The Women's EMPOWER Survey: Women's Knowledge and Treatment of Vulvar and Vaginal Atrophy (VVA) Remains Low Years after Previous Surveys

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Background

- Postmenopausal women's knowledge about VVA, a component of genitourinary syndrome of menopause (GSM), and available treatment options has been historically low, as reported from several previously published surveys¹⁻⁸
- Barriers to treatment include the reluctance to speak with healthcare professionals (HCPs) about VVA symptoms, safety concerns of hormone therapies (HT), and inadequate symptom relief and inconvenience with available treatments^{7,8}
- Recent direct-to-consumer marketing and educational efforts would be expected to have increased understanding of the condition and treatment options

Objective

• Results of the Women's EMPOWER survey of postmenopausal women with VVA were examined in comparison with past VVA surveys to assess progress in women's understanding and approaches to VVA treatment

Design and Methods

- The Women's EMPOWER survey, an internet-based survey of US postmenopausal women with VVA symptoms, assessed women's awareness of VVA and their behaviors and attitudes associated with symptom treatment
- The Women's EMPOWER survey results were compared with results from multiple other surveys evaluating knowledge, behavior, and attitudes associated with VVA among US and international postmenopausal women (Table 1)
- Since questions varied across surveys and questions on similar topics were asked differently between surveys, the most relevant comparisons were made as practically as possible and are summarized here

Name / Sponsor	Date	Country	Respondents	Sample	Method	Compensation
REVEAL ¹ Revealing Vaginal Effects At mid-Life (Wyeth®)	12/2008	United States	N=1006	Women (45-65) who were naturally menopausal and not taking HT	25-min telephone interview	NR
			N=255	Subset of women experiencing dyspareunia		
Women's Voices in the Menopause (WVM) ² (Novo Nordisk FemCare AG)	03/2009 to 04/2009	International	N=4246 Sweden (604), Finland (606), UK (1008), Canada (1016), US (1012)	Women (55-65)	Computer- assisted web interviews	NR
VIVA ^{3,4} Vaginal Health: Insight, Views, and Attitudes (Novo Nordisk FemCare AG)	08/2010	International survey ³	N=3520 Canada (500), Denmark (500), Finland (500), Norway (520), Sweden (500) UK (500), US (500)	Women (55-65) who ceased menstruation for ≥12 months	Online survey	None
Tembale AG)		US survey ⁴	N=500	Subset of US women		
CLOSER ^{5,6} Clarifying Vaginal Atrophy's Impact on Sex and Relationships (Novo Nordisk A/S)	12/2011 to 02/2012	European survey⁵	N=2600ª Northern Europe (1600), Southern Europe (1000)	Married or co- habiting women (55-65) who had ceased menstruating for ≥12 months and experienced vaginal discomfort	Online survey	None
		North America survey ⁶	N=1003ª US (501), Canada (502)			
REVIVE ^{7,8} REal Women's Vlews of Treatment Options for Menopausal Vaginal ChangEs (Shionogi Inc.)	05/2012 to 06/2012	US survey ⁷	N=3046	Postmenopausal women (45-75) who	Online survey	Points for merchandise, gift cards, or cash
	06/2014 to 07/2014	European survey ⁸	N=3768 Italy (1000), Germany (1000), Spain (768), UK (1000)	experienced ≥1 VVA symptom		Points for vouchers or gadgets
Women's EMPOWER survey (TherapeuticsMD)	01/2016 to 03/2016	United States	N=1858	Postmenopausal women ≥45 with VVA symptoms	Online survey	\$10

Table 1: Major survey-based studies compared

^aCLOSER gueried both men and women, but only women respondents are indicated here

Results

Prevalence of vulvar and vaginal symptoms

- In US and international surveys of postmenopausal women, vulvar and vaginal symptoms occurred in 39-51% of women¹⁻⁴ with 55-62% of those women experiencing moderate-to-severe vaginal symptoms²⁻⁴
- Across surveys of those who reported VVA symptoms, the most commonly reported menopause-related vulvar and vaginal symptoms were vaginal dryness (55-85%), dyspareunia (29-59%) and vaginal itching/irritation (26-77%) (Figure 1)^{3,4,7,8}
- Other symptoms reported included involuntary urination (30%), soreness (27%), burning (14%), and pain when touching the vagina $(11\%)^3$

