Dr. DiSaia honored with naming of first Prestigious Chair Endowment

Dr. Philip J. DiSaia, Group Chair of the Gynecologic Oncology Group (GOG), was recognized for over three decades of dedication to gynecologic oncology at the University of California Irvine (UC Irvine) School of Medicine’s Department of Obstetrics and Gynecology.

On January 29 2012, on the UC Irvine’s campus for the School of Medicine, Dr. DiSaia was honored with the naming of the school’s first-ever Prestigious Chair in Gynecologic Oncology. This honor recognizes the former chief of the school’s Department of Obstetrics and Gynecology’s Division of Gynecologic Oncology contributions to the study of gynecologic cancer.

The Prestigious Chair was created to recruit and retain a top clinician and researcher in the field of gynecologic oncology. The recipient of the Prestigious Chair serves as the department’s division chief, focusing on the research and treatment of gynecologic cancers.

As such, Dr. Robert E. Bristow, gynecologic oncologist at UC Irvine, was also recognized as the Philip J. DiSaia Prestigious Chair at the January ceremony.

“Congratulations Dr. DiSaia on this great honor, and for the legacy you have created in influencing the field of gynecologic oncology, and improving the lives of countless women around

DiSaia continued on Page 2
Update on the formation of the new federation of groups

Progress is steady and congenial on the large task of creating a Federation of our three Groups (GOG, RTOG and NASBP) or NRG. The following is an approximate time table for the process.

- **BSA Concept Review**
  - November 2011

- **NCI DEA & NIH Review FOA/Guidelines**
  - November 2011-July 2012

- **New FOA Released/Published**
  - July 2012

- **Receipt Competing Applications**
  - Winter 2012
  - **November 2012-Feb 2013**

- **Review Competing Applications**
  - Summer 2013
  - **May 2013-August 2013**

- **NCAB Review**
  - Dec 2013

- **Rollout of Awards in FY2014**
  - March 2014

Multiple working groups have been created with the goal of meeting the deadlines set by NCI/CTEP for the grant submission. Reports to the members will be forthcoming as we proceed toward our goals. Dr. Norman Wolmark, Chairman of NASBP, has agreed to be a guest speaker for our July 2012 meeting in Boston and undoubtly will comment further on these issues.

Dr. DiSaia honored at ceremony (cont’d)

Dr. DiSaia, center, shares a light moment prior to the Prestigious Chair ceremony.

Dr. Ralph Clayman, recognizes Dr. Robert Bristow as the first recipient of the Dr. Philip DiSaia Prestigious Chair.

**DiSaia from Page 1**

the world,” Dr. Bristow said during the event.

Dr. DiSaia currently serves as GOG’s Group Chair, helping to lead the organization by “...promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies.” He has held the position since 2002.

Congratulations Dr. DiSaia on this well-deserved honor and your many years of dedication to the study and treatment of gynecologic oncology.
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For applicable clinical trials initiated on or after March 7, 2012, informed consent documents must be in compliance with the new requirement in 21 CFR 50.25(c) and include the following statement word-for-word:

“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you.

At most, the Web site will include a summary of the results. You can search this Web site any time.”

The guidance document with additional information regarding this requirement can be found at:


Requirements for the GOG CME Program Accreditation

The GOG Continuing Medical Education Program is accredited by the American Council for Continuing Medical Education (ACCME) to award AMA PRA Category 1 Credits™. GOG undergoes regular accreditation review by the ACCME to maintain it and must regularly submit documentation that we have complied based on ACCME’s 22 accreditation criteria. The accreditation criteria requires educational planning that includes the assessment of need (or “gap”) for a particular educational topics, content management to close documented gaps, a clear absence of commercial bias, and continued self-assessment and improvement. The GOG CME staff work diligently to develop evidence of compliance with all of the required criteria to maintain accreditation.

Your feedback is essential

This program cannot move forward without your input. Your feedback can easily translate into an effective educational program or a specific topic within a broader program. However, attendee evaluation submission is extremely low. Please consider your particular interests and contact us with your suggestions and willingness to become a part of this important effort to improve healthcare and promote the growth of GOG CME Education Programs. Please take the time to complete and submit GOG CME evaluations and post surveys. The GOG Education and Planning Committee must evaluate the effectiveness of each activity and use data from those evaluations to plan future activities. The information gathered should question whether or not attendees think that the objectives were met.

Send suggestions, questions, or comments about the GOG CME Program to Michelle N. Small, Associate Director, GOG Education Programs and CME Compliance, at msmall@gog.org, or Jill Reese, CME Administrator, at jreese@gog.org.

Upcoming GOG CME activities

• July 26, 2012: Summer 2012 Symposium: “Current Clinical Controversies and Management Dilemmas in Gynecologic Cancers”
• July 26, 2012: Data Management Training Session
• July 27 – 29, 2012: GOG 85th Semi-Annual Meeting Committee Workshops
Carboplatin-based chemotherapy remains the mainstay of treatment for many patients with gynecologic malignancies. In routine practice the carboplatin dose is calculated using an estimated creatinine clearance that is derived from formulas that incorporate the patient’s serum creatinine. In the past, multiple assays were used to measure serum creatinine resulting in considerable interlaboratory variability in the reporting of creatinine values. In 2006, in an effort to standardize serum creatinine reporting across North America, the National Kidney Disease Education Program published recommendations to recalibrate serum creatinine assays to an isotope dilution mass spectrometry (IDMS) traceable reference method. All laboratories were expected to comply by December 31, 2010. In some patients with normal renal function the new standardized IDMS method produced creatinine values that were on average 10-20% lower than older non-IDMS values. Therefore, in patients with relatively low serum creatinine the use of IDMS method generated abnormally low values, leading to an overestimation of creatinine clearance, and consequently higher calculated carboplatin doses.

