## Predictors of sexual distress in gynecologic cancer survivors (2241)

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### Objectives
To quantify and identify predictors of sexual distress among gynecologic oncology patients undergoing routine surveillance to provide intervention and improve wellbeing.

### Methods
We performed a cross-sectional study of patients who have completed treatment for gynecologic malignancy at a single academic institution. Our primary outcome was sexually related personal distress, which was classified using the Female Sexual Distress Survey—Revised (FSDS-R). A score of 11 or above indicated sexually related personal distress with high reliability, discriminative ability, and construct validity. The PROMIS Female Sexual Function and Satisfaction Questionnaire (SexSF) is a validated instrument that looks at domains of sexual function over the past 30 days. Based on the PROMIS SexSF, sexual activity was defined to include masturbation, oral sex, and sexual intercourse. We performed a one-sided *t*-test and logistic regression statical analyses using STATA version 17.0.

### Results
From May to August 2022, 152 of the total 162 eligible patients completed the survey (overall response rate of 93%). The median age of respondents was 60 years old (range: 27–83, IQR: 20.5). Thirty-three percent of patients had a history of ovarian, 47% uterine, and 23% cervical/vaginal/vulvar cancer; 64% of patients had Stage I disease. The median years from finishing treatment (IQR) was 3.6 (2). Fifty-two percent of patients self-identified as non-Hispanic White, while 48% were non-White (Black, Asian, Pacific Islander, and Latinx). Overall, 68 (44.7%) reported being sexually active within the past 30 days. FSDS-R scores ranged from 0 to 52 with a median (IQR) of 5 (14). Overall, 37% of gynecologic cancer survivors reported sexually related personal distress. Age was significantly associated with less sexual distress (OR: 0.96, 95% CI: 0.94–0.99, $P = 0.01$). Lack of sexual activity was also significantly associated with less distress, impacting almost half of this group (OR: 0.33, 95% CI: 0.17–0.68, $P < 0.01$). Uterine cancer was significantly associated with less sexual distress (OR: 0.49, 95% CI: 0.24–0.97, $P = 0.04$). In contrast, the combined group of cervical/vagina/vulvar cancer patients was also found to have a significantly increased rate of sexual distress (OR: 3.56, 95% CI: 1.56–8.10, $P < 0.01$). However, this was not seen in ovarian cancer patients. Non-White race/Hispanic ethnicity was not associated with increased sexual distress, nor was menopausal status. When looking at the treatment received, 44% of patients underwent surgery alone, among which 37.9% met distress criteria. Thirty percent of patients underwent external beam radiation and/or brachytherapy, of which 41% reported sexual distress. Chemotherapy was administered to 68% of patients with a 32% rate of sexual distress. Treatment type was not a predictor of sexually related personal distress in our cohort.

### Conclusions
Younger age, cancer type, and sexual activity were significant factors associated with sexual distress. Prevalence of sexual distress did not differ significantly by race/ethnicity, menopausal status, or treatment type. Our results will help identify at-risk gynecologic oncology patients facing sexual distress and provide an opportunity to intervene and improve their quality-of-life outcomes.

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## Cost-effectiveness of *POLE* testing for high intermediate risk endometrial cancer (2242)

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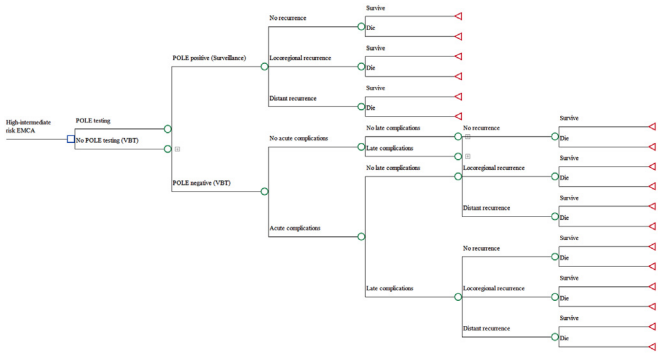
### Objectives
The Cancer Genome Atlas identified four subtypes of endometrial cancer, and patients with DNA polymerase epsilon (*POLE*) ultramutated tumors have an improved prognosis. The high intermediate-risk subtype of endometrial cancer is a heterogenous group, and the patients with POLE in this group may benefit from surveillance instead of vaginal brachytherapy. This study sought to determine the cost-effectiveness of *POLE* testing in patients with stage I high intermediate-risk endometrial cancer.

### Methods
A decision model was developed to compare *POLE* testing with next-generation sequencing and no *POLE* testing (TreeAge 2021, Williamstown, MA). A healthcare payor's perspective and a five-year time horizon were used. *POLE*-tested patients were assumed to undergo surveillance if positive, and if negative, received adjuvant vaginal brachytherapy. All patients without *POLE* testing underwent adjuvant treatment with vaginal brachytherapy. *POLE* testing was performed using next-generation sequencing (NGS). *POLE* prevalence was assumed to be 6% of those undergoing testing. Cost and utility data were derived from public databases and literature. The two strategies were compared using the incremental cost-effectiveness ratio (ICER), with effectiveness measured in quality-adjusted life years (QALYs), with a willingness to pay (WTP) threshold of $100,000 per QALY. One-way sensitivity analyses were performed by varying the prevalence of *POLE* mutations and the cost of testing.

