https://doi.org/10.48048/tis.2022.4171

A study of Factors Affecting the Decision Making of Paper-based Analytical Device Utilization for HPV Type 16 Detection among Medical Technologists in Thailand

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Received: 23 November 2020, Revised: 22 May 2021, Accepted: 29 May 2021

Abstract

This research aims to determine the factors affecting the decision making of using the paper-based HPV screening test. This is quantitative research; the questionnaire was used to collect the data from 411 medical technologists working in the laboratory nationwide. Data analysis involved descriptive statistics, Exploratory Factor Analysis, and Ordinal logistic regression analysis. The results showed standardization of test kits approved by the Food and Drug Administration and industry standards is the top priority with an average opinion score of 5.0. Consequently, the factor of After-sales service in terms of on-time delivery and user training was prioritized as a score of 4.96 and 4.75, respectively. Meanwhile, the factor that was considered as the least important to decision making of the usage of a paper-based HPV screening test was the test kit that has previously been used in Medical school hospitals with an average score of 3.13. The factors affecting the decision making of using the paper-based HPV screening test consist of 7 factors that were analyzed by Univariable analysis with Ordinal logistic regression analysis. The factor significantly (p-value < 0.05) affect to the decision making of medical technologist who working in laboratory clinic OR = 1.79, 95 %CI: 1.01 - 3.17, p-value = 0.044) were factor of perceived and understood the principle of standard method and factor (OR = 1.82, 95 %CI: 1.13 - 2.91, p-value = 0.013) and after-sales service (OR = 0.43, 95 %CI: 0.23 - 0.78, p-value = 0.006).

Keywords: HPV screening test, Factors affecting, Decision making, Medical technologist

Introduction

Currently, Thailand is in the developing stage with Thailand 4.0 strategy which aims to drive Thailand toward developed country by focusing on research and innovation to unlock Thailand from several economic challenges and help the country break free from the middle-income trap and support social well-being to reach their full potential and reducing social disparity and income inequality. With advanced technology, both local and international universities and research institutes have been interested in the development of a paper-based device with chemical and biosensor technology for science [1], agriculture medicine, and public health purpose [2,3]. However, the researchers are mainly still using the lab-scale which could not be commercialized because there is no expert in both research & science and business & industrial perspectives. Also, the linkage between research and business is required to push technology and develop them to fulfill the needs of users and their stakeholders which is the important step to create and develop a new competitive product that leads to patent licensing and commercialization.

The medical device consists of many variables and different parts including hardware, software, and some chemical or medicine [2]. There are many challenges in the development of medical devices such as rules and regulation which control and monitor its usage and any adverse event for safety purpose. New product development is the key process for innovation. New product development started to design the product based on customer needs and developed a new product to fulfill market requirements [5]. Focus on the target market is the key driver for new product development. New product development starts with

Concept testing to identify customer insight and their Unmet needs to differentiate and have a Superior product over competitors [6]. And to be a cost leader [7].

The infectious disease that causes a high mortality rate in Thailand, Cervical cancer is in the top tier. Cervical cancer is caused by the infection of the Human Papilloma Virus (HPV) which I commonly found in Sexually transmitted disease, STD. Cervical cancer is the 2nd most common cancer in women worldwide, while breast cancer is the top one [8]. Cervical cancer is curable if it is detected at the beginning phase or stage before cancer. However, its mortality rate is more than half of detected. The major problem is 50 % of Thai women see the doctor for screening after the infection has more severe which is hard to treat. It is not only embarrassing to see the doctor that caused the delay in HPV screening but also the limited health facilities that are the barrier to access the screening and treatment such as in rural areas, there is no proper laboratory to test/screen it. They must send out to the provincial hospital, then it caused a delay in screening and treatment [9]. While in the city, there are many hospitals with standard laboratory. But transportation to the hospital is the key issue, patients do not want to go to the hospital until they have a severe symptom.

