AXIS Medical Education

# Improving Outcome and Addressing Racial Disparities in Patients With HR+/HER2- Early Breast Cancer:

## A Shared Decision-Making Guide

Provided by

AXIS Medical Education

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# Shared Decision-Making

## WHAT IS SHARED DECISION-MAKING?

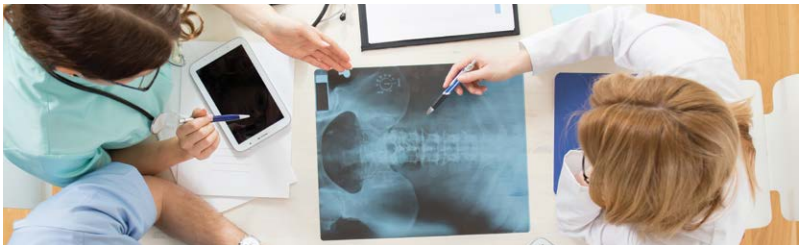
Shared decision-making (SDM) occurs when a healthcare provider and a patient work together to make a healthcare decision that is best for the patient. Optimal decision-making takes into account evidence-based information about available options, the provider's knowledge and experience, and the patient's values, goals and preferences. Patients and their families/caregivers who are engaged in an SDM process are more likely to arrive at a treatment decision that works best for all those involved.

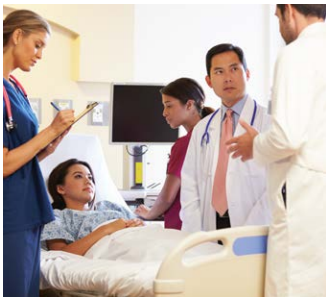
## WHY IS SHARED DECISION-MAKING IMPORTANT?

Making informed decisions about cancer treatment is challenging and can be daunting to the patient, who may be overwhelmed by therapeutic options and how they differ based on benefits, risks, and potential complications. Quite often, the choice of treatment may hinge on patient preferences. Patients and caregivers can play a collaborative and integral role with their healthcare team in determining a course of therapy that is in line with their lifestyles, goals, and desires for disease control.

Two-way communication between patients/caregivers and providers can facilitate shared decision-making, helping to improve patient adherence to therapy, enhance satisfaction with care delivery, and elevate quality of life. By successfully engaging with the healthcare team through shared decision-making, patients may experience better therapeutic outcomes and higher quality care.

Optimal care of cancer involves the use of effective therapies that are supported by the latest evidence and guidelines, selected through a shared decision-making process, and individualized to each patient's needs.





# National Quality Partners Playbook™ on Shared Decision-Making in Healthcare

- The National Quality Forum issued a call to action to make SDM a standard of care for all patients, across all settings and conditions
- Offers vital guidance for this process of communication in which clinicians and patients work together to make healthcare decisions that align with what matters most to patients

## SDM REQUIRES 3 COMPONENTS

1. Delivering clear, accurate, and unbiased medical evidence about reasonable alternatives/treatment options – including no medical intervention – and the risks and benefits of each.
2. Clinician expertise in communicating and tailoring evidence for individual patients.
3. Eliciting and integrating patient values, goals, informed preferences, and concerns, which may include treatment burdens, into treatment planning.

## 6 FUNDAMENTALS TO GUIDE SDM IN HEALTHCARE ORGANIZATIONS

1. **Promote Leadership and Culture**
2. **Enhance Patient Education and Engagement**
3. **Provide Healthcare Team Knowledge and Training**
4. **Take Concrete Actions for Implementation**
5. **Track, Monitor, and Report**
6. **Establish Accountability for Organizations, Clinicians, and Patients**

National Quality Forum. *National Quality Partners Playbook™: Shared Decision-Making in Healthcare*. Washington DC: National Quality Forum; 2018.

# The AXIS 6 Ease ("E's") to SDM

### ENSURE
Ensure you see and treat the patient as an individual not a disease.

### ELEVATE
Elevate the patient-centric experience and improve satisfaction with care.

### ENABLE
Enable a long-term personal connection with your patients.

### ESTABLISH
Establish co-created treatment plans that align medical evidence with patient preferences to foster adherence and optimize outcomes.

