Breast Cancer®

An Audio Review Journal for Surgeons Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Eleftherios P Mamounas, MD, MPH Daniel F Hayes, MD Stephen B Edge, MD Eric P Winer, MD

EDITOR

Neil Love, MD





Breast Cancer Update for Surgeons

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Historically, surgery has been the primary mode of treatment for early breast cancer. However, the diagnostic, surgical and medical management of breast cancer has escalated in complexity because of numerous advances in novel technologies and available adjunctive medical therapies. Hence, the multifaceted treatment of breast cancer now requires the input of an interdisciplinary group of expert care providers. This paradigm shift has created the challenge of ensuring that major clinical advances in local and systemic breast cancer therapy are effectively disseminated among all members of the crossfunctional team. To bridge the gap between research and patient care, *Breast Cancer Update* for Surgeons uses one-on-one interviews with leading breast cancer investigators to translate the latest research developments into clinical practice. By providing access to cutting-edge data and expert perspectives, this CME program assists breast surgeons in the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Use genomic assays to quantify recurrence risk and aid in individualized recommendations for systemic therapy for
 postmenopausal patients with node-negative or node-positive, ER-positive breast cancer.
- Evaluate issues related to the accuracy, reliability and interpretation of the ER and HER2 status of breast tumors in the context of local laboratory practices and national guidelines.
- Formulate an evidence-based approach to the surgical management of patients with a positive sentinel lymph node biopsy.
- Assess long-term outcomes with magnetic resonance imaging and screening compared to prophylactic mastectomy for women with BRCA mutations and family history of premenopausal breast cancer.
- Develop an approach to monitor and facilitate patient adherence to orally administered antineoplastic therapies.
- Counsel appropriately selected patients about the option of participating in ongoing clinical trials.

ACCREDITATION STATEMENT

Research To Practice is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

CREDIT DESIGNATION STATEMENT

Research To Practice designates this enduring material for a maximum of 2.75 AMA PRA Category 1 CreditsTM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

HOW TO USE THIS CMF ACTIVITY

This CME activity contains an audio component. To receive credit, the participant should review the CME information, listen to the CDs, complete the Post-test with a score of 75% or better and fill out the Educational Assessment and Credit Form located in the back of this booklet or on our website at **ResearchToPractice.com/BCUS111/CME**.

This activity is supported by an educational grant from Genomic Health Inc.

Last review date: September 2011; Release date: September 2011; Expiration date: September 2012

This educational activity contains discussion of published and/or investigational uses of agents that are not indicated by the Food and Drug Administration. Research To Practice does not recommend the use of any agent outside of the labeled indications. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications and warnings. The opinions expressed are those of the publisher or grantor.

If you would like to discontinue your complimentary subscription to *Breast Cancer Update* for Surgeons, please email us at **Info@ResearchToPractice.com**, call us at (800) 648-8654 or fax us at (305) 377-9998. Please include your full name and address, and we will remove you from the mailing list.

Breast Cancer®

U P D A T E

FACULTY AFFILIATIONS



Eleftherios P Mamounas, MD, MPH Professor of Surgery Northeastern Ohio Universities College of Medicine; Medical Director, Aultman Cancer Center Canton, Ohio



Stephen B Edge, MD
Alfiero Foundation Endowed
Chair in Breast Oncology
Chief, Breast Surgery
Professor of Surgery and
Oncology, Roswell Park Cancer
Institute/University at Buffalo
School of Medicine and
Biomedical Sciences
Buffalo, New York



Daniel F Hayes, MD
Clinical Director, Breast Oncology
Program; Stuart B Padnos
Professor in Breast Cancer
Research, University of Michigan
Comprehensive Cancer Center
Professor of Internal Medicine
University of Michigan
School of Medicine
Ann Arbor, Michigan



Eric P Winer, MD
Thompson Investigator in
Breast Cancer Research
Chief, Division of Women's
Cancers, Dana-Farber Cancer
Institute; Professor of Medicine
Harvard Medical School
Boston, Massachusetts

EDITOR



Neil Love, MD Research To Practice Miami, Florida

CONTENT VALIDATION AND DISCLOSURES

Research To Practice (RTP) is committed to providing its participants with high-quality, unbiased and state-of-the-art education. We assess potential conflicts of interest with faculty, planners and managers of CME activities. Real or apparent conflicts of interest are identified and resolved through a conflict of interest resolution process. In addition, all activity content is reviewed by both a member of the RTP scientific staff and an external, independent physician reviewer for fair balance, scientific objectivity of studies referenced and patient care recommendations.