Regarding information mentioned above, a trend of Preventive Medicine, statistic data of cervical cancer mortality rate in Thai women population that showed increasing trend year on year, the problem of diagnosis technology access in a rural area, the problem of transportation in the city and also the advancement of education and research in Thai universities. The researcher has an idea of paper-based technology HPV screening development as a case study of new product development that started from a readiness of university research and technology requirement factors from medical technologist as lab user, and to evaluate the technology acceptance for new infectious screening test kit which is compiled to the model integrated technology and customer needs (Coupling) which is an innovation that concerns to customer needs and existing technology to develop innovation that fulfilled customer needs and uplift the existing technology at the same time [6,10].

There are 3 factors that impact or influence on decision making of using an innovative paper-based HPV screening test [12]. 1) External factor: This factor comes from outside that impacted the cognition and attitude which is the internal factor [13,14]. For example, subjective norm or motivation to use. 2) Internal factor: It is a happening or existing factor that impacted their attitude and believes which can be influenced by an external factor [2]. For example, User's anxiety, self-efficacy, perceived usefulness, perceived ease of use, intention to use, etc. 3) Supportive factor: This is another external factor that stimulates or influence the external or internal factors to be increased or decreased. Such as gender, age, educational background, working experience, or hospital type that they work with.

Materials and methods

Study design

This descriptive cross-sectional study was performed between September and October 2020 and the data collection was conducted in October 2020.

Study procedure

Cochran's sample size formula (1963) [11];

Sample size = Z2 [P (1-P)]/ e2

P is (the estimated) proportion of the population which has the attribute in question = 0.5
e is the desired level of precision (e.g. The margin of error) = 0.05
Z is valuing the confidence level at 95 % = 1.96

As calculated, the sample size is 385 and add up 10 %, the sample size will be 424 samples
Inclusion criteria
Medical technologists who work in a laboratory
Exclusion criteria
1) Medical technologist who does not work in a laboratory
2) Medical technologist who did not complete a questionnaire

Materials

The questionnaires were made by researchers from reviewing the body of the literature. Self-administered questionnaires were used for the data collection that consisted of 2 parts.

Part I: General information (8 items)

Part II: Factors that influence to decision making of the usage of a paper-based HPV screening test in a laboratory with limitation of lab setting (34 items) with Likert scale (1 - 5), 1 = lowest; 2 = low; 3 = medium; 4 = High; and 5 = Highest.

Content validity was approved by 3 public health academicians. The index of Item-Objective Congruence (IOC) of Part I was 1.00 and Part II was 0.76.

The reliability of decision making of the usage of a paper-based HPV screening test in the laboratory was analyzed by using Kuder-Richardson 20 (K-R20); the coefficient was 0.819. Cronbach's **α** coefficient was used to test for the measures of decision making of the usage of a paper-based HPV screening test in the laboratory; **α** coefficient was 0.851.

Data analysis

Frequency and percentage were used to analyze category data of each part and the association between variables and factors to decision making of the usage of a paper-based HPV screening test were analyzed by Exploratory Factor Analysis: EFA and Ordinal logistic regression analysis.

Ethical consideration

Ethical consideration and approval were made by the Ethics Committee for Human Research Subjects of the Faculty of Medicine, Chulalongkorn University, Thailand (Project code:738/63).

Results and discussion

Most of the samples were 78.1 % female with a mean age of 40.51 years (SD = 6.34 years) and more than half completed a bachelor's degree, 57.7 % of them had working experience about 16.29 year (SD = 6.44 years). Most of them were Medical technologists working in the clinic (51.3 %), followed by a private hospital (17.0 %) and Standard-level hospital (14.6 %). They mainly lived in the central region (47.9 %), the rest lived in Bangkok (21.7 %) and the Northeast region (11.2 %) respectively. All the samples have tested Strip test in laboratory (100 %) and almost of them had any experience of PCR testing more than 5 years (95.6 %) (**Table 1**)

Table1 Descriptive data of Medical Technologists.

