# Welcome to the 2023 Annual Meeting Scientific Debrief!

May 20<sup>th</sup>, 2023

11:30 AM to 1:00 PM CST







# A Special Thank You to the Patient Education Alliance!













# **Ovarian Cancer SGO 2023 Annual Meeting Updates**

Lisa M. Barroilhet, MD, MS **Associate Professor** Director of Translational Research

University of Wisconsin School of Medicine and Public Health Madison, WI







GOG 3026 A Phase II Trial of Letrozole + Ribociclib in Women with Recurrent Low-Grade Serous Carcinoma of the Ovary, Fallopian Tube or Peritoneum (LGSOC): A GOG Foundation Study

Brian M. Slomovitz, Director, Gynecologic Oncology, Mount Sinai Medical Center, Miami Beach, Florida

#### **Purpose**

- 2/3 of LGSOC have loss of P16
- CDK4/6 inhibitors may overcome resistance to endocrine therapy

#### **Inclusion & Exclusion**

#### Inclusion criteria:

- Recurrent, measurable LGSOC by RECIST v1.1
- Central pathology confirmation
- Unlimited no. prior therapies

#### Exclusion criteria:

- Prior CDK 4/6 inhibitor
- Prior letrozole

## Results

- Efficacy (n = 48)
- ORR: 23%(n=11, all PR)
- PFS: 19.1 months
- Duration of response: 19.1 months
- 64% of evaluable patients experienced a reduction in target tumor size
- 38% (n=18) remain on study
- Reasons off study: 17 progression, 5 patient withdrawal, 3 deaths, 3 other, 2 toxicity
- Number of cycles: median 8 (1-45)

## **Conclusions & Real-World Applications**

- Ribociclib and letrozole is an active combination in LGSOC ORR, PFS, DOR compare favorably to most active agents previously investigated
- AE profile is as expected
- These results are promising. Women with this disease have limited treatment options. The progression-free survival and duration of response are both 6 months greater than what we have observed with the current standard treatments.





#### NOW: NEOADJVUANT OLAPARIB WINDOW TRIAL IN NEWLY DIAGNOSED BRCA MUTANT OVARIAN **CANCER**

Shannon N. Westin, MD, MPH

#### **Objectives**

- Determine feasibility of Olaparib in neoadjuvant setting for *BRCA* mutant ovarian cancer defined by unacceptable toxicity (dose interruption > 2 weeks, 2 dose reductions)
- Disease progression (RECIST v 1.1, new disease, increase CA125 > 50%)
- Estimate efficacy by RECIST v1.1 and proportion of pts able to proceed to interval TRS
- Determine PFS
- Determine complete pathologic response rate
- Determine toxicity of Olaparib in the neoadjuvant setting

#### **Key Eligibility**

- Germline BRCA1/2, RAD51C/D, PALB2mutation
- High grade serous histology
- Disposition to NACT with planned interval tumor reductive surgery
- Measurable or evaluable disease
- No prior treatment
- ECOG 0-2

- Adequate normal organ and marrow function
  - Hq >9
  - ANC >1.5
  - Plt>100
  - Bilirubin < 1.5
  - AST/ALT <2.5 ULN</li>
  - CrCl>40 ml/min

#### **Conclusions & Real-World Applications**

- Neoadjuvant Olaparib is feasible
- Surgical outcomes outstanding with only 2 cycles even in stage IV disease
- Expected safety profile during Olaparib window treatment
- Patients interested in PARPi alone therapy
- Ongoing molecular assessment of pre-and post-treatment changes in ctDNA and tissue biomarkers





Mirvetuximab Soravtansine(MIRV) in Patients with Platinum-**Resistant Ovarian Cancer with High Folate Receptor Alpha** (FRα) Expression: Evaluation of Sequence of Therapy on **Anti-Tumor Activity in the SORAYA Study** 

Robert Coleman, MD

#### **Objective**

Evaluate efficacy and safety of MIRV in patients with FRαhigh platinum-resistant ovarian cancer

