AXIS Medical Education

Getting on Board With Real-World Evidence About CDK 4/6 Inhibitors for HR+/HER2- mBC:

A Patient/Clinician Shared Decision-Making Guide

This activity is 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 SDM IMPORTANT IN BREAST CANCER?

Making informed decisions about treatment for breast cancer 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.

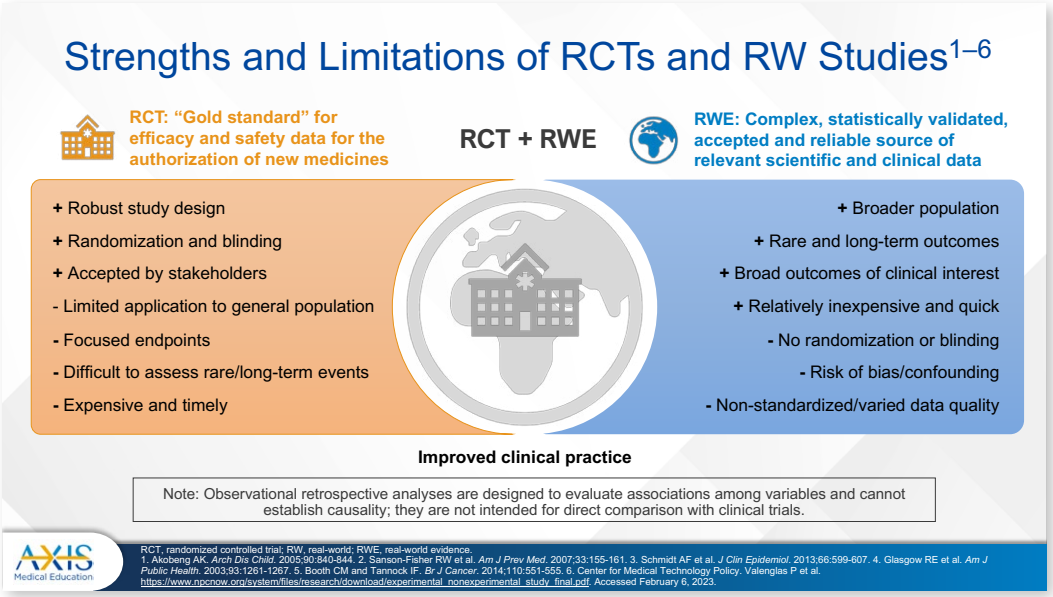
Communication among patients/caregivers and providers can facilitate SDM, helping to improve patient adherence to therapy, enhance satisfaction with care delivery, and elevate quality of life. By successfully engaging with the healthcare team through SDM, patients may experience better therapeutic outcomes and higher-quality care.

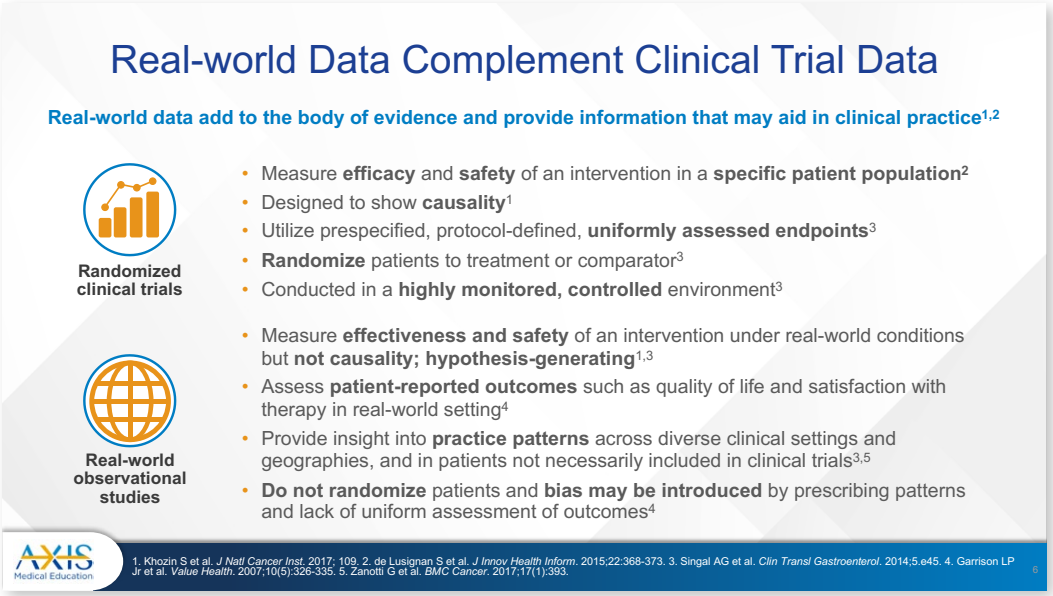
Optimal care of breast cancer involves the use of effective therapies that are supported by the latest evidence and guidelines, selected through a SDM process and individualized to each patient's needs.