FACULTY — **Dr Edge** had no real or apparent conflicts of interest to disclose. The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Mamounas** — Advisory Committee: Genomic Health Inc, Novartis Pharmaceuticals Corporation; Consulting Agreement: Genomic Health Inc; Speakers Bureau: Celgene Corporation, Genomic Health Inc. **Dr Hayes** — Consulting Agreements: BioMarker Strategies, Chugai Pharmaceutical Co Ltd; Paid Research: Novartis Pharmaceuticals Corporation, Pfizer Inc, Veridex LLC; Patent: Immunicon Corporation; Stock Ownership: Oncimmune Ltd. **Dr Winer** — Advisory Committee: Novartis Pharmaceuticals Corporation.

EDITOR — Dr Love is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME activities from the following commercial interests: Allos Therapeutics, Amgen Inc, Astellas Pharma Global Development Inc, Bayer HealthCare Pharmaceuticals/Onyx Pharmaceuticals Inc, Biogen Idec, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Cephalon Inc, Daiichi Sankyo Inc, Dendreon Corporation, Eisai Inc, EMD Serono Inc, Genentech BioOncology, Genomic Health Inc, ImClone Systems, a wholly owned subsidiary of Eli Lilly and Company, Lilly USA LLC, Millennium: The Takeda Oncology Company, Mundipharma International Limited, Myriad Genetics Inc, Novartis Pharmaceuticals Corporation, OSI Oncology, Sanofi and Seattle Genetics

RESEARCH TO PRACTICE STAFF AND EXTERNAL REVIEWERS — The scientific staff and reviewers for Research To Practice have no real or apparent conflicts of interest to disclose.

Breast Cancer Update for Surgeons — Issue 1, 2011

QUESTIONS (PLEASE CIRCLE ANSWER):

- The NSABP-B-32 trial for patients with clinically node-negative breast cancer evaluated sentinel lymph node resection (SLNR) with conventional axillary lymph node dissection (ALND) versus SLNR alone or with ALND only if sentinel nodes were positive.
 - a. True
 - b. False
- The Phase II ACOSOG-Z1071 study is evaluating the role of sentinel lymph node biopsy and ALND after preoperative chemotherapy for patients with pathologically node-positive breast cancer at initial diagnosis.
 - a. True
 - b. False
- 3. The TAILORx study is evaluating adjuvant hormonal therapy with or without combination chemotherapy in women with ________, ER-positive breast cancer who have intermediate Oncotype DX® Recurrence Scores® of 11 to 25.
 - a. Node-positive
 - b. Node-negative
 - c. Both a and b
- 4. The NSABP-B-43 trial is evaluating

 as a radiosensitizer for
 women with HER2-positive DCIS who
 undergo lumpectomy and receive
 radiation therapy.
 - a. Lapatinib
 - b. Gefitinib
 - c. Trastuzumab
 - d. T-DM1

- 5. Which genomic assay requires freshfrozen tumor specimens?
 - a. Oncotype DX
 - b. MammaPrint®
 - c. Both a and b
 - d. Neither a nor b
- 6. The Phase II ACOSOG-Z0011 trial randomly assigned patients with clinical T1-2NOMO breast cancer and a positive sentinel node to ALND versus no ALND.
 - a. True
 - b. False
- 7. RxPONDER is a retrospective study of outcomes among patients with hormone receptor-positive, HER2-negative, node-negative breast cancer who had Oncotype DX Recurrence Scores of 25 or lower and received endocrine therapy alone or with chemotherapy.
 - a. True
 - b. False
- 8. The NSABP-B-47 trial is evaluating adjuvant chemotherapy with and without trastuzumab in patients with breast cancer.
 - a. HER2-positive, node-negative
 - b. HER2-negative, node-negative
 - c. HER2-positive, node-positive
 - d. HER2-low, node-positive or high-risk node-negative

