

1 **Abstract**

2 **Purpose:** To develop an evidence-based guideline for nurses and other health care
3 professionals involved in pre- and postsurgical care of women with vulvar cancer (VC) or
4 vulvar intraepithelial neoplasia (VIN).

5 **Methods:** This evidence-based guideline was developed according to six domains of the
6 methodological framework AGREE II. Literature research with focus on cancer care,
7 symptom management and self-management/counselling was conducted from April to
8 August 2013 in the databases CINAHL, Cochrane Library, PsycINFO, PubMed as well as in
9 14 international guideline databases. Interdisciplinary experts (n=14) were involved in the
10 development of the guideline from December 2013 to January 2014. This guideline is
11 currently tested in the WOMAN-PRO II RCT (Clinical Trial No: NCT=1986725).

12 **Results:** For the definition of recommendations, five guidelines, one meta-analysis, two
13 systematic reviews and two randomized controlled trials were included. In total, 24
14 recommendations were formulated to answer 22 clinical questions based on patients'
15 perspective and experts' opinion. Evidence ranged from 3.5 to 5 (3.5 = weak evidence and/or
16 clinical relevance, 5 = best evidence and/or clinical relevance). The recommendations were
17 subsumed under different themes regarding physical, psychological and psychosocial
18 aspects.

19 **Conclusions:** The clinical practice guideline developed in this study firstly provides
20 recommendations for symptom management issues focusing on self-management
21 interventions for women with VC or VIN. As an interdisciplinary guideline it should be used in
22 addition to the existing medical guideline in the German speaking context.

23 **Keywords:** Evidence-based guideline; vulvar cancer; vulvar intraepithelial neoplasia;
24 symptoms and distress; self-management; symptom-management

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31 **Introduction**

32 An annual incidence of two to seven per 100,000 women has been reported for vulvar
33 neoplasms (VN) in the United States and Europe (Hampl et al., 2011). The term “vulvar
34 neoplasms” comprises vulvar intraepithelial neoplasia (“pre-malignant lesions”, VIN) and
35 vulvar cancer (VC) (Sideri et al., 2005). One predisposing factor for VIN mostly seen in
36 younger patients is Human Papilloma Virus (HPV). VC is more widespread in elderly women
37 and its cause is almost unknown (Alkatout et al., 2015). It is the fourth most common
38 gynaecologic cancer comprising several histological types, with squamous cell carcinoma
39 being the most common category. The gold standard for treating VC and high-grade VIN is
40 surgery (Alkatout et al., 2015). After vulvar surgical therapy women often experience
41 symptoms and related distress. Symptoms may be categorized into three types: wound-
42 related symptoms (e.g. swelling), psychosocial symptoms (e.g. tiredness) and difficulties in
43 daily life (e.g. during sitting) (Senn et al., 2013). Even minimal surgical treatment causes a
44 variety of symptoms and postsurgical complications (Baker-Glenn et al., 2011). Women’s
45 symptom experience can vary depending on the FIGO stage (International Federation of
46 Gynaecology and Obstetrics [Belhadj et al., 2014]) as well as on the type of treatment and
47 may affect the perceived quality of life (Novackova et al., 2015).

48 Due to reduced hospital length of stay after vulvar surgical therapy, women’s self-
49 management of challenging situations has become a high priority in order to prevent
50 negative outcomes (Humphreys et al., 2008). Self-management can be defined as tasks
51 undertaken by individuals to deal with medical, role and emotional management of their
52 health condition (McCorkle et al., 2011). The three types of symptoms (wound-related,
53 psychosocial and difficulties in daily life) can be allocated to the tasks of self-management.
54 To support self-management, verbal and written information provide a basis for educating
55 patients about their condition and care (Silva, 2011). Structured counselling, including
56 identification of pre-surgical risks for complications and planning of post-surgical
57 interventions can lower patient morbidity (Senn et al., 2015). However, women report a lack
58 of pre- and postsurgical counselling (Jefferies and Clifford, 2011). They described receiving

59 limited information from health care professionals with regard to symptom management
60 (Senn et al., 2011). To achieve effective symptom management, it is essential to understand
61 the individual's symptom experience (Senn et al., 2011). According to Dodd et al. (2001),
62 symptom management may be understood as a dynamic process with the aim of preventing
63 negative outcomes. Given et al. (2004) developed a nurse-delivered intervention to reduce
64 the severity of physical and psychological symptoms in patients receiving chemotherapy. For
65 this purpose, standardized information and approaches to problem solving were used to
66 reduce symptom severity. To implement self-management interventions and to develop care
67 plans, a patient-provider partnership is important (McCorkle et al., 2011). As Allen (2003)
68 stated in her study, women with VC need high-quality information delivered in an appropriate
69 environment by a clinical nurse specialist as part of a multidisciplinary team.

