

# Development of a Postsurgical Patient-Reported Outcome Instrument for Women With Vulvar Neoplasia

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**V**ulvar neoplasia, which includes vulvar intraepithelial neoplasia (VIN) (Sideri et al., 2005) and vulvar cancer (Maclean, 2006), is an uncommon disease with increasing incidence rates in Europe and the United States (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe, 2009; Lanneau et al., 2009). In Germany, annual incidence rates are 2.9 per 100,000 women for VIN and 2.5 per 100,000 women for vulvar cancer (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe, 2009). In the United States, an estimated 4,490 new cases and 950 deaths from vulvar cancer occurred in 2012 (National Cancer Institute, 2012). VIN can affect women at any age; however, the disease is more common in those younger than 50 years (Jones, Rowan, & Stewart, 2005; Pepas, Kaushik, Bryant, Nordin, & Dickinson, 2011). High-grade VIN is associated with human papillomavirus infection and may progress to invasive disease (Pepas et al., 2011). The mean age of vulvar cancer diagnosis is 72 years (Dittmer, Katalinic, Mundhenke, Thill, & Fischer, 2011). In addition, women with VIN or vulvar cancer have a high recurrence rate of 30%–40% (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe, 2009; Nugent et al., 2010).

Although vulvar neoplasia includes different diseases, surgical treatment is the standard therapy for women with VIN and vulvar cancer (Lai & Mercurio, 2010; National Cancer Institute, 2010). Different surgical treatment methods are used for vulvar neoplasia, such as local excision, skinning vulvectomy, laser vaporization, partial or radical vulvectomy, and inguinofemoral lymph node dissection, depending on disease stage and lymph node involvement.

**Purpose/Objectives:** To (a) develop the Women With Vulvar Neoplasia—Patient-Reported Outcome (WOMAN-PRO) instrument as a measure of women's post-vulvar surgery symptom experience and informational needs, (b) examine its content validity, (c) describe modifications based on pilot testing, and (d) examine the content validity of the revised instrument.

**Design:** Mixed-methods research project.

**Setting:** One Swiss and two German university hospitals.

**Sample:** 10 patients and 6 clinicians participated in the pilot test.

**Methods:** The instrument was developed based on literature searches, clinician feedback, and patient interviews. Thirty-seven items were first pilot tested by patients and clinicians. The revised 36 items were pilot tested by patients. The content validity index (CVI) for each item and the entire instrument was calculated.

**Main Research Variables:** Symptom experience and informational needs of patients with vulvar neoplasia.

**Findings:** The initial pilot test showed excellent scale CVI based on feedback from patients (CVI = 0.98) and clinicians (CVI = 0.92). After revising six items based on low individual CVIs and participant comments, the revised WOMAN-PRO showed excellent item and scale content validity (CVI = 1).

**Conclusions:** The newly developed WOMAN-PRO instrument can guide patients and clinicians in assessing symptoms, informational needs, and related distress.

**Implications for Nursing:** Use of the WOMAN-PRO instrument in clinical practice can offer patients guidance in self-assessment and early recognition of symptoms. The instrument also can provide clinicians with systematic information about key symptoms from a patient perspective, as well as women's unmet informational needs. If the results of additional psychometric testing are promising, the WOMAN-PRO tool may provide an outcome measure for clinical trials.