#### **Design & Patient Population**

#### **Patient population**

- Platinum-resistant ovarian cancer (recurrence within 6 months after last platinum dose) trèated with 1to 3 prior regimens
- Primary platinum-refractory disease\* was excluded
- High-grade serous histology
- All patients enrolled received prior bevacizumab; prior PARP inhibitor was allowed
- Tumor demonstrated FRα-high membrane staining by the Ventana FOLR1 assay with at least 75% of viable tumor cells exhibiting at least 2+ staining intensity with IHC

#### **Treatment schedule**

- Patients received MIRV 6 mg/kg adjusted ideal body weight, IV once every 3 weeks
- Sample size calculation: 105 patients

## Results

- Consistent with prior clinical experience, 36% of patients screened found to have high tumor FRa expression, representing a significant proportion of patients with ovarian cancer who could potentially benefit from MIRV-based therapy.
- Expansion phase of the phase I evaluation of MIRV revealed that patients who had received three or fewer lines of prior treatments had better efficacy outcomes than those who developed resistant disease beyond the third line.
- The confirmed ORR in the SORAYA study population as assessed by the investigator was 32.4%, with five complete responders, and a median DOR of 6.9 months; assessment is ongoing.
- Benefit from MIRV was observed in all prespecified subgroups, including patients who had received one to two or three prior lines of treatment and regardless of whether patients had received a prior PARPi

#### Summary

- New oral drug combinations
- New drug timing
- New drug delivery





# Cervical, Vulvar, & Vaginal Cancer **SGO 2023 Annual Meeting Updates**

Deanna Gerber, MD Clinical Assistant Professor

Department of Obstetrics & Gynecology NYU Long Island School of Medicine Mineola, NY







## A randomized Phase II study of chemoradiation and pembrolizumab for locally advanced cervical cancer

Duska L et al

#### **Purpose**

Evaluate the safety of adding immunotherapy to standard chemoradiation for locally advanced cervical cancer and assess the bodies immune response.

#### **Methods**

- The immunotherapy Pembrolizumab was given either during chemoradiation or after
- All patients were monitored closely for safety and treatment response
- Blood samples and biopsies were collected before, during and after treatment

## Results

- In patients who received immunotherapy after treatment, 43% had a complete response, 43% partial response and 15% progression of disease
- In patients who received immunotherapy during treatment, 44% had a complete response, 54% partial response and 2% progression of disease
- Increased immune response in bloodwork was only seen when immunotherapy given during chemoradiation

### **Conclusions & Real-World Applications**

- From other studies it is known that chermo-radiation plus immunothepay may work synergistically
- This study shows that adding immunotherapy to standard treatment is safe and feasible
- The addition of immunotherapy seems to increase immune response and the longterm results from this study will help us better understand if and when to give immunotherapy





#### Cervical cancer recurrence among women undergoing surgery for early-stage disease

Polen-De C et al.

#### **Purpose**

To evaluate the association of pre-hysterectomy conization procedure, uterine manipulator use and surgical approach, with cervical cancer recurrence

#### Methods

Patients who had previously undergone treatment of stage I cervical cancer were retrospectively reviewed

#### Results

- Of the 761 women included, 47% had a conization within 6 months of surgery
- The risk of recurrence was lower in those who had prior conization, regardless of surgical approach
- Among women who had minimally invasive surgery without conization, the risk of recurrence was higher for patients with manipulator use
- In women with conization, the use of manipulator was not associated with higher risk of recurrence

#### Conclusions, Real-World Applications, & Caveats

- Recent studies have shown an increased risk of cervical cancer recurrence in women who underwent minimally invasive hysterectomy
- We do not yet fully understand the reason or mechanism for this
- In this study, a prior conization may be protective against recurrence
- The use of a manipulator was shown to increase risk of recurrence if no prior conization had been done





A Phase II trial evaluating cisplatin and gemcitabine concurrent with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva

Horowitz N et al

#### **Purpose**

Evaluate the benefit and safety of adding gemcitabine to cisplatin and radiation

#### **Methods**

- Patients with locally advanced vulvar cancer that could not be managed surgically were enrolled
- IMRT was prescribed along with weekly cisplatin and gemcitabine