### ELICIT
Elicit patient/caregiver preferences, values, and goals for therapy.

### EVALUATE
Evaluate the risk/benefits and costs of treatment so they are aligned with patient expectations.

AXIS Oncology Shared Decision-Making Resource Center. https://axismeded.com/slides-and-resources/?order_by=2&page=1&specialty=857

## The SHARE Decision-Making Approach

**STEP 1** **SEEK** your patient's participation.

**STEP 2** **HELP** your patient explore & compare treatment options.

**STEP 3** **ASSESS** your patient's values and preferences.

**STEP 4** **REACH** a decision with your patient.

**STEP 5** **EVALUATE** your patient's decision.

AHRQ. The SHARE Approach. https://www.ahrq.gov/health-literacy/professional-training/shared-decision/index.html

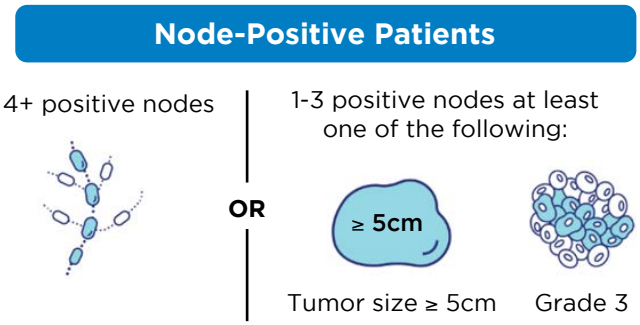
## Early Breast Cancer

- Disease confined within the breast and/or neighboring lymph nodes
- ~90% of breast cancer diagnoses are early breast cancer (EBC)
- ~70% of patients with EBC are HR+, HER2-
- ~20% of patients with EBC experience recurrence within 10 years
  - Risk of recurrence is highest in the first 2 years following diagnosis
  - Patients with disease recurrence have a worse prognosis
  - Patients with high-risk clinical and/or pathologic features are more likely to experience recurrence or distant metastases

Redig AJ, McAllister SS. *J Intern Med*. 2013;274(2):113-126. Wang R, et al. *BMC Cancer*. 2019;19(1):1091. Sheffield KM, et al. *Future Oncol*. 2022;18(21):2667-2682. Huppert LA, et al. *CA Cancer J Clin*. 2023;73(5):480-515. Colleoni M, et al. *J Clin Oncol*. 2016;34(9):927-935. Pan H, et al. *N Engl J Med*. 2017;377(19):1836-1846. Richman J, Dowsett M. *Nat Rev Clin Oncol*. 2019;16(5):296-311.
HER2, human epidermal growth factor receptor 2; HR, hormone receptor.

# Treatment Options for HR+/HER2- EBC

- Biomarker testing for tumor ER, PR, and HER2 status is recommended for all patients
  - Methods for testing include: PCR, NGS, FISH, and IHC
- Goal of HR+, HER2- EBC treatment: eradicate cancer and prevent disease recurrence
- Standard of care for HR+, HER2- EBC includes locoregional therapies (surgery, radiation therapy) and adjuvant/neoadjuvant systemic therapies (chemotherapy, endocrine therapy)
  - Endocrine Therapy
    - Tamoxifen, aromatase inhibitors
    - Ovarian suppression (LHRH analogues) in high risk premenopausal women
    - Extended adjuvant therapy (10 years vs. 5 years)
  - Adjuvant ET for 5 years results in a substantial reduction in the risk of local recurrence, contralateral BC, distant recurrence, and risk of death
- The addition of chemotherapy to adjuvant ET is recommended in certain patients with HR+/HER2- breast cancer based on recurrence risk
  - Molecular profiling tests help to determine whether to add chemotherapy to ET for patients with HR+/HER2- EBC
  - Gene expression assays critical in determining need for adjuvant chemotherapy:
    - The 21-gene assay (Oncotype Dx) is preferredby the NCCN® for prognosis and prediction of chemotherapy benefit
  - High risk of recurrence based on:
    - Extent of nodal involvement
    - Tumor size
    - Tumor grade
  - Clinical practice guidelines (NCCN®) recommend to consider the addition of a CDK4/6 inhibitor (abemaciclib) to systemic adjuvant ET for node-positive, high-risk, HR+/HER2- EBC patients




