

American College of Surgeons Clinical Research Program

Kelly K. Hunt, MD
Program Director



ACS CLINICAL RESEARCH PROGRAM EDUCATION COMMITTEE

AGENDA

Friday, May 15, 2015

8 am – 10 am

Loews Chicago O'Hare Hotel

Education Committee Members

Chair: Judy C. Boughey MD

Vice-Chair: Nancy You MD

Committee Members: Waddah Al-Refaie, Steven Chen, Max Meng, David J. Winchester, David P. Winchester, David Kwon

I. ACS Clinical Congress

- 2015 Clinical Congress sessions (see attached)
- Ideas for 2016 Clinical Congress

II. ACS Bulletin Articles

- Current schedule of articles (see attached)
- Solicitation of new ideas

Article description

- Articles should be no more than 750 words (3 to 4 pages double spaced max)
- Style should be similar to magazine article and interesting for the surgical ACS readership on the subject
- Submit biosketch and photo with article
- Goals:
 - Increase surgeon involvement in Alliance
 - Report results to shorten time of implementation
 - Promote Alliance and educational programs
 - Great to include a photo and perhaps short table

III. ACS-CRP Corner of the Alliance Newsletter

Future articles – ideas?

IV. Alliance Scholar Awards

V. Annual American College of Surgeons Lecture for Alliance Group Meetings

- Dr. Clifford Ko is the invited speaker and speak at Alliance plenary session
- ACS CRP Special Presentation, Friday, May 15, 12:00-1:30pm, Louvre
This will be in the same room, once the main plenary session is completed and people leave off to their respective their meetings. We plan to build on the discussion from Dr Ko's presentation and have a series of talks related to the ACS-CRP program.

12:00-12:10 – Welcome and update on Surgical Standard Manual – Kelly Hunt

12:10-12:25 – Improving cancer care through the Commission on Cancer – Dan McKellar

12:25-12:40 – NCDB for benchmarking and quality improvement (David J. Winchester)

12:40-1:10 – The CoC and the ACS CRP/Alliance: A unique partnership for can care delivery research – George Chang/Caprice Greenberg/Deborah Schrag/Ethan Basch

1:10-1:30 – Questions for the panel – Clifford Ko / Dan McKellar / David J. Winchester/ George Chang / Caprice Greenberg / Deborah Schrag / Ethan Basch

- Ideas for lecturer for Alliance May 2016 meeting

VI. Investigator Meetings

American Society of Colon and Rectal Surgeons, Boston, MA, May 30-June 3, 2015

Moderator: Nancy You

San Antonio Breast Cancer Symposium, December 8-12, 2015

Moderator:

Society of Surgical Oncology Cancer Symposium, March 2016

Moderator: Judy Boughey and Nancy You

American Society of Breast Surgeons, May 2016

Moderator: Judy Boughey

IX. Other Business

2015 Clinical Congress Proposals

Accepted:

Panel— Best Practices and Latest Evidence. How should recently reported Clinical Trials change the Surgical Oncology Practice today?

Description: The panel will present the results from the highest impact clinical trials in cancer that have reported results over the last 1+ year. They will discuss how these results should impact the current management of the surgical oncology patient. They will address controversial issues surrounding the trial, interpretation of results, surgical training required and informed discussion of new procedures or indications for procedures with patients in the clinical practice. An interactive session will allow audience members to voice concerns and have questions answered about how best to implement these findings into their practice. Studies that will be covered will be dependent on the reporting of clinical trial results, however are likely to include topics such as management of borderline resectable pancreatic breast cancer, cryoablation for breast cancer, laparoscopic resection of rectal cancer,

Suggested moderator: Judy Boughey and Mitch Posner

Panel— Current Controversies in Surgical Oncology

Description: Panelists will address controversies in the surgical management of breast, lung and colorectal cancer including how these controversies are currently handled in the clinical practice and how can we obtain data to guide the clinical practice moving forward. Current, open clinical trials that address some of these controversies will be described. Additionally this session will discuss how we can further our understanding and guide surgical management in areas where prospective clinical trials are not feasible. Knowledge gaps and areas that are ripe for future research related to these unresolved controversies will be identified.

