<table>
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<th><strong>Titre</strong></th>
<th>Creating and validating a patient-pertinent instrument to assess symptoms experienced related to surgical wounds in women with vulvar neoplasms - a mixed methods study</th>
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<td><strong>Acronyme</strong></td>
<td>WOMEN-PRO</td>
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<td><strong>Statut (dates début-fin)</strong></td>
<td>Terminé (01.01.2010 – 30.06.2012)</td>
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<td><strong>Requérant-e principal-e (site)</strong></td>
<td>• Dr. med. Michel Mueller (Inselspital, Bern, <a href="http://www.insel.ch/">http://www.insel.ch/</a>)</td>
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| **Collaborateur-trice(s) (site)** | • Beate Senn (Université de Bâle, [http://www.unibas.ch/](http://www.unibas.ch/))  
• Rebecca Spirig (Université de Bâle, [http://www.unibas.ch/](http://www.unibas.ch/)) |
| **Source de financement (partenaire financier)** | • Fondation Recherche suisse contre le cancer ([http://www.krebsforschung.ch/](http://www.krebsforschung.ch/)) |
| **Résumé** | Wound related complications occur in 20-40% of women following surgery for vulvar intraepithelial neoplasia and vulvar cancer. The prevalence of complications after surgery for vulvar neoplasms is especially high for lower extremity lymph edema (30-70%), wound dehiscence and infections (20-40%) and psychosexual effects from distortion of the vulva. The high prevalence of complications in women with vulvar neoplasms (WVN) result in a variety of physical and psycho-social problems and contribute to high health care costs. Since the major part of care takes place in an extramural setting, assessment and treatment of complications is based on patients' awareness and reporting of symptoms. Nevertheless, to date, there is limited research describing symptoms after surgical treatment of vulvar neoplasms. Symptoms are indicators reported directly from WVN, e.g. odor, swelling, and bleeding. Patients' symptom experience encompasses the occurrence of such symptoms as well as their distress, causing shame or embarrassment. As patients are usually discharged before their surgical wound has healed it can be assumed that symptom experiences after surgical treatment are a major issue for patients. Despite this, no structured assessment instrument is available, symptom experiences are unmapped and there is little guidance for the assessment of the symptom experiences in WVN.  
Aims  
Therefore, the aims of this PhD project are (1) to explore symptom experience, more specifically symptom occurrence and symptom distress of women during the first three months following surgical treatment of vulvar neoplasms, (2) to develop a self administered WOund assessMent in vulvAr Neoplasms – Patient Reported Outcome (WOMAN-PRO) instrument for monitoring the post-vulvar surgery symptom experience by WVN, (3) to test psychometric properties of the developed WOMANPRO instrument and (4) to examine the wound-related symptom experience of WVN during the first 3 weeks following hospital discharge following vulvar surgery.  
Methods  
A mixed methods design will be used with a sequential exploratory strategy integrating qualitative and quantitative techniques. Initially in the qualitative research phase a qualitative hermeneutic approach will be utilized to explore women's symptom experience related to their surgical wounds. A purposeful sample of 20 WVN will be recruited in the University Hospital Bern and Munich. One to three month post surgery, problemcentered interviews with open-
ended questions will be conducted. Most interviews will be conducted in participant’s home, will last about one hour and will be recorded and transcribed. Content analysis, according the seven-stage process to Diekelmann and Allen (1989), will be employed to analyze the data considering WVN's experiences and social perceptions. This process will be assisted by Atlas ti (AIM 1). The WOMAN-PRO instrument will be developed based on the themes from the qualitative research phase according to the U.S. Food and Drug Administration Center guidelines. Based on pilot testing with ten WVN and ten health professionals recruited in the University Hospital Bern and Munich content validity will be analyzed and scoring procedures will be refined (AIM 2). In the quantitative research phase a cross-sectional multi-center study will be conducted with women recruited from three Swiss (Zurich, Basel, Bern) and three German University Hospitals (Munich, Berlin, Düsseldorf). A convenience sample will comprise 150 WVN, who complete the WOMANPRO instruments during the first 3 weeks following hospital discharge following vulvar surgery. The psychometric properties of the instrument (validity, reliability and responsiveness) will be examined based on the American Educational Research Association standards (AIM 3). The prevalence for each of the measured symptoms and the self-reported distress associated with each symptom will be calculated for the overall sample of patients and for each center (AIM 4).

Partenaire(s) de terrain
• Trois hôpitaux universitaires suisses : Zürich, Basel, Bern
• Trois hôpitaux universitaires allemands : Munich, Berlin, Düsseldorf

Contact
• Manuela.eicher@hefr.ch
• +41 429 26 6055

Valorisation (publications, conférences, congrès)
• Gafner, D., Eicher, M., Spirig, R., & Senn, B. (2013). Living between anxiety and hope: The experiences of women with vulvar intraepithelial neoplasia during their course of illness – A qualitative study. 17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress (ECC2013), Amsterdam, 27th September - 1st October.
• Senn, B., Eicher, M., Mueller, M., Engberg, S., & Spirig, R. (2011). Self-
monitoring the post-surgery symptom experience of women with vulval neoplasia: Development and content validity of a Patient-Reported Outcome instrument (WOMAN-PRO). 9th European Academy of Nursing Science Summer School, July 4-8, Lund University, Sweden.