#### Results

- 52 patients evaluated, all received full protocol dose of treatment
- 8% came off of trial due to toxicity with 82% of patients experiencing a moderate or severe side effect
- Over 70% had a complete response
- 74% of patients were without recurrence at 12 months and 70% were alive at 24 months

#### **Conclusions & Real-World Applications**

- Recurrence after standard chemoradiation is high after locally advanced vulvar cancer
- Improved radiation techniques of IMRT with the addition of gemcitabine to cisplatin improved the response to treatment and reduced rate of recurrence

#### **Caveats to Consider**

- The toxicity of this treatment may limit its usefulness, but warrants further studies
- Unclear if the benefit seen in this study is due to improved radiation technique or use of gemcitabine





# **Endometrial Cancer SGO 2023 Annual Meeting Updates**

Lynn P. Parker, MD

**Norton Cancer Institute** Louisville, KY







Pembrolizumab versus placebo in addition to carboplatin and paclitaxel for measurable stage III or IVA, stage IVB, or recurrent endometrial cancer: The phase 3, NRG GY018 Study

Eskander, RN et al

#### **Purpose**

- 1. To access whether addition of pembrolizumab to standard of care paclitaxel and carboplatin chemotherapy improves progression free survival in pMMR and dMMR populations
- 2. Secondary endpoints included safety, ORR/DOR per Recist v1.1 by BICR or investigator by treatment arm and MMR IHC status, OS in pMMR and dMMR population, PRO/QoL in pMMR population, and concordance of institutional vs central MMR IHC testing results

#### **Methods**

- 1. 591 patients with pMMR tumor and 225 patients with dMMR tumor on IHC testing were randomized to either:
  - Paclitaxel 175 mg/m2 IV, carboplatin AUC 5 IV and placebo IV every three weeks followed by placebo IV every 6 weeks for up to 14 additional cycles
  - Paclitaxel 175 mg/m2 IV, carboplatin AUC 5 IV, and pembrolizumab 200 mg IV every three weeks followed by pembrolizumab 400 mg IV every 6 weeks for up to 14 additional cycles
- 2. Protocol specific progression free survival analysis when both populations reached half the information time

### Results

- 1. There was a 70% (dMMR group) and 46% (pMMR group) reduction in risk of disease progression or death if pembrolizumab was added to standard of care chemotherapy followed by pembrolizumab maintenance
- 2. The addition of pembrolizumab to chemotherapy did not increase the common paclitaxel/carboplatin chemotherapy adverse events or increase the incidence of immune-mediated adverse events

### **Conclusions & Real-World Applications**

- Based on this study, the addition of immunotherapy to chemotherapy followed by maintenance immunotherapy resulted in a reduction in risk of disease progression or death in patients with dMMR and pMMR advanced stage or recurrent endometrial cancer
- 2. Adverse events with the combination of chemotherapy and immunotherapy were consistent with known events associated with chemotherapy and there was no increase in immune – mediated adverse events





Overall survival in NRG Oncology GOG258, a randomized phase III trial of chemo-radiation vs. chemotherapy alone for locally advanced endometrial carcinoma

Matei, D et al

#### **Purpose**

- 1. To evaluate if combined systemic chemotherapy and tumor volume directed radiotherapy improves recurrence-free survival and overall survival compared to systemic chemotherapy alone in patients with surgically staged III/IVA uterine cancer
- 2. To determine if C-RT reduces the rate of death compared to chemotherapy
- 3. Compare acute and late adverse effects as well as patient-reported quality of life

## **Methods**

- 1. Surgical Stage III or IVA EC, stage I or II clear cell or serous EC positive cytology randomized to:
  - cisplatin 50 mg/m2 IV day 1 and 29 plus volume-directed radiation therapy (45 Gy +/- brachytherapy) followed by carboplatin AUC 5 plus paclitaxel 175 mg/m2 for 4 cycles- 407 pts
  - carboplatin AUC 6 plus paclitaxel 175 mg/m2 for 6 cycles 406 pts
- 2. Median follow up 112 months