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update for Surgeons — Issue 1, 2011

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART ONE — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 5 11 1 0 0		
4 = Excellent 3 = Good	2 = Adequate	1 = Suboptimal
	BEFORE	AFTER
NSABP-B-47: A Phase III trial of adjuvant chemotherapy with or without trastuzumab in HER2-low breast cancer	4 3 2 1	4 3 2 1
Prognostic and predictive value of the Onco <i>type</i> DX Recurrence Score for postmenopausal patients with node-negative and node-positive early breast cancer	4 3 2 1	4 3 2 1
Quality control in the assessment of ER and HER2 status	4 3 2 1	4 3 2 1
Ongoing prospective studies — TAILORx and RxPONDER — of the Onco $type$ DX assay in early breast cancer	4 3 2 1	4 3 2 1
ACOSOG-Z0011: ALND versus no ALND for patients with sentinel lymph node metastasis	4 3 2 1	4 3 2 1
Was the activity evidence based, fair, balanced and free from co ☐ Yes ☐ No If no, please explain:		
Change the management and/or treatment of my patientsOther (please explain):		
		•
The content of this activity matched my current (or potential) so	ope of practice.	
The content of this activity matched my current (or potential) so Yes No If no, please explain: Please respond to the following learning objectives (LOs) by circ	ope of practice.	e selection:
The content of this activity matched my current (or potential) sc	ope of practice.	e selection:
The content of this activity matched my current (or potential) so Yes No If no, please explain: Please respond to the following learning objectives (LOs) by circ 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = As a result of this activity, I will be able to:	ope of practice. ling the appropriate LO not met N/A =	e selection:
The content of this activity matched my current (or potential) so Yes No If no, please explain: Please respond to the following learning objectives (LOs) by circ 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = As a result of this activity, I will be able to:	ope of practice. ling the appropriate LO not met N/A = ualized ts with	e selection: Not applicable
The content of this activity matched my current (or potential) so Yes No If no, please explain:	ope of practice. ling the appropriate LO not met N/A = ualized nts with	e selection: Not applicable 2 1 N/M N/A
The content of this activity matched my current (or potential) so Yes No If no, please explain: Please respond to the following learning objectives (LOs) by circ 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = Is a result of this activity, I will be able to: Use genomic assays to quantify recurrence risk and aid in individe recommendations for systemic therapy for postmenopausal patien node-negative or node-positive, ER-positive breast cancer. Evaluate issues related to the accuracy, reliability and interpretatic ER and HER2 status of breast tumors in the context of local labor practices and national guidelines. Formulate an evidence-based approach to the surgical managem patients with a positive sentinel lymph node biopsy.	ope of practice. ling the appropriate LO not met N/A = ualized nts with	e selection: Not applicable 2 1 N/M N/A 2 1 N/M N/A
The content of this activity matched my current (or potential) so Yes No If no, please explain: Please respond to the following learning objectives (LOs) by circ 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = As a result of this activity, I will be able to: Use genomic assays to quantify recurrence risk and aid in individe recommendations for systemic therapy for postmenopausal patien node-negative or node-positive, ER-positive breast cancer. Evaluate issues related to the accuracy, reliability and interpretatic ER and HER2 status of breast tumors in the context of local labor practices and national guidelines. Formulate an evidence-based approach to the surgical managem patients with a positive sentinel lymph node biopsy.	ope of practice. ling the appropriate LO not met N/A = ualized nts with	e selection: Not applicable 2 1 N/M N/A 2 1 N/M N/A
Please respond to the following learning objectives (LOs) by circ 4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = As a result of this activity, I will be able to: Use genomic assays to quantify recurrence risk and aid in individe recommendations for systemic therapy for postmenopausal patien node-negative or node-positive, ER-positive breast cancer Evaluate issues related to the accuracy, reliability and interpretation ER and HER2 status of breast tumors in the context of local laboratices and national guidelines. Formulate an evidence-based approach to the surgical management patients with a positive sentinel lymph node biopsy. Assess long-term outcomes with magnetic resonance imaging an compared to prophylactic mastectomy for women with BRCA mu	ope of practice. ling the appropriate LO not met N/A = ualized nts with	e selection: Not applicable 2 1 N/M N/A 2 1 N/M N/A 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities: Would you recommend this activity to a colleague? □ No If no, please explain: Additional comments about this activity: As part of our ongoing, continuous quality-improvement effort, we conduct postactivity followup surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey. Yes, I am willing to participate in a follow-up survey. No. I am not willing to participate in a follow-up survey. PART TWO — Please tell us about the faculty and editor for this educational activity 4 = Excellent 3 = Good2 = Adequate 1 = Suboptimal**Faculty** Knowledge of subject matter Effectiveness as an educator Eleftherios P Mamounas, MD, MPH 3 2 Daniel F Haves, MD 3 2 3 2 1 4 1 4 Stephen B Edge, MD 4 3 2 1 4 3 2 1 Eric P Winer, MD 4 3 2 1 4 3 2 1 **Editor** Knowledge of subject matter Effectiveness as an educator 2 Neil Love, MD 3 1 3 1 Please recommend additional faculty for future activities: Other comments about the faculty and editor for this activity: REQUEST FOR CREDIT — Please print clearly Name: Specialty: Professional Designation: □ DO □ PharmD □ NP □ RN □ PA □ Other Street Address: Box/Suite: City, State, Zip; Telephone: Fax: Research To Practice designates this enduring material for a maximum of 2.75 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity. I certify my actual time spent to complete this educational activity to be hour(s). Signature: Date: To obtain a certificate of completion and receive credit for this activity, please complete

