

Assisting Community-Based Oncologists and Surgeons in Making Treatment Decisions for Patients with ER-Positive, HER2-Negative Early Breast Cancer

CME Information

TARGET AUDIENCE

This activity is intended for medical oncologists, hematologists, hematology-oncology fellows, general and breast surgeons, surgical oncologists and other healthcare providers involved in the treatment of breast cancer.

OVERVIEW OF ACTIVITY

Breast cancer remains the most frequently diagnosed cancer in women, and in 2017 in the United States alone the disease will culminate in an estimated 255,180 new cases and 41,070 deaths. Advances in screening and prevention have resulted in a steady down-stage migration at the time of disease presentation, such that only approximately 5% of patients have identifiable distant metastases at primary diagnosis. The optimal management of localized breast cancer is consequently an essential issue with broad-reaching public health implications.

ER-positive disease is perhaps the most nuanced of the widely acknowledged breast cancer phenotypes with regard to therapeutic decision-making in the early disease setting, and in recent years tissue-based prognostic and predictive multigene assays designed to estimate the incremental benefit of chemotherapy have been introduced. In addition, controversy exists regarding the indications for neoadjuvant therapy in this patient subset, and heterogeneity is evident in the use of genomic assays in the preoperative setting. Finally, the confirmation of the benefit of extending adjuvant hormonal therapy beyond the traditional 5-year period for select patients has led many clinicians to explore the potential use of prognostic assays to shade decision-making in this regard.

Although consensus- and evidence-based treatment guidelines are available and aim to assist clinicians with making management decisions in the face of this dynamic clinical and research environment, many areas of controversy persist within academic and community settings. These proceedings from a roundtable conversation centered around the results of a comprehensive case-based survey focused on decision-making for patients with ER-positive/HER2-negative early breast cancer are meant to aid clinicians as they approach the many difficult and challenging situations that arise each day and to ensure that patients with breast cancer receive optimal and evidence-based care.

LEARNING OBJECTIVES

- Describe the self-reported practice patterns of medical oncology and surgical experts with regard to the treatment of localized ER-positive, HER2-negative breast cancer, and use this information in the development of up-to-date management recommendations.
- Appreciate the similarities and differences among existing genomic assays, and use this information to select an appropriate platform or platforms to assess risk and individualize therapy for patients with early breast cancer.
- Evaluate available and emerging data sets to optimize the use of genomic assays in treatment decision-making for patients with ER-positive, HER2-negative early breast cancer.
- Consider relevant clinical factors and investigator perspectives in the identification of patients for whom extended endocrine therapy would be a reasonable therapeutic consideration.
- Implement strategies to increase collaboration between various subspecialists involved in the diagnosis and management of early breast cancer to improve the quality and coordination of patient care.

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 2.25 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

ABS MAINTENANCE OF CERTIFICATION

This activity provides Category 1 CME that may be used as self-assessment credit toward Part 2 of the American Board of Surgery MOC Program. It is the responsibility of each individual to remain apprised of the current requirements for his or her board-specific MOC Program. For more information about the ABS MOC Program, visit www.absurgery.org.

HOW TO USE THIS CME ACTIVITY

This CME activity consists of a video component. To receive credit, the participant should review the CME information, watch the video, complete the Post-test with a score of 80% or better and fill out the Educational Assessment and Credit Form located at ResearchToPractice.com/EarlyBreast17/CME.

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 conflicts of interest with faculty, planners and managers of CME activities. 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 — The following faculty (and their spouses/partners) had no relevant conflicts of interest to disclose:

Harold J Burstein, MD, PhD

Associate Professor of Medicine
Harvard Medical School
Breast Oncology Center
Dana-Farber Cancer Institute
Boston, Massachusetts

Tari King, MD

Chief, Breast Surgery
Dana-Farber Cancer Institute
Associate Division Chief for Breast Surgery
Brigham and Women's Cancer Center
Associate Professor of Surgery
Harvard Medical School
Boston, Massachusetts

MODERATOR — **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: AbbVie Inc, Acerta Pharma, Adaptive Biotechnologies, Agendia Inc, Agios Pharmaceuticals Inc, Amgen Inc, Ariad Pharmaceuticals Inc, Array BioPharma Inc, Astellas Pharma Global Development Inc, AstraZeneca Pharmaceuticals LP, Baxalta Inc, Bayer HealthCare Pharmaceuticals, Bodesix Inc, bioTheranostics Inc, Boehringer Ingelheim Pharmaceuticals Inc, Boston Biomedical Pharma Inc,