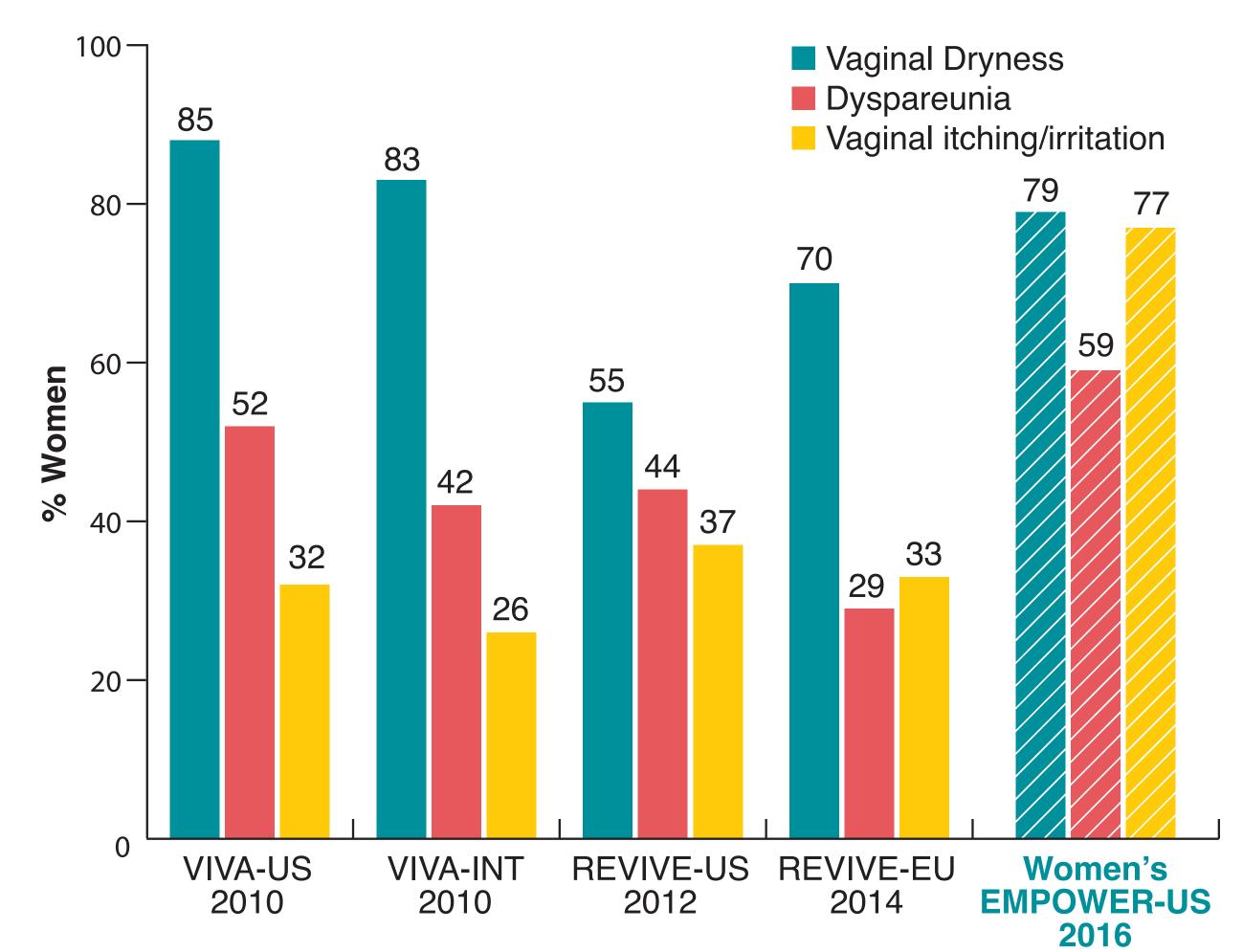


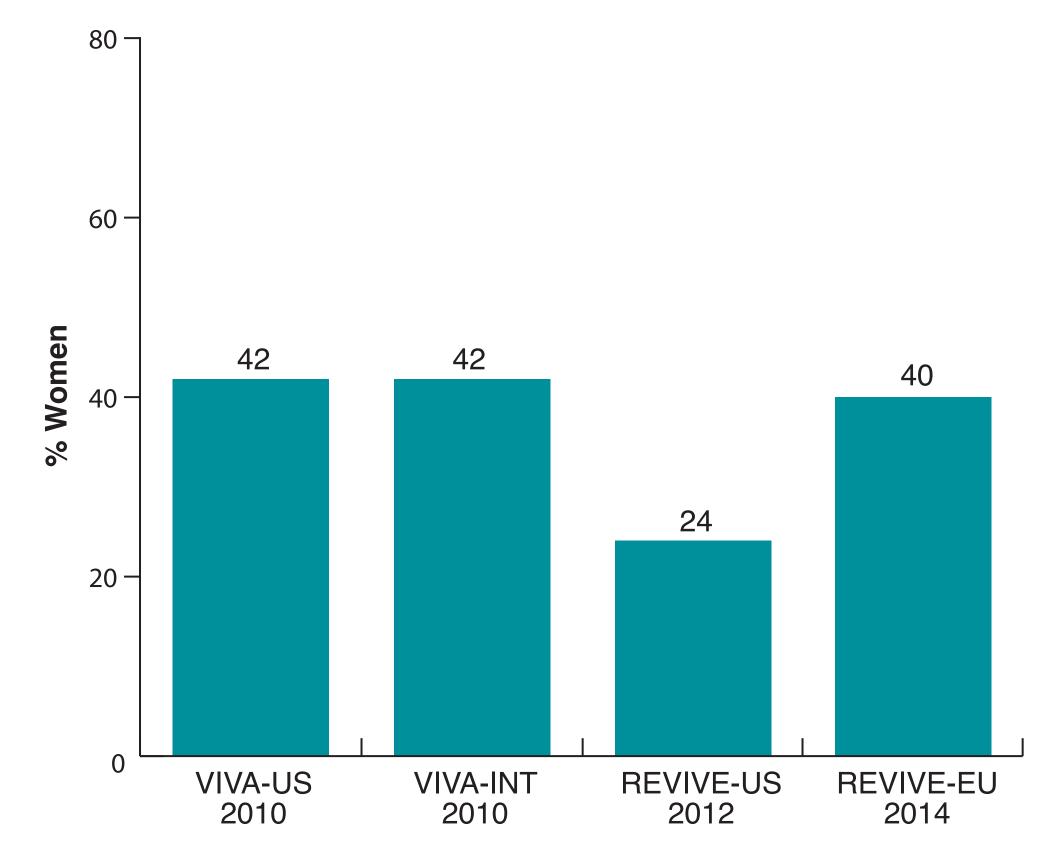
Figure 1: Prevalence of symptoms in women with VVA

• In REVEAL, 72% of women with dyspareunia still engaged in sex at least once a month, and 34% at least once weekly,¹ while in the Women's EMPOWER survey, 38% of women with VVA were no longer sexually active, but 29% still engaged in sex at least once per month

Many were not aware that their symptoms were associated with menopause or VVA

