# EQUALS: Vaginal/Sexual Health (VSH) in Patients with ER+/HER2- Metastatic Breast Cancer (mBC)

Sarah L Sammons, 1\* Jane L Meisel, 2\* Kelly Shanahan, 3\* Timothy J Pluard, 4\* David J Portman, 5 Elizabeth Attias 5

<sup>1</sup>Dana Farber Cancer Institute, Harvard Medical School, Boston, MA; <sup>2</sup>Emory Winship Cancer Institute, Atlanta, GA; <sup>3</sup>Metavivor Research and Support, Inc, Annapolis, MD; <sup>4</sup>Saint Luke's Cancer Institute, Kansas City, MO; <sup>5</sup>Sermonix Pharmaceuticals, Columbus, OH \*Members of the EQUALS Steering Committee

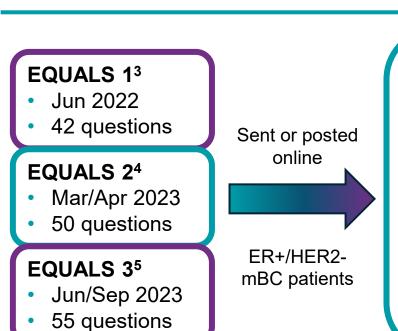
## Introduction

- Vaginal and sexual health (VSH) issues are commonly reported, in more than two-thirds, of women with breast cancer (BC)<sup>1,2</sup>
- However, these concerns are often under-recognized and understudied in women with BC being treated with endocrine therapy (ET)
- Studies on the prevalence, impact, and management of vaginal and sexual side effects are limited in women with metastatic BC (mBC)
- The overall objectives of EQUALS (ESR1 QUAlity of Life Survey) were to explore quality of life (QoL) and symptoms, biomarkers, treatment side effects, and patient-medical team communication of women with ER+/HER2- mBC<sup>3-5</sup>
- Among these surveys, we found that VSH issues were a primary QoL concern among women with mBC<sup>3-5</sup>

# **Objective**

To summarize the common VSH thread in ER+/HER2- mBC patients from three EQUALS studies<sup>3-5</sup>

## Methods

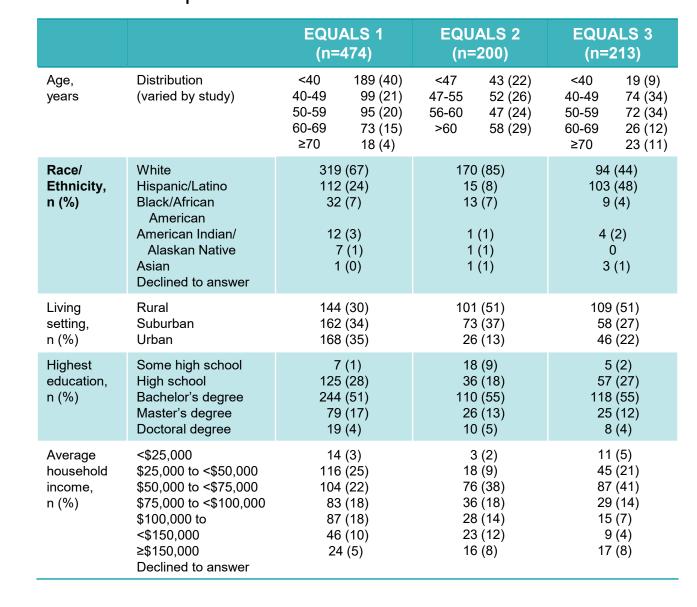


- Cure Media Group
- Facebook and Twitter groups
- Authors' contactsBreast cancer clinic
- METAvivor
- FORCE (Facing Hereditary Cancer EMPOWERED)
   The Chrysalis Initiative
- Questions on QoL varied between surveys (EQUALS 2 focused mostly on VSH)
- Survey answers were summarized descriptively and reported according to questions asked in each survey
- Patients received a \$10 gift card at survey completion

# Results

- Women (n=887) were a wide range of ages; one-third and onehalf were non-white in EQUALS 1 and 3,respectively; most were white in EQUALS 2
- Half (EQUALS 2 and 3) to almost three-quarters (EQUALS 1) lived in an urban and/or suburban setting
- About three-quarters had completed some higher education
- Most household incomes ranged from \$25,000 to \$100,000
- Women had received 1-4 lines of mBC treatment, including endocrine therapies, targeted therapies, antibody-drug conjugates, chemotherapy, and others

#### Table 1. Responder characteristics<sup>3-5</sup>



#### Vaginal symptoms prevalence

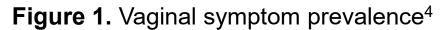
- Common side effects impacting QoL were vaginal atrophy/ dryness in EQUALS 1 and 3,<sup>3,5</sup> and sexual dysfunction in EQUALS 3<sup>5</sup>
- In EQUALS 2,<sup>4</sup> vaginal symptoms were experienced by 61% of patients (**Figure 1**) and associated with BC treatment for a mean of 4.8 years
- Most bothersome symptoms were vaginal dryness, painful intercourse, vaginal itching, and vaginal irritation (**Figure 1**)<sup>4</sup>

