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Developing a Measure of Health Related Quality of Life for Women with Cervical Dysplasia Resulting from Human Papillomavirus Infection

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SUMMARY

Human Papillomavirus (HPV) infection is the most common sexually transmitted infection in the United States, and has major physical and psychological consequences including fear, anxiety, and stigma. To date, there is no measure of health-related quality of life specifically designed to assess symptoms and functioning for people with HPV infection. In the present study, we set out to develop an HPV-specific measure of health-related quality of life. We conducted literature reviews, open-ended interviews with patients, clinican surveys, and cognitive interviews which guided item development. The result is a 36-item measure, the Functional Assessment of Chronic Illness Therapy – HPV, which assesses the physical and psychological health-related quality of life aspects of HPV infection.

INTRODUCTION

Recent data indicate that genital Human Papillomavirus (HPV) infections are the most common sexually transmitted infection in the United States, with an estimated prevalence of 28% for high and low risk types among women in the United States between 14 to 59 years.[1] Of concern to women with HPV infection is its association with invasive cervical cancer, a cancer estimated to account for 12% of all cancers among women worldwide.[2]

Psychosocial and quality of life research has shown that HPV infection and abnormal Papanicolaou tests (Pap smears) are associated with fear and anxiety.[3],[4] Women who receive abnormal Pap results report fear of future reproductive impairment, cervical cancer, and associated procedures.[5],[6] The anxiety reported by these women also includes concern about disclosing information to partners, families, and friends due to stigma,[5] and concerns about transmission and sexual relationships.[6] Altered self-image, as represented by feeling contaminated, shame, guilt, self-blame, decreased self-esteem, and negative body image, is another theme frequently reported by these women.[5]–[8] HPV positive women also report negative impact on feelings about sex, sexual activity, and sexual enjoyment.[6],[7]

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Measures used to assess quality of life and symptoms associated with HPV infection are few, and have included measures psychological distress.[9] While these and other general quality of life measures are available to assess patient outcomes in drug trials and clinical practice, there is a need for a targeted HPV index that can provide a precise evaluation of quality of life, physical symptoms, and psychosocial distress. In this study, we set out to develop an HPV-specific measure of health-related quality of life, which included assessment of both physical and psychological functioning associated with HPV infection.

METHODS

We used a multistep process to develop the HPV specific measure of quality of life. These methods were consistent with the Patient Reported Outcomes Measurement Information System (PROMIS) initiative and Functional Assessment of Chronic Illness Therapy (FACIT) system, which prioritize information gathered from patients to guide instrument development.[10],[11] We first reviewed the literature, conducted open-ended interviews with women diagnosed with HPV infection, surveyed clinicians practicing in the area of gynecologic oncology on the appropriateness of draft items gathered from literature review and the FACIT questionnaire item database, conducted cognitive interviews, and refined items based on participant feedback.

Participants

For open-ended and cognitive interviews, participants were recruited from the colposcopy clinic of a suburban community hospital. Participants provided informed consent before completing study interviews. Participants were women over 18 years of age with evidence of cervical infection positive for human papillomavirus (HPV). A physician determined each participant to have one of the following: Low-grade squamous intraepithelial lesions (LSIL) after adequate colposcopic examination ruling out high grade disease or cancer, low-grade squamous intraepithelial lesions (LSIL) on cytology, atypical squamous cells of undetermined significance (ASC-US), or normal cytology and a risk factor indicating a high probability of persistent infection with high risk HPV (e.g. age >30 years, still positive on repeat Pap smear testing). Participants with high-grade squamous intraepithelial lesions (HSIL) were excluded from participation.

Interview Procedures

In open-ended interviews, a trained research assistant queried participants on how they defined quality of life and the most important physical and psychological symptoms they experienced. After completing open-ended interviews, 20 participants provided an importance rating on items from the draft pool of items from the literature review and items from the FACIT database. We evaluated these importance ratings and used an iterative process to revise or drop items based on participant responses. Item content (overlap with existing items) and clinical relevance were also used to guide decision-making.

