The vaccinaTion & Hpv Knowledge (THinK) questionnaire: a reliability and validity study on a sample of women living in Sicily (southern-Italy)

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Objective. The aim of this study was to introduce the VaccinaTion & Hpv Knowledge (THinK) questionnaire to assess knowledge about human papillomavirus (HPV) and attitude to HPV- vaccination. Its reliability and validity was demonstrated in a sample of women living in Sicily (Southern-Italy). **Methods.** A cross-sectional survey was conducted on a sample of 220 women at the "Paolo Giaccone" University Hospital in Palermo (Sicily), aged 18-61. Data were analyzed through Cronbach's alpha and exploratory factor analysis, followed by a structural equation model with measurement component. The two-level data structure was explicitly considered. **Results.** Three dimensions were found: "knowledge of HPV infection (kHPV), "Attitude to be vaccinated against HPV (aHPV)" and "Knowledge about vaccines (KV)" (97% overall explained variance). Internal consistency was good for the whole questionnaire (0.82) and the first dimension (0.88) and acceptable for the second (0.78) and the third dimension (0.73). 23% of women showed no or little knowledge of HPV and 44.3% of women had no or little knowledge about HPV induced lesions. **Discussion.** The use of a validated questionnaire may serve as a useful measure to assess general knowledge about HPV and attitude towards vaccination against HPV in the primary prevention setting.

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18 ## ABSTRACT

19 **Objective.** The aim of this study was to introduce the VaccinaTion & Hpv Knowledge (THinK)
20 questionnaire to assess knowledge about human papillomavirus (HPV) and attitude to HPV-
21 vaccination. Its reliability and validity was demonstrated in a sample of women living in Sicily
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30 dimension (0.88) and acceptable for the second (0.78) and the third dimension (0.73). 23% of
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32 about HPV induced lesions.
33 **Discussion.** The use of a validated questionnaire may serve as a useful measure to assess general
34 knowledge about HPV and attitude towards vaccination against HPV in the primary prevention
35 setting.
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37

38 ## INTRODUCTION

39 Human Papilloma Virus (HPV) infection is the most frequent among sexually transmitted
40 diseases in the world. Cervical cancer is closely related to virus action, which is the main cause
41 of cervical intraepithelial neoplasia and invasive lesions [1].
42 Three HPV vaccines are at the moment available in many countries throughout the world. The
43 bivalent (Cervarix, GSK biologicals) HPV vaccine prevents infections with the high-risk (HR)
44 HPV 16 and 18. These genotypes are responsible for approximately 70% of cervical cancer cases
45 globally and are considered responsible for a significant number of cervical low- and high- grade
46 squamous intraepithelial lesions (LSIL and HSIL, respectively) [2]. The quadrivalent HPV
47 vaccine (Gardasil, Sanofi Pasteur MSD), in addition to HR 16 and 18, also targets the LR HPV 6
48 and 11 that are associated with 90% of anogenital warts in men and women [3]. Both bivalent
49 and tetravalent vaccines have been shown to be effective and immunogenically valid in trials
50 conducted in recent years with efficacy tests up to 55 years, especially in those who are virus-
51 naïve [4]. Finally, the enavalent HPV vaccine (Merk, Sanofi Pasteur MSD, 9vHPV, trade name
52 Gardasil9), in addition to the four genotypes of the quadrivalent vaccine, also targets five
53 additional HR genotypes, namely HPV 31/33/45/52/58, which are the most frequently detected
54 types in invasive cervical cancer worldwide, after HPV 16 and HPV 18 [5]. Vaccination can be
55 administered to people who did not have any contact with the genotypes that are covered; for this
56 reason, it is preferable to get vaccinated in adolescence, before sexual activity begins and before
57 any potential exposure to virus [6].
58 A cross-sectional study showed a prevalence of HR HPV infections of 24% in a group of young
59 Sicilian women (18-24) [7]. According to the official statistics about the HPV vaccine coverage
60 (year 2015), in Sicily the percentage of young women (fully) vaccinated against HPV is 44.10 %
61 compared to the national average rate of 62.15 % [8]. In a female population living in Sicily, it
62 has been shown that the switch to the enavalent vaccine would increase the prevention of
63 cervical HSIL in up to 90% of cases [5].
64 Awareness of the risks associated to HPV infection is extremely important. In a large systematic
65 review, Hendry et al [9] showed that misperception of risk could prevent from accepting
66 vaccination; moreover, the correct knowledge of virus epidemiology can lead to adopt behaviors,
67 as an example the use of condom, to minimize the risk of infection. Most of the surveys
68 conducted until now about HPV awareness and attitude to specific vaccination have involved
69 young people [10-11]. In 2008 an Italian Survey among women 14-24 showed the need to
70 strengthen HPV knowledge, since only 23.3% of interviewed have heard about HPV and cervical
71 cancer [12]. Knowledge about HPV infection has been shown to be poor among the public,
72 students, patients and health professionals [13-14] and, more recently, among European
73 adolescents [15]. Furthermore, according to other studies, vaccination in women over 25 years,
74 together with a screening program, offers the opportunity to reduce the incidence of cervical
75 cancer in countries with limited resources and high disease burden. In 2017, results from a large
76 survey in Italy showed that 73,8% of interviewed people were conscious about availability of
77 HPV vaccine, but no trust in vaccines and believe that PAP test is enough for prevention were
78 expressed by 14,0% and 14,3% of women respectively [16].