Suggested moderators: James Fleshman and Elizabeth Mittendorf

Panel— Patient Centered Outcomes Research: What Is it and How to Do It

Description: Patient-centered outcomes research is guided by patients, caregivers and the broader health care community. One of its primary goals is to help people make informed healthcare decisions and improve healthcare delivery by promoting evidence-based practice informed by these stakeholders. Panelists who are recipients of awards from the Patient Centered Outcomes Research Institute (PCORI) or who have pending PCORI proposal submissions will discuss the concept and value of patient-centered outcomes research; how to effectively engage stakeholders such as cancer survivors, patient advocates, health care providers and health outcomes researchers to inform choice of study design and outcomes; and how such research findings can be effectively implemented into practice.

Suggested moderators: George Chang, Caprice Greenburg and Benjamin Kozower

Panel— Genomic Testing for Cancer: What You Need to Know for Your Practice

Description: Sequencing of tumors to identify genomic alterations as targets for drug therapy is increasingly being utilized in clinical trials and in some clinical practices to guide selection of therapy. This session will discuss the opportunities that genomic sequencing information provides for identification of drug targets and drug development. Several trials will be highlighted – Alchemist trial, Match trial, Master trial and information learned from the TCGA. For surgeons to be actively engaged in trial development, running of these trials and interpretation of these studies requires (1) understanding of genomic sequencing – advantages and complexity (2) be competent at tissue collection and preservation of tissue samples and (3) have knowledge of pathways.

Suggested moderators: Tari King and Dennis Wigle

Meet the Experts

How to write a successful PCORI grant – George Chang, Caprice Greenberg, Benjamin Kozower.

Description: Created by the Affordable Care Act, the Patient Centered Outcomes Research Institute (PCORI) helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader healthcare community. The Alliance for Clinical Trials in Oncology and the University of Virginia are recipients of PCORI-funded awards to study post-treatment surveillance for breast, colon and lung cancer patients. The principle investigators, Caprice Greenberg MD, George Chang MD and Benjamin Kozower MD will discuss the requirements for PCORI proposals and how to effectively engage stakeholders such as cancer survivors, patient advocates, health care providers and health outcomes researchers to inform choice of study design and outcomes.

Optimizing Outcomes in Liver and Pancreatic Surgery – Perry Shen and Flavio Rocha

Description: Hepatobiliary and pancreatic surgery for malignancy are complex procedures that are known to have potential for significant perioperative morbidity. However new developments in the field are producing better outcomes for higher risk patients with even more advanced disease. This session will discuss the role of new technology and minimally invasive approaches as well as preoperative workup and clinical risk assessment strategies to get the best results for patients with these challenging hepatobiliary and pancreatic neoplasms.

Declined:

Panel— **Strategies for Establishing and Funding Multi-center Clinical Trials**

Description: Funding through the NCI for co-operative group clinical trials is limited and the cost of prospective trials continues to rise. What mechanisms can we use to continue to address critical questions and advance the practice of surgical oncology? This panel will discuss mechanism for clinical trials independent of the classic NCI mechanism and highlight with examples of ongoing and future opportunities. The session will cover (1) Foundation funding for co-operative groups (NSABP foundation, Alliance foundation) (2) partnership with industry (ACCRU) (3) Foundation grants (I-SPY, TBCRC – translational breast cancer research consortium)

Suggested moderators: Shelley Hwang and David J. Winchester

PROGRAM COMMITTEE RECOMMENDATIONS

Retitle- "Strategies for Establishing and Funding Multi-center Clinical Trials"; Recommendation that they include NCI and non-NCI, cooperative and non-cooperative groups in the topic Done

Town Hall—Surgical Standards Manual focusing on the key questions (Controversial Issues in Breast, Colon, Lung and Pancreatic Oncology) (Declined)

Description: *Operative Standards for Cancer Surgery*, sponsored by the American College of Surgeons Clinical Research Program and the Alliance for Clinical Trials in Oncology, will be published in November 2014. This Manual outlines operative standards for breast, colon, pancreatic and lung cancer appropriate for use in clinical trials and clinical practice including narratives and checklists useful in creating clinical trials, but also as EMR templates. Also included in the Manual are “key questions” in each of the four disease sites that discuss controversial areas and provide evidence-based recommendations on their use. This session will discuss one key question from each of the four disease sites and will discuss the oncologic principles and outcomes for the recommended procedure.