70 The current guideline for diagnosis and management of VC proposes an integrative
71 approach to caring for women with VC, including a skilled nurse as a key factor for patient
72 management in coordination with medical treatment (Royal College of Obstetricians and
73 Gynaecologists [RCOG], 2014).

74 Offering support provided by skilled nurses during treatment is a first step to put into practice
75 guideline recommendations. Nurses and other health care providers need evidence-based
76 guidelines for symptom management in order to support women systematically and
77 comprehensively in their symptom management. It can be expected that evidence-based
78 guidelines promote positive treatment outcomes (Puhan et al., 2014). In this context the
79 German Society for Gynaecology and Obstetrics (DGGG) (Working Group of Gynaecological
80 Oncology, 2009) developed guidelines for the treatment of vulvar premalignant and
81 malignant lesions, targeting surgery, radio- and chemotherapy. However, there remains a
82 shortage of recommendations concerning symptom management. To our knowledge, a
83 guideline containing recommendations focusing on the most prevalent physical and
84 psychosocial symptoms in women with VIN and VC does not yet exist. Consequently, it is
85 difficult for nurses and other health care providers to support symptom management in a
86 systematic and comprehensive manner. In response to an absence of synthesized evidence,

87 we developed a guideline for health care professionals with a focus on the most prevalent
88 postsurgical symptoms described in a previous study (Senn et al., 2013). Professionals can
89 use this guideline in counselling for women with VC or VIN after surgical treatment.

90 **Therefore, our main research question was:** Which recommendations are appropriate to
91 support symptom self-management with regard to the most prevalent postsurgical
92 symptoms/problems in women with VIN and VC?

93 **Based on results from Senn et al. (2013), which focused the most prevalent postsurgical**
94 **symptoms, the main research question was operationalized into 22 clinical questions shown**
95 **in table 1.**

96 **[table 1: Clinical questions]**

97 **Methods**

98 The development of this guideline is based on the six domains of AGREE II, an instrument
99 internationally acknowledged for (I) assessing quality of guidelines, (II) providing a
100 methodological strategy for the development of guidelines and (III) supporting authors with
101 regard to reporting information in guidelines (Brouwers et al., 2010). Domains 1 to 4 are
102 defined 'scope and purpose', 'stakeholder involvement', 'rigour of development' and 'clarity of
103 presentation'. The last two domains consist of 'applicability' and 'editorial independence'.

104 **A nursing counselling concept was developed according to the PEPPA framework (Bryant-**
105 **Lukosius and Dicenso, 2004), including a clinical pathway. According to the six domains of**
106 **AGREE II (Brouwers et al., 2010) we developed a draft of the guideline in December 2013. A**
107 **group of six experts, consisting of physicians, specialist nurses and nursing scientists,**
108 **assessed this draft. We incorporated the experts' comments in our guideline which is**
109 **currently tested in the WOMAN-PRO II randomized controlled trial (Clinical Trial No:**
110 **NCT01986725).**

111 **Domain 1: Scope and Purpose**

112 The target population of the guideline includes women with VC or VIN and surgical treatment
113 with a curative and not a palliative intention. Results of previous studies in patients with VC
114 or VIN undergoing surgery have shown that patients suffer from a high number of
115 postsurgical symptoms (Senn et al., 2011; Senn et al., 2013). Affected women mentioned on
116 average 20 symptoms, comprising wound-related symptoms, psychosocial issues and
117 activities of daily living (Senn et al., 2012). Based on these results, we determined the
118 primary and secondary outcomes.

