

Development and validation of 'educational pamphlet' in prevention of human papilloma virus (HPV) infection among age eligible adults for HPV vaccination in kedah State, Malaysia

Abstract

Human Papilloma Virus (HPV) infection is highly contagious and affects all males and females at least once in their sexually active lifetime. Though it is spontaneously cured, certain HPV types are responsible for HPV related cancers. This study aimed to develop and evaluate the effectiveness of educational pamphlet in creating awareness regarding HPV infection and vaccination. Main outcome measures include pre- post test assessment of adult's knowledge regarding HPV infection and HPV vaccination, using pre-validated, 16-item knowledge based questionnaire. The pamphlet development, validation and translation was done potential adults aged 18–26 years who were age eligible for HPV vaccination in urban and rural areas of Kedah state, Malaysia. The research findings showed a significant increase in knowledge gain from 63% to 89% [N=121, Mdn=10 (IQR=4) to Mdn=14 (IQR=3), $p<.001$] and reveals moderate knowledge and benchmark information before HPV infection and vaccination. At the two-week follow-up, a statistically significant increase in correct responses at pre-post-tests were observed at 90%, [N=92, Mdn=11 (IQR=4) to Mdn=14.5 (IQR=3), $p<.001$]. The educational pamphlet significantly increased knowledge regardless of sociodemographic characteristics and was found to be good. Effective, well-structured and informative pamphlets with repeated booster campaigns can help in increasing awareness of HPV infection and awareness among sexually active young adults.

Keywords: adults, educational pamphlet, human papilloma virus, HPV, infection, HPV, vaccine, knowledge

Volume 4 Issue 1 - 2017

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Received: September 13, 2017 | **Published:** October 25, 2017

Abbreviations: CDC, centre for disease control; HPV, human papilloma virus; STI, sexually transmitted infection; US, united states; WHO, world health organization

Introduction

Human papillomavirus (HPV) is one of the most common sexually transmitted infections (STI), and cumulative prevalence rates have been reported up to 82% in sexually active adolescent and young adults in the United States,¹ whereas, genital warts are common, in Malaysia but its prevalence has not been determined yet. A commendable knowledge of Human Papilloma Virus (HPV) infection is essential in prevention of HPV related diseases including cancers. The high prevalence and potentially serious complications among sexually active young adults demonstrate a poor understanding of HPV infection, HPV vaccination and Pap tests.²⁻⁶ It is very unfortunate that the healthcare system of many countries initiated the national HPV vaccination policy for a specific age cohorts (13 years old girls in Malaysia, since 2010) and the other age eligible population (14 to 26 years) were not considered for economic reasons. Presently, the young adults aged 20 years and above are still un-vaccinated though they are eligible for vaccination. There exists a relationship between knowledge and HPV vaccine uptake. The relatively low vaccine uptake in women aged 18–26 years has been reported, thus understanding the factors affecting adult's knowledge on HPV is vital.⁷ The awareness of HPV has been low in the general public.⁸⁻¹¹ Recent increases in HPV awareness and knowledge are related to the availability of HPV vaccines. Although findings have been mixed,¹²

several studies suggest that greater HPV knowledge is associated with both greater HPV vaccine acceptability¹³⁻¹⁴ and uptake.^{15,16}

Of late, WHO recommends 2-doses of HPV vaccine starting before the 15th birthday and the second dose given 6 to 12 months later and a 3-dose regimen is given for 9 through 26-year-old for immuno-compromised including HIV infected.¹⁷ The current national HPV vaccination programme in Malaysia has achieved vaccination rate about 87% per calendar year, 2011 meaning another 13% left-outs add to the eligible un-vaccinated young adult population.¹⁸ However, the latest approval of Gardasil 9, offers protection against nine HPV types – 6, 11, 16, 18, 31, 33, 45, 52 and 58. Seven of which can cause cervical, vulvar and vaginal cancers, as well as anal cancer in both males and females.¹⁹⁻²¹ After HPV types 16 and 18, the five additional HPV types in Gardasil 9 are the most common cervical cancer-causing types globally and in Malaysia, types 52 and 58 are most common in females.²² With cervical cancer ranking second most common cancer in Malaysia, there is a great need to increase prevention through vaccination and regular screening. Though, sexually-active women get free pap screening within three years of sexual debut and once every three years subsequently at government hospitals and clinics.²² Adequate knowledge is a prerequisite for making informed decisions on vaccination and screening initiatives.²³ Among the very few intervention studies conducted, simple strategies (providing written materials or verbal information) improved knowledge among adult women.^{24,25} The objective of this study was to evaluate the effectiveness of educational pamphlet developed to fill the gap in literacy by assessing whether such intervention (educational

pamphlet) could increase the baseline knowledge among age eligible adults.