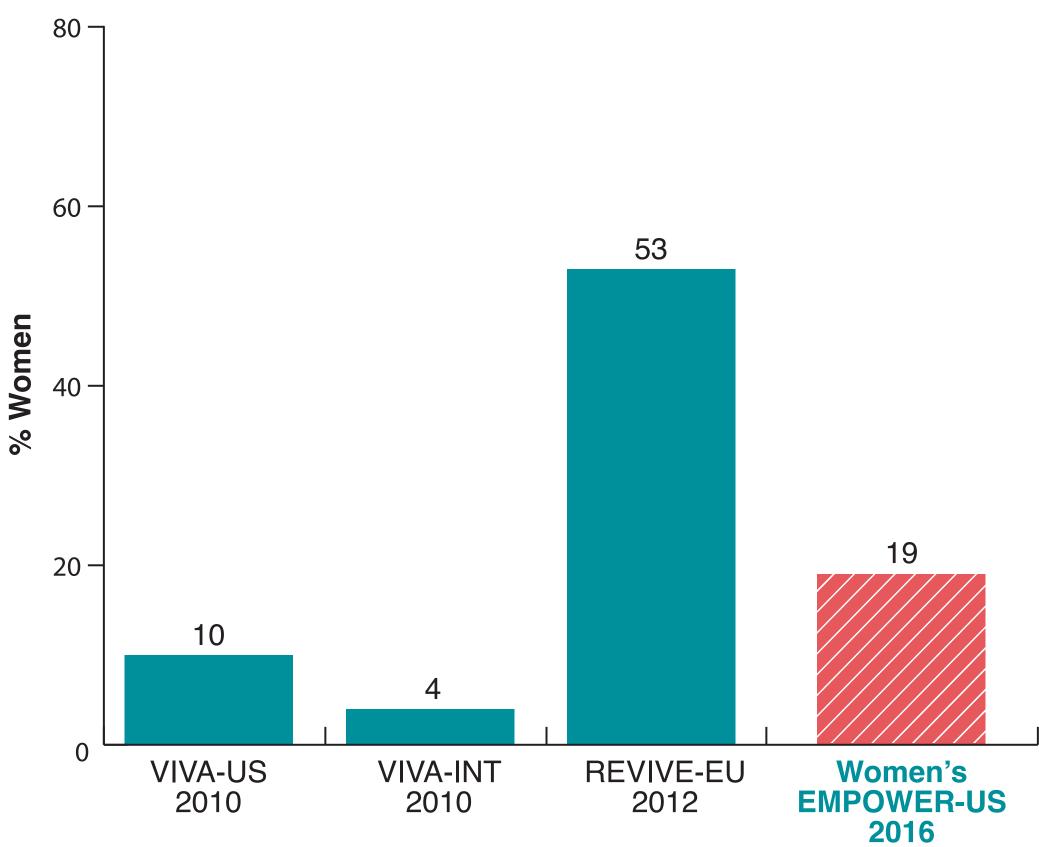
- Approximately 40% of women associated VVA symptoms with menopause (Figure 2)^{3,4,7,8}
- [•] However, in REVEAL, 82% and 57% of women were aware that vaginal dryness and dyspareunia were menopausal symptoms, respectively¹
- In the Women's EMPOWER survey, only 19% of women were aware that VVA is a medical condition, while in REVIVE-EU, about half (53%) were aware of VVA (Figure 3)⁸