- Potential for expanding adjuvant CDK4/6 inhibitor (ribociclib) use in a broader patient population
  - Stage II and III HR+/HER2- EBC, including those with no nodal involvement

Pan H, et al. *N Engl J Med*. 2017;377(19):1836-1846. Sheffield KM, et al. *Future Oncol*. 2022;18(21):2667-2682. Johnston SRD, et al. *Lancet Oncol*. 2023;24(1):77-90. Gradishar WJ, et al. NCCN Guidelines. Breast Cancer. Version 2.2024. Markopoulos C, et al. *Eur J Surg Oncol*. 2020;46(4 Pt A):656-666. Blanchette P, et al. *Curr Oncol*. 2022;29(4):2599-2615. Harbeck N, et al. ESMO 2023. Abstract LBA17. Slamon DJ, et al. *Ther Adv Med Oncol*. 2023;15:17588359231178125.

BC, breast cancer; CDK, cyclin-dependent kinase; EBC, early breast cancer; ER, estrogen receptor; ET, endocrine therapy; FISH, fluorescence in situ hybridization; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; IHC, immunohistochemistry; NCCN, National Comprehensive Cancer Network; NGS, next-generation sequencing; PCR, polymerase chain reaction; PR, progesterone receptor.

# CDK4/6 Inhibitors For HR+/HER2- EBC

| | Indication | Trial | Trial Results |
|---|---|---|---|
| **Abemaciclib** | In combination with ET (tamoxifen or an AI) for the adjuvant treatment of adult patients with HR+, HER2-, node-positive EBC at high risk of recurrence | monarchE | **Abemaciclib + ET vs ET**<br>• 32% reduction in the risk of developing an iDFS event with abemaciclib + ET (HR 0.68)<br>– Absolute difference in iDFS rates between arms: 7.6% at 5 years<br>• 32.5% reduction in the risk of developing a DRFS event with abemaciclib + ET (HR 0.675)<br>– Absolute difference in DRFS rates between arms: 6.7% at 5 years |
| **Ribociclib** | In combination with an aromatase inhibitor for the adjuvant treatment of adults with HR+, HER2- stage II and III early breast cancer at high risk of recurrence | NATALEE | **Ribociclib + NSAI vs NSAI**<br>• Risk of invasive disease was reduced by 25.1% with ribociclib + NSAI (HR 0.749)<br>– Absolute iDFS benefit with ribociclib + NSAI: 3.1% at 3 years<br>• Risk of distant disease was reduced by 25.1% with ribociclib + NSAI (HR 0.749)<br>– Absolute DDFS benefit with ribociclib plus NSAI: 2.7% at 3 years |
| **Palbociclib** | – | PALLAS<br>Penelope-B | Has not shown a benefit in this setting |

Harbeck N, et al. ESMO 2023. Abstract LBA17. Hortobagyi G, et al. SABCS 2023. Abstract GS03-03. FDA.gov. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-early-breast-cancer-indication-abemaciclib-endocrine-therapy

FDA.gov. FDA approves Kisqali with an aromatase inhibitor and Kisqali Femara Co-Pack for early high-risk breast cancer. September 17, 2024. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-kisqali-aromatase-inhibitor-and-kisqali-femara-co-pack-early-high-risk-breast-cancer

AI, aromatase inhibitor; DDFS, distant disease-free survival; DRFS, distant relapse-free survival; ET, endocrine therapy; HR, hazard ratio; iDFS, invasive disease-free survival; NSAI, nonsteroidal aromatase inhibitor.