After a draft measure was developed, a new set of 10 participants, recruited from the same clinic, completed cognitive interviews to help ensure that items would be understood as intended.[12] The research assistant queried participants on the language, comprehensibility, and relevance of the items. Both the open-ended and cognitive interviews were digitally recorded and transcribed verbatim. These qualitative data were then content analyzed and prominent themes were extracted.[13]

RESULTS

Literature Review

Nineteen articles in peer-reviewed journals were identified to help determine symptoms and concerns affecting people with HPV infection. Special effort was made to distinguish between disease-related and treatment-related problems. Final tabulation showed that 23 symptoms or concerns were documented (Table 1).

Clinician Survey

The symptoms and concerns identified provided a guide to selecting items for the measure. Items were selected from the Functional Assessment for Chronic Illness Therapy (FACIT) item library, and the set of items were then reviewed by 3 clinician-investigators who were proficient in the diagnosis and treatment of patients with HPV infection. The clinicians completed a self-administered survey in which they provided an importance rating on 111 potential items. This information was then used to reduce the number to a 68 item pool.

Open-Ended Interviews

Twenty participants with HPV infection provided self-reported socio-demographic and clinical information, completed open-ended interviews, and gave importance ratings on the 68 items in the pool (See Tables 2 and 3). Psychosocial concerns were prominent themes that emerged from the interviews, as participants had particular concerns around *embarrassment*, *disclosure, social support,* and *anxiety*. From information gathered in these interviews and importance ratings, we narrowed the pool to the 33 items that became the draft measure.

Cognitive Interviews

Socio-demographic information for the cognitive interview participants is provided in Table 4. Ten new participants first completed the 33 item draft measure, provided a severity rating on each item using Likert-type response categories (0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit, 4=Very much), and gave feedback on the understandability of the draft scale. Some participants did not have a partner or did not tell a family member about their infection. Therefore, we added 2 conditional questions to give participants the opportunity not to answer questions about partner and family if not applicable, which completed the final version of the scale (Table 5).

DISCUSSION

Overall, a 36-item scale was constructed that assesses the health-related quality of life of HPV infection. The scale assesses both the physical and psychological consequences of HPV infection. More specifically, the items on the scale assess concerns around physical well-being (including gynecologic and sexual difficulties), general perceptions around quality of life, emotional well-being, and social relationships.

The study's primary limitation was based on its preliminary and developmental design. The study used a small sample size to obtain qualitative data for scale development. The study was not designed to obtain psychometric or statistical data on the scale. In future studies, we plan to further develop the scale and test its psychometric properties; once those are established, the scale could be used in clinical trials as well as clinical practice.

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Table 1

Summary of symptoms and concerns from literature review

Symptoms and Concerns (N = 23)
Anger[8]
Concern about sexual activity, reproductive function[3–4, 14–22]
Depression[16]
Disturbance in everyday life[16,20,21]
General anxiety, fear/worry of cancer, fertility loss, cost/time involved with treatment[3–5, 15–25]
Disturbance in body image, poor self esteem [5, 15, 21–22]
Gynecologic complaints[20]
Guilt[5]
Headaches[17]
Irritability[17]
Lack of information, poorly informed about abnormal Pap or HPV[4–5, 19–20]
Lack of support[20]
Lack of usual interests[17]
Misunderstanding of available information[5,21]
Mood impairment[16]
Pessimism[17]
Poor concentration[17]
Powerlessness[8]
Self-blame[5, 8, 21–22]
Stigma, concealment of illness, panic[5, 8, 17, 21, 26–27]
Sleep disturbance[16–17]
Struggling with disclosure[5, 19, 21]
Worry about risk of transmission[14, 21]

Table 2

Socio-demographic information for open-ended interview participants

Characteristic (N = 20)	**Mean/Frequency (Percent)**
Age in years:	33.7
Spanish/Hispanic/Latino Origin	
Yes	4 (20%)
No	16 (80%)
Race/Ethnicity	
White	16 (80%)
Black	4 (20%)
Asian	0 (0%)
Unknown/Refused	0 (0%)

