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WOund assessMent in vulvAr Neoplasms – creating and validating a Patient-Reported Outcome (WOMAN-PRO) instrument
A mixed methods study

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BACKGROUND

Due to localization, stigmata and high complication rate, wound management after surgery for women with vulvar neoplasms (WVN), i.e. vulvar intraepithelial neoplasia and vulvar cancer is challenging.

Complication rates are high [1], especially for:

- lower extremity lymph edema (30-70%)
- wound dehiscence and infections (20-40%)
- psychosexual effects

To date:

- Patients' perspectives and symptom experience i.e. symptom occurrence (frequency, severity, duration e.g. of odor) and symptom distress (emotions associated with the symptom) remain unmapped.
- There is little guiding theory for the assessment of the symptom experience in WVN.
- No structured assessment instrument for symptom experience in WVN is available.

AIMS

1. To explore the symptom experience of women during the first three months following surgical treatment of vulvar neoplasms.
2. To develop a self administered WOMAN-PRO instrument for monitoring the post-vulvar surgery symptom experience by WVN.
3. To test psychometric properties of the developed WOMAN-PRO instrument.
4. To examine the wound-related symptom experience of WVN during the first 3 weeks following hospital discharge following vulvar surgery.

METHODS

Design two-phase, sequential exploratory mixed methods study [3]

AIM 1 - Qualitative phase

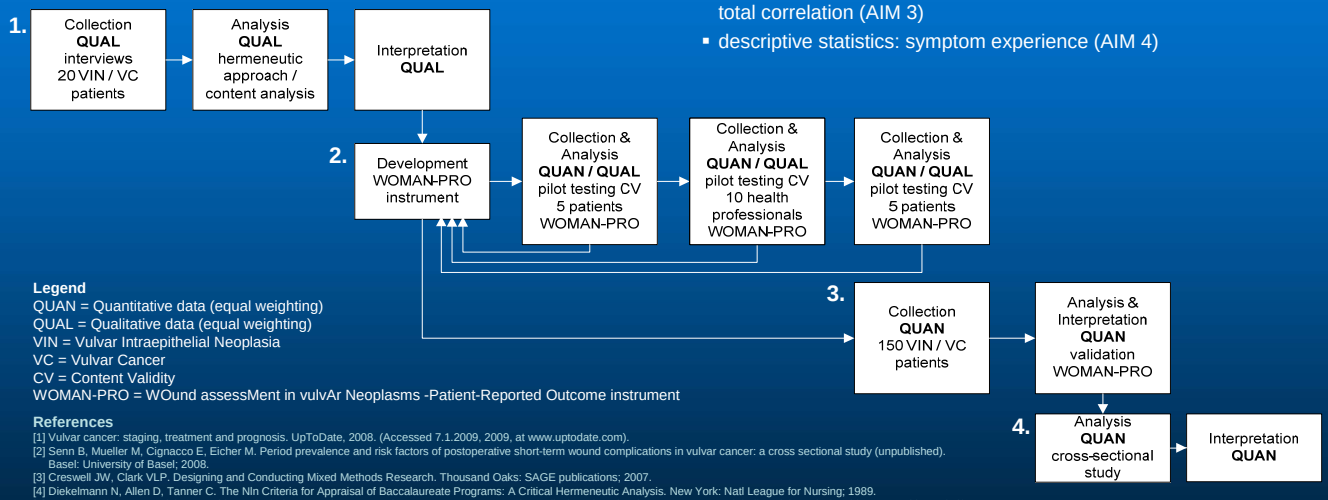
Approach hermeneutics

Sample / Setting purposeful sampling of 20 WVN, University Women Hospital Bern (CH) & Munich (D), participants' home

Data collection 20 problem-centered interviews (50-60'), 1-12 weeks post surgery, demographic & medical data; Oct 2009 – Mar 2010

Data analysis content analysis seven-stage process [4]

Fig. I: Mixed methods: Sequential exploratory design



Legend
QUAN = Quantitative data (equal weighting)
QUAL = Qualitative data (equal weighting)
VIN = Vulvar Intraepithelial Neoplasia
VC = Vulvar Cancer
CV = Content Validity
WOMAN-PRO = WOund assessMent in vulvAr Neoplasms -Patient-Reported Outcome instrument

AIM 2 - WOMEN-PRO instrument

Approach PRO instrument development (Fig. II) & pilot testing

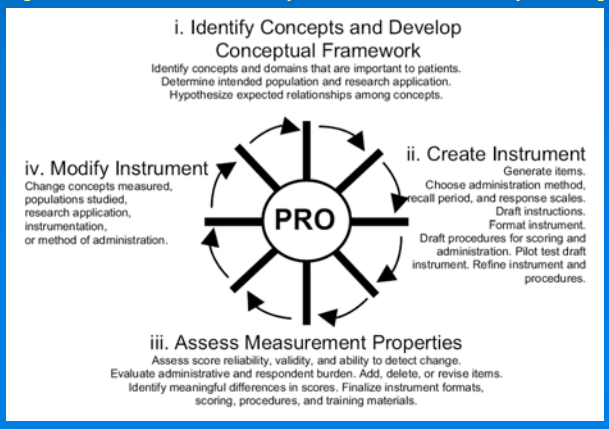
Sample / Setting 10 WVN, 10 health professionals, University Women Hospital Bern (CH) & Munich (D)

Variables WOMAN-RRO content validity (e.g. relevance of each item)

Data collection content validity form; Apr 2010 – Oct 2010

Data analysis content analysis & descriptive statistics

Fig. II: PRO instrument development and modification process [5]



AIM 3 & 4 - Quantitative phase

Approach cross-sectional

Sample / Setting ~150 WVN University Women Hospitals Bern, Basel, Zurich (CH) & Munich, Düsseldorf, Berlin (D)

Variables WOMEM-PRO instrument items, demographic & medical data; 1-3 weeks following hospital discharge following surgery

Data collection survey Oct 2010 – Jun 2010

Data analysis descriptive statistics: demographic & medical data

- psychometric properties: validity, reliability and responsiveness [6]: missing values, patterns, factor analysis, cronbach's alpha, item to total correlation (AIM 3)
- descriptive statistics: symptom experience (AIM 4)

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