#### Impact of vaginal/sexual side effects on QoL

- In EQUALS 1, vaginal atrophy/dryness impacted QoL the most or moderately in 47%) of patients (**Figure 2A**)<sup>3</sup>
- Sexual dysfunction and vaginal atrophy/dryness were the first and third side effects impacting QoL the most in EQUALS 3 (Figure 2B)<sup>5</sup>
- In EQUALS 2, vaginal/sexual side effects negatively impacted frequency of sexual intercourse (61%) and selfesteem (64%) and made 51% feel isolated
- Most commonly reported effects of vaginal dryness were limited enjoyment of sexual activity, pain with intercourse, and vaginal itching/burning (Figure 3)<sup>4</sup>
- More than half (54%) reported that they never/almost never felt sexual desire/interest in the past month<sup>4</sup>
- This was especially true when prior ET had negatively impacted sexual health (61%)<sup>4</sup>
- Low sexual desire bothered 56% of patients<sup>4</sup>

### Vaginal/sexual Side effects were concerning

- EQUALS 1: 64% of patients worried about sexual intimacy<sup>3</sup>
- EQUALS 2: 80% of patients were concerned about the vaginal and sexual side effects of BC treatment<sup>4</sup>
- EQUALS 3: In 27% of patients, sexual dysfunction was reported as extremely/moderately concerning<sup>5</sup>



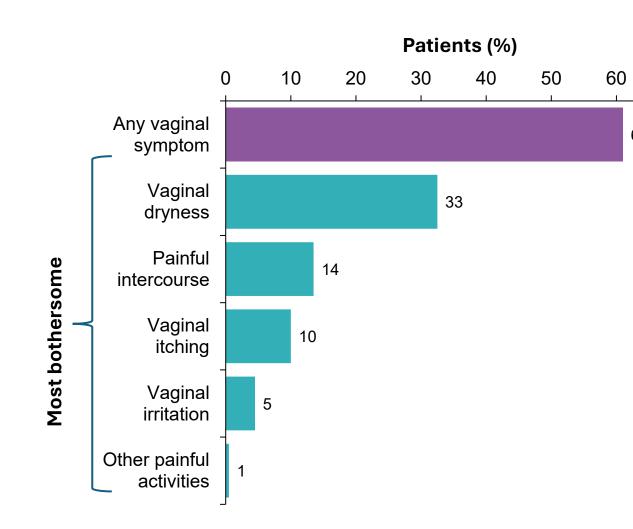


Figure 3. Impact of vaginal/sexual side effects on QoL<sup>4</sup>

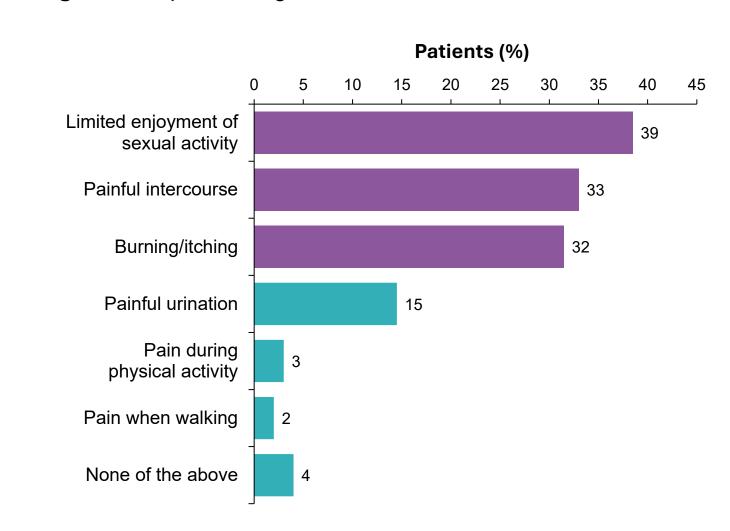
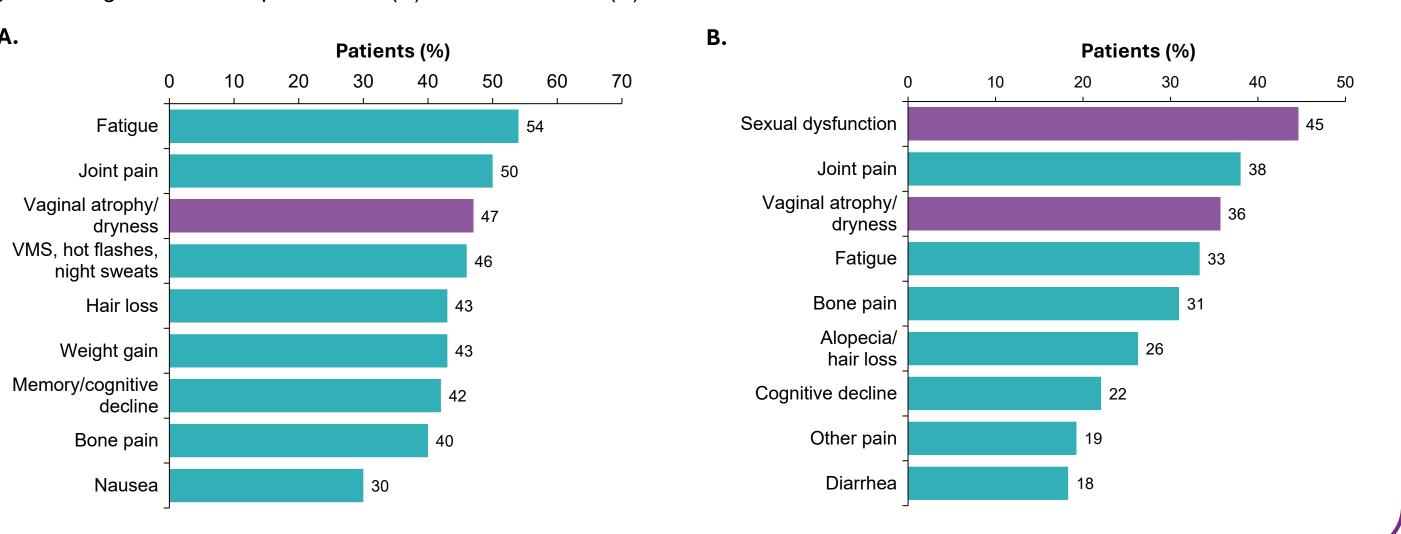


