Standard of Care for HR+/HER2- Breast Cancer:
Integrating the "Yale Model Shared Decision-Making Multidisciplinary Team Solution" Into the Practice Setting

Elaine Rudell*, Senior VP, Chief Content Officer and Managing Editor; Patty Peterson*, Executive Director, PIK Education Planning; Michele Fallon Ingram*, COO and Sr. Executive Vice President;
Tarjani Agrawal, PhD*, Data Scientist; Brant Oliver**, Improvement Scientist and SDM Methodologist, Chronic Health Improvement Research Program; Kerin Adelson, MD[†], Chief Quality Officer and Deputy Chief Medical Officer

*Projects In Knowledge, Powered by Kaplan; **The Dartmouth Institute/Geisel School of Medicine at Dartmouth; [†]Smilow Cancer Hospital at Yale-New Haven/Yale Cancer Center

Background

Women with HR+/HER2- breast cancer (68% of the estimated 287,850 new cases of invasive breast cancer diagnosed in 2022 in the United States) are faced with treatment choices that can involve complex preference-sensitive decisions.[1] Research advancements have led to the approval of new oral targeted therapies that improve both overall survival and progression-free survival of these patients with advanced disease—the cyclin-dependent kinase 4 and 6 (CDK4/6) inhibitors: abemaciclib, palbociclib, and ribociclib.[2-6] However, these treatments have different dosing regimens, testing and monitoring requirements, and side effect profiles that are subject to patient preferences. Patient adherence and persistence to CDK4/6 inhibitors is suboptimal for a variety of reasons including lack of understanding about benefits of treatment and adherence, treatment-associated adverse events, poor management of adverse events, and suboptimal patient-provider relationships with a need for open and assertive communications with their clinician.[7]

The National Quality Forum initiated a "Call to Action" to integrate shared decision-making (SDM) processes into practice where clinicians and patients work together to make healthcare decisions that align with what matters most to patients.[8] Projects In Knowledge, @Point of Care, the Chronic Health Improvement Research Program at Dartmouth, and Yale collaborated to develop a pilot educational initiative to address and improve patient-centered care and SDM processes in the institutional cancer care setting.

Objectives

Assess the impact of SDM and CDK4/6 educational training and "hands-on" simulation experiences on improved clinician-patient interactions as evidenced by improved quantitative and qualitative measures.

Methods

The 11 Yale Breast Cancer team members who participated in this educational initiative included: 6 physicians, 3 nurse practitioners, 1 nurse, and 1 pharmacist.

ASSESSMENTS
Qualitative semi-structured interviews and simulation case role play observational methods were used to assess practice performance at baseline (prior to educational interventions), interim time point and end of pilot (EOP). Each clinician team member acted as his or her own control (N = 11), comparing their baseline pre-intervention with interim post-intervention and EOP post-intervention findings.

Semi-Structured Interviews
- Qualitative semi-structured interviews were conducted by interviewers utilizing a series of 8 questions with sub-questions addressing the clinician's understanding of SDM and the methodology they use in practice in treatment discussions with patients with HR+/HER2- metastatic breast cancer
- Baseline pre-intervention interview assessments were compared with interim post-intervention and EOP post-reinforcement training intervention interviews

Simulation Case Role Plays
- Simulation case role plays included the moderator (who guides the clinician-patient discussion), the clinician who interacts with the patient to discuss treatment options, and a professional patient
- Using a two-rater system, clinicians were assessed on whether they discussed the 8 domains of decision quality in their patient discussion (the domains reflect patient-centric areas of interest)
- "Real-time" feedback provided to each learner to address areas in need of further improvement as well as areas where they demonstrated strength
- Baseline pre-intervention case role-play assessments were compared with interim post-intervention and EOP post-reinforcement training intervention case role-play assessments (using a Likert scale 0-4 rating score: 0 = 0%; 1 = 25%, 2 = 50%; 3 = 75%; 4 = 100%)

Methods

TRAINING MATERIALS/VIDEOS
Initial Training Videos
- Through a collaborative partnership, Projects In Knowledge co-developed training materials and training videos for the Yale Breast Cancer interdisciplinary team (N = 11: oncologists, nurses/NPs, pharmacist). The videos address:
  - SDM: Addressing methodology and importance of implementing SDM into clinician-patient treatment discussions
- CDK4/6 inhibitors: Discussing CDK4/6 Inhibitor treatment of metastatic HR+/HER2- breast cancer, including dosing schedules, testing and monitoring requirements, side effects, and contraindications of each treatment
- Simulation case role play: Demonstrating methods for incorporating SDM into clinician-patient treatment discussions in order to achieve optimal informed decisions

DOMAINS OF DECISION QUALITY IN SDM

Reasonable Options
Clinician narrows list of options to a limited menu of reasonable options. The shared decision making process then focuses on this menu.

Risk/Burden Tolerance
Tolerances are discussed, articulated, and aligned with discussion of wellness options.

Accessibility
Insurance coverage status and out-of-pocket expenses, as applicable, are understood and factored into the decision.

Activation, Engagement, Self-Efficacy
Decision is realistically aligned with and encourages activation, self-efficacy, and engagement.

Decision Style Preference
Style preference is articulated and respected by patient and clinician.

Trade-Off Decisions
Trade-offs are made explicit, are articulated, and are understood by patient and clinician.