Materials and methods

This was a prospective, longitudinal, cross sectional study involving snowball sampling, conducted an HPV education campaign using intervention sessions among young adults aged 18 to 26 years at pre-university/university campus or general public at work places representing both urban and rural population. The content and format of the HPV educational pamphlet was developed in consultation and discussion with a group of five experts from a private medical university involving physicians (Community Medicine, General Medicine, and gynaecologist), an epidemiologist and a practicing clinical pharmacist in Malaysia. The pamphlet was outlined with information that could be easily understood, fairly easy to read and free from jargon's which took roughly 15 minutes to read through and contained the following information: HPV prevalence and transmission, diseases associated, abnormal Pap test, clinical manifestation and complications, risk factors, prevention of HPV related diseases, HPV vaccination, sources of infection and vaccine availability, vaccine course and dosage schedule, side effects, efficacy and safety recommendations.^{19,26-28} The prepared intervention tool was presented for review to the above expert panel and their remarks were accommodated. The tool was then content validated in two sessions by a group of five experts from pharmacology unit, followed by 8 members from clinical pharmacy and pharmacy practice unit from a private university. Readability analysis was performed on the educational intervention tool using well-validated scales that have been commonly used to evaluate healthcare-related materials and to assess the simplicity and readability using online 'Text Readability Consensus Calculator.' The finalized intervention tool was then forward and backward translated to the local Bahasa Malaysia language. The inter-rater reliability was assessed using Cohen kappa test guidelines, which indicated the level of agreement between the two versions of the pamphlet.²⁹⁻³¹ The finalized intervention tool (pamphlet) was then administered with a specific goal to assess the effectiveness of pamphlet for its readability, understand ability and clarity. The potential respondents were approached for participation in the study for repeated measures of knowledge levels.

The study was conducted using pre-validated questionnaire to assess the baseline knowledge level about HPV infection and HPV vaccination before intervention (N=121) and educational pamphlets were distributed. The post-intervention test was conducted after two days among the same participants and data was collected for post-test or intervention study (stage 1, N=121) to assess knowledge gained due to intervention. Subsequently, a follow-up study after two weeks from intervention, was repeated with pre- post- intervention (stage 2, N=92) to assess the knowledge retention among the same respondents. The 24% drop outs were due to unavailability for participation in the stage 2 study. While generating the knowledge score summary, the correct responses were given '1 point' and incorrect responses given 'Zero point.' The numbers of correct items for all the 16 knowledge items were summed to derive the total knowledge score. The scoring grades attributed was based on original Blooms' cut off grades, score <60% was 'Poor', 60%-79% 'Moderate', and score ≥80% was considered 'Good'.³²⁻³⁴

Statistical analysis

The survey data was tabulated using Microsoft excel workbook

and analyzed using Statistical Package for Social Sciences 'SPSS version-23' (IBM SPSS Statistical software) for windows. The percentage, frequency, median (IQR) score was computed for categorical variables and inferential statistics was done using McNemar's test, to estimate the difference in knowledge scores and Wilcoxon signed rank test to assess the precise difference in knowledge scores. The significance level was set at .05 for all statistical tests and p value < .05 was considered significant. All percentage displayed in the text or in parentheses are with no decimal places as per APA reporting guideline recommendation.^{35,36}

Ethical considerations

The research proposal along with the study instruments and informed consent form was submitted to the Institutional Review Board (IRB), AIMST University Human & Animal Ethical Committee and the ethical clearance was obtained. The signed informed consent forms were obtained from the participants after explaining the aims and objectives of the study and policy of confidentiality for data collected before filling in the survey forms.

Results

Readability test

The text readability of the pamphlet using Flesch reading ease score (69), Flesch-Kincaid grade level (7), and Gunning Fog score (10), were all found to be fairly easy to read and understand.