# Adverse Events Related to CDK4/6 Inhibitor Therapies

Ribociclib was associated with higher rates of hematological toxicity, primarily neutropenia, and liver—related adverse events

Abemaciclib was associated with a high rate of gastrointestinal toxicities, primarily diarrhea (grade 1–2)

Adjuvant abemaciclib has a tolerable safety profile with symptoms that are reversible and can be managed by dose reductions without compromising efficacy

Rastogi P, et al. *J Clin Oncol*. 2024;42(9):987-993. VERZENIO (abemaciclib). Prescribing information. Eli Lilly and Company; 2024. KISQALI (ribociclib). Prescribing information. Novartis; 2023.

| | |
|---|---|
| **Diarrhea** | At the first sign of loose stools, start treatment with antidiarrheal agents and increase intake of oral fluids |
| **Neutropenia** | Monitor complete blood counts prior to the start of therapy and periodically during treatment |
| **Hepatotoxicity** | Monitor LFTs (ALT, AST, and serum bilirubin) prior to the start of therapy and periodically during treatment |
| **QT interval prolongation** | Monitor ECGs and electrolytes prior to start of therapy and periodically during treatment |
| **ILD/pneumonitis** | Monitor for clinical symptoms or radiological changes indicative of ILD/pneumonitis. Permanently discontinue CDK4/6 inhibitor in all patients with Grade 3 or 4 ILD or pneumonitis |
| **VTE** | Use CDK4/6 inhibitor + tamoxifen with caution in patients with risk factors for VTE. Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate |

AE, adverse events; ALT, alanine aminotransferase, AST, aspartate aminotransferase; ECGs, electrocardiograms; ILD, interstitial lung disease; LFTs, liver function tests; VTE, venous thromboembolism.

# Tips for Eliciting Patient Participation in Treatment Planning

## TIPS FOR ENGAGING YOUR PATIENT

- Summarize for your patient the current status of their disease.
- Ask your patient and their caregivers to participate with the healthcare team in making treatment and disease management decisions. Explain that this open dialogue will assist the patient in selecting an option that will align with their preferences and goals of therapy.
- Ask your patient to share their feelings, challenges, and triumphs with regards to living with breast cancer. This can help uncover what is most important to them or barriers that may inform the selection of one treatment approach over another.
- Help your patient feel empowered to share their opinion by explaining to them that they are an important contributor to the successful management and control of their breast cancer.

## TIPS FOR EXPLORING TREATMENT OPTIONS WITH YOUR PATIENT

- Determine the patient's preferred role in the decision-making process.
- Assess what your patient already knows about his or her current treatment options.
- Provide your patient and/or caregivers with a printed list of the currently available treatment options with a brief description of each in plain language; review and describe the options for their type of cancer.
- Clearly communicate the risks and benefits of each option. Explain the limitations of what is known and unknown about the treatment options and what would happen with no treatment.
- Communicate numbers in a way that your patient can understand. Use simple visual aids (graphs, charts, pictographs) to help your patient understand your explanations.
- Offer evidence-based decision aid tools whenever possible and explain how to use them to arrive at a decision that reflects their preferences, goals, and values.
- Encourage patients to play an active role in treatment selection.
- Use the teach-back technique to check for understanding: ask your patients to explain the options in his or her own words.

## TIPS FOR ASSESSING VALUES AND PREFERENCES

- Encourage your patient to talk about what matters most to him or her.
- Ask open-ended questions (See sample questions below).
- Listen actively to your patient. Show empathy and interest in what is currently impacting your patient's everyday life.
- Acknowledge the values and preferences that matter to your patient.
- Agree on what is important to your patient.
- Recap with your patient your interpretation of what is most important to them as a priority for consideration when mutually selecting the best treatment option.

# Tips for Eliciting Patient Participation in Treatment Planning (continued)

## TIPS FOR ASSESSING VALUES AND PREFERENCES (CONTINUED)

### *Sample Questions*

- What is your #1 priority that we accomplish during our visit today?
- How do feel? Are you experiencing any symptoms?
- Are you experiencing any side effects related to your treatment? How has this impacted your lifestyle and quality of life?
- Is your condition interfering with your work, social events, or everyday activities at home?
- Do you have any questions about the benefits or risks of the different treatments we are considering for your disease?
- What goals do you have regarding your treatment? Have these goals changed since our last visit?