### Results

- 1. Chemo-RT did not improve overall survival or progression free survival compared to chemotherapy
- Chemo-RT was associated with decreased incidence of vaginal, pelvic, or para-aortic recurrence but increased incidence of distant recurrences

## **Conclusions & Real-World Applications**

- Chemo-RT did not improve overall survival or progression free survival compared to chemotherapy in patients with surgical stage III or IVA endometrial cancer, stage I or II clear cell or serous endometrial cancer with positive cytology
- 2. The study had a long median follow up of 112 months
- 3. It is important to remember that patients with carcinosarcoma, recurrent endometrial cancer, and residual disease greater than 2 cm were not eligible for the study





# Endometrial cancer molecular staging: Updates from AJCC, FIGO, European Guidelines

Olawaiye, A

#### **Purpose**

- 1. Discuss alignment of FIGO and AJCC staging
- Review the molecular classification of endometrial cancer and the staging implications
- 3. Present FIGO's 2023 staging for endometrial cancer

#### **Key Background Information**

Genomic characterization of endometrial cancer

- ultramutated group (POLE-EDM)- Good prognosis
- hypermutated group (MSI) Intermediate prognosis
- Copy number low (NSMP) Intermediate prognosis
- Copy number high (Serous-like)- Poor prognosis
- 2. These groups are associated with differences in progression free survival and identify patients who have increased risk of recurrence not necessarily identified with histologic characteristics
- 3 ERGO/ESTRO/ESP recommendations: molecular classification encouraged in all endometrial cancers, POLE mutational analysis can be omitted if low or intermediate risk endometrial cancers with low grade histology. Histologic type, grade, myometrial invasion, and LVSI should be recorded in all patients with endometrial cancer



**Stage IA**-disease limited to endometrium or non-aggressive histologic type with invasion less than half the myometrium with no or focal LVSI or good prognostic disease

Stage IA1- confined to a polyp or confined to endometrium

Stage IA2-non-aggressive histologic type involving less than half of the myometrium with no or focal LVSI

Stage IA3-low grade endometrioid carcinomas limited to the uterus and ova

Stage IB- non-aggressive histology, less than half myometrial invasion with no or focal LVSI

Stage II-Invasion of cervical stroma without extrauterine extension or extensive LVSI

Stage IIA- invasion into cervical stroma

Stage IIB- substantial LVSI

Stage IIC-aggressive histologic subtypes with myometrial invasion

Stage IIIA- Invasion of uterine serosa, adnexa, or both by direct extension or metastasis

Stage IIIA1- spread to ovary or fallopian tube

Stage IIIA2- involvement of uterine subserosa or spread through uterine serosa

Stage IIIB- metastasis or direct spread to the vagina and/or parametria, or pelvic peritoneum

Stage IIIB1- metastasis or direct spread to the vagina, and/or parametria

Stage IIIB2- metastasis to pelvic peritoneum

Stage IIIC- metastasis to pelvic or paraaortic lymph nodes or both

Stage IIIC1i- micrometastasis to pelvic nodes

Stage IIIC1ii – macrometastasis to pelvic nodes

Stage IIIC2i- micrometastasis to paraaortic lymph nodes

Stage IIIC2ii- macrometastasis to paraaortic lymph nodes

Stage IV-spread to bladder, and/or intestinal mucosa and/or distant metastasis

Stage IVA- invasion of the bladder, intestinal mucosa, or both

Stage IVB- abdominal peritoneal metastasis, intraperitoneal metastasis beyond the pelvis

Stage IVC- distant metastasis including metastasis to inguinal lymph nodes, lungs, liver, or bone

## **Q&A Breakout Rooms**

## Ovarian Cancer | Cervical/Vulvar/Vaginal Cancer | Endometrial/Uterine Cancer

You'll be able to choose whichever breakout room you'd like to enter. This is your time to ask questions and dive deeper!

You can switch between the rooms at your leisure using the 'Breakout Room' button on your zoom toolbar.