Agreement of translation between english and malay version

For inter-rater reliability, Cohen's κ was run to determine the agreement between both versions of the educational intervention tool among 30 participants. There was a good agreement between the two versions of the intervention tool as shown in the Table 1.

Table 1 Agreement between english and malay version of educational pamphlet

Variable		Concordance N (%)	k-Value*	p-Value
Adults knowledge level				
(N = 30)	Poor	19	0.69	< .001**
	Moderate	11		
	Good	0		

*Cohen kappa test statistics, **p < .05 is significant

Effect of HPV educational intervention tool before and after intervention

The median (IQR) age of adult respondents (N=121) in stage 1 was 23 (IQR 2, ranging 20-26) years. Ninety seven (80%) of the respondents were females, 85 (70%) of the respondents were Chinese, only 2% of the respondents were married, 66 (55%) revealed undergoing graduate education and 64 (53%) were from urban areas.

Construct and content validation of HPV educational pamphlet

The response of 30 potential participants of the intended study was summarized for the entire ten question/statements using four

point Likert type scale: Strongly Agree – 4 points, Agree – 3 point; Disagree =2 points; and Strongly Disagree = 1 point. Analysis of the items is shown in Table 2. The correct responses of pre and post-educational intervention test are shown in Table 3. The percentage of correct answers increased significantly from 63% to 89% [Mdn. score 10(4) vs. 14(3), $p<.001$] at stage 1. However, the percentage of pre- post-knowledge test score increased to 66% & 90% [Mdn. score 11(4) vs. 14.5(3), $p<.001$] at the two-weeks follow-up (Stage 2). This result was significantly higher than the pre-educational intervention test (63%) at stage 1, yet was slightly different from the percentage responding correctly at the follow-up visit, showing that the respondents' retention of information over the two weeks' time increased from 63% to 66% but was not substantial. Subjective information was gathered for further development of the tool among the survey respondents regarding the contents of the pamphlet.

The results of pre-test reveal the respondents had a moderate knowledge as per original Bloom's cut-off score and benchmark information about HPV infection and HPV vaccination, however were keen to learn more about HPV vaccination and observed the tool to be useful and successful instrument for expanding their knowledge. The question 12 which evaluated the number of vaccination shots produced more than 280% increase in knowledge and questions 4 which tested gender susceptibility produced over 100% increase in knowledge and the rest of the questions produced about 60–80% increase in knowledge. The questions to produce less than 25% knowledge increase were question numbers 2, 5, 6, 10, 14 and 16. Most of the respondents were not aware about the best age for HPV vaccination and are mostly affected by HPV infection. The data concerning transmission of HPV vaccination age made a generous impact on the respondents. Statistical analysis of stage 2 revealed that pre-intervention knowledge scores did not contrast by age, gender, race, education or location. Be that as it may, the median knowledge scores at pre-intervention, 11(4) were higher in the age category of 24–26 years in contrast to other age categories. Knowledge scores at post-intervention did not vary by socio-demographic variables. The median age in stage 2 was 23 (IQR 6, range 20–26 years). Of the 92 respondents, 54(59%) were 21–23 years old, 71(77%) female, and 66(72%) Chinese, with 50% undergraduate education and 47(51%) belonging to urban areas. The outcome of the pre and post-educational intervention analysis in stage 2 was like those for stage 1 and is shown in Table 3. Though the percentage of knowledge retained only increased marginally from pre-to post- intervention at follow-up visit from 63% to 66%, the knowledge gained substantially increased from 66% to 90% [Mdn. score=11(4) vs. 14.5(3), $p<.001$]. Before accepting the educational intervention, most of the respondents were not aware of the HPV vaccination age.