Suggested moderators: Kelly Hunt, Nirmal Veeramachaneni

Panel—Surgical Emergencies in Advanced Cancer Patients (Declined—resubmit next year)

Description: This session will describe common diagnoses in advanced cancer patients requiring emergent surgical consultation. A case study prior to each topic will highlight the following clinical scenarios in which a surgeon is often involved: (1) bowel perforation in cancer patients; (2) neutropenic enterocolitis; (3) anorectal infections in advanced cancer patients; and (4) emergent palliative surgical consultation. Diagnostic criteria, treatment modalities, expected outcomes and indicators of outcome for patients requiring surgical consultation for their malignancy or treatment-related complications of their malignancy will be described.

Suggested moderator: Brian Badgwell, perhaps Bridget Fahy at Univ. of New Mexico?

Panel— Introducing New Technologies into Clinical Practice (Declined)

Description: Advances in technology and innovation are key drivers to move clinical practice forward. As new technologies are discovered and we strive to incorporate them into the surgical management of cancer patients, how are we sure this is performed with technical and oncologic safety? Key questions addressed by the panel will include: How much training is required – is surgical credentialing needed? What should be discussed with patients? What is the role of clinical trials in evaluating new technology—how do they impact peri-operative and long-term oncologic outcomes? How to manage the relationship with Industry? Examples include minimally-invasive surgery for rectal cancer, radioactive seed localization and reverse mapping for sentinel node surgery for breast cancer, minimally-invasive surgery for hepatobiliary malignancies, and image-guided surgery.

Suggested moderators: Y. Nancy You and Steven Chen

Incorporating the Surgical Standards Manual into clinical practice – Sarah Blair and Nirmal Veeramachaneni (Declined)

Description: "Operative Standards for Cancer Surgery," (also known as the Surgical Standards Manual) sponsored by the American College of Surgeons Clinical Research Program and the Alliance for Clinical Trials in Oncology, outlines operative standards for breast, colon, pancreatic and lung cancer that are appropriate for use in clinical trials, surgical practices, and CoC-accredited programs. The Manual consists of narrative text covering oncologic principles, operative techniques that achieve oncologic goals, and surgical checklists that may help formulate trial data entry forms. Sarah Blair MD, chair of the Breast Team, and Nirmal Veeramachaneni MD, chair of the Lung Team, will discuss how to incorporate into clinical practice the standards delineated in the Manual and participants will discuss how to incorporate the standards into their individual practices.

2015 Bulletin Schedule

Author	Topic	Issue	Due Date
Alessandro Fichera and Marty Weiser	PROSPECT trial	April	2/1/15
Nasser Altorki, Leslie Kohman, Linda Veit	Limited Surgical Resection	May	3/1/15
Nirmal Veeramachaneni, Linda Martin, et al	Surgical Standards Manual	June	4/1/15
Robert Roses	CALGB 80101, 80403 for esophageal/gastric CA	July	5/1/15
		August	6/1/15
		September	7/1/15
		October	8/1/15
		November	9/1/15
		December	10/1/14

Possible future article ideas:

Health disparities - Highlight health disparity issues in cancer care, how nurse navigator can help

GI - Meyerhardt--Interim analysis results of CALGB 80702 3 vs 6 mo adjuvant folfox +/- coxII

Prevention - Report results of CALGB 70806 Vitamin D trial-- Marie Wood

Elderly in cancer trials; ACOSOG Z901101-- Waddah Al-Rafaie-- Wait until results published

ALCHEMIST?

Neoadjuvant endocrine therapy for breast

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