79 The aim of this study was to assess knowledge of HPV and attitude to HPV-vaccination in a
80 sample of Sicilian adult women and to demonstrate reliability and validity of the questionnaire
81 used. The choice of an adult target population for this study relates to the importance of
82 disseminating the culture of vaccination, just increasing parental awareness and attitude. The
83 VaccinaTion & Hpv Knowledge (THinK) questionnaire was developed to be used in the first
84 approach to the patient both in hospital and in outpatient service.

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86

87 MATERIALS & METHODS

88 *Participants*
89 A cross-sectional survey was conducted at the "Paolo Giaccone" University Hospital in Palermo
90 (Sicily) from April to December 2017. The study included 220 women, aged 18-61,
91 consecutively enrolled from the Unit of Gynecology and Obstetrics (Ob/Gyn) (136 women) and
92 from the University ambulatory clinic (UAC) (84 women). The Ob/Gyn is an outpatient service
93 for women of all age groups while the UAC supplies free healthcare services to students and
94 fresh graduates. Women apply to the Ob/Gyn either as they complain about some acute or
95 chronic disorders or as they ask for a complete gynecological check-up. Alternatively, women
96 apply to the UAC in order to receive information on contraception, sexually transmitted diseases
97 (STD) and/or gynecological screening visits. Women already vaccinated against HPV were
98 excluded from the study.

99

100 *The vaccinaTion & Hpv Knowledge (THinK) questionnaire*
101 Enrolled women were given advices about the aim of the study. This study was conducted
102 according to the guidelines laid down in the Declaration of Helsinki and all procedures were
103 approved by the Research Ethics Committee at "Paolo Giaccone" University Hospital (Reference
104 number 8/09/2018). Verbal informed consent was obtained from all participants. The THinK
105 questionnaire included 16 items (Figure 1), using a 5-level Likert scale (yes, much somewhat,
106 little, no). Questions concerned general knowledge about vaccination (acceptance,
107 administration, effectiveness), HPV and related risks and acceptability of vaccine. Age,
108 birthplace and education of each respondent were requested too. The draft of the THinK
109 questionnaire was reviewed by five experts within "Paolo Giaccone" University Hospital to
110 check its completeness and its suitability to be used in the first approach to the patient both in
111 hospital and in outpatient service. Recommendations for improvement were also sought.