If you don't see it, try clicking the 'More' button:





# Survivorship **SGO 2023 Annual Meeting Updates**

Shannon Armbruster, MD, MPH **Assistant Professor** 

Virginia Tech Carilion Clinic Division of Gynecologic Oncology Roanoke, VA







#### Use of cryocompression to reduce peripheral neuropathy in gynecologic cancer: A randomized controlled trial

Mary Katherine Montes de Oca, MD, et al.

#### **Hypothesis**

Cryocompression can prevent/ reduce chemotherapy-induced peripheral neuropathy.

#### **Methods**

- Randomized, self-controlled trial of cryocompression in gynecologic cancer survivors receiving 6 cycles of chemotherapy (with agents that can cause neuropathy).
- Cryocompression either on dominant or nondominant hand and foot. Other side was not treated.
- Compression socks and ice bags were applied to the hand and foot 15 minutes prior to chemotherapy, throughout the chemotherapy infusion, and 15 minutes after completion.

#### Results

- With each cycle, more subjects had more moderate/ severe sensory symptoms on the control compared to the cryocompression side.
  - Baseline: 2.2% vs 3.3% at baseline,
  - Cycle 3: 8.8% versus 6.6% at cycle 3
  - Final Assessment: 13.2% versus 7.7%
- Quality of life scores were higher on the cryocompression side.

#### **Conclusions & Real-World Applications**

- Cryocompression reduces chemotherapy-induced peripheral neuropathy and is acceptable and tolerable to patients.
- This is a low-cost intervention than can be widely implemented.

#### **Caveats to Consider**

- 14 of 86 survivors withdrew from participation after 1-2 cycles.
- Other "high-tech" cryocompression devices are available but were not tested in this study.





## **Chemotherapy Drug Shortages in Gynecologic Cancers Update**

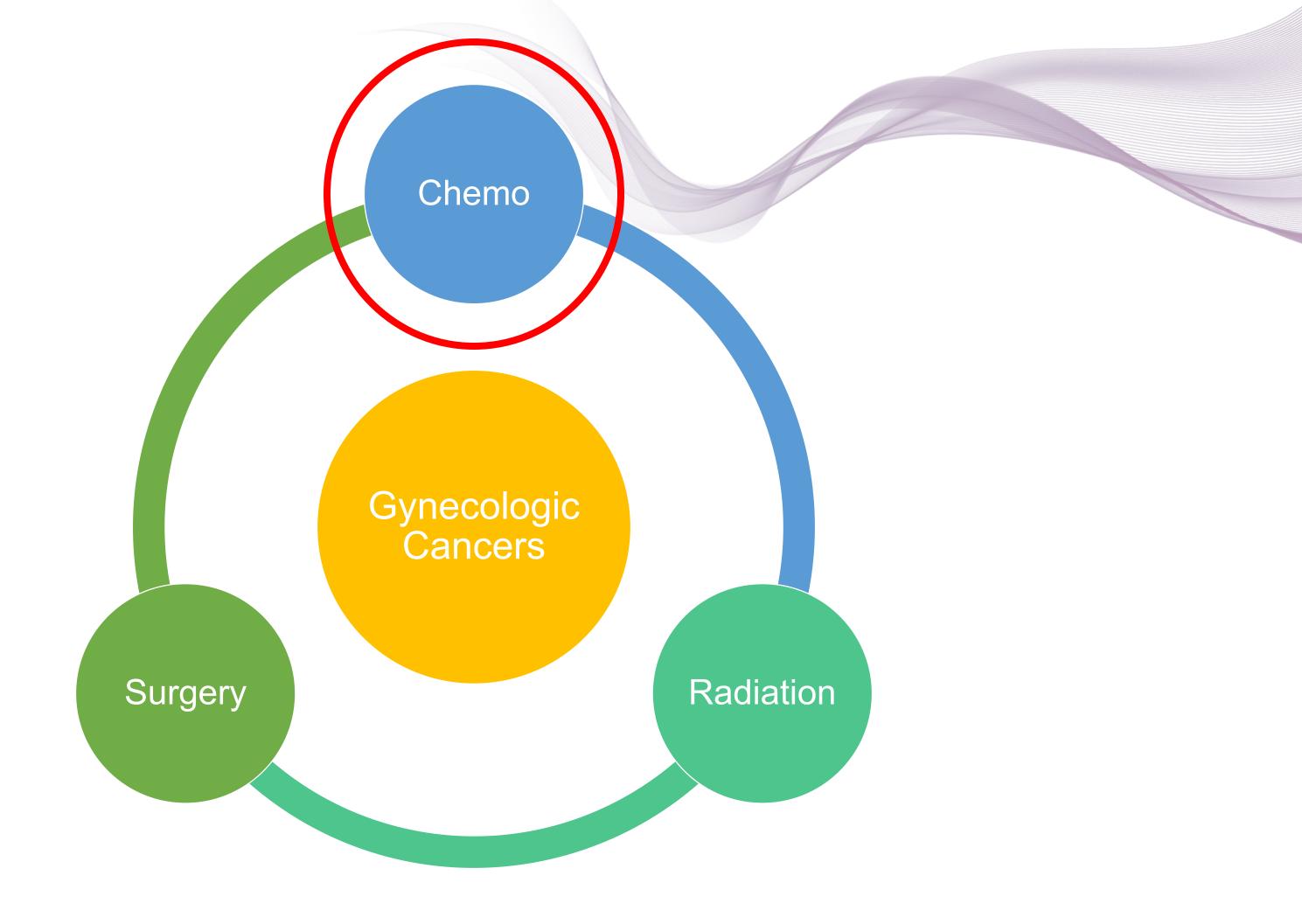
Lori Cory, MD, MSCE Co-Associate Fellowship Director