119 **Domain 2: Stakeholder Involvement**

120 In order to assess views and preferences of the target population, we conducted semi-
121 structured interviews with patients with VC or VIN and surgical treatment. These interviews
122 focused on the experience of postsurgical symptoms and resulting constraints to which
123 women are exposed. Furthermore, we assessed the women`s needs and investigated which
124 improvements they regard as necessary for their care. Target users of the guideline are
125 advanced practice nurses. **Therefore, a gynaecologic-oncology nurse was part of the group**
126 **of four experts who formulated and rated the guideline`s recommendations.**

127 **Moreover,** physicians and other health care professionals focusing on care of this specific
128 patient population may apply the guideline too. **To assess the view of these stakeholders,**
129 **experts from different areas (gynaecology, oncology, radiology, nursing science) were**
130 **involved in the development of the counseling intervention as well as in the review of the**
131 **guideline.**

132 **Domain 3: Rigour of Development**

133 *Criteria for selecting evidence:* To identify current **guidelines and** studies focusing on care for
134 women with VC or VIN undergoing surgery, we conducted a literature review **guided by the**
135 **22 clinical questions shown in table 1. Inclusion criteria for guidelines were (1) description of**
136 **the methodological approach, (2) at least partly designed for nursing, (3) publication date**
137 **from 2003 to 2013, (4) guidelines focusing on symptoms due to an oncological disease and**
138 **(5) English or German language. Exclusion criteria for guidelines were (1) thematic focus on**

139 palliative care and end-of-life care, (2) guidelines in terms of guidebooks and (3) guidelines
140 concerning chronic oncological symptoms.

141 Inclusion criteria for studies were (1) studies focusing on oncological symptoms, (2)
142 randomized controlled trial, systematic review, meta-analysis, (3) publication date from 2003
143 to 2013 and (4) English language. Exclusion criteria for studies were focus on patients in a
144 palliative or end-of-life situation.

145 We searched the following guideline-specific databases: American Cancer Society, Working
146 Group Supportive Care in Oncology, Rehabilitation and Social Medicine of The German
147 Cancer Society, Association of the Scientific Medical Societies in Germany, BC Cancer
148 Agency, EONS, European Society for Medical Oncology, GIN, Multinational Association of
149 Supportive Care in Cancer, NCCN, National Guideline Clearinghouse, NICE, New Zealand
150 Guidelines Group, ONS and SIGN. To identify meta-analyses, systematic reviews or
151 randomized controlled trials we selected the databases CINAHL, Cochrane Library,
152 PsycINFO and PubMed. Furthermore, we also checked reference lists of all included studies
153 for additional literature.

154 Based on the 22 clinical questions (table 1) thematic focuses were given. The thematic
155 focuses comprised Advanced Practice Nursing, assessment, counseling, information, self-
156 management and symptom management. For each thematic focus we developed questions
157 according to PICO which supported the identification of relevant search terms. The search
158 term used for each thematic focus are shown in table 2.

159 **[table 2: search terms]**

160 The search terms were adapted for each database. An example for a search string for the
161 database PubMed is as follows: (((("Advanced Practice Nursing"[Mesh]) OR "Nurse
162 Clinicians"[Mesh])) AND (((("Vulvar Neoplasms"[Mesh]) OR vulvar intraepithelial neoplasia)
163 OR "Genital Neoplasms, Female"[Mesh]) OR "Carcinoma in Situ"[Mesh]) Filters: Meta-
164 Analysis; Randomized Controlled Trial; Systematic Reviews; Publication date from
165 2003/01/01 to 2013/07/30; English.

166 One person conducted the research between April and August 2013. The flowcharts of the
167 literature search are shown in figure 1 and 2.

168 [figure 1: Flowchart of literature search to identify guidelines]

169 [figure 2: Flowchart of literature search to identify studies]

170 *Strengths and limitations of the body of evidence:* Two authors independently assessed the
171 methodological quality of all included studies. Guidelines were evaluated using the DELBI
172 instrument for methodological guideline appraisal (Association of the Scientific Medical
173 Society in Germany and Agency for Quality in Medicine, 2008). Meta-analyses, systematic
174 reviews and randomized controlled trials were appraised according to the FIT Nursing Care
175 tool (Panfil and Ivanovic, 2011) which was developed according to the guidelines of the
176 Cochrane Collaboration (Higgins and Green, 2011) and GRADE (Puhan et al., 2014). As in
177 the Swiss/German speaking context the FIT Nursing Care tool is well known, it has been
178 chosen in order to enhance the transparency of our approach especially for our target users.