112

113 *Statistical methods*
114 Descriptive statistics were calculated for participants' general characteristics.
115 As a first step, an exploratory factor analysis (EFA) was carried out to describe the joint
116 variability of the dimensions of the THinK questionnaire. Factors were rotated using the varimax
117 approach to ease interpretation. Internal consistency was assessed for each dimension using the
118 Cronbach's alpha coefficient. Higher values indicate that scores on the considered dimension are

119 internally consistent. Internal consistency is considered poor if the alpha value is below 0.60,
120 questionable if between 0.60 and 0.70, acceptable between 0.70 and 0.80, good between 0.80 and
121 0.90 and excellent if not less than 0.90 [17]. The sample size for this study was calculated
122 according to the rule required in internal validity studies, which uses the ratio of the number of
123 subjects (N) to the number of items (p) [18].
124 As a second step, a structural equation model with measurement component was estimated to
125 confirm the factor structure obtained through EFA. It was assumed a generalized linear model
126 for ordinal response and link logit. As a final step, in order to take into account that participants
127 are nested within two groups Ob/Gyn and UAC, a two-levels measurement model was
128 considered. The LR test, AIC and BIC were used for comparison between the one-level and two-
129 levels SEM models. The Student's t test was used to assess statistical significance of the
130 difference between two women's groups with respect to questionnaire's items and dimensions. A
131 p-value<0.05 was chosen for statistical significance. Statistical analysis was conducted using
132 Stata SE/14.2.
133
134

135 **RESULTS**
136 All five experts concurred that the measures should effectively capture any changes in the
137 knowledge about HPV and attitude to vaccination and HPV vaccines, with concern to the first
138 approach to the patient both in hospital and in outpatient service.
139 Women enrolled at UAC were on average younger (23.1±2.45) and more educated (100% high
140 school and more) than women enrolled at Ob/Gyn (35.5±9.89 years old and 63% high school and
141 more) (Table 1).
142 Three dimensions were found trough EFA: "knowledge of HPV infection (kHPV) " (48%
143 explained variance), correlated with items between Q9 and Q13, "Attitude to get vaccinated
144 against HPV (aHPV)" (26%), correlated with items Q14-Q15-Q16, and "Knowledge about
145 vaccines (KV)" (23%), correlated with items from Q1 to Q5. Three items (Q6-Q7, Q8) resulted
146 with high uniqueness (≥0.80). Internal consistency was good for the whole questionnaire (0.82)
147 and the first dimension (0.88) and acceptable for the second (0.78) and the third dimension (0.73)
148 (Table 2).
149 Results of the 1-level measurement SEM model confirmed the three factors structure of the
150 THinK questionnaire (Figure 2). By including the group's level information (Figure 3), the
151 model fit was improved (p=0.0223).
152 Of note, 23.1% of responders showed poor knowledge of HPV and 16.7% had never heard of it
153 (Q12); For what concerns specific immunization, 21.8% of patients (Q14) responded that they
154 are very little or not at all available to carry out vaccination. Poor knowledge of HPV induced
155 lesions was expressed by almost half of the women interviewed (44.3% of women answered no
156 or little at Q11), without any correlation with age or education. About the 19% of women
157 expressed a clear refusal just to receive even simple information about HPV vaccination (Q16)
158 (data not shown in Tables).

159   On average, women enrolled at the UAC reported scores significantly higher compared to
160   women enrolled at Ob/Gyn for Q3 (2.49±1.41 vs 1.95±1.12), Q14 (2.60±1.70 vs 2.14±1.20),
161   Q15 (2.96±1.79 vs 2.44±1.28) and aHPV (0.17±1.27 vs -0.28±0.93). Conversely, their score was
162   significantly lower for Q6 (2.96±1.41 vs 3.57±1.14) and Q7 (3.15±1.15 vs 3.68±1.14) (Table 3).
163
164