Real-World Evidence

WHAT IS REAL-WORLD EVIDENCE AND WHY IS IT IMPORTANT?

Real-world evidence (RWE) complements data gathered from gold-standard randomized clinical trials (RCT). RWE can complement RCT data that have inherent limitations, such as in patients who would not have met clinical trial inclusion criteria. Not all patient populations are represented in RCTs with strict inclusion/exclusion criteria. RWE can inform therapeutic decisions and future research. The U.S. Food and Drug Administration also recognizes the importance of RWE.





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US Food & Drug Administration. October 19, 2022. Real-world evidence. https://www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence

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.**

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

6 FUNDAMENTALS TO GUIDE SDM IN HEALTHCARE ORGANIZATIONS

1 Promote Leadership and Culture

Strong leadership is essential to the success of a healthcare organization's efforts to integrate SDM as a standard of care across the healthcare continuum. Support from leadership at all levels, including the board of directors, C-suite, and departmental and team leaders, encourages broad adoption of SDM as a core value of the organization. Embracing a culture in which leaders promote SDM as a cornerstone of care enables patients and clinicians to become equal members of the care team. Further, framing SDM as part of informed consent, patient safety, and patient rights and responsibilities and promoting SDM as a way to support personalized medicine can bolster person-centered culture change.

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2 Enhance Patient Education and Engagement

Healthcare organizations can engage and educate patients and families about what SDM means, why SDM is beneficial to them, what their role can be, and what to expect from clinicians and the system of care. Organizations can provide educational resources and coaching for patients, families, and caregivers about SDM, including how patients can make more informed decisions and how to identify their values, goals, and preferences, With appropriate support and time to absorb information, SDM is achievable for most people; this includes those with lower health literacy and/or health numeracy and families and caregivers for those individuals unable to make decisions on their own. Once patients understand their role and have access to high-quality resources, most are enthusiastic participants in becoming informed and involved in decisions about their care.

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3 Provide Healthcare Team Knowledge and Training

Healthcare organizations can educate members of the healthcare team about the benefits of SDM for their patients, encourage authentic conversations about patients' preferences and concerns, and emphasize the importance of understanding a patient's level of interest or ability to engage in SDM. Training can include coaching on communicating risks and benefits; eliciting patient values, goals, and preferences; using SDM tools such a decision aids; the role of families and caregivers in supporting SDM; and incorporating what matters most to patients into care decisions. Improved knowledge and skills can foster mutual respect and trust between patients and their healthcare teams. Healthcare team members should be key stakeholders in the planning and design of SDM programs including the thoughtful redesign of patient care workflows to incorporate use of decision aids and SDM conversations, the selection of appropriate measures of success, and ongoing process improvement.