University of Pennsylvania Division of Gynecologic Oncology West Chester, PA













# Drug shortages in the news

M Medscape · 55m

#### Drug Shortages in US at 10-Year High

Drug shortages hit a 10-year high in early 2023. Among the current shortage are 15 cancer drugs, some of which lack an ...



The New york Times . 1d

#### Drug Shortages Near an All-Time High, Leading to Rationing

A worrisome scarcity of cancer drugs has heightened concerns about the troubled generic drug industry. Congress and the White ...



#### The New york Times . 9h

#### **Prescription Drug Shortages**

The broader shortages partly reflect supply chain problems for generic drugs, which make up 90 percent of prescriptions. But ...



yahoo!news · 2d

#### Nationwide shortage of chemotherapy drugs hits Tallahassee

Cancer drugs among top 5 most affected by shortages in the US

shortage of about two dozen chemotherapy drugs, the fifth most of any drug ...

As the US faces a near-record number of drug shortages, cancer treatments are among the hardest hit. There is an active

In February, the U.S. Food and Drug Administration announced a national shortage of carboplatin and cisplatin, drugs used to ...



HR Becker's Hospital Review · 1d

#### Chemo drug shortage could lead to 'inferior care': American Cancer Society

Further, William Dahut, MD, chief medical officer of the American Cancer Society, said that "if these drugs are no are going to get inferior care. That's the bottom line. These aren ...

#### Ipm · 10h

#### As drug shortages hit near-record highs, pharmacists shield Kentucky and Southern Indiana patients

Managing drug shortages is a routine part of a pharmacist's job, but it's become increasingly more difficult as shortages of ...



Fox 5 NY · 16h

#### Drug shortages reach near-historic levels

Drug shortages in the United States are reaching near-historic levels, causing a public help crisis. The shortage is ...







# Shortages impacting gynecologic cancers

Drug	Date Shortage Posted
Cisplatin	02/10/23
Methotrexate	03/13/23
Carboplatin	04/28/23
Fluorouracil	05/05/23
Docetaxel	05/05/23



# This may seem scary, but there is support...

- For patients:
  - FWC communique
  - FWC webinar
  - Supportive services
- For providers:
  - SGO communiques
  - SGO/FWC and GOG partners communique (clinical trials)
  - SGO educational webinars



# And advocacy...

- From our societies and providers:
  - Regulatory/Policy plan
  - Legislative engagement
  - Contact with manufacturers
  - Discussion with oncology societies











# SGO Communique I: Carboplatin and Cisplatin Shortages

## **Guiding principles for providers:**

- 1. Minimize ordering of non-essential platinum.
  - If there's an alternative with comparable efficacy and safety is available, consider use of the alternative.
- 2. Increase the interval between cycles and reduce the total platinum dose when clinically acceptable to do so.
  - As long as within the range recommended within the National Comprehensive Cancer Network (NCCN) guidelines.
- 3. Consider minimizing or omitting cisplatin or carboplatin for recurrent platinumresistant ovarian and other cancers.