165   **DISCUSSION**
166   The aim of our study was to perform a reliability and validity study of the proposed THinK
167   questionnaire as well as to assess knowledge of HPV and attitude towards HPV-vaccination in a
168   sample of women living in Palermo.
169   The THinK questionnaire was found to measure three domains, which we named knowledge of
170   HPV infection, attitude to be vaccinated against HPV and knowledge about vaccines, and it
171   demonstrated adequate internal consistency as a whole and for each one of its three domains.
172   We developed a short and succinct questionnaire with only 16 items in order to get it easier to be
173   used in the first approach to the patient both in hospital and in outpatient service. There are many
174   studies employing questionnaires about HPV issues, but just few use validated questionnaires,
175   and their validity results are in line with those found for the THinK questionnaire. The HAVIQ
176   questionnaire [19], which was designed to evaluate the efficacy of an intervention to affect HPV
177   vaccination knowledge, obtained Cronbach's alpha >0.6 for three of its four dimensions. The 25-
178   item HPV general knowledge and 11-item HPV vaccination scale, validated on a national sample
179   of Canadian parents of boys, showed internal consistency >0.70 [20]. Two questionnaires to
180   measure HPV knowledge on an international sample of adults showed Cronbach's alpha >0.83
181   [21]. Similar reliability was demonstrated for other instruments validated on undergraduates
182   from Pakistan (Cronbach's alpha (0.79) [22] and on adolescents from Greece [23].
183   The context proposed in our analysis concerns adult females living in Palermo. Rationale for
184   choosing this target was to have indications about women that are yet (or not yet) mothers of
185   girls and boys in vaccination age. Parents' attitude about immunization is extremely important to
186   vaccination of younger girl [24]; disagreement of parents has been the main reason for non-
187   adherence to vaccination of girls aged 11-12 in an Italian Cross sectional study [25].
188   When analyzing results of our paper, it is necessary to keep in mind that two groups involved in
189   the survey are representative of two different populations. In fact, participants from Ob/Gyn are
190   adult women referred for therapeutic purposes while those from the UAC are students or fresh
191   graduates mostly referred for prevention and contraceptive prescription. Results from the 2-
192   levels measurement SEM model showed that the group information explains a significant share
193   of the total variability of the responses. This finding strengthens the importance of validating the
194   questionnaire to measure HPV knowledge in specific populations.
195   One important finding of our study is that more than one in three of women were not conscious
196   about HPV prevention and one in five would be little or no willing to be vaccinated against HPV.
197   Roots of these disappointing results can be explained by a general poor knowledge of HPV [9-
198   12], lack of information on HPV vaccination given by health professionals to young women [26]

199 and widespread ignorance about HPV-specific lesions [27], which has been reported also for the
200 Italian general practitioners (GPs) [28]. It's already been suggested that lack of information
201 could represent an important barrier to vaccine acceptation [6]; a cross-sectional pilot study
202 showed higher vaccine-related knowledge in women vaccinated than in non-immunized [29].
203 Our results are consistent with Censis data, which show that judgment on available information
204 on HPV and vaccinations is not positive, in terms of clarity and quantity [16].
205 By evaluating answers to the last question, it is possible to hypothesize a strong cultural
206 resistance to vaccination and let us to reflect that a rooted resistance to immunization could play
207 an important role in the HPV vaccine hesitancy [30]. Comparison between response to our
208 questions Q3 and Q4 appears interesting, with 18.6% of respondents declaring that they were
209 little or not at all favorable to vaccination in adulthood and only 8.6 % being little or nothing
210 convinced of vaccination in pediatric age. The found resistance to vaccination in adulthood,
211 compared to the consolidated acceptance of vaccination in pediatric age, should help to explain
212 the scarce attitude to be vaccinated against HPV in the Ob/Gyn group. Barriers to vaccination in
213 adulthood have been long discussed by several authors and one of the most frequent reasons for
214 failure to immunize is a lack of communication or bad information [31].
215 Different authors showed the impact of socioeconomic variables on HPV awareness and
216 vaccination: a few reported positive relationship between school education and mother's school
217 level, HPV knowledge and vaccination [32], between age and HPV awareness [33] and between
218 education and the intention to be vaccinated against HPV [34]. Concerning the association with
219 education, findings of our study do not allow to draw definitive conclusions, as it is not possible
220 to distinguish if the major attitude of women enrolled at UAC depends on either the younger age
221 or the higher education of this group compared to Ob/Gyn.
222 Through this study, we have provided initial evidence for validation of the THinK questionnaire.
223 There are some margins for improvement of the instrument, as deleting those items resulted with
224 high uniqueness or including additional items to get it more HPV-specific, e.g. concerning sexual
225 behaviors (age at first sexual relationship, number of life partners, partner HPV status),
226 knowledge about HPV induced lesions, smoking cigarettes, alcohol consumption, use of
227 hormonal contraceptives or IUD, personal hygiene, prior infections of the cervico-vaginal tract,
228 parity, HSV. Finally, more research is desirable to examine other aspects as concurrent validity
229 and test-retest reliability with larger sample sizes.
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232