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

4 Take Concrete Actions for Implementation

For SDM to succeed, healthcare organizations and teams must engage in SDM with all patients who wish to do so as a central part of care decisions about interventions, tests, treatments, clinical trials, and care settings. Healthcare organizations should strive to make it easy to do the right thing through technology and thoughtful workflow redesign that can reduce time constraints for the healthcare team. Identifying a designated member of the healthcare team to document patient decisions in a standardized way into the electronic health record, deliver decision aids when appropriate, and regularly update, review, and share the care plan throughout the patient's care can also support treatment consistent with those decisions. Successful implementation includes health information technology that integrates clinical and patient information and suppports SDM and process improvement.

5 Track, Monitor, and Report

Mechanisms to track, monitor, and report patient, clinician, and healthcare team engagement in SDM can help healthcare organizations identify opportunities to improve SDM implementation and results. Standardized data collection and regular sharing of performance and patient experience data with organizational leadership, clinicians, patients, and the public can strengthen these efforts. Measurement may start small with process measures and progress to patient experience measures and outcome measures as the program matures. Systems can also track when and why patients choose not to engage in SDM. To inform the SDM process, data collection and interpretation should add value and not unnecessarily burden healthcare teams.

6 Establish Accountability for Organizations, Clinicians, and Patients

To establish accountability for the board of directors, C-suite, and department and team leaders, healthcare organiztions should articulate clear expectations and establish incentives for engaging patients in SDM. Incorporating SDM measures into performance management systems can incentivize leaders to embrace SDM as a mechanism for improving person-centered outcomes and patient experience and delivering high-value, high-quality care.

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.

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

- 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 breast 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.
- Review RWE, including what RWE is, how it differs from clinical trial data, strengths and limitations of both RWE and RCT data, and the value of RWE in treatment decisions.
- 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.
- Repeat the treatment options for their type of breast cancer.
- Use the teach-back technique to check for understanding: ask your patients to explain the options in his or her own words.

Tips for Eliciting Patient Participation in Treatment Planning (continued)

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.

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?
- Do you have any questions about the RWE?
- What goals do you have regarding your breast cancer 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.

- 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?

- Do you have any questions about the real-world evidence, or how it complements clinical trial data?

- Would you like to review the real-world evidence or randomized clinical trial data again?

Documenting SDM

The OPTION scale, or "observing patient involvement," was developed specifically for measuring the extent and quality of integrating SDM by clinical professionals. One clinician uses this tool to observe the other during a patient encounter and "scores" their ability to engage the patient in decision making during that visit.

The OPTION scale is one example of a tool that could be integrated into clinical practice to document that SDM occurs with each patient encounter. The OPTION scale uses items to score each patient encounter on a scale of 0 (behavior is not observed) to 4 (behavior is exemplary).

Please consider integrating the OPTION instrument below to document that SDM occurs across your breast cancer patient population. Documenting that SDM occurs in clinical practice can enhance your reimbursement under the Quality Payment Program parameters.

THE OBSERVER OPTION - *MEASURE SCORE SHEET*

Date _____ Clinician Name _____

0 No effort (Zero effort observed)

1 Minimal effort (Effort to communicate could be implied or interpreted)

2 Moderate effort (Basic phrases or sentences used)

3 Skilled effort (Substantive phrases or sentences used)

4 Exemplary effort (Clear, accurate communication methods used)

Item 1

The clinician **draws attention to or confirms** that different breast cancer treatments or management options exist or that the need for a decision exists. If the patient rather than the clinician draws attention to the availability of options, the clinician responds by agreeing that the options need deliberation.

0	1	2	3	4

Item 2

The clinician reassures the patient or re-affirms that the clinician **will support the patient to become informed or deliberate** about the options. If the patient states that they have sought or obtained information prior to the encounter, the clinician supports such a deliberation process.

0	1	2	3	4

Item 3

The clinician **gives information or checks understanding about the options** that are considered reasonable (this can include taking no action) to support the patient in comparing alternatives. If the patient requests clarification, the clinician supports the process.

0	1	2	3	4

Item 4

The clinician makes an effort to **elicit the patient's preferences** in response to the options that have been described. If the patient declares their preference(s), the clinician is supportive.