# SGO Communique I: Carboplatin and Cisplatin Shortages

## **Guiding principles for providers:**

- 4. Ration dosing by rounding doses down to the nearest vial size as a first step to ensure efficient use.
- 5. Consult with your oncology pharmacy to determine your healthcare system's current supply of these platinum agents and escalate any shortages promptly along the supply chain and to your clinical teams.
- 6. If adequate supplies are unavailable, select an alternative, <u>evidence-based</u> <u>regimen</u> and consider a consultation with oncology/hematology colleagues.



# SGO Communique II: Considerations in Cervical, Vulvar and Vaginal Cancer

#### **Cervical Cancer:**

- Cisplatin and carboplatin should be reserved for cervical cancer treatment with curative intent.
- The use of concomitant platinum-based chemoradiotherapy as adjuvant therapy following radical hysterectomy should be restricted to patients with early-stage, high-risk disease.
- Cisplatin or carboplatin may be omitted from radiotherapy in intermediate-risk cervical cancer patients when the drug supply is limited.
- For patients receiving concomitant chemoradiation for locally advanced cervical cancer, cisplatin 40 mg/m² (capped at 70mg) IV weekly remains the preferred chemotherapy drug.





# SGO Communique II: Considerations in Cervical, Vulvar and Vaginal Cancer

## **Cervical Cancer:**

- 5. When cisplatin is not available, consider alternative and evidence-based radiosensitizing agents.
- 6. When selecting alternative radiosensitizing agents, regimen toxicity, intensity, ease of administration, and cost must be considered.
- 7. For patients with recurrent or persistent cervical cancer following primary chemoradiation or primary metastatic cervical cancer, consider alternative and <u>evidence-based</u> non-platinum based regimens.





# SGO Communique II: Considerations in Cervical, Vulvar and Vaginal Cancer

## **Vulvar/Vaginal Cancer:**

- In the treatment of vulvar cancer, allocation of cisplatin should be prioritized to regimens administered with curative intent.
  - When considering alternative radiosensitizing treatments, careful consideration of potential efficacy, toxicity, workflow, and cost, is critical, as discussed above.
- 2. In treating vaginal cancer, the combined use of radiation and concurrent chemotherapy should be prioritized as is recommended in cervical cancer treatment algorithms.





# Discussion/Q&A on Drug Shortages





## 2024 Annual Meeting on Women's Cancer

in San Diego, CA March 16<sup>th</sup> – March 19<sup>th</sup>

#### **Patient-Focused Events**

- **Patient Education Session**
- Poster Walk & Patient Advocate's **Hope Award Voting** 
  - Coffee, Chat, & Debrief









## Patient & Caregiver Education Materials & Courses

## **Patient Education Material Updates**

- All brochures now available in English, Spanish, and Mandarin online and in print!
  - Looking towards additional languages for future translations
- QR Code Cards available in English
  - Soon to come in Spanish, Mandarin, and more!
- Brochures & QR Code Cards available for purchase through the Foundation for Women's Cancer Store

## **Upcoming Educational Courses: Caregiver Series**

- Six module toolkit for all caregivers
- Objectives:
- Become active participant in care team & effectively interact with all cancer treatment team
- 2. Recognize role as caregiver, support your loved one
- Identify key steps in treatment plan
- Find and select communities that will support you on all levels
- Releasing June 27th
  - Launching on majorly updated Foundation for Women's Cancer website





# Thank you so much for coming!

# Thank you to the Patient Education Alliance and all participants for making this possible!