233 **CONCLUSIONS**
234 The THinK questionnaire demonstrated adequate reliability and validity in a sample of Italian
235 women living in Palermo. This instrument, short and easy to complete and to score, may serve as
236 a useful measure in the primary healthcare setting in order to assess general knowledge about
237 vaccination and HPV vaccines. Even if, in agreement with the guidelines of the Italian Ministry
238 of Health, HPV vaccination is offered free of charge to girls in the twelfth year of life in all

239 Italian regions since 2007/2008, efforts must be made to create a sound basis for understanding
240 HPV issues and related risks, with a view to preventing and protecting patients.

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Descriptive statistics of 220 Sicilian women by recruitment group

§Student's t-test for quantitative variables, Chi² or Fisher's exact test for categorical variables

Variables	Ob/Gyn Department (N=136)	University outpatient service (N=84)	p-value§
Age (Mean±SD)	35.50±9.89	23.12±2.45	<0.001
Education (n,%)			<0.001
No, primary	1 (0.8)	0 (0.0)	
Low Middle School	49 (36.6)	0 (0.0)	
High Middle School	49 (36.6)	70 (83.3)	
Graduate	35 (26.0)	14 (16.7)	
Citizenship (n,%)			<0.001
Italian	131 (96.3)	80 (95.2)	0.830
European	2 (1.5)	3 (3.6)	
Extra-European	2 (1.5)	1 (1.2)	
n.a.	1 (0.7)	-	
Living place (n,%)			
Italy	134 (98.6)	81 (96.4)	0.213
Europe	1 (0.7)	3 (3.6)	
Extra-Europe	-	-	
n.a.	1 (0.7)	-	

Internal consistency of the THinK questionnaire

	Cronbach's alpha
Whole questionnaire	0.816
kHPV	0.882
aHPV	0.784
KV	0.732

Knowledge and attitude of 220 Italian women by group: Mean (SD) of responses to THinK questionnaire's items and dimensions

Questionnaire's Items	Ob/Gyn Department (N=136)	University outpatient service (N=84)	p-value§§
Q_1	1.74 (1.01)	1.75 (0.99)	0.9310
Q_2	1.55 (0.95)	1.83 (1.15)	0.0589
Q_3	1.95 (1.12)	2.49 (1.41)	**0.0019**
Q_4	2.92 (1.21)	2.91 (1.23)	0.9770
Q_5	2.58 (1.25)	2.24 (1.37)	0.0662
Q_6	3.57 (1.14)	2.96 (1.41)	**0.0066**
Q_7	3.68 (1.14)	3.15 (1.15)	**0.0029**
Q_8	3.58 (1.30)	3.93 (1.44)	0.0705
Q_9	2.63 (1.32)	2.75 (1.47)	0.5195
Q_{10}	2.30 (1.06)	2.50 (1.61)	0.2619
Q_{11}	3.06 (1.43)	3.09 (1.59)	0.8929
Q_{12}	2.58 (1.42)	2.99 (1.64)	0.0597
Q_{13}	2.63 (1.07)	2.75 (1.51)	0.4966
Q_{14}	2.14 (1.20)	2.60 (1.70)	**0.0198**
Q_{15}	2.44 (1.28)	2.96 (1.79)	**0.0138**
Q_{16}	2.14 (1.24)	2.38 (1.70)	0.2304
Dimensions§			
kHPV	-0.01 (0.98)	0.00 (1.16)	0.9412
KV	-0.06 (1.24)	0.04 (1.19)	0.5699
aHPV	-0.28 (0.93)	0.17 (1.27)	**0.0026**

The 16-items THinK questionnaire

1. Do you know what vaccines are?

   □ Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

2. Are you favourable with paediatric vaccination?

   □ Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

3. Are you favourable with adults' vaccination?

   □ Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

4. Do you know what vaccines are available today for the Italian population?
   □ Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

5. Do you know by who and where could you be vaccinated?

   □ Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

6. Do you think that vaccines have any side effects?

   □ Yes
   □ Much

□ Somewhat
□ Little
□ No

7. Can you contract a disease even if you are vaccinated against it?

   □ Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

8. Do you think that vaccination is effective even after contracting infection or having been in contact with a contagious case?