Factors	**N**	**%**
Age (year), Mean ± SD	40.51 ± 6.34	
(Min - Max)	(27 - 59)	
Gender		
Male	90	21.9
Female	321	78.1
Education		
Bachelor's degree	237	57.7
Master's degree	153	37.2
PhD	21	5.1
Working Experience (Year), Mean ± SD	16.29 ± 6.44	
(Min - Max)	(3 - 37)	
Hospital type		
Standard-level hospital	60	14.6
Laboratory clinic	211	51.3
Middle-level hospital	30	7.3
Medical school hospital	40	9.7
Private hospital	70	17.0
Region		
North	30	7.3
Central	197	47.9

Factors	N	%
East	10	2.4
Northeast	46	11.2
South	39	9.5
Bangkok	89	21.7
Strip test in laboratory		
Tested	411	100.0
Not tested	0	0.0
Working experience with PCR testing		
No	0	0.0
Less than 1 year	0	0.0
1 - 5 years	18	4.4
More than 5 years	393	95.6

Regarding the analysis of factors affecting decision making to the usage of a paper-based HPV screening test found that 411 responders gave a priority to the standardization of test kits which includes the food and drug administration approval and an industry-standard, its score was shown highest as 5.00 that corresponded to the research from Brown *et al.* [15] that conducted the survey of success factors in

New Product Development in the medical device industry. Their result showed the success factors for new product development was the standardization of production and factor of after-sales service in terms of on-time delivery and user's training were scored as 4.96 and 4.75, respectively. While the lowest score from their opinion was "The Paper-based HPV screening test kit has previously been used in medical hospital" as 3.13 points which differed from the research of Darlin *et al.* [4] that have studied the new method of HPV screening, its result showed an important factor affecting to acceptance of new principle or method analysis as the test must be used in Medical school hospital before that resulted from the responders work in medical school hospital while the responders from this research work in laboratory clinic (**Table 2**).

Table 2 The analysis of factors affecting decision making to the usage of a paper-based HPV screening test.

Factor	Mean	SD	Result
1. Be confident in the genetic/molecular technique analysis	4.34	0.47	Highest
2. Genetic/Molecular method analysis has high sensitivity and specificity with less sample volume	4.39	0.49	Highest
3. A laboratory test kit for Infectious detection can be developed from paper	4.30	0.61	Highest
4. A result from a paper-based laboratory test for infectious disease detection is reliable for lab interpretation	4.17	0.55	High
5. Nowadays, there is a developed paper-based technology for viral genetic detection	4.18	0.57	High
6. The standard of test kit made in Thailand is equivalent to the international standard	4.44	0.55	Highest
7. The clean, modern packaging contributes to the reliability of the test kit	4.76	0.43	Highest
8. The molecular technique method has a complex process and requires skilled staff	4.54	0.59	Highest