179 We formulated the recommendations on the basis of the identified literature. In a voting
180 procedure of four experts with clinical and scientific expertise, each recommendation has
181 been discussed with regard to available evidence, health benefits, side effects and risks.
182 Eight external experts reviewed the guideline. An update is planned for 2018.

183 **Domain 4: Clarity of Presentation**

184 For optimal visibility, the recommendations are presented in a blue box. A list of all
185 recommendations can be found in the front section of the guideline.

186 **Domain 5: Applicability**

187 In the methodological part of the guideline, we named facilitators and barriers possibly
188 having an impact on the application of the recommendations. Furthermore, structure criteria
189 (e.g. ensuring that a specialized nurse is available for counselling in patients with vulvar
190 neoplasms), process criteria (e.g. providing contact with other healthcare services involved in

191 caring and treatment) and outcome criteria (e.g. pain level) were determined (Donabedian,
192 2008).

193 **Domain 6: Editorial Independence**

194 The Federal Office of Public Health (Switzerland) and the University of Applied Sciences St.
195 Gallen (Switzerland), funded the guideline. All persons involved in developing the guideline
196 made their contribution within their institutional work. The members of the development
197 group had no competing interests to declare.

198 **Results**

199 To determine the recommendations, we included five guidelines, one meta-analysis, two
200 systematic reviews and two randomized controlled trials.

201 Table 3 shows the results of the methodological guideline appraisal.

202 In figure 3 and figure 4, the results of the methodological appraisal of the remaining studies
203 are visible.

204 **[table 3: Methodological guideline appraisal, DELBI]**

205 **[figure 3: Methodological appraisal of systematic reviews and meta-analyses]**

206 **[figure 4: Methodological appraisal of randomized controlled trials]**

207 In the domain “methodological rigour of purpose” four of the included guidelines reached a
208 percentage of 52% or more (Cruickshank M.E., 2011; Mitchell et al., 2007; Poage et al.,
209 2008; Scottish Intercollegiate Guidelines Network [SIGN], 2008). Only one guideline
210 achieved 48 % but could nevertheless be included because of its clinical relevance (Sheldon
211 et al., 2008). Three guidelines (Mitchell et al., 2007; Poage et al., 2008; Sheldon et al., 2008)
212 achieved rather low scores in the domain “stakeholder involvement”. Reasons were that they
213 missed to report or did not involve key stakeholders, especially patients in the guideline’s
214 development. Low scores in the domain “general applicability” (e.g. Cruickshank M.E., 2011;
215 Mitchell et al., 2007; Sheldon et al., 2008) can be explained by the fact that guidelines failed
216 to report barriers and facilitators to implementation of the guideline as well as resource

217 implications for applying the guideline. Within the domain 8 “methodological rigour of
218 development when using existing guidelines” especially in three of the included studies
219 (Mitchell et al., 2007; Poage et al., 2008; Sheldon et al., 2008) there was a lack of description
220 how the search for already existing guidelines was conducted, if included guidelines were
221 critically appraised and how the content of the guideline has influenced the
222 recommendations.

223 With regard to the included studies the meta-analysis was of good methodological quality
224 except for the domain “description of selection process of included studies” (McNeely et al.,
225 2011). Both systematic reviews had methodological weaknesses, e.g. in the domain
226 “literature research” or “assessment of included studies” (Luckett et al., 2009; Ridner et al.,
227 2012).

228 The randomized controlled trials had adequate research questions, recruitment and equal
229 treatment but nevertheless the sample size was too small (Beatty et al., 2010; Thomas et al.,
230 2012).

231 In total, it was possible to formulate 24 recommendations on the basis of 22 clinical
232 questions which were categorized into the following themes: *symptom self-assessment*,
233 *surgical wound and vulva care*, *postsurgical pain*, *postsurgical tiredness*, *postsurgical urinary*
234 *symptoms*, *lymphedema*, *difficulties concerning sitting*, *wearing clothes and activities of daily*
235 *living*, *uncertainty* and *body image*. The recommendations for symptom management in
236 women with VC or VIN and surgical treatment are visible in table 4. The source of evidence
237 and grades of recommendations are included.

238

239 [table 4: Recommendations, including time, source of evidence and grade of
240 recommendation]

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242 The grades of recommendations range from 3.5 to 5 (3.5 = weak evidence and /or clinical
243 relevance, 5 = best evidence and / or clinical relevance). For each recommendation the
244 literature source and the time are listed (table 3). Eleven recommendations were classified

245 as grade 4, three were classified as grade 3.5, 3.75 and 4.25, and two as grade 4.75 or 5.
246 For each recommendation a maximum of three external sources were identified.