   □Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

9. Do you know what HPV is?

   □Yes
   □ Much
   □ Somewhat
   □ Little
   □ No

10. Do you think that HPV is dangerous?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

11. Do you know lesions related to HPV infection?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

12. Have you ever heard about vaccination and prevention against HPV?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

13. Do you think that is high the probability of contracting HPV infection?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

14. Would you be willing to get vaccinated against HPV?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

15. Do you consider useful asking to your partner to get vaccinated against HPV?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

16. Do you want to receive information about HPV vaccination?

    □Yes
    □ Much
    □ Somewhat
    □ Little
    □ No

Figure 2

Construct validity of the HPV Questionnaire in a sample of Sicilian adult women: paths obtained from 1-level measurement SEM model

kHPV= "knowledge of HPV infection", KV="Knowledge about vaccines", aHPV="Attitude to get vaccinated against HPV",Q1-Q16=Questionnaire's items
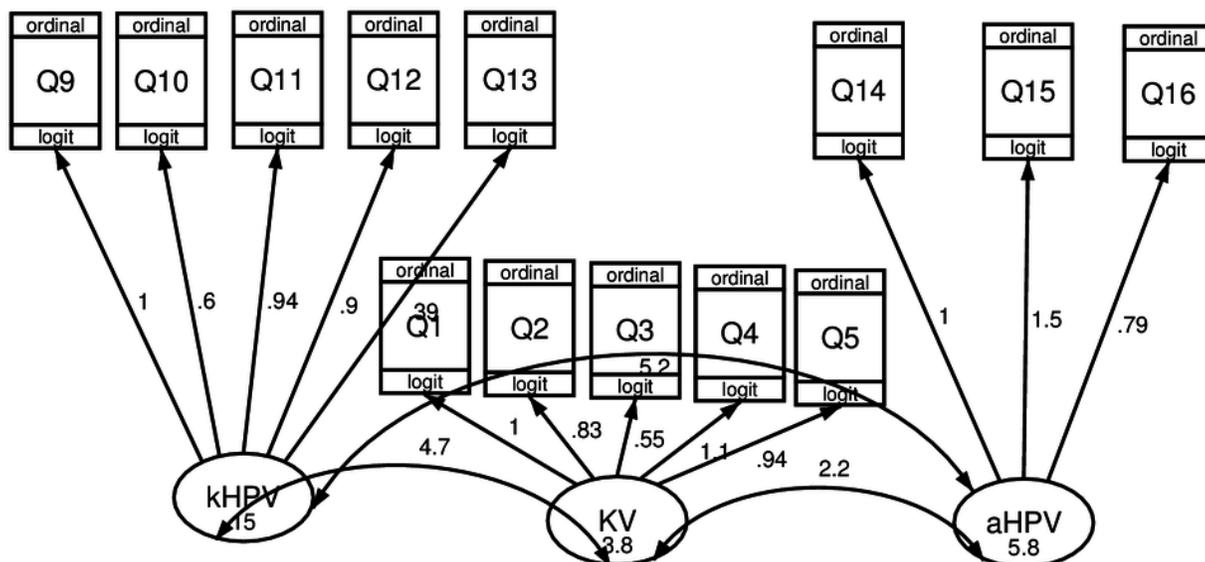
Figure 3

Construct validity of the HPV Questionnaire in a sample of Sicilian adult women: paths obtained from two-levels measurement SEM model

kHPV= "knowledge of HPV infection", KV="Knowledge about vaccines", aHPV="Attitude to get vaccinated against HPV",Q1-Q16=Questionnaire's items