Various formulas have been used to estimate renal function. The Cockcroft-Gault equation is the most common formula recommended by pharmaceutical manufacturers to determine drug dosages for patients with impaired renal function. Historically, the Gynecologic Oncology Group used a different formula, the Jelliffe equation, to estimate creatinine clearance for carboplatin dosing. Unlike the Cockcroft-Gault formula, the Jelliffe formula does not require the patient’s weight. Both formulas were developed and validated using non-IDMS creatinine values.

More recently, the Modification of Diet in Renal Disease (MDRD) formula was developed to estimate the glomerular filtration rate (GFR) in order to identify patients with early-stage renal impairment. The MDRD estimated GFR is now commonly automatically reported by many laboratories whenever a serum creatinine is ordered. Numerical values for estimated GFRs greater than 60ml/min/1.73m2 are not reported as the formula was derived in patients with renal impairment. The MDRD formula has been reexpressed using the new IDMS creatinine values but cannot be used for carboplatin dosing as it has not been validated for this purpose.

The Calvert formula incorporates GFR to calculate the patient’s carboplatin dose. Although the creatinine clearance is always slightly higher than the GFR the two estimates of renal function are used interchangeably in the Calvert formula.

**Calvert Formula**

Total Carboplatin Dose (mg) = (target AUC) X (GFR + 25)

Following the switch to the IDMS method of serum creatinine measurement the NCI/CTEP noted a potential for an increase in carboplatin-related adverse events. This prompted the publication of an action letter on guidelines for carboplatin dosing in October 2010.

Carboplatin continued on Page 6
Carboplatin from Page 5

• They advised that the GFR used in the Calvert formula for carboplatin dosing should not exceed 125ml/min.

• They recommended capping the maximum carboplatin dose based on target area under the curve (AUC).

| Maximum AUC-based Carboplatin Dose |
|---|---|
| **AUC** | **Maximum Carboplatin Dose** |
| 6 | 900 mg |
| 5 | 750 mg |
| 4 | 600 mg |

• Back-conversion of IDMS creatinine to non-IDMS values was NOT permitted for carboplatin dosing.

This prompted the Gynecology Oncology Group (GOG) to switch from the Jelliffe to Cockcroft-Gault formula for estimation of GFR in carboplatin dosing. The Cockcroft-Gault equation was found to overestimate the creatinine clearance in obese patients or in patients with abnormally low creatinine values. Overestimation of patients’ renal function could result in higher than intended carboplatin doses with a potential for increased toxicity. These concerns for patient safety led the GOG to make further recommendations for carboplatin dosing.

• In patients with abnormally low serum creatinine they recommend using a minimum serum creatinine value of 0.6mg/dL when estimating GFR. This minimum value was subsequently increased to 0.7mg/dL to reflect the fact that the newer IDMS values tend to be lower than non-IDMS.

• Surgery and/or aggressive intravenous hydration can lead to artificially low serum creatinine values so for postoperative patients they indicate that clinicians could consider using a more appropriate (higher) value from the pre-operative period when estimating GFR.

• They recommend using an “adjusted” rather than actual body weight in patients who were over-weight (i.e. BMI ≥25kg/m²). Actual weight is used for patients with BMI <25kg/m².

• Patients who have ≥ 10% weight change from baseline or who experience CTCAE ≥ grade 2 renal toxicity (serum creatinine >1.5 ULN) require recalculation of the carboplatin dose for subsequent cycles.

• In patients who require carboplatin dose modification: if the creatinine at the time of dose modification is lower than the baseline creatinine that was used they recommend using the prior (higher) creatinine value. If the creatinine at the time of dose modification is higher than the baseline creatinine value they recommended using the current (higher) value. This is to ensure that patients receive the intended dose reduction.

References:
1) http://ctep.cancer.gov/content/docs/Carboplatin_Information_Letter.pdf
2) https://gogmember.gog.org
San Diego 2012

Terra Draper from Sturgis, MI, addresses the General Session.

Meeting attendees got to experience a little bit of Paris in San Diego.

Members of GOG’s Industry Collaboration Team share a light moment.

Attendees investigate the meeting’s exhibit hall.

Abbott Oncology
Advaxis
AltheaDX
Amgen, Inc.
Astellas Oncology
Boehringer Ingelheim
Bristol-Myers Squibb
Celgene Corporation
Cell Therapeutics, Inc.
Egen, Inc.

Eisai Oncology
Eli Lilly & Company
Endocyte
Genentech BioOncology
GlaxoSmithKline

GOG ICT Industry Collaboration Team

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OxiGENE, Inc.
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Precision Therapeutics, Inc.
Regeneron Pharmaceuticals
Sanofi-Aventis
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Announcing the 85th Semi-Annual Meeting for the Gynecologic Oncology Group

July 26-29, 2012
Sheraton Hotel
Boston, Massachusetts

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