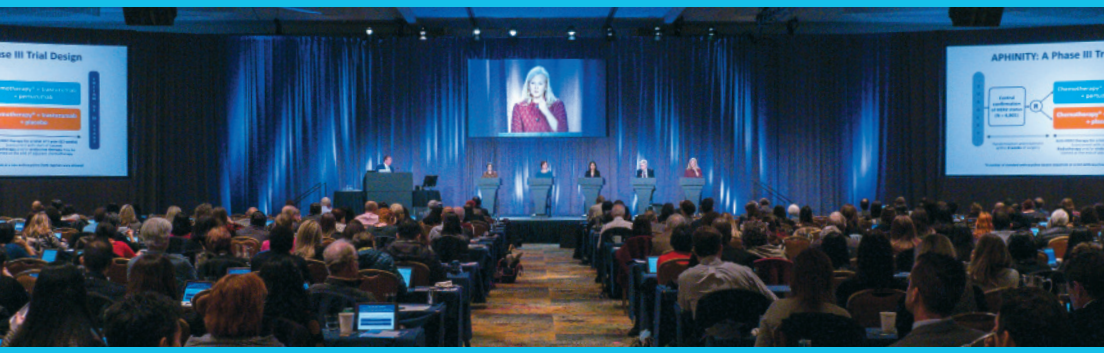
Cases from the Community

Clinical Investigators Provide Their Perspectives on Actual Breast Cancer Cases and the Implications of Emerging Research



A special audio supplement to a CME conference held during the 2017 San Antonio Breast Cancer Symposium featuring expert comments on the application of emerging research to patient care

Faculty Interviews

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ABIM CME MOC ACCREDITED

Breast Cancer® UPDATE

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Cases from the Community: Clinical Investigators Provide Their Perspectives on Actual Breast Cancer Cases and the Implications of Emerging Research

OVERVIEW OF ACTIVITY

Breast cancer (BC) remains the most frequently diagnosed cancer in women, with an estimated 268,670 new cases and 41,400 deaths in the United States in 2018. The current clinical management of BC is multidisciplinary and includes surgical resection of local disease with or without radiation therapy and the treatment of micro- or macroscopic systemic disease with cytotoxic chemotherapy, endocrine therapy, biologic therapy or combinations of these agents. The indications for and utility of these options are based largely on prognostic and predictive risk factors in the patient or the tumor at the time of diagnosis. Despite various evidence- and/or consensus-based guidelines and algorithms that aim to assist oncologists in making treatment decisions, many areas of controversy persist within the academic and community settings. These 2 faculty interviews recorded after the 40th annual San Antonio Breast Cancer Symposium explore the most significant therapeutic advances of the previous year by using the perspectives of leading BC experts on challenging cases and questions submitted by clinicians in the community to frame discussion of how those advances have aided in the refinement of routine clinical practice and ongoing research. This CME activity will help medical oncologists find answers to the individualized questions and concerns that they frequently encounter and so provide high-quality cancer care.

LEARNING OBJECTIVES

- Consider published data to guide the use of biomarkers and genomic classifiers to assess risk and customize therapy for patients with hormone receptor-positive BC in the neoadjuvant, adjuvant and extended-adjuvant settings.
- Appraise available and emerging research evidence to individualize the selection and duration of neoadjuvant and adjuvant chemobiologic regimens for patients with HER2-overexpressing early BC.
- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing and investigational targeted treatments.
- Develop an evidence-based algorithm for the treatment of advanced hormone receptor-positive pre- and postmenopausal BC, including the use of endocrine, biologic and chemotherapeutic agents.
- Consider published research findings and patient preferences in the selection and sequencing of available therapeutic agents for patients with metastatic triple-negative BC.