***Sample goals***

- Keeping the symptoms of disease under control
- Minimizing risks and side effects from treatment
- Finding a treatment with a dosing option that's easy and convenient
- Selecting a treatment that is cost effective

- What is most important to you/your family as we discuss current or new treatment options?
  - What is most important to your patient? It might be:
    - Keeping out-of-pocket costs low
    - Resolving disease symptoms
    - Avoiding treatment-related adverse events
    - Maintaining a specific level of functionality
    - Improving quality of life

## TIPS FOR DECISION-MAKING

- Help your patient move to a decision by asking if he or she is ready to make a decision.
- Ask if your patient would like additional information or tools such as educational materials or decision aids to help make a decision. Review the treatment's Patient Information.
- Check to see if your patient needs more time to consider the options or discuss the options with others.
- Confirm the decision with your patient, if he or she is ready.
- Schedule follow-up appointments as needed.

## TIPS FOR EVALUATION OF THE DECISION

- Monitor the response to the treatment that is implemented.
- Reflect with your patient on whether the decision was consistent with the patient's goals.
- Revisit the decision with your patient and determine if other decisions need to be made.

# Applying SDM Tactics in Clinical Practice

## CONSIDER THESE QUESTIONS TO ELICIT PATIENTS' PERSPECTIVES AND CONCERNS ABOUT THEIR DISEASE AND TREATMENT

- Would you like to discuss your medical care plan and treatment goals?
- Of the goals, which are the most important to you?
- What bothers you most about having breast cancer?
- What would you like most from your treatment?
- Are you able to tolerate the treatment we've chosen? If not, why not? How can we provide improved support to enhance your treatment?
- Do you understand the different treatment choices? What else would you like to know about them?
- Do you understand why we've chosen this treatment? What else would you like to know about it?
- Are you able to make a decision now, or do you need more time to think about it?
- What are the biggest challenges you face as a result of your condition?
- How can we better support you to cope with these challenges?
- Would you like to be involved with a patient/caregiver support group?