0	1	2	3	4

Item 5

The clinician makes an **effort to integrate the patient's elicited preferences** as decisions are made. If the patient indicates how best to integrate their preferences as decisions are made, the clinician makes an effort to do so.

0	1	2	3	4

Elwyn G, Edward A, Wensing M, et al. Shared decision making: developing the OPTION scale for measuring patient involvement. *Qual Saf Health Care.* 2003;12:93-99.

Resources

LEARN MORE ABOUT SHARED DECISION-MAKING

- National Learning Consortium: SDM Fact Sheet

  https://www.healthit.gov/sites/default/files/nlc_shared_decision_making_fact_sheet.pdf

- National Quality Partners Playbook™: SDM in Healthcare.

  https://store.qualityforum.org/collections/shared-decision-making/products/national-quality-partners-playbook%E2%84%A2-shared-decision-making

- OPTION Training Pack: Evaluating the extent that clinicians involve patients in decisions.

  http://www.glynelwyn.com/uploads/2/4/0/4/24040341/option_12_training_pack.pdf

- AXIS Oncology SDM Resource Center

  https://axismeded.com/portal.mainpages.aspx?OSDMR

- Agency for Healthcare Research and Quality (AHRQ). The SHARE approach: A Model for Shared Decision Making

  https://www.ahrq.gov/sites/default/files/publications/files/share-approach_factsheet.pdf

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- Spronk I, Burgers JS, Schellevis FG, Vliet LM van, Korevaar JC. The availability and effectiveness of tools supporting shared decision making in metastatic breast cancer care: a review. *BMC Palliat Care*. 2018;17(1):74.

LEARN MORE ABOUT REAL-WORLD EVIDENCE WITH CDK4/6 INHIBITORS IN BREAST CANCER

- DeMichele A, Cristofanilli M, Brufsky A, et al. Comparative effectiveness of first-line palbociclib plus letrozole versus letrozole alone for HR+/HER2- metastatic breast cancer in US real-world clinical practice. *Breast Cancer Res*. 2021;23(1):37.

- Rugo HS, Brufsky A, Liu X, et al. Real-world study of overall survival with palbociclib plus aromatase inhibitor in HR+/HER2 metastatic breast cancer. *NPJ Breast Cancer* 2022;8:114.

- Rugo HS, Brufsky A, Liu X, et al. Overall survival with first-line palbociclib plus an aromatase inhibitor (AI) vs AI in metastatic breast cancer: a large real-world database analysis. Poster presented at European Society for Medical Oncology (ESMO) Breast Cancer 2022 Congress; May 3-5, 2022; Berlin, Germany. Poster 169P.

- Smyth EN, Beyrer J, Saverno KR et al. Real-world patient characteristics, utilization patterns, and outcomes of US patients with HR+, HER2 metastatic breast cancer treated with abemaciclib. *Drugs Real World Outcomes*. 2022;9(4):681-693.

- Staropoli N, Geuna E, Rinaldi G, et al. Real-world clinical outcomes of ribociclib in combination with a non-steroidal aromatase inhibitor and a luteinizing hormone-releasing hormone agonist in premenopausal HR+/HER2- advanced breast cancer patients: an Italian managed access program. *Curr Oncol.* 2022;29:6635-6641.

- Wong V, de Boer R, Baron-Hay S, et al. Real-world outcomes of ribociclib and aromatase inhibitor use in first line hormone receptor positive, HER2-negative metastatic breast cancer. *Clin Breast Cancer.* 2022;22(8):792-800.

About AXIS Medical Education, Inc.

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The mission of AXIS is to enhance the knowledge, skills, competence, and performance of the interprofessional healthcare team to ensure patients receive quality care, resulting in improved patient outcomes. We engage healthcare professionals in fair-balanced, scientifically rigorous, expert-led certified educational activities designed to foster lifelong learning that is applicable to clinical practice and patient-centered care.

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