Figure 2: Aware that vaginal symptoms are associated with menopause



 In the VIVA surveys, 43% (US)⁴ and 63% (Int'I)³ of women failed to recognize that VVA is a chronic condition

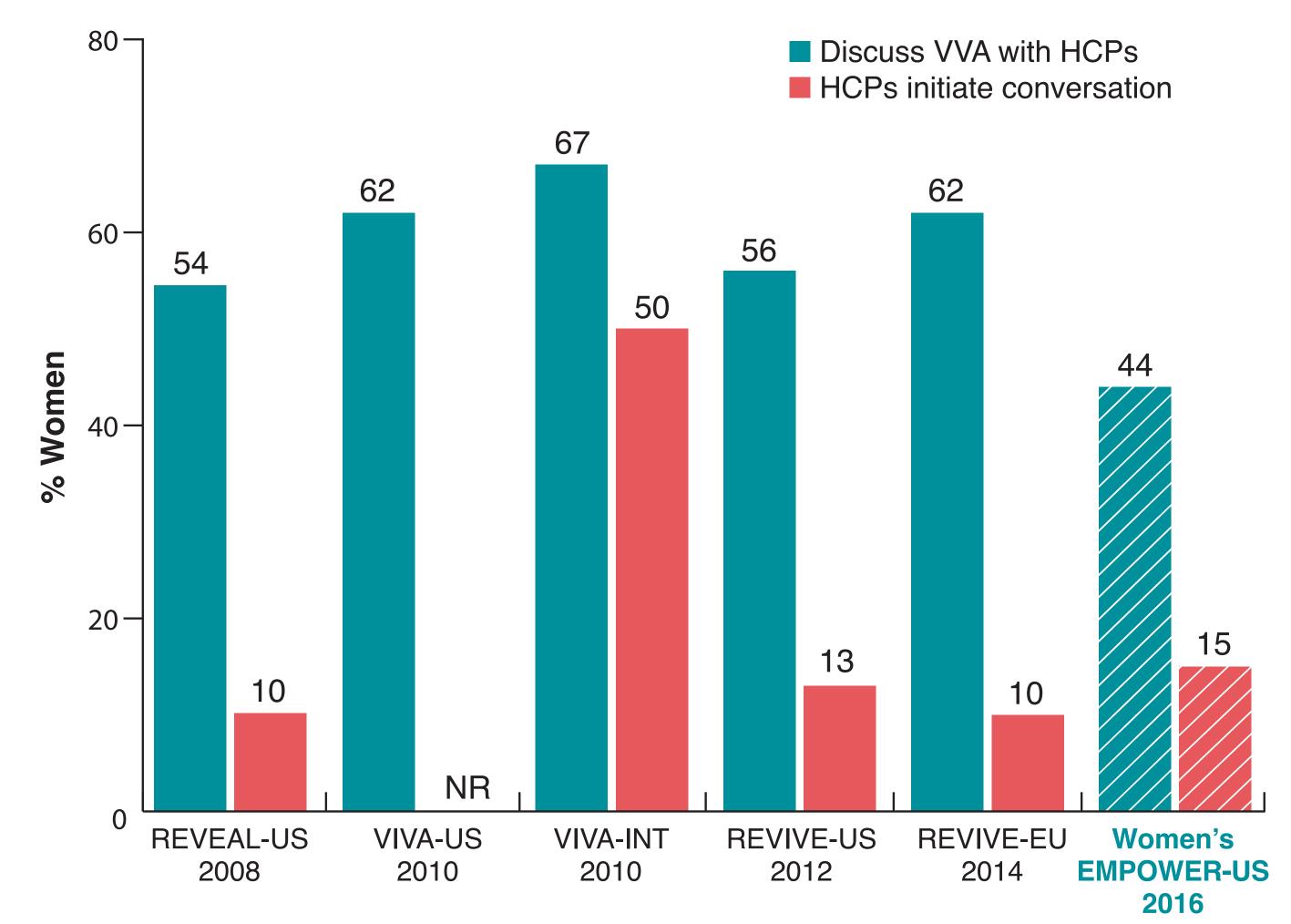
Figure 3: Aware that vaginal symptoms are part of VVA