Factor	Mean	SD	Result
9. The molecular test kit for virus detection which can be interpreted /read by lab staff themselves will allow all lab to access molecular testing	4.40	0.59	Highest
10. The package design includes disposing of the test kits after use to prevent contamination	4.64	0.48	Highest
11. Paper-based HPV screening test can reduce the cervical cancer screening and reporting process	4.06	0.52	Highest
12. Paper-based HPV screening test can be tested in any laboratory	3.95	0.41	High
13. Paper-based HPV screening test can be tested with urine instead of a vaginal specimen, then it will encourage more women to do an examination	4.60	0.50	Highest
14. Paper-based HPV screening test can reduce lab cost of automated testing	4.38	0.57	Highest
15. Paper-based HPV screening can be tested at your lab, shortened turnaround time from out-lab testing	4.13	0.53	High
16. Paper-based HPV screening able to support the registration system through the phone and generate a QR code for labeling during the test	4.45	0.62	Highest
17. Results of Paper-based HPV screening can read through photo taking, then analyzed and recorded into the system	4.62	0.52	Highest
18. Results of Paper-based HPV screening can be looked back	3.88	0.66	High
19. The Paper-based HPV screening test kit must be presented research results on the efficacy of the test kit by a specialized doctor	4.24	0.51	Highest
20. The Paper-based HPV screening test kit must be approved by the Food and Drug Administration	5.00	0.00	Highest
21. The Paper-based HPV screening test kit must be certified by industry standards	5.00	0.00	Highest
22. The Paper-based HPV screening test kit has previously been used in the medical hospital	3.13	0.54	Medium
23. The Paper-based HPV screening test kit has previously been used in the general hospital	4.25	0.56	Highest
24. Result in interpretation with visual reading through color analysis is an easy-to-operate system	4.24	0.57	Highest
25. The Paper-based HPV screening test kit is easy to dispose	4.64	0.48	Highest
26. The Paper-based HPV screening test kit saves space of a storage e	4.58	0.55	Highest
27. The Paper-based HPV screening test kit which has an individual pack is easy to use	4.68	0.47	Highest
28. The Paper-based HPV screening test kit should have a duration of 30-45 minutes of testing until reading the results	3.94	0.50	Highest
29. Storage condition of the test kit at 2 - 10 C is easy to store	4.61	0.49	Highest

Factor	Mean	SD	Result
30. After-sales service, laboratory user training is provided	4.75	0.44	Highest
31. After-sales service, there are easy ways to contact Company	4.63	0.49	Highest
32. After-sales service, delivery is on time as committed	4.96	0.21	Highest
33. After-sales service, there is a support system in reading the test results	4.64	0.51	Highest
34. After-sales service, there is a support system in recording and collecting the test results	3.97	0.52	Highest

The results from decision making to use a paper-based HPV screening showed the highest score of 54.3 %, sample decided to use a paper-based HPV screening test. The average price was 79.48 Baht (SD = 13.01), the minimum price was 50 Baht, and the maximum price was 120 Baht (**Table 3**).

Table 3 A decision making to use a paper-based HPV screening toward price of test kit

Level	Total	%
Moderate	14	3.4
Most	174	42.3
Modest	223	54.3
Price of test kit (Baht), Mean ± SD	79.48 ± 13.01	

Exploratory factor analysis (EFA): Factor affecting the decision making of the usage of a paper-based HPV screening test was measured variable factor which has value more than 0.4. Factor analysis of Kaiser-Meyer-Olkin (KMO) value is 0.661 and value from Bartlett's Sphericity testing had p-value < 0.001. Percentage of variance and cumulative variance indicated that component of a factor affecting the decision making of the usage of a paper-based HPV screening consists of 7 components; Eigenvalue of each component ranged from 1.432 - 3.343 and it is explained the variance value ranged from 4.48 - 10.45 and percentage of variance was 41.289 (**Table 4**).

Table 4 Factor affecting the decision making of the usage of a paper-based HPV screening test

Components	Eigen value	% of Variance	Cumulative%
1) Perceived and trust in technology	3.343	10.45	10.45
2) Perceived of ease of result interpretation	2.045	6.39	16.84
3) Perceived and understood the principle of standard method	1.813	5.67	22.50
4) Perceived usefulness of testing	1.663	5.20	27.70
5) Perceived ease of use	1.476	4.61	32.31
6) After sales service	1.439	4.50	36.81
7) Perceived usefulness of package	1.432	4.48	41.29

Factor 1: Perceived and trust in technology were explained by 4 components which weighted its components between 0.56 - 0.93. Factor2: Perceived ease of use of result interpretation was explained by 4 components which weighted its components between 0.41 - 0.59. Factor 3: Perceived and understood the principle of the standard method was explained by 2 components which weighted its components between 0.78 - 0.80. Factor 4: Perceived usefulness of testing was explained by 2 components which weighted its components between 0.79 - 0.80. Factor 5: Perceived ease of use was explained by 2 components which weighted its components between 0.45 - 0.52. Factor 6: After-sales service was explained by 3 components which weighted its components between 0.45 - 0.55 and Factor 7 Package detail was explained by 3 components which weighted its components between 0.44 - 0.61. The weighted value of each factor is shown in **Table 5**