3CUS111

To obtain a certificate of completion and receive credit for this activity, please complete the Post-test, fill out the Educational Assessment and Credit Form and fax both to (800) 447-4310, or mail both to Research To Practice, One Biscayne Tower, 2 South Biscayne Boulevard, Suite 3600, Miami, FL 33131. You may also complete the Post-test and Educational Assessment online at www.ResearchToPractice.com/BCUS111/CME.



Editor Neil Love, MD

Managing Editor and CME Director Kathryn Ault Ziel, PhD

Scientific Director Richard Kaderman, PhD

Editorial Clayton Campbell

Gloria Kelly, PhD Jean Pak Margaret Peng

Creative Manager Fernando Rendina

Graphic Designers Jessica Benitez

Jason Cunnius Tamara Dabney Silvana Izquierdo Deepti Nath

Copy Editing Manager Kirsten Miller

Senior Production Editor Aura Herrmann

Copy Editors Margo Harris

David Hill
Rosemary Hulce
Pat Morrissey/Ha

Pat Morrissey/Havlin Alexis Oneca Carol Peschke

Production Manager Tracy Potter

Audio Production Frank Cesarano
Web Master John Ribeiro

Multimedia Project Manager Marie Philemon

Faculty Relations Manager Melissa Molieri

Continuing Education Administrator for Nursing Julia W Aucoin, DNS, RN-BC, CNE

Contact Information Neil Love, MD

Research To Practice One Biscavne Tower

2 South Biscayne Boulevard, Suite 3600

Miami, FL 33131 Fax: (305) 377-9998

Email: DrNeilLove@ResearchToPractice.com

For CME/CNE Information Email: CE@ResearchToPractice.com

Copyright © 2011 Research To Practice. All rights reserved.

The compact discs, Internet content and accompanying printed material are protected by copyright. No part of this program may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or utilizing any information storage and retrieval system, without written permission from the copyright owner.

The opinions expressed are those of the presenters and are not to be construed as those of the publisher or grantor.

Participants have an implied responsibility to use the

newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management.

Any procedures, medications or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information and comparison with recommendations of other authorities.



Copyright © 2011 Research To Practice.
This activity is supported by an educational grant
from Genomic Health Inc.

Research To Practice®

Sponsored by Research To Practice.

Last review date: September 2011 Release date: September 2011 Expiration date: September 2012 Estimated time to complete: 2.75 hours