Knowledge
Patient and clinician have a shared working knowledge of the most important information involved in the decision.

Readiness
Patient and clinician feel confident and comfortable in making the decision.

Reinforcement Training/Video
- Reinforcement training video provided a case role-play simulation scenario customized to meet specific needs of the team members based on clinical performance changes observed in case role plays when comparing baseline with interim assessment time points
- Areas of performance deficiencies that remained after initial training are specifically addressed in this video, showing the "right" and "wrong" way of implementing SDM discussions about CDK4/6 inhibitors

FOCUS GROUP
Following the training and assessments, a focus group comprised of the Yale Breast Cancer team members was held to provide insights into the performance of the group, assess the acceptability, feasibility, and repeatability of the program, and elicit further needs from the group to inform future education

Results

To evaluate the interdisciplinary team members' improved understanding of SDM and CDK4/6 inhibitors, and implementation of practice changes, the following baseline (pre-intervention) and EOP (post-intervention) assessments were compared:
- Qualitative semi-structured interviews
- Simulation case role play (with professional patient)

SUMMARY OF QUALITATIVE SEMI-STRUCTURED INTERVIEW FINDINGS
Thematic analysis results of semi-structured interviews revealed that clinicians learned about nuances of CDK4/6 inhibitors and crystallized their understanding of SDM through reinforcement training (customized in real time).

Feedback Re: CDK4/6 Inhibitor Training
- Clinicians are now better able to make distinctions across the CDK4/6 inhibitors regarding administration schedules, side effects, lab testing, and monitoring requirements of each
- Although some clinicians saw the differences across these therapies to be minimal, they acknowledged that patients may view these differences as significant for them and should be given the opportunity to choose based on their preferences

Feedback Re: SDM and Domains of Decision Quality
- As a result of training, clinicians had a more in-depth understanding of SDM and realized it goes beyond discussion of treatments, and involves patient preferences
- Clinicians realized there were many topics they had not discussed with patients prior to training, such as decision style preference, risk/burden tolerance, trade-off discussions, and readiness to make a decision

Feedback Re: Breast Cancer/SDM Training and Assessments
- Reasons clinicians liked the training and assessments
  - Training provides "conceptual framework/structure and common terminology" for SDM
  - CDK4/6 inhibitor training contrasted the differences (some clinicians said they needed the reinforcement)
  - Simulation case role-play assessments provided "real-time" feedback at the end of the case role-play assessments "…was phenomenal"
  - Reinforcement training video: crystallized SDM process, showcased "right" and "wrong" way to implement SDM, provided helpful clinician-patient dialogue, incorporated key phrases to engage patients in discussion, illustrated insightful "teach-back" techniques, demonstrated supportive techniques for using decision aids and tips cards

Feedback Re: SDM Team Approach
- Overall, clinicians indicated that, after the training, they could see their individual roles as part of a collaborative team, providing time efficiencies
  - *Physicians*: could see obtaining patient preference information from the nurse and then providing patients with in-depth information about appropriate treatment choices
  - *Nurses/NPs*: could see obtaining patient preference information and sharing this with physicians and other team clinicians
  - *Pharmacist*: sees his role as asking patients if they are comfortable with their treatment or have any concerns that he could address; he has already implemented this in practice and plans to share the SDM methodology with other pharmacists

Results

Summary of Simulation Case Role-Play Scenario Findings
Clinicians felt they were better able to implement SDM as a result of their case role-play assessments and "real-time" feedback.

CASE ROLE PLAY ASSESSMENTS

*P<0.05; **P<005. N=11.
Proprietary data from Projects In Knowledge, Powered by Kaplan. 2022.

Training empowered the Yale Breast Cancer team to show pre- to post-education improvement in SDM case role-play scenarios, ranging from 16% to 39%.

Areas of greatest improvement:
1) determining decision style preference (+36%);
2) determining patients' risk/burden tolerance (+32%);
3) determining patients' activation, engagement, and self-efficacy (+34%);
4) determining trade-off decisions with patients (+39%); and
5) determining patients' readiness to make a decision (+32%).

"Take Away" Messages from the Yale Breast Cancer Team Members (Post-interventions)
- "Well designed program" —NP
- "Will address differences among CDK4/6 inhibitors to better inform patients for optimal decisions" —several MDs
- "Many physicians think they do a good job with SDM, but don't recognize that they need training" —MD
- "SDM is now top of mind when I see my patients" —MD
- "SDM training changed the way I interact with my patients" —MD
- "SDM training made me more mindful of patient concerns" —MD
- "Immediate feedback is valuable…Never get feedback of this type" —NP
- "Real-time feedback is …"critical … role play is different in your head than when you say it out loud" —MD
- "Terrific reinforcement training" —MD
- "After observing the reinforcement training video which demonstrated the "right" and "wrong" way to implement SDM, I stepped back to reassess what I do" —MD
- "Will initiate discussions with patients to ensure they understand their treatment, are comfortable with the regimen, and address any questions they may have" —Pharm

Conclusions

Educational training demonstrated initial feasibility, acceptability, and utility. This virtual program improved SDM skills for the interdisciplinary Yale Breast Cancer team, which can lead to improved clinician-patient decision making and patient-centric care. The training process also facilitated team building and encouraged ongoing participation in SDM. Future research should build on these interventions and provide additional virtual training that empowers clinicians to best integrate SDM into the real world, time-restricted clinical practice.

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