247 **Discussion**

248 Within the framework of this study we developed an evidence-based guideline focusing for
249 the first time on symptom management in women with VC or VIN after surgical treatment.
250 The development was based on the methodological principles of AGREE II (Brouwers et al.,
251 2010). As described in the domains of AGREE II, stakeholder involvement and the rigour of
252 development are essential parts of a guideline's development. Current approaches for
253 guidelines development recommend an even stronger focus on different sources of
254 knowledge (e.g. including quantitative and qualitative research, contextual information and
255 expert practical and experience knowledge). The consideration of different sources of
256 knowledge should strengthen the guideline's relevance, applicability and practicability for
257 target users (Lukersmith et al., 2016). Therefore, besides the inclusion of the current best
258 external evidence, we included patients, experts in gynaecologic oncology and gynaecologic-
259 oncology nurses as target users in the guideline's development. Especially patient
260 engagement is strongly recommended before and during the guideline's development as well
261 as in the phase of dissemination and implementation (Armstrong et al., 2016). Thus semi-
262 structured interviews were conducted with women with VC or VIN and surgical treatment.
263 The women's opinion has been incorporated in framing the clinical questions, conducting the
264 review and the development of the recommendations. It is important to bear in mind that
265 stakeholders, including patients and health care professionals, should not only be included in
266 the developmental phase but also informed about the presence of such guidelines. Studies
267 have shown that, especially in patients, the awareness of guidelines is low but they have a
268 wish to be informed in order to be supported when choosing between different treatment
269 options (Fearn's et al., 2016). We try to enhance the dissemination of our guideline by making
270 it accessible online for free and providing institutions with information about the guideline. To
271 support the guideline's applicability in clinical practice, the recommendations have been

272 formulated in an easily accessible, patient-centered and comprehensive manner (Allen,
273 2003; National Institute for Health and Care Excellence [NICE], 2012).

274 **Strengths and limitations**

275 This guideline was developed according to stringent methodological principles,
276 systematically considering all six steps of the AGREE II guideline (Brouwers et al., 2010).
277 The available literature was rated independently by two persons using internationally
278 accepted checklists. However, the literature search was conducted by only one researcher,
279 due to limited resources. To define recommendations, we included five guidelines, one meta-
280 analysis, two systematic reviews and two randomized controlled trials. As the literature
281 offered only a limited number of interventions supporting women in their management of VC
282 or VIN after surgical treatment, we extended our research on women with other
283 gynaecological tumours, e.g. breast cancer. Due to limited external evidence, seven
284 recommendations are based on expert opinions.

285 **Conclusions**

286 This clinical practice guideline for symptom management in women with vulvar neoplasms is
287 the first interdisciplinary guideline focusing on self-management. It should be used in addition
288 to the existing medical guideline developed by the DGGG (Working Group of Gynaecological
289 Oncology, 2009) and the new medical guideline of the NCCN (National Comprehensive
290 Cancer Network, 2016). Our guideline supports early detection and assessment of
291 postsurgical symptoms on predefined timeframes, the use of evidence-based symptom-
292 relieving interventions and interdisciplinary decisions regarding therapy by systematically
293 involving the patient as well as the medical perspective. The application of this guideline
294 should be tailored to the individual patient's needs with regard to treatment history, risk
295 factors, comorbidities and lifestyle. By using the WOMAN-PRO symptom diary, women can
296 be actively involved in symptom management. Empowerment concerning their self-
297 management can be strengthened.

298 The development of this guideline has been conducted systematically in cooperation with all

299 relevant stakeholders (NICE, 2012) and on the basis of currently available evidence
300 (Association of the Scientific Medical Society in Germany and Agency for Quality in
301 Medicine, 2008; Royal College of Obstetricians and Gynaecologists, 2014; Working Group of
302 Gynaecological Oncology, 2009). Further research is required to test the guideline's
303 effectiveness and feasibility in home care settings. Future guideline development should
304 consider also additional postsurgical symptoms as well as side effects of adjuvant therapies,
305 such as chemotherapies and radiotherapies, in women with VIN and VC.

306 **Conflict of interest**

307 The authors declare no conflict of interest.

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