Most HCPs do not initiate dialogue on VVA symptoms with their patients

- In Women's EMPOWER, only 44% of women had discussed VVA symptoms with their HCP, and of these, 85% had initiated the conversation (Figure 4)
- While 70% of current or former HT users discussed their symptoms and treatment options with their HCPs, only 28% of women who had never used HT or overthe-counter products (OTC) spoke to their HCPs
- The majority of women who spoke to their OB/GYNs or their primary care physicians about their symptoms did so during their annual exam
- In most other surveys,^{1,3,4,7,8}
- About half to two-thirds (56-67%) of women spoke to their HCPs about their vaginal symptoms (Figure 4)
- Few HCPs initiated a conversation about vulvar and vaginal health (Figure 4)
- Many women (40-65%) would like HCPs to initiate the conversation and provide information on this topic

Figure 4: Discussion of vulvar and vaginal symptoms



Concerns regarding available prescription VVA products are still high • In the Women's EMPOWER survey, reasons women decide not to use HT (route not specified) for their VVA symptoms were concerns over safety, HCP-related reasons, method inconvenience, and cost (Table 2)

• The top concerns of current vaginal HT users in REVIVE are similar (Table 3)^{7,8} Concerns over risk of systemic absorption for current HT users appeared to be higher in the Women's EMPOWER survey (48%) versus 35% in REVIVE-US⁷ and 17% in REVIVE-EU⁸

Table 2: Why women decide not to use HT for VVA symptoms

Women's EMPOWER Survey	US (n=1657)
Safety	
Concern over risk of side effects (heart attack, stroke) associated with HT	44%
Concern over hormone safety in women with cancer or history of familial cancer	30%
HCP-related reasons	
HCP recommended against use of HT because of the risks	15%
HCP did not offer or recommend	12%
HCP did not recommend because he/she didn't see the need to treat symptoms	8%
Method	
Method of taking the product was not desirable	8%
Other	
Cost was too high	13%
Not enough information about products to make a decision	12%
Other	13%
Don't know	9%

Table 3: Top concerns about vaginal HT in current users

REVIVE	EU N=381 ⁸	US N=357 ⁷
Safety		
Concern about breast cancer	11%	30%
Concerns about hormone exposure	17%	35%
Concerns about safety in long-term use	21%	41%
Vaginal discharge	15%	13%
Concern about other side-effects	16%	26%
Efficacy		
Vagina not restored to natural state	26%	36%
Not enough relief of symptoms	13%	23%
Takes a long time to start	12%	10%
Method		
Messy	13%	20%
Inconvenient to administer	15%	19%
Method of administration	12%	22%
Other		
Cost	7%	32%

- In the VIVA surveys, women were twice as likely to associate negative effects (increased risk for breast cancer and blood clot/stroke) to systemic HT than to local estrogen therapies^{3,4}
- 49% of women would take vaginal prescription therapies if they knew they were effective and could maintain normal hormone levels

Conclusions

- The Women's EMPOWER survey was consistent with previous VVA surveys (REVEAL, WVM, VIVA, CLOSER, REVIVE)
- Postmenopausal women generally failed to recognize VVA and its chronic, progressive course, and almost half did not discuss vaginal or sexual symptoms with their HCPs
- Main reasons why postmenopausal women do not take or stopped taking HT products include safety concerns, lack of efficacy, and product inconveniences
- Overall, women in Europe seem less concerned about overall risk of HT than women in the US
- HCPs should proactively initiate education and discussions with postmenopausal women so they can better understand VVA as a medical condition, symptoms associated with VVA, and the risk-benefit ratio regarding treatment options
- Despite educational and media efforts, a disconnect remains between discussing and treating this prevalent condition

References

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Disclosures

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