Discussion

In this study, an educational intervention tool (pamphlet) was developed, translated and tested to validate the efficiency of the pamphlet in increasing awareness and knowledge regarding HPV infection and HPV vaccination. The intervention tool was found to significantly increase the knowledge and awareness irrespective of age, gender, ethnicity, education and location. The educational pamphlet was developed based on the factual information given by WHO and the CDC along with the vaccine manufacturer's information leaflet. Studies have demonstrated that educational interventions on HPV-related illness effectively increased knowledge along with vaccine acceptability in America,^{37,38} Malaysia,³⁹ Korea,⁴⁰ Turkey^{41,42}

and Hong Kong.^{43,44} The responses reported in respondents' feedback form were positive. Studies link literacy as an index of positive health outcomes. A study identified literacy and culture as indispensable factors for HPV educational material.⁴⁵ This provides additional challenges related to language and information in the HPV pamphlet for both, educated as well as less educated respondents. The pamphlet was tested for readability and translated to only one language, Bahasa Malaysia, as the study was conducted in Malaysia dominated by the translated literacy. Further, the Cohen's kappa statistic, κ , was used to measure the agreement between both versions of translation between the two raters.⁴⁶ All were found to be satisfactory with good agreement.

The HPV pamphlet met the appreciation and approval of the participants. More than 90% indicated the educational tool was acceptable in content, appearance and readability. There was no total disagreement for any item assessed in the evaluation form (Table 2). The final revised pamphlet was colour printed and used for the intervention study. Hence the validation of the pamphlet satisfied the basic requirements. After substantial care was taken in the development of the pamphlet and subjecting it for the various validation studies, the effect of intervention tool (pamphlet) in increasing knowledge regarding HPV infection and HPV vaccination was tested using pre-validated, 16 knowledge based questions. This cross-sectional study was conducted among adults aged 18 – 26 years in the rural and urban areas of Sungai Petani, Kedah state, Malaysia. After the intervention, the respondents showed significantly higher awareness and more favorable attitude and beliefs towards prevention of HPV infections. Results endorse that female respondents had better knowledge at baseline.^{9,47} However, similar increase in knowledge was revealed among either genders, whose knowledge seemed to be retained during the 2-weeks follow-up period. A study in Germany, reported "using a balanced health information leaflet can increase girls' and parents' knowledge of HPV vaccination and its uptake".⁴⁸ Another study reported, a threefold increase in intent to vaccination among college girls using a 20-minute educational intervention.⁴⁹ After the intervention, the respondents were more tending to practice careful sexual practice with new partner. Results endorse that female respondents had higher knowledge of HPV infection and vaccination at baseline.^{9,48}

All studies are investigating the effectiveness of interventions, irrespective of the methods used, aimed at common goals, either to protect from STDs or to improve sexual health. The study also found that prior to intervention; adults had moderate knowledge regarding the cause, transmission, vulnerability, consequences and treatment of HPV. Previous studies reported most young adults have a poor HPV knowledge.^{25,45,50–52} Educational pamphlet developed for this study may be useful for providers to guide patients in clinical setting as well as stake holders in community setting. The possible approaches based on provider and patient for HPV education include the use of pamphlets/brochures or leaflets to reach the large population, providing answers to frequently asked questions. However, those with positive Pap test results or HPV infection would require one-on-one education in a clinical setting. A few people prefer information from providers due to privacy.⁵³ Proper education intervention like this can be used as the first-line approach in preventing HPV related infection and illness. Our study results provide new information on effectiveness of educational pamphlets among the respondents regarding HPV infection and vaccination.

Table 2 Tabulation for HPV pamphlet evaluation response

No.	Questions	SA	A	DA	SD	p value
1	Evaluate the appearance of the pamphlet	12 (40)	11 (37)	7 (23)	0 (0)	0.497
2	Is the front of the alphabets appropriate?	23 (77)	5 (17)	2 (7)	0 (0)	<.001*
3	Is the content on HPV infection easy to read and understand	17	11	2	0	.003*
4	Is the content on the Pap Smear easy to read and understand	16	13	1	0	.002*
5	Is the content on the age of HPV vaccine easy to read and understand	18	12	0	0	0.273
6	Is the content on the dose of HPV vaccine easy to read and understand	22	8	0	0	.011*
7	Is the content on the dose frequency of HPV vaccine easy to read and understand	17	12	1	0	.001*
8	Is the content on the availability of HPV vaccine easy to read and understand	17	13	0	0	0.465
9	Would you take the pamphlet home to read later	18	12	0	0	0.273
10	Will you get HPV vaccinated for yourself or your child	14 (47)	13 (43)	3 (10)	0 (0)	.025*

SA: Strongly agree; A: Agree; DA: Disagree; SD: Strongly disagree

*Chi square test, $p < .05$ is significant.