Bristol-Myers Squibb Company, Celgene Corporation, Clovis Oncology, CTI BioPharma Corp, Dendreon Pharmaceuticals Inc, Eisai Inc, Exelixis Inc, Foundation Medicine, Genentech BioOncology, Genomic Health Inc, Gilead Sciences Inc, Halozyme Inc, ImmunoGen Inc, Incyte Corporation, Infinity Pharmaceuticals Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, administered by Janssen Scientific Affairs LLC, Jazz Pharmaceuticals Inc, Kite Pharma Inc, Lexicon Pharmaceuticals Inc, Lilly, Medivation Inc, a Pfizer Company, Merck, Merrimack Pharmaceuticals Inc, Myriad Genetic Laboratories Inc, NanoString Technologies, Natera Inc, Novartis, Novocure, Onyx Pharmaceuticals, an Amgen subsidiary, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Prometheus Laboratories Inc, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Sanofi Genzyme, Seattle Genetics, Sigma-Tau Pharmaceuticals Inc, Sirtex Medical Ltd, Spectrum Pharmaceuticals Inc, Taiho Oncology Inc, Takeda Oncology, Tesaro Inc, Teva Oncology and Tokai Pharmaceuticals Inc.

RESEARCH TO PRACTICE STAFF AND EXTERNAL

REVIEWERS — The scientific staff and reviewers for Research To Practice have no relevant conflicts of interest to disclose.

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

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

Hardware/Software Requirements:

A high-speed Internet connection
A monitor set to 1280 x 1024 pixels or more
Internet Explorer 7 or later, Firefox 3.0 or later, Chrome, Safari 3.0 or later
Adobe Flash Player 10.2 plug-in or later
Adobe Acrobat Reader
(Optional) Sound card and speakers for audio

Last review date: November 2017

Expiration date: November 2018

Select Publications

- Aebi S et al. **Chemotherapy for isolated locoregional recurrence of breast cancer (CALOR): A randomised trial.** *Lancet Oncol* 2014;15(2):156-63.
- Badwe R et al. **Locoregional treatment versus no treatment of the primary tumour in metastatic breast cancer: An open-label randomised controlled trial.** *Lancet Oncol* 2015;16(13):1380-8.
- Bear HD et al. **Using the 21-gene assay from core needle biopsies to choose neoadjuvant therapy for breast cancer: A multi-center trial.** *J Surg Oncol* 2017;115(8):917-23.
- Cardoso F et al. **70-gene signature as an aid to treatment decisions in early-stage breast cancer.** *N Engl J Med* 2016;375(8):717-29.
- Harris LN et al. **Use of biomarkers to guide decisions on adjuvant therapy for women with early-stage breast cancer: American Society of Clinical Oncology Clinical Practice Guideline.** *J Clin Oncol* 2016;34(10):1134-50.
- King TA et al. **Prognostic impact of 21-gene Recurrence Score in patients with Stage IV breast cancer: TBCRC 013.** *J Clin Oncol* 2016;34(20):2359-65.
- Krop I et al. **Use of biomarkers to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer: American Society of Clinical Oncology Clinical Practice Guideline focused update.** *J Clin Oncol* 2017;35(24):2838-47.
- Love N et al. **Beyond the guidelines: Clinical investigators' (CI) self-reported use of genomic assays (GA) to assist in decision-making regarding use of neoadjuvant (NA) and adjuvant chemotherapy for patients (pts) with ER-positive/HER2-negative (ER+/HER2-) early breast cancer (BC).** *Proc ASCO* 2017;Abstract e18187.
- Masuda N et al. **Adjuvant capecitabine for breast cancer after preoperative chemotherapy.** *N Engl J Med* 2017;376(22):2147-59.
- Nitz U et al. **Reducing chemotherapy use in clinically high-risk, genomically low-risk pN0 and pN1 early breast cancer patients: Five-year data from the prospective, randomised phase 3 West German Study Group (WSG) PlanB trial.** *Breast Cancer Res Treat* 2017;[Epub ahead of print].
- Petkov VI et al. **Breast-cancer-specific mortality in patients treated based on the 21-gene assay: A SEER population-based study.** *NPJ Breast Cancer* 2016;2:16017.
- Sparano JA et al. **Prospective validation of a 21-gene expression assay in breast cancer.** *N Engl J Med* 2015;373(21):2005-14.
- Stemmer SM et al. **Clinical outcomes in ER+ HER2- node-positive breast cancer patients who were treated according to the Recurrence Score results: Evidence from a large prospectively designed registry.** *NPJ Breast Cancer* 2017;3:32.
- Yardley DA et al. **A phase II trial of ixabepilone and cyclophosphamide as neoadjuvant therapy for patients with HER2-negative breast cancer: Correlation of pathologic complete response with the 21-gene recurrence score.** *Breast Cancer Res Treat* 2015;154(2):299-308.