Table 5 The weighted value of affecting factor

Factor	Communality	Varimax						
		F_1	F_2	F_3	F_4	F_5	F_6	F_7
1. Be confident in the genetic/molecular technique analysis	0.65			0.80				
2. Genetic/molecular method analysis has high sensitivity and specificity with less sample volume	0.63			0.78				
3. A laboratory test kit for Infectious detection can be developed from paper	0.80	0.88						
4. A result from a paper-based laboratory test for infectious disease detection is reliable for lab interpretation	0.86	0.91						
5. Nowadays, there is a developed paper-based technology for viral genetic detection	0.89	0.93						
6. The standard of test kit made in Thailand is equivalent to the international standard	0.50	0.56						
7. The clean, modern packaging contributes to the reliability of the test kit	0.44							0.44
8. The molecular technique method has a complex process and requires skilled staff	0.50	−0.59						
9. The molecular test kit for virus detection which can be interpreted /read by lab staff themselves will allow all lab to access molecular testing	0.37							0.52
10. The package design includes disposing of the test kits after use to prevent contamination	0.07							
11. Paper-based HPV screening test can reduce the cervical cancer screening and reporting process	0.66				0.80			

Factor	Communality	Varimax						
		F_1	F_2	F_3	F_4	F_5	F_6	F_7
12. Paper-based HPV screening test can be tested in any laboratory	0.68				0.79			
13. Paper-based HPV screening test can be tested with urine instead of a vaginal specimen, then it will encourage more women to do an examination	0.31					−0.45		
14. Paper-based HPV screening test can reduce lab cost of automated testing	0.34						0.45	
15. Paper-based HPV screening can be tested at your lab, shortened turnaround time from out-lab testing	0.28							
16. Paper-based HPV screening able to support the registration system through the phone and generate a QR code for labeling during the test	0.39		0.58					
17. Results of paper-based HPV screening can read through photo taking, then analyzed and recorded into the system	0.24		0.43					
18. Results of paper-based HPV screening can be looked back	0.47		0.59					
19. The paper-based HPV screening test kit must be presented research results on the efficacy of the test kit by a specialized doctor	0.21							
20. The paper-based HPV screening test kit must be approved by the Food and Drug Administration	0.43		−0.53					
21. The paper-based HPV screening test kit must be certified by industry standards	0.19							
22. The paper-based HPV screening test kit has previously been used in a medical hospital	0.23		0.41					
23. The paper-based HPV screening test kit has previously been used in a general hospital	0.35					0.45		
24. Result in interpretation with visual reading through color analysis is an easy-to-operate system	0.44							0.61
25. The paper-based HPV screening test kit is easy to dispose	0.15							
26. The paper-based HPV screening test kit saves space the storage	0.37					0.52		

Factor	Communality	Varimax						
		F_1	F_2	F_3	F_4	F_5	F_6	F_7
27. The paper-based HPV screening test kit which has an individual pack is easy to use	0.26							
28. The paper-based HPV screening test kit should have a duration of 30 - 45 min of testing until reading the results	0.10							
29. Storage condition of the test kit at 2 - 10 C is easy to store	0.38						0.55	
30. After-sales service, laboratory user training is provided	0.35							
31. After-sales service, there are easy ways to contact company	0.30						0.47	
32. After-sales service, delivery is on time as committed	0.37		−0.45					