Figure 2. Vaginal/sexual impact QoL in (A) EQUALS 1<sup>3</sup> and (B) EQUALS 3<sup>5</sup>



#### Discussing vaginal/sexual side effects

- 31% to 61% of women were uncomfortable discussing sexual side effects with their medical team<sup>3,4</sup>
- Oncologist gender influenced women's comfort discussing vaginal/sexual side effects<sup>3,4</sup>
- 41% to 60% of women with female oncologists felt uncomfortable
- 56% to 64% of women with male oncologists felt uncomfortable

- Approximately one-third of women felt<sup>4</sup>
- Poorly informed about these side effects by their medical team (38%)
- Poorly equipped to improve these side effects (33%)
- Most (93%) patients in EQUALS 2 expressed interest in an FDA-approved, well-tolerated, BC treatment that also improved vaginal and sexual health<sup>4</sup>

# **Key Takeaways**

- Many women with mBC experience vaginal and sexual symptoms that negatively impact their QoL
- These women are also uncomfortable discussing VSH with their medical teams and feel poorly equipped to manage the symptoms

# Conclusions

- Our review of three EQUALS confirms that
- Women being treated for ER+/HER2- mBC experienced and were concerned about their vaginal/sexual side effects
- Such side effects negatively impacted many women's frequency of intercourse, selfesteem, and feelings of isolation
- Many women were uncomfortable discussing these symptoms with their medical team and felt poorly informed and equipped to manage them
- While patients with mBC were surveyed, earlystage BC patients also encounter such treatment side effects, highlighting the need for
- Therapies that improve vaginal/sexual outcomes and side effects
- Better communication between patients and their medical team about managing these side effects

#### References

- 1. Huynh V, et al. Ann Surg Oncol. 2022;29(10):6238-6251
- 2. Gambardella A, et al. *Endocrine*. 2018;60(3):510-515.
- 3. Sammons SL, et al. *Cancer Res.* 2023;83(5 Suppl): P6-09-01.
- Shanahan K, et al. *Menopause*. 2023;30:P-89.
  Sammons S, et al. *Cancer Res*. 2024;84(9 Suppl): PO5-12-06.
- ·

#### Disclosures

- SLS received research funding (paid to institution) from AstraZeneca, Abbvie, Bristol Myers Squibb, Eli Lilly, Relay, Seagen, and Sermonix; and has consulted for Foundation Medicine, AstraZeneca, Daichii Sankyo, Eli Lilly, Pfizer, Sermonix, and Novartis. JLM received research funding (paid to institution) from Seagen, Pfizer, AstraZeneca; and has consulted for AstraZeneca, Clovis, Genentech, Glaxo SmithKline, Novartis, Pfizer, Puma, Sanofi Genzyme, and Seagen. KS is on the patient advisory board for Sermonix; and is on scientific advisory board for Napo Pharmaceuticals. TJP has received research support from AstraZeneca, Gilead, Novartis, Nuvation, Pfizer, Sanofi, and Sermonix; is a consultant for AstraZeneca, DSI, Gilead, Novartis, Pfizer, Sanofi and Seagen; and has been a speaker for AstraZeneca, Gilead, Stemline, and Seagen. DJP and EA are employees and stockholders of Sermonix.
- Sermonix Pharmaceuticals sponsored the survey and provided support for the medical writing assistance of Kathleen Ohleth, PhD (Precise Publications, LLC).