Table 3 Proportion of Correct Responses to knowledge based questions, before and after Intervention among Adults

No.	Knowledge items of adults	Stage 1 of intervention tool development (N = 121)			Stage 2 of intervention tool development (N = 92)		
		Pre-test N (%)	Post-test N (%)	p value	Pre-test N (%)	Post-test N (%)	p value
1	HPV infection affects skin and the moist membranes that line the human body.	63 (52)	108 (89)	< .001*	49 (53)	81 (88)	< .001*
2	I came to know about HPV infection through advertisements (radio, TV, internet)/ friends/ parents/ teachers).	96 (79)	109 (90)	.037*	75 (82)	82 (89)	0.23
3	HPV can infect males, females or both.	73 (60)	108 (89)	< .001*	58 (63)	80 (87)	0.405
4	HPV infects mostly females.	53 (44)	108 (89)	< .001*	36 (39)	81 (88)	< .001*
5	Women infected with HPV are more likely to get cancer of the cervix.	95 (79)	108 (89)	.037*	73 (79)	81 (88)	0.152
6	Those infected with HPV are more likely to get pelvic warts, genital warts, penile cancer, cervical cancer and some other less common cancers.	91 (75)	102 (84)	0.109	57 (62)	83 (90)	< .001*
7	Most people who are infected with HPV do not know that they are infected.	75 (62)	106 (88)	< .001*	53 (58)	81 (88)	< .001*
8	Signs and symptoms of HPV infection will take few months to years for developing.	68 (56)	107 (88)	< .001*	52 (57)	83 (90)	< .001*
9	Mostly, HPV infection is transmitted through sexual intercourse.	65 (54)	108 (89)	< .001*	78 (85)	85 (92)	0.189
10	A vaccine is a biological preparation that improves immunity against a particular disease.	95 (79)	107 (88)	.045*	69 (75)	83 (90)	.018*
11	The HPV vaccination prevents HPV infection-associated development of cervical cancer, penile cancer, genital warts, and some less common cancers.	83 (69)	106 (88)	.001*	56 (61)	84 (91)	< .001*

Table Continued...

No.	Knowledge items of adults	Stage 1 of intervention tool development (N = 121)			Stage 2 of intervention tool development (N = 92)		
		Pre-test N (%)	Post-test N (%)	p value	Pre-test N (%)	Post-test N (%)	p value
12	The course of the HPV vaccination comprises of one, two or three doses.	29 (24)	113 (93)	.003*	70 (76)	85 (92)	< .001*
13	The best age for HPV vaccination is between 9-14, 15-20 or 21-26 years.	71 (59)	108 (89)	< .001*	67 (73)	84 (91)	.009*
14	The HPV vaccination can be given from the age of 9 to 26 years.	94 (78)	108 (89)	< .001*	49 (53)	83 (90)	.005*
15	Pap smear test can be used to screen pelvic cancer, cervical cancer or oral cancer.	63 (52)	102 (84)	.026*	58 (63)	82 (89)	< .001*
16	Under 30 years of age, Pap smear test is done once in every one, two or three year(s)	96 (79)	106 (88)	.003*	73 (79)	82 (89)	0.064
17	Total Median Score	10 (4)	14 (3)	< .001+	11 (4)	14.5 (3)	< .001+
	Percentage of correct answers	63%	89%		66%	90%	

*McNemar's Test; p < .05, +Wilcoxon Signed Rank Test; p < .05 is significant

Conclusion

In conclusion, the results presented in this study give an insight into the effects of educational pamphlet in improving knowledge among adult population regarding HPV infection and HPV vaccination. This study results confirm that educational initiatives have proven to improve awareness and enhance beliefs for appropriate practice towards HPV prevention. Therefore, in addition to providing clear, precise and tailored information regarding implications of HPV infection, addressing misconceptions of vaccination, its prevention, fears of pap screening, vaccine side effects and vaccination is of utmost importance. Further, a comprehensive and sustainable HPV and cervical cancer education should be incorporated into health education from the early teen-ages in order to achieve the desired outcome.

Acknowledgements

We would like to express my deepest gratitude to all of the participants for their time, cooperation, support and patience that have been given during the repeated data collection exercise.

Conflict of interest

None declared.

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