## CONSIDER FACTORS SURROUNDING RACIAL/ETHNIC DISPARITIES AMONG MINORITY PATIENTS

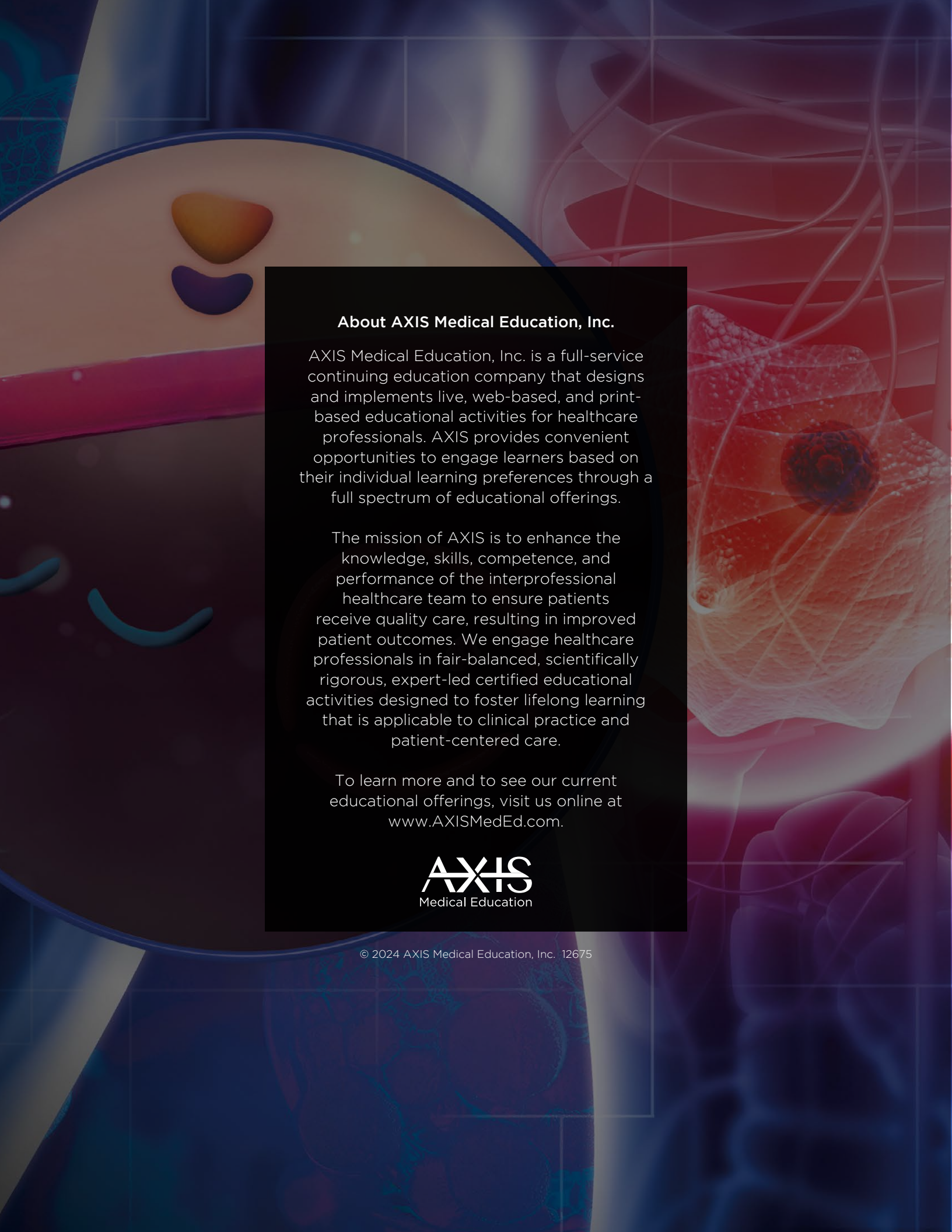
- Black patients have higher morality rates for HR+/HER2- BC compared to other subgroups
- Higher risk of recurrent breast tumors
  - Black race is associated with distant recurrence in ER+/HER2-
- Access to care
  - Delay in referral to cancer providers
- Prognostic testing and risk assessment
  - Access and engagement with screening, mammography, and molecular risk assessment
- Assessing and encouraging adherence to endocrine therapy
- Discussing recurrence risk
  - Decreased awareness of cancer risk and/or distrust of the medical system

# Applying SDM Tactics in Clinical Practice (continued)

## IMPLEMENTING ORGANIZATIONAL AND INDIVIDUAL STRATEGIES TO RECOGNIZE AND MITIGATE UNCONSCIOUS BIAS CAN CONTRIBUTE TO REDUCING THESE DISPARITIES

- Meaningful diversity training
- Self-reflection on personal biases
- Questioning and actively countering stereotypes
- Mentorship and sponsorship
- Cultural humility and curiosity
- Intentionally diversifying experiences

Schermerhorn MC, et al. *Ann Surg Oncol*. 2022;29(12):7652-7658. Lovejoy LA, et al. *J Environ Res Public Health*. 2023;20(4):2903. Moore JX, et al. *Breast Cancer Res Treat*. 2023;197(3):633-645. Moore J, et al. *Cancer Epidemiol Biomarkers Prev*. 2022;31(4):821-830. Terman E, et al. *Breast Cancer Res Treat*. 2023;200(1):75-83. O'Brien KM, et al. *Clin Cancer Res*. 2010;16(24):6100-6110. Warner ET, et al. *J Clin Oncol*. 2015;33(20):2254-2261. FitzGerald C, Hurst S. *BMC Med Ethics*. 2017;18(1):19. Marcelin JR, et al. *J Infect Dis*. 2019;220(220 Suppl 2):S62-S73.



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