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Interview with Kimberly L Blackwell, MD

Tracks 1-10

Track 1	Duration of pertuzumab/trastuzumab maintenance for metastatic HER2-positive disease
Track 2	Locoregional therapy in patients with metastatic disease
Track 3	Management of diarrhea in patients receiving pertuzumab
Track 4	Management of oligometastatic disease to the bone
Track 5	**Case:** A 33-year-old woman with ER/PR-positive infiltrating ductal carcinoma (IDC), 2 positive nodes and a 21-gene assay Recurrence Score® (RS) of 7
Track 6	Utility of the 21-, 70-gene and PAM50 assays in clinical practice
Track 7	**Case:** A 35-year-old woman with an 8.5-cm, Grade I, ER/PR-positive, HER2-negative, node-positive IDC and an RS of 15
Track 8	**Case:** A 41-year-old woman previously treated for HER2-positive disease presents with locally advanced triple-negative breast cancer (TNBC) in the ipsilateral breast
Track 9	**Case:** A 35-year-old woman with TNBC and local disease recurrence
Track 10	Therapeutic approach for younger patients with BC and a germline BRCA mutation

Interview with Joyce O'Shaughnessy, MD

Tracks 1-15

Track 1	**Case:** A 51-year-old woman with ER-positive, HER2-negative lobular BC treated with 5 years of tamoxifen presents 1 year later with a local recurrence
Track 2	**Case:** A 33-year-old pregnant woman with ER/PR-positive, HER2-positive locally advanced BC
Track 3	Update of a combined analysis of the TEXT and SOFT trials: Adjuvant exemestane with ovarian function suppression (OFS) versus tamoxifen and OFS for premenopausal women with HR-positive early BC
Track 4	Factors influencing use and duration of adjuvant pertuzumab
Track 5	Risks of anti-HER2 therapy for pregnant patients
Track 6	Clinical utility of postadjuvant neratinib
Track 7	**Case:** A 42-year-old woman with a 1.8-cm, Grade III, ER/PR-negative, HER2-positive, node-negative BC
Track 8	**Case:** A 50-year-old postmenopausal woman with a 1.3-cm, Grade II, strongly ER/PR-positive, "HER2-positive" invasive lobular carcinoma
Track 9	**Case:** A 40-year-old woman with a 3.7-cm, Grade II, ER/PR-positive, HER2-negative suspected ductal carcinoma with 1 of 17 positive nodes declines adjuvant chemotherapy
Track 10	Evolution of circulating tumor DNA analyses as a diagnostic tool
Track 11	**Case:** A 45-year-old woman with triple-negative IDC and 2 large palpable lymph nodes achieves a pathologic complete response to neoadjuvant AC → T
Track 12	Perspective on the potential addition of carboplatin to neoadjuvant chemotherapy for TNBC
Track 13	Therapeutic options for patients with ER-positive, HER2-negative, BRCA2 germline mutation-positive BC and residual disease after neoadjuvant chemotherapy and surgery
Track 14	Reliability and concordance of Ki-67 testing
Track 15	Viewpoint on the clinical utility of the 21- and 70-gene assays for patients with 1 to 3 positive lymph nodes

SELECT PUBLICATIONS

A randomized, double-blind, parallel group, placebo-controlled multi-centre phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with gBRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy. NCT02032823

Albain KS et al. **Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: A retrospective analysis of a randomised trial.** *Lancet Oncol* 2010;11(1):55-65.

Barroso-Sousa R et al. **Clinical development of the CDK4/6 inhibitors ribociclib and abemaciclib in breast cancer.** *Breast Care (Basel)* 2016;11(3):167-73.

Bartlett JM et al; OPTIMA TMG. **Comparing breast cancer multiparameter tests in the OPTIMA prelim trial: No test is more equal than the others.** *J Natl Cancer Inst* 2016;108(9).

Finn RS et al. **Palbociclib and letrozole in advanced breast cancer.** *N Engl J Med* 2016;375(20):1925-36.

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Goss PE et al. **Exemestane versus anastrozole in postmenopausal women with early breast cancer: NCIC CTG MA.27 — A randomized controlled phase III trial.** *J Clin Oncol* 2013;31(11):1398-404.

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Jimenez MM et al. **Neratinib after trastuzumab (T)-based adjuvant therapy in early-stage HER2+ breast cancer (BC): 5 year analysis of the phase III ExteNET trial.** *Proc ESMO* 2017;**Abstract 149O**.

Leung SCY et al. **Analytical validation of a standardized scoring protocol for Ki67: Phase 3 of an international multicenter collaboration.** *NPJ Breast Cancer* 2016;2:16014.

