The CONSYDER Study: Effectiveness and implementation of a decision support tool to improve surgical decision making in young women with breast cancer

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In the United States, many young women are choosing contralateral prophylactic mastectomy (CPM) or bilateral ("double") mastectomy, with removal of the unaffected breast despite longstanding evidence that breast conserving surgery with radiation is equally effective. Women report choosing CPM for symmetry, peace of mind, and the ability to forego continued imaging surveillance; however, CPM has been associated with a greater risk of surgical complications, an increased number of procedures, delays in cancer treatment, poorer quality of life, and higher patient out-of-pocket costs. Consequently, both the American Society of Breast Surgeons and Choosing Wisely guidelines recommend against the routine use of CPM among average-risk women with unilateral breast cancer, yet protect patient autonomy for personal choice.

Our prior work suggests that many young women lack a full understanding of the benefits and risks of surgical options. Further, young-adult specific concerns related to heightened anxiety, financial toxicity, body image, fertility, sexuality and breastfeeding may further complicate this decision and potentially contribute to decisional conflict. In an effort to promote shared decision-making and decrease decisional conflict, we developed CONSYDER (**C**ommunicating **O**ptio**N**s about **S**urgery for **Y**oung women **D**iagnosed with **E**arly stage breast canc**R**), a web-based decision support tool tailored to the unique concerns of young breast cancer patients. In a pilot study, utilization of CONSYDER was associated with a reduction in decisional conflict vs. usual care. Women also reported that CONSYDER facilitated improved understanding of surgical tradeoffs and clarified personal values around surgical choice.

Building on the pilot findings, we designed a Type II hybrid effectiveness-implementation, step-wedged trial. The multi-center CONSYDER Study aims to test the effectiveness of CONSYDER on reducing decisional conflict and evaluate the implementation of CONSYDER in 800 women diagnosed with breast cancer at age <45 at 4 sites: Weill Cornell, Yale, Duke, and Dana-Farber Cancer Institute. Our pragmatic trial will implement CONSYDER (English/Spanish) as part of usual care for women <45 years old with stage 0-III breast cancer. To evaluate the effectiveness and implementation of CONSYDER across sites, we will survey and interview patients and providers, conduct staff focus groups, and audio-record consultations among a subset of participants. The primary effectiveness outcome is decisional conflict (16-item Decisional Conflict Scale); additional patient-reported outcomes include decision-making preferences, knowledge, treatment goals/preferences, decisional regret, and self-efficacy in communication. We will also explore whether CONSYDER impacts surgical choice for CPM. Implementation outcomes will include acceptability, adoption, feasibility, fidelity, penetration and sustainability. Our *short-term* goal is to characterize implementation in clinical care and evaluate the impact of CONSYDER on surgical decision-making. Our *long-term* goal is to help young women and their doctors make informed, patient-centered treatment decisions.