### Results
Compared to universal treatment with vaginal brachytherapy, *POLE* testing with NGS had an incremental cost of $4681 with incremental effectiveness of 0.01 QALY, resulting in an ICER of $476,162. The sensitivity analyses showed that the model was most sensitive to



variations in *POLE* prevalence. One-way sensitivity analysis suggested that the ICER crossed our WTP threshold at a *POLE* mutation prevalence of 15% and would be cost-effective. A second sensitivity analysis estimated that *POLE* testing was cost-effective at a WTP of $100,000 if the cost of *POLE* testing was less than $1639. Performing *POLE* testing with Sanger sequencing with a cost of $500 as opposed to NGS was associated with lower cost and increased QALYs compared to usual care with brachytherapy.

**Conclusions**
*POLE* testing alone by NGS was not a cost-effective strategy in the high intermediate-risk endometrial cancer population. With its decreased costs, Sanger sequencing was cost-effective and below the WTP threshold. Continued research into high-fidelity yet less expensive methods to identify *POLE* tumors is warranted.

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## Trends in major gynecologic malignancies in the United State: The good, the bad, and the ugly (2243)

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**Objectives**
To determine the incidence trends in survival of ovarian, cervical, and uterine cancer in the United States based on representative population data over the last 10 to 20 years as relates to novel trial data.

**Methods**
Incidence data were drawn from the United States Cancer Statistics (USCS) program. Survival trends data were assessed from key phase III clinical trials and the Surveillance, Epidemiology, and End Results Program (SEER) and National Cancer Database (NCDB).

**Results**
Based on USCS data from 2001 to 2019, the incidence of ovarian cancer decreased from 15.08 to 11.85 (per 100,000) with an average annual percent change (AAPC) of −1.26% ($P < 0.001$). Based on the trials for upfront stage III and IV ovarian cancer, in the chemotherapy era (GOG 182-ICON5), compared to the antivascular era (GOG 218, ICON 7), and PARP-inhibitor era (PAOLA-1, PRIMA), the median overall survival (OS) increased from 42.4 to 48.9 to 56.5 months. Separately, according to SEER modeled trends, the 5-year overall survival for all stages rose from 42.51% in 1994 (paclitaxel approval) to 50.35% in 2011 (GOG 218 publication) and 54.31% in 2020 (PARP upfront approval). Using the NCDB, 5-year OS for stage III-IV ovarian cancer was 28.1% in 2004–2009 (chemotherapy era) versus 32.5% in 2010–2015 (biologic era). For cervical cancer, the incidence decreased from 9.24 to 7.75 (per 100,000) from 2001 to 2019, with an AAPC of −0.98% ($P = 0.006$). Based on the chemotherapy (GOG 204, GOG 169), antivascular (GOG 240), and immunotherapy trials (KEYNOTE-826), OS has increased from 10 to 16.8 and 24.4 months. According to the SEER modeled trends, the 5-year OS for all stages of cervical cancer was 72.07% in 2004 (GOG 169 publication) to 71.33% in 2014 (GOG 240) and 70.96% in 2019 (KEYNOTE-158). The 5-year OS for stage III-IV cervical cancer has improved from 32.4% in 2004–2009 to 36.7% in 2010–2015 from NCDB. In contrast, uterine cancer incidence increased from 25.81 to 36.01 from 2001 to 2019 (AAPC: +1.85, $P < 0.001$). Due to the limited upfront trials using novel therapies in advanced uterine cancer, we compared trials in recurrent disease. In the chemotherapy era (GOG 177), OS was 15.3; the addition of bevacizumab may have improved OS to 34.0 (GOG 86P); only recent immunotherapy trials have shown an increase in OS (18.3 for pembrolizumab/lenvatinib vs 11.4 for chemotherapy, KEYNOTE-775). Modeled SEER data showed that 5-year OS went from 84.44% in 2001 to 83.65% in 2019. Using the NCDB, 5-year OS remained unchanged for stage III-IV at 41.9% in 2004–2009 and 41.6% in 2010–2015, with no new agents in development over these periods.

**Conclusions**
The survival of advanced-stage ovarian cancer patients has improved over the last 20 years, likely due to the advent of targeted agents, such as antivascular agents and PARP inhibitors. The increase in mortality for uterine cancer with the corresponding lack of relatively effective clinical trials on novel agents calls for further investigation in this unmet need population.

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## Principal investigator gender and trial success in gynecologic oncology clinical trials (2244)

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**Objectives**
To assess how United States (US) gynecologic oncology clinical trials vary with regards to principal investigator (PI) gender and features of trial success.

**Methods**
A cross-sectional study was conducted of all US-based gynecologic oncology clinical trials registered on ClinicalTrials.gov (2007–2020). We examined associations between PI gender and three primary outcomes: early discontinuation, results reporting of completed trials to ClinicalTrials.gov, and publication on PubMed.gov.

**Results**
Of 1089 US-based gynecologic oncology trials, 777 (71.3%) had PI gender information. Trials included those led by all-female (F:394 trials, 50.7%), all-male (M:371, 47.7%), or a mix of male and female PIs (12, 1.5%). The percentage of trials led by all-female PIs increased from 26.4% in 2007 to 50.0% in 2020 (Fig. 1A). Most trials were led by PIs in gynecologic oncology ($n = 356$, 45.8%), followed by medical oncology ($n = 241$, 31.0%), "other"/combination specialty ($n = 70$,