Masuda N et al. **Adjuvant capecitabine for breast cancer after preoperative chemotherapy.** *N Engl J Med* 2017;376(22):2147-59.

Pagani O et al. **Randomized comparison of adjuvant aromatase inhibitor exemestane (E) plus ovarian function suppression (OFS) vs tamoxifen (T) plus OFS in premenopausal women with hormone receptor positive (HR+) early breast cancer (BC): Update of the combined TEXT and SOFT trials.** San Antonio Breast Cancer Symposium 2017;**Abstract GS4-02**.

Rimawi MF et al. **A phase III trial evaluating pCR rates with HR+, HER2-positive breast cancer treated with neoadjuvant docetaxel, carboplatin, trastuzumab, and pertuzumab with or without estrogen deprivation: NRG Oncology/NSABP B-52.** San Antonio Breast Cancer Symposium 2016;**Abstract S3-06**.

Robertson JFR et al. **Peri-operative aromatase inhibitor treatment in determining or predicting longterm outcome in early breast cancer — The POETIC trial (CRUK/07/015).** San Antonio Breast Cancer Symposium 2017;**Abstract GS1-03**.

Sestak I et al. **Prediction of late distant recurrence after 5 years of endocrine treatment: A combined analysis of patients from the Austrian Breast and Colorectal Cancer Study Group 8 and Arimidex, Tamoxifen Alone or in Combination randomized trials using the PAM50 risk of recurrence score.** *J Clin Oncol* 2015;33(8):916-22.

Sledge GW et al. **MONARCH 2: Abemaciclib in combination with fulvestrant in women with HR+/HER2- advanced breast cancer who had progressed while receiving endocrine therapy.** *J Clin Oncol* 2017;35(25):2875-84.

Sparano JA et al. **Prospective validation of a 21-gene expression assay in breast cancer.** *N Engl J Med* 2015;373(21):2005-14.

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Swain SM et al. **Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer.** *N Engl J Med* 2015;372(8):724-34.

Von Minckwitz G et al. **Adjuvant pertuzumab and trastuzumab in early HER2-positive breast cancer.** *N Engl J Med* 2017;377(2):122-31.

Related Video Program

Visit www.ResearchToPractice.com/SanAntonioBC17 to view video proceedings from the satellite meeting held during the 2017 San Antonio Breast Cancer Symposium and earn additional *AMA PRA Category 1 Credit™*.

Topics covered include:

- Management of newly diagnosed localized HER2-positive BC
- Use of genomic assays to assist in clinical decision-making for patients with ER-positive early BC
- Selection and sequence of therapy for patients with ER-positive, HER2-negative metastatic BC
- Protocol and off-protocol decision-making for patients with HER2-positive metastatic BC
- Novel targeted agents and other emerging therapeutic strategies

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POST-TEST

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Among patients with BC and bulky axillary lymph node metastases who undergo lumpectomy or mastectomy, radiation therapy has been shown to result in an improvement in locoregional control.**
   a. True
   b. False

2. **In the Phase III CREATE-X trial, the addition of adjuvant capecitabine after standard neoadjuvant chemotherapy elicited the greatest benefit among patients with _____ BC and residual invasive disease.**
   a. ER-positive, HER2-negative
   b. Triple-negative
   c. HER2-positive

3. **In the CLEOPATRA study evaluating the addition of pertuzumab to docetaxel/trastuzumab for previously untreated HER2-positive metastatic BC, pertuzumab and trastuzumab were administered for 6 cycles with docetaxel and then _____.**
   a. Trastuzumab was continued until disease progression
   b. Trastuzumab and pertuzumab were continued until disease progression

4. **In the CLEOPATRA study, which of the following was observed with the addition of pertuzumab to docetaxel/trastuzumab?**
   a. No improvement in overall survival
   b. No improvement in overall survival but significant improvement in progression-free survival
   c. An approximately 16-month improvement in overall survival

5. **Despite the absence of evidence for benefit with perioperative aromatase inhibition in the overall population of patients with ER-positive early BC, the POETIC trial did demonstrate low versus high Ki-67 levels to be an independent, significant indicator of good versus poor prognosis.**
   a. True
   b. False