Table 3

Summary of participants' open-ended responses

Themes from open-ended responses	**Number of References**
General concerns around having an infection	9
Cancer concern	12
General facts about HPV, procedures, treatment, medications	32
Partner/Spouse relationship	16
Effect on future pregnancy	3
General social relations	1
Concerns pertaining to work	3
Telling friends and others	14
Support from others	10
Family relations	3
Others' negative attitudes	2
Patient-clinician communication, discussion of medical/sexual history	15
Confidentiality	2
Spirituality	2
Anxiety/Fear, Stress	15
Anger with self	2
Shame, embarrassment	3
Sadness/depression	2
Fear of spreading infection	1
Coping	2
Expense, insurance	4
Scheduling of treatments/testing	19
Physical/sexual restrictions, impact on lifestyle	6
General physical symptoms	3
Pain/Cramping, Discomfort, Bleeding	10
Treatment side effects	5
No problems	31

Table 4

Socio-demographic information from the 10 participants who completed cognitive interviews

Characteristics (last 10 participants)	**Mean (Median)/Frequency (Percent)**
Age in years	Mean: 41 years (Median: 38 years)
Spanish/Hispanic/Latino Origin	
Yes	3 (30%)
No	7 (70%)
Race/Ethnicity	
White	8 (80%)
Black	1 (10%)
Asian	0 (0%)
Unknown/Refused	1 (100%)

Table 5

Final FACIT-HPV items

	Not at all	A little bit	Some- what	Quite a bit	Very much
Physical Well-Being					
1. I have discomfort in my pelvic area.	0	1	2	3	4
2. I have pain in my pelvic area.	0	1	2	3	4
3. I have cramping in my pelvic area.	0	1	2	3	4
4. I am bothered by discharge or bleeding from my vagina.	0	1	2	3	4
5. I am bothered by side effects of treatment.	0	1	2	3	4
6. I worry that the infection will get worse.	0	1	2	3	4
Are you sexually active or would you like to be sexually active? If yes, answer questions 8 – 11. If no, skip these questions and move on to question 12.					
7. I have pain or discomfort with intercourse.	0	1	2	3	4
8. I have to limit my sexual activity because of the infection.	0	1	2	3	4
9. I have concerns about my ability to become pregnant.	0	1	2	3	4
10. I worry about spreading the infection.	0	1	2	3	4
Treatment Satisfaction					
11. I have confidence in my doctor(s).	0	1	2	3	4
12. I feel that I received the treatment that was right for me.	0	1	2	3	4
13. My doctor gave me explanations that I could understand.	0	1	2	3	4
14. My doctor explained the possible benefits of my treatment.	0	1	2	3	4
General Perceptions					
15. I am able to work (include work at home).	0	1	2	3	4
16. I am able to enjoy life.	0	1	2	3	4
17. I am hopeful about the future.	0	1	2	3	4
18. I find comfort in my faith or spiritual beliefs.	0	1	2	3	4
19. I am content with the quality of my life right now.	0	1	2	3	4
20. I feel that I can manage things that come up around this infection.	0	1	2	3	4
21. I have accepted that I have this infection.					
Emotional Well-Being					
22. I have hidden this problem so others would not notice.	0	1	2	3	4

	Not at all	A little bit	Some- what	Quite a bit	Very much
23. The cost of my treatment is a burden to me or my family.	0	1	2	3	4
24. I worried about other people’s attitudes towards me.	0	1	2	3	4
25. I felt embarrassed about the infection.	0	1	2	3	4
26. I tended to blame myself for the infection.	0	1	2	3	4
27. I was careful who I told about the infection.	0	1	2	3	4
28. I have had difficulty telling my partner/spouse about the infection.	0	1	2	3	4
29. I am frustrated by the infection.	0	1	2	3	4
30. I am depressed about the infection.	0	1	2	3	4
Relationships					
31. I have told my partner/spouse about my infection.	Yes	No			
32. [If yes] I get emotional support from my partner/spouse.	0	1	2	3	4
33. I have told family members about my infection.	Yes	No			
34. [If yes] I get emotional support from family members.	0	1	2	3	4
35. I feel close to my friends.	0	1	2	3	4
36. I have people to help me if I need it.	0	1	2	3	4