The analysis of factors affecting the decision making of the usage of a paper-based HPV screening test was analyzed by multivariable factors with Multiple ordinal logistic regression analyses which considered factor affecting the decision making of the usage of a paper-based HPV screening test statistic significant (p-value < 0.05). From the relation of univariable analysis such as Laboratory clinic, Factor 3 Perceived and understood the principle of standard method and Factor 6 After-sales service (p-value < 0.05) once controlling for confounding factors such as Laboratory clinic ; OR = 1.79, 95 %CI: 1.01 - 3.17, p-value = 0.044) component No.3 : Perceived and understood the principle of standard (OR = 1.82, 95 %CI: 1.13 - 2.91, p-value = 0.013) and component No.6 : after-sales service (OR = 0.43, 95 %CI: 0.23 - 0.78, p-value = 0.006) (**Table 6**)

Table 6 Results from multivariable factors with Multiple ordinal logistic regression analysis

Variables	Univariable analysis			Multivariable analysis		
	OR[1]	95 %CI	p-value	OR_{adj}[2]	95 %CI	p-value
Age (Year)	1.02	(0.99 - 1.06)	0.132			
Gender						
Male	1.00	Reference				
Female	1.29	(0.82 - 2.03)	0.274			
Education						
Bachelor's degree	1.00	Reference				
Master's degree	0.95	(0.63 - 1.41)	0.783			
PhD	0.98	(0.39 - 2.43)	0.961			
Working Experience (Year)	1.02	(0.99 - 1.05)	0.215			
Hospital type						
Standard-level Hospital	1.00	Reference		1.00	Reference	
Laboratory clinic	1.83	(1.04 - 3.21)	0.036	1.79	(1.01 - 3.17)	0.044
Middle-level Hospital	1.13	(0.48 - 2.65)	0.782	1.25	(0.53 - 2.97)	0.612
Medical school hospital	1.42	(0.64 - 3.15)	0.384	1.47	(0.65 - 3.30)	0.352
Private hospital	1.36	(0.69 - 2.66)	0.376	1.31	(0.66 - 2.59)	0.442

Area						
Bangkok	1.00	Reference				
Upcountry	1.16	(0.73 - 1.85)	0.528			
Working Experience with PCR testing						
1 - 5 years	1.00	Reference				
> 5 years	1.23	(0.48 - 3.14)	0.659			
Factor affecting decision making						
$Foctor_1$	0.71	(0.48 - 1.07)	0.099			
$Foctor_2$	0.96	(0.56 - 1.63)	0.867			
$Foctor_3$	1.72	(1.09 - 2.73)	0.021	1.82	(1.13 - 2.91)	0.013
$Foctor_4$	0.98	(0.61 - 1.59)	0.945			
$Foctor_5$	0.72	(0.42 - 1.25)	0.247			
$Foctor_6$	0.44	(0.24 - 0.80)	0.007	0.43	(0.23 - 0.78)	0.006
$Foctor_7$	0.81	(0.45 - 1.44)	0.470			

Conclusions

This research study the factors affecting the decision making of using the paper-based HPV screening test from main users. From the theory review and related research, it can be concluded the impacting factors and designed the research questionnaire. Data were collected from 411 Medical technologists who work in the laboratory. The result showed that Exploratory Factor analysis considered the factor loading greater than 0.4. The KMO statistic was 0.661 and Bartlett's Sphericity statistic showed a p-value < 0.001. The components of the factors affecting the decision making of using the paper-based HPV screening test are 7 components which are perceived and trust in technology, perceived ease of use of result interpretation, Perceived and understood the principle of the standard method, perceived usefulness of testing, Perceived ease of use, After-sales service and Perceived value of its Package. The factors affecting the decision making of using the paper-based HPV screening test was analyzed by Univariable analysis with Ordinal logistic regression analysis. This research also examined general information such as gender, age, educational background, working experience, hospital type, working area, and experience with PCR testing and factors affecting decision making toward 7 components. The result showed the factors were considered affecting statistically (p-value < 0.05) to sample, medical technologists working in laboratory clinic were a factor of perceived and understood the principle of standard method and factor of after-sales service. Regarding collected data, this can be developed the concept of paper-based HPV screening test further to commercialization.

Acknowledgements

The authors are extremely grateful to the medical technologist who participated in this study. The authors report no conflicts of interest in this work.

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