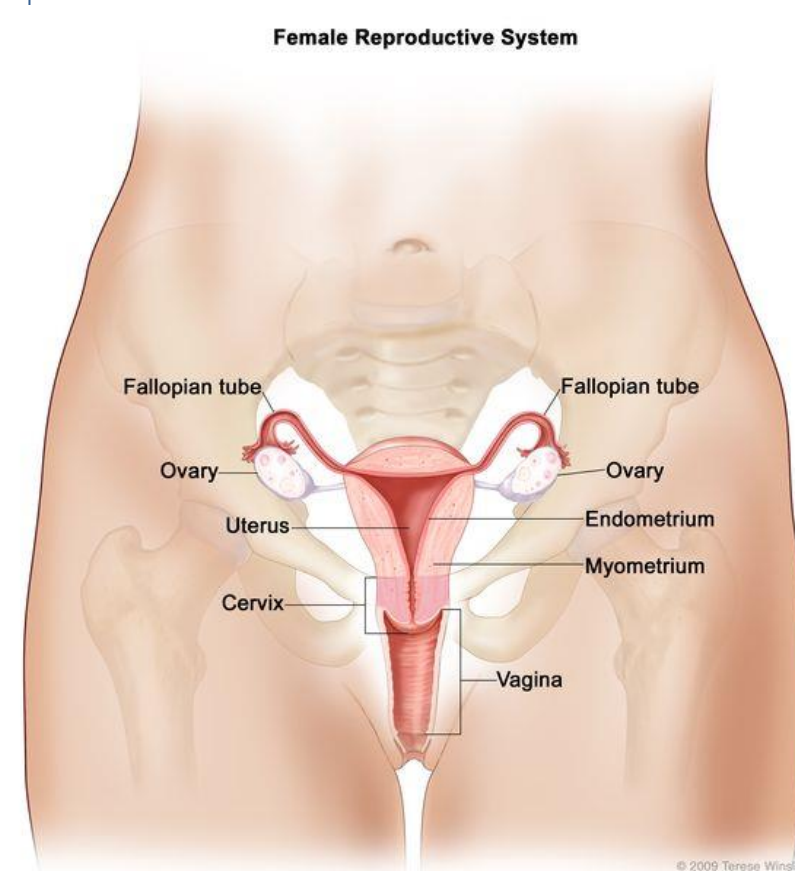
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Introduction

Female Reproductive System

- Ovarian cancer
    - Known as a silent killer
- CDC and other governmental organizations have played a role in promoting public health information of gynecological disease through the Inside Knowledge campaign
- Literature Review of ovarian cancer risk factors, public health agenda, and current challenges of ovarian cancer research

Background

Ovarian Cancer- An Orphan Drug

" drugs in the diagnosis, prevention, or treatment of a medical condition affecting fewer than 200,000 people in the U.S.-grants a product market exclusivity for a seven-year period if the sponsor complies with certain FDA specifications, as well as tax credits and prescription drug user fee waivers. This designation does not, though, shorten the duration of the regulatory review and approval process"

Methods

- Used the NIH's National Library of Medicine's PubMed.gov database
    - Searched terms related to
        - Ovarian cancer and public policy response
        - Orphan disease status
        The public health response to increase drug discovery

Results

Lit Review: Ovarian Cancer in the world: epidemiology and risk factors

- The most common gynecologic cancers that ranks third after cervical and uterine cancer and is three times more lethal than breast cancer
- Highest prevalence of ovarian cancer is seen in non-Hispanic white women (12.0 per 100,000), followed by Hispanic (10.3 per 100,000), non-Hispanic black (9.4 per 100,000), and Asian/Pacific Islander women (9.2 per 100,000)
- Risk reduced with pregnancy, induced abortion, risk decreases with more children, use of oral contraception
- Risk increased with nulliparity, infertility, family history of breast or ovarian cancer
    - BRCA gene
- Socioeconomic status is a predictor of incidence and survival of ovarian cancer

Results

Lit Review: Expanding the Public Health Research Agenda for Ovarian Cancer

Recommendations/Discussions

U.S. Preventive Services Task Force (USPSTF) recommended genetic counseling and BRCA1 and BRCA2 testing for women with a strong family history of breast or ovarian cancer

The merits of an annual ovarian cancer screen among the average-risk population with a combination of the serum biomarker CA-125 and transvaginal ultrasonography

Research related to CDC's gynecologic cancer awareness campaign, Inside Knowledge: Get the Facts About Gynecologic Cancer, as a response to the Gynecologic Cancer Education and Awareness Act of 2005.

1) provide information about the five major gynecologic cancers,

2) disseminate materials conveying the key message that when many cancers are found early, treatment is most effective,

3) educate women and healthcare providers about the signs and symptoms of gynecologic cancer, available screening tests, prevention strategies, and risk factors.

Lit Review: Using Inside Knowledge Campaign Materials to Improve Gynecologic Cancer Knowledge in Underserved Women

- A piece in the Journal of Women's Health that evaluated the effectiveness of the Inside Knowledge: Get the Facts about Gynecologic Cancer campaign
- Three different groups of women who attended educational sessions through CDC-funded National Networks, including SelfMade, National Behavioral Health Network (NHBN), and Nuestras Voces that recruited female participants from the general public aged 18 years and older
- A collaboration between Inside Knowledge campaign and its Consortium of National Networks to Impact Populations Experiencing Tobacco-Related and Cancer Health Disparities.

Discussion

- The Food and Drug Administration has designated ovarian cancer treatments as an orphan drug designation
- The Orphan Drug Act was established to create the financial incentives needed to encourage companies to research and develop treatment for new drugs for these diseases

- Congress designated funds towards ovarian research through the Gynecologic Cancer Education and Awareness Act (also known as Johanna's Law)
- CDC in 2015 also tasked the Institute of Medicine (IOM) to "make recommendations for public and private sector efforts that could facilitate progress in reducing the incidence of and the morbidity and mortality from ovarian cancer"
    - Current CA-125 and transvaginal ultrasound screening protocols have not led to reductions in mortality
    - Oral contraception as a protective factor for ovarian cancer in many studies, however, many of these studies evaluate populations born before the 1950s who had access to earlier, more potent forms of contraceptives

Conclusion

- The literature review has highlighted some of the challenges with ovarian cancer research and public health preventative work.
    - Risk factors include age, infertility, family history of cancer, and socio-economic status.
- How do government organizations fund research of orphan diseases?
- What factors play a role incentivizing scientific research?
- What does the future of ovarian cancer research look like?

Acknowledgements

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