6. **Which of the following categories reflects the mechanism of action of neratinib?**
   a. Antibody-drug conjugate
   b. Anti-PD-1/PD-L1 antibody
   c. HER2-blocking tyrosine kinase inhibitor

7. **The Phase III BIG 1-98 trial comparing letrozole versus tamoxifen as adjuvant endocrine therapy for postmenopausal women with HR-positive early BC demonstrates that even in patients with luminal A indolent lobular disease, the efficacy of tamoxifen is _____ to letrozole.**
   a. Equivalent
   b. Inferior
   c. Superior

8. **The Phase III NCIC CTG MA.27 trial evaluating exemestane versus anastrozole for postmenopausal women with HR-positive early BC demonstrated no difference in efficacy between the 2 arms in the overall patient population.**
   a. True
   b. False

9. **Results from the Phase III NSABP-B-52 trial evaluating pathologic complete response rates for patients with HR-positive, HER2-positive BC treated with neoadjuvant docetaxel, carboplatin, trastuzumab and pertuzumab with or without estrogen deprivation demonstrated _____ in pathologic complete response rates for patients who received estrogen deprivation.**
   a. No difference
   b. A significant increase

10. **In the Phase III APHINITY trial, the addition of pertuzumab to trastuzumab and chemotherapy significantly improved invasive disease-free survival for patients with HER2-positive early BC.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Cases from the Community: Clinical Investigators Provide Their Perspectives on Actual Breast Cancer Cases and the Implications of Emerging Research

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 1 — Please tell us about your experience with this educational activity

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

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Magnitude of benefit of pertuzumab as a component of adjuvant therapy for patients with early-stage HER2-positive BC	4 3 2 1	4 3 2 1
Magnitude of benefit observed with neratinib as extended adjuvant therapy and clinical factors guiding the selection of patients with early-stage HER2-positive BC for this therapy	4 3 2 1	4 3 2 1
Activity of CDK4/6 inhibitors in combination with fulvestrant for invasive lobular carcinoma	4 3 2 1	4 3 2 1
Current guidelines and published data regarding the use of genomic assays to guide decision-making on neoadjuvant and adjuvant therapy for women with early-stage HR-positive, HER2-negative invasive BC	4 3 2 1	4 3 2 1
Monitoring and management of gastrointestinal toxicities associated with pertuzumab administration	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice
☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with breast cancer do you see per year? ..... patients

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice
☐ Create/revise protocols, policies and/or procedures
☐ Change the management and/or treatment of my patients
☐ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

.....

The content of this activity matched my current (or potential) scope of practice.

☐ Yes ☐ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

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As a result of this activity, I will be able to:

- Consider published data to guide the use of biomarkers and genomic classifiers to assess risk and customize therapy for patients with hormone receptor-positive BC in the neoadjuvant, adjuvant and extended-adjuvant settings..... 4 3 2 1 N/M N/A
- Appraise available and emerging research evidence to individualize the selection and duration of neoadjuvant and adjuvant chemobiologic regimens for patients with HER2-overexpressing early BC..... 4 3 2 1 N/M N/A
- Implement a long-term clinical plan for the management of metastatic HER2-positive BC, incorporating existing and investigational targeted treatments..... 4 3 2 1 N/M N/A

As a result of this activity, I will be able to:

- Develop an evidence-based algorithm for the treatment of advanced hormone receptor-positive pre- and postmenopausal BC, including the use of endocrine, biologic and chemotherapeutic agents. . . . . 4 3 2 1 N/M N/A
- Consider published research findings and patient preferences in the selection and sequencing of available therapeutic agents for patients with metastatic triple-negative BC. . . . . 4 3 2 1 N/M N/A

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?

☐ Yes ☐ No If no, please explain: . . . . . .

PART 2 — Please tell us about the faculty and editor for this educational activity

4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal

Faculty	**Knowledge of subject matter**	**Effectiveness as an educator**
Kimberly L Blackwell, MD	4 3 2 1	4 3 2 1
Joyce O'Shaughnessy, MD	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